Clinical trial results:
Phase III study for evaluation of the diagnostic performance of [18F] CTT1057 PET imaging in patients with prostate cancer with rising PSA levels [biochemical recurrence (BCR)] (GuidePath)

Summary

EudraCT number	2020-003959-16
Trial protocol	FR ES
Global end of trial date	23 November 2023

Results information

Result version number	v1 (current)
This version publication date	08 December 2024
First version publication date	08 December 2024

Trial information

Trial identification

Sponsor protocol code	CAAA405A12301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04838613
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	CH 4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.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	23 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives were:
- Evaluate the region-level Correct localization rate (CLR) of vidoflufolastat (18F)
- Evaluate the patient-level Positive predictive value (PPV) (with anatomical localization) of vidoflufolastat (18F)

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2021
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	France: 69
Country: Number of subjects enrolled	Spain: 104
Country: Number of subjects enrolled	Switzerland: 12
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	190
EEA total number of subjects	173

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)	66
From 65 to 84 years	123
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

190 participants were randomized using a 1:1 ratio to receive either Sequence 1 (vidoflufolastat (18F) followed by gallium (68Ga) gozetotide; N= 96) or Sequence 2 (gallium (68Ga) gozetotide followed by vidoflufolastat (18F); N=94). Out of the 190 randomized participants, 169 completed the study.

Pre-assignment

Screening details:

Prior to participation in the study, patients had to have biopsy proven prostate adenocarcinoma and diagnosis of biochemical recurrence following initial definitive therapy with either radical prostatectomy or curative intent radiation therapy.

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	Sequence 1: Vidoflufolastat(18F) then gallium (68Ga)gozetotide

Arm description:

All eligible participants were assigned to this PET/CT scan sequence 1 at random in a 1:1 ratio: - Sequence 1: vidoflufolastat (18F) on Day 1 (investigational imaging agent of interest) followed by gallium (68Ga) gozetotide at least 14 days apart (as part of CTS if required, and for secondary endpoint)

Arm type	Experimental
Investigational medicinal product name	Gallium (68Ga) gozetotide
Investigational medicinal product code	AAA517
Other name	[68Ga]Ga-PSMA-11
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

This drug was injected as a single intravenous injection of approximately 150 MBq (range 111 - 185 MBq).

Investigational medicinal product name	vidoflufolastat (18F)
Investigational medicinal product code	AAA405
Other name	[18F]CTT1057
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

This drug was injected as a single intravenous dose of approximately 370 MBq (range 266 - 407 MBq).

Arm title	Sequence 2: Gallium(68Ga) gozetotide then vidoflufolastat(18F)

Arm description:

All eligible participants were assigned to the following PET/CT scan sequence 2 at random in a 1:1 ratio: - Sequence 2: gallium (68Ga) gozetotide (as part of CTS if required, and for secondary endpoint) on Day 1 followed by vidoflufolastat (18F) (investigational imaging agent of interest) at least 14 days apart

Arm type	Experimental

Investigational medicinal product name	Gallium (68Ga) gozetotide
Investigational medicinal product code	AAA517
Other name	[68Ga]Ga-PSMA-11
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

This drug was injected as a single intravenous injection of approximately 150 MBq (range 111 - 185 MBq).

Investigational medicinal product name	vidoflufolastat (18F)
Investigational medicinal product code	AAA405
Other name	[18F]CTT1057
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

This drug was injected as a single intravenous dose of approximately 370 MBq (range 266 - 407 MBq).

Number of subjects in period 1	Sequence 1: Vidoflufolastat(18F) then gallium (68Ga)gozetotide	Sequence 2: Gallium(68Ga) gozetotide then vidoflufolastat(18F)
Started	96	94
Completed	88	81
Not completed	8	13
Consent withdrawn by subject	3	6
Physician decision	2	-
Protocol Deviation	3	2
Technical Problems	-	5

Baseline characteristics

Reporting groups	
Reporting group title	Sequence 1: Vidoflufolastat(18F) then gallium (68Ga)gozetotide

Reporting group description:

All eligible participants were assigned to this PET/CT scan sequence 1 at random in a 1:1 ratio: - Sequence 1: vidoflufolastat (18F) on Day 1 (investigational imaging agent of interest) followed by gallium (68Ga) gozetotide at least 14 days apart (as part of CTS if required, and for secondary endpoint)

Reporting group title	Sequence 2: Gallium(68Ga) gozetotide then vidoflufolastat(18F)

Reporting group description:

All eligible participants were assigned to the following PET/CT scan sequence 2 at random in a 1:1 ratio: - Sequence 2: gallium (68Ga) gozetotide (as part of CTS if required, and for secondary endpoint) on Day 1 followed by vidoflufolastat (18F) (investigational imaging agent of interest) at least 14 days apart

Reporting group values	Sequence 1: Vidoflufolastat(18F) then gallium (68Ga)gozetotide	Sequence 2: Gallium(68Ga) gozetotide then vidoflufolastat(18F)	Total
Number of subjects	96	94	190
Age categorical Units: Subjects			
Adults (18-64 years)	34	32	66
From 65-84 years	62	61	123
85 years and over	0	1	1
Age Continuous Units: Years			
arithmetic mean	66.8	67.6	
standard deviation	± 7.59	± 8.09	-
Sex: Female, Male Units: Participants			
Female	0	0	0
Male	96	94	190
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	31	32	63
Not Hispanic or Latino	54	54	108
Unknown or Not Reported	11	8	19
Race/Ethnicity, Customized Units: Subjects			
White	87	93	180
Black or African American	3	1	4
Asian	2	0	2
Unknown	4	0	4

Subject analysis sets	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

The Full Analysis Set (FAS) includes all randomized participants.

Subject analysis set title	Efficacy Analysis Set (EFF) - Central Reader 1
Subject analysis set type	Per protocol

Subject analysis set description:

The Efficacy Analysis Set (EFF) included all randomized participants who received vidoflufolastat(18F) and have both an evaluable vidoflufolastat(18F) PET/CT scan imaging, and at least one evaluable CTS assessment and have not received any prohibited systemic antineoplastic therapy before the completion of PET/CTs and CTS procedures. Results are reported independently for each of the three central readers.

Subject analysis set title	Efficacy Analysis Set (EFF) - Central Reader 2
Subject analysis set type	Per protocol

Subject analysis set description:

The Efficacy Analysis Set (EFF) included all randomized participants who received vidoflufolastat(18F) and have both an evaluable vidoflufolastat(18F) PET/CT scan imaging, and at least one evaluable CTS assessment and have not received any prohibited systemic antineoplastic therapy before the completion of PET/CTs and CTS procedures. Results are reported independently for each of the three central readers.

Subject analysis set title	Efficacy Analysis Set (EFF) - Central Reader 3
Subject analysis set type	Per protocol

Subject analysis set description:

The Efficacy Analysis Set (EFF) included all randomized participants who received vidoflufolastat(18F) and have both an evaluable vidoflufolastat(18F) PET/CT scan imaging, and at least one evaluable CTS assessment and have not received any prohibited systemic antineoplastic therapy before the completion of PET/CTs and CTS procedures. Results are reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF)
Subject analysis set type	Safety analysis

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)).

Subject analysis set title	Gallium (68Ga) gozetotide safety Set (Ga-SAF)
Subject analysis set type	Safety analysis

Subject analysis set description:

Ga-SAF included all participants who received Gallium (68Ga) gozetotide.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF)
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)).

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 1
Subject analysis set type	Per protocol

Subject analysis set description:

For intra-reader variability endpoint, scans for a subset of 19 patients from the vidoflufolastat (18F) safety set were read by each reader at 2 different time points. Results were reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2
Subject analysis set type	Per protocol

Subject analysis set description:

For intra-reader variability endpoint, scans for a subset of 19 patients from the vidoflufolastat (18F) safety set were read by each reader at 2 different time points. Results were reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3
Subject analysis set type	Per protocol

Subject analysis set description:

For intra-reader variability endpoint, scans for a subset of 19 patients from the vidoflufolastat (18F) safety set were read by each reader at 2 different time points. Results were reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) Central Reader 1

Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)). Results were reported independently for each of the three central readers for some secondary endpoints.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)). Results were reported independently for each of the three central readers for some secondary endpoints.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)). Results were reported independently for each of the three central readers for some secondary endpoints.

Reporting group values	Full Analysis Set (FAS)	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2
Number of subjects	190	161	161
Age categorical Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous Units: Years			
arithmetic mean	67.2	67.8	73.3
standard deviation	± 7.83	±	±
Sex: Female, Male Units: Participants			
Female	0		
Male	190		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	63		
Not Hispanic or Latino	108		
Unknown or Not Reported	19		
Race/Ethnicity, Customized Units: Subjects			
White	180		
Black or African American	4		
Asian	2		
Unknown	4		

Reporting group values	Efficacy Analysis Set (EFF) - Central Reader 3	Vidoflufolastat (18F) Safety Set (F-SAF)	Gallium (68Ga) gozetotide safety Set (Ga-SAF)
Number of subjects	161	171	178
Age categorical Units: Subjects			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age Continuous Units: Years arithmetic mean standard deviation	67.2 ±	±	±
Sex: Female, Male Units: Participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Black or African American Asian Unknown			

Reporting group values	Vidoflufolastat (18F) Safety Set (F-SAF)	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 1	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2
Number of subjects	171	19	19
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	65.5 ±	100 ±	61.2 ±
Sex: Female, Male Units: Participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Black or African American Asian Unknown			

Reporting group values	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3	Vidoflufolastat (18F) Safety Set (F-SAF) Central Reader 1	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2
Number of subjects	19	171	171
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	 100 ±	 49.4 ±	 50.9 ±
Sex: Female, Male Units: Participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Black or African American Asian Unknown			

Reporting group values	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3		
Number of subjects	171		
Age categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: Years arithmetic mean standard deviation	 54.3 ±	 	
Sex: Female, Male Units: Participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			

White Black or African American Asian Unknown			

End points

End points reporting groups

Reporting group title	Sequence 1: Vidoflufolastat(18F) then gallium (68Ga)gozetotide

Reporting group description:

All eligible participants were assigned to this PET/CT scan sequence 1 at random in a 1:1 ratio: - Sequence 1: vidoflufolastat (18F) on Day 1 (investigational imaging agent of interest) followed by gallium (68Ga) gozetotide at least 14 days apart (as part of CTS if required, and for secondary endpoint)

Reporting group title	Sequence 2: Gallium(68Ga) gozetotide then vidoflufolastat(18F)

Reporting group description:

All eligible participants were assigned to the following PET/CT scan sequence 2 at random in a 1:1 ratio: - Sequence 2: gallium (68Ga) gozetotide (as part of CTS if required, and for secondary endpoint) on Day 1 followed by vidoflufolastat (18F) (investigational imaging agent of interest) at least 14 days apart

Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

The Full Analysis Set (FAS) includes all randomized participants.

Subject analysis set title	Efficacy Analysis Set (EFF) - Central Reader 1
Subject analysis set type	Per protocol

Subject analysis set description:

The Efficacy Analysis Set (EFF) included all randomized participants who received vidoflufolastat(18F) and have both an evaluable vidoflufolastat(18F) PET/CT scan imaging, and at least one evaluable CTS assessment and have not received any prohibited systemic antineoplastic therapy before the completion of PET/CTs and CTS procedures. Results are reported independently for each of the three central readers.

Subject analysis set title	Efficacy Analysis Set (EFF) - Central Reader 2
Subject analysis set type	Per protocol

Subject analysis set description:

The Efficacy Analysis Set (EFF) included all randomized participants who received vidoflufolastat(18F) and have both an evaluable vidoflufolastat(18F) PET/CT scan imaging, and at least one evaluable CTS assessment and have not received any prohibited systemic antineoplastic therapy before the completion of PET/CTs and CTS procedures. Results are reported independently for each of the three central readers.

Subject analysis set title	Efficacy Analysis Set (EFF) - Central Reader 3
Subject analysis set type	Per protocol

Subject analysis set description:

The Efficacy Analysis Set (EFF) included all randomized participants who received vidoflufolastat(18F) and have both an evaluable vidoflufolastat(18F) PET/CT scan imaging, and at least one evaluable CTS assessment and have not received any prohibited systemic antineoplastic therapy before the completion of PET/CTs and CTS procedures. Results are reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF)
Subject analysis set type	Safety analysis

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)).

Subject analysis set title	Gallium (68Ga) gozetotide safety Set (Ga-SAF)
Subject analysis set type	Safety analysis

Subject analysis set description:

Ga-SAF included all participants who received Gallium (68Ga) gozetotide.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF)
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)).

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 1
Subject analysis set type	Per protocol

Subject analysis set description:

For intra-reader variability endpoint, scans for a subset of 19 patients from the vidoflufolastat (18F) safety set were read by each reader at 2 different time points. Results were reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2
Subject analysis set type	Per protocol

Subject analysis set description:

For intra-reader variability endpoint, scans for a subset of 19 patients from the vidoflufolastat (18F) safety set were read by each reader at 2 different time points. Results were reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3
Subject analysis set type	Per protocol

Subject analysis set description:

For intra-reader variability endpoint, scans for a subset of 19 patients from the vidoflufolastat (18F) safety set were read by each reader at 2 different time points. Results were reported independently for each of the three central readers.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) Central Reader 1
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)). Results were reported independently for each of the three central readers for some secondary endpoints.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)). Results were reported independently for each of the three central readers for some secondary endpoints.

Subject analysis set title	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3
Subject analysis set type	Per protocol

Subject analysis set description:

F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)). Results were reported independently for each of the three central readers for some secondary endpoints.

Primary: Region-level correct localization rate (CLR) of vidoflufolastat (18F)

End point title	Region-level correct localization rate (CLR) of vidoflufolastat (18F)[1]

End point description:

Region-level correct localization rate (CLR) is defined as the percentage of regions containing at least one True Positive (TP) lesion (exactly localized correspondence between PET imaging and the reference standard), regardless of any co-existent False Positive (FP) findings within the same region, out of all regions containing at least one PET-positive finding.

End point type	Primary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

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 comparison was done between central readers. The lower bound of the 95% confidence interval was compared against the predefined threshold for each central reader.

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of regions				
number (confidence interval 95%)	67.8 (54.44 to 78.75)	73.3 (60.79 to 82.98)	67.2 (55.13 to 77.30)	

Statistical analyses

No statistical analyses for this end point

Primary: Patient-level positive predictive value (PPV) (with anatomical localization) of vidoflufolastat (18F)

End point title	Patient-level positive predictive value (PPV) (with anatomical localization) of vidoflufolastat (18F)[2]

End point description:

Patient-level positive predictive value (PPV) is defined as the percentage of participants who have at least one True Positive (TP) lesion (exactly localized correspondence between PET imaging and the reference standard), regardless of any co-existent False Positive (FP) findings, out of all participants who are PET/CT scan positive.

End point type	Primary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

Notes:

[2] - 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 comparison was done between central readers. The lower bound of the 95% confidence interval was compared against the predefined threshold for each central reader.

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of participants				
number (confidence interval 95%)	67.8 (54.36 to 79.38)	74.5 (61.00 to 85.33)	66.7 (53.31 to 78.31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level sensitivity of vidoflufolastat (18F)

End point title	Patient-level sensitivity of vidoflufolastat (18F)

End point description:

Patient-level sensitivity is defined as the percentage of participants who test positive on vidoflufolastat

(18F) and Composite Truth Standard (CTS) (True Positive (TP)) among those that are CTS positive (True Positive (TP) or False Negative (FN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of participants				
number (confidence interval 95%)	66.7 (53.31 to 78.31)	68.3 (55.04 to 79.74)	66.7 (53.31 to 78.31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level negative predictive value (NPV) of vidoflufolastat (18F)

End point title	Patient-level negative predictive value (NPV) of vidoflufolastat (18F)

End point description:

Patient-level negative predictive value is defined as the percentage of participants who are both vidoflufolastat (18F) and CTS negative (True Negative (TN)) among those who test negative on vidoflufolastat (18F) (True Negative (TN) or False Negative (FN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	161	161		
Units: Percentage of participants				
number (confidence interval 95%)	82.1 (73.43 to 88.85)	80.2 (71.09 to 87.46)		

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level specificity of vidoflufolastat (18F)

End point title	Patient-level specificity of vidoflufolastat (18F)

End point description:

Patient-level specificity is defined as the percentage of participants who test negative on vidoflufolastat (18F) and CTS (True Negative (TN)) among those that are CTS negative (True Negative (TN) or False Positive (FP)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of participants				
number (confidence interval 95%)	81.2 (72.19 to 88.28)	86.1 (77.84 to 92.21)	80.2 (71.09 to 87.46)	

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level detection rate

End point title	Patient-level detection rate

End point description:

Patient-level detection rate is defined as the percentage of participants who have at least one PET positive lesion, regardless of True Positive (TP) or False Positive (FP) findings, out of all participants who are scanned.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of participants				
number (confidence interval 95%)	36.6 (29.20 to 44.59)	34.2 (26.88 to 42.04)	37.3 (29.79 to 45.23)	

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level correct detection rate (CDR)

End point title	Patient-level correct detection rate (CDR)

End point description:

Patient-level correct detection rate (CDR) is defined as the percentage of participants who have at least one True Positive (TP) lesion (exactly localized correspondence between PET imaging and the reference standard), regardless of any co-existent False Positive (FP) findings, out of all participants who are scanned.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percenage of participants				
number (confidence interval 95%)	24.8 (18.38 to 32.26)	25.5 (18.94 to 32.92)	24.8 (18.38 to 32.26)	

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level accuracy of vidoflufolastat (18F)

End point title	Patient-level accuracy of vidoflufolastat (18F)

End point description:

Patient-level accuracy is defined as the percentage of participants who are CTS and vidoflufolastat (18F) positive (True Positive (TP)) and negative (True Negative (TN)) among those participants that identified on vidoflufolastat (18F) (True Positive (TP), True Negative (TN), False Positive (FP) or False Negative (FN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of participants				
number (confidence interval 95%)	75.8 (68.41 to 82.17)	79.5 (72.44 to 85.45)	75.2 (67.74 to 81.62)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region-level sensitivity of vidoflufolastat (18F) (Overall)

End point title	Region-level sensitivity of vidoflufolastat (18F) (Overall)

End point description:

Region level sensitivity is defined as the percentage of regions that test positive on both vidoflufolastat (18F) and CTS (True Positive (TP)) among those regions that are CTS positive (True Positive (TP) or False Negative (FN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of regions				
number (confidence interval 95%)	58.2 (46.69 to 68.81)	54.3 (43.44 to 64.80)	57.0 (45.69 to 67.60)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region level specificity of vidoflufolastat (18F)

End point title	Region level specificity of vidoflufolastat (18F)

End point description:

Region level specificity is defined as the percentage of regions that test negative on both vidoflufolastat (18F) and CTS (True Negative (TN)) among those regions that are CTS negative (False Positive (FP) or True Negative (TN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of regions				
number (confidence interval 95%)	97.0 (95.44 to 98.04)	97.8 (96.42 to 98.64)	97.0 (95.44 to 98.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region level negative predictive value (NPV) of vidoflufolastat (18F)

End point title	Region level negative predictive value (NPV) of vidoflufolastat (18F)

End point description:

Region level negative predictive value is defined as the percentage of regions that are CTS and vidoflufolastat (18F) negative (True Negative (TN)) among those regions that test negative on vidoflufolastat (18F) (True Negative (TN) or False Negative (FN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of regions				
number (confidence interval 95%)	95.5 (93.75 to 96.82)	95.0 (93.22 to 96.38)	95.4 (93.61 to 96.75)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region level accuracy of vidoflufolastat (18F)

End point title	Region level accuracy of vidoflufolastat (18F)

End point description:

Region level accuracy is defined as the percentage of regions that are CTS andvidoflufolastat (18F) positive (True Positive (TP)) and negative (True Negative (TN)) among those regions that identified on vidoflufolastat (18F) (True Positive (TP), True Negative (TN), False Positive (FP) and False Negative (FN)).

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of regions				
number (confidence interval 95%)	93.2 (91.18 to 94.74)	93.4 (91.48 to 94.94)	93.0 (91.07 to 94.61)	

Statistical analyses

No statistical analyses for this end point

Secondary: Patient-level positive predictive value (PPV) of vidoflufolastat (18F) related to PSA levels

End point title	Patient-level positive predictive value (PPV) of vidoflufolastat (18F) related to PSA levels

End point description:

Patient-level positive predictive value related to PSA levels is defined as the percentage of participants who have at least one True Positive (TP) lesion (exactly anatomically localized correspondence between vidoflufolastat (18F) PET imaging and the reference standard), regardless of any co-existent False

Positive (FP) findings, out of all participants who are vidoflufolastat (18F) positive, stratified by PSA levels. This endpoint was analyzed in each of the following subgroups: PSA ≤ 0.5 ng/mL; 0.5 ng/mL<PSA≤1 ng/mL; 1 ng/mL<PSA≤2 ng/mL; 2 ng/mL<PSA≤5 ng/mL; PSA > 5 ng/mL.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Efficacy Analysis Set (EFF) - Central Reader 1	Efficacy Analysis Set (EFF) - Central Reader 2	Efficacy Analysis Set (EFF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	161	161	161	
Units: Percentage of Participants				
number (confidence interval 95%)				
Subgroup: PSA <= 0.5 ng/mL (n = 100,100,100)	59.3 (38.80 to 77.61)	61.5 (40.57 to 79.77)	51.9 (31.95 to 71.33)	
Subgroup: 0.5 ng/mL <PSA <= 1 ng/mL (n=29, 29, 29)	66.7 (34.89 to 90.08)	90.9 (58.72 to 99.77)	81.8 (48.22 to 97.72)	
Subgroup: 1 ng/mL <PSA <= 2 ng/mL (n = 11, 11, 11)	71.4 (29.04 to 96.33)	85.7 (42.13 to 99.64)	62.5 (24.49 to 91.48)	
Subgroup: 2 ng/mL <PSA <= 5 ng/mL (n=11,11,11)	85.7 (42.13 to 99.64)	83.3 (35.88 to 99.58)	87.5 (47.35 to 99.68)	
Subgroup: PSA > 5 ng/mL (n = 6,6,6)	100 (39.76 to 100)	100 (39.76 to 100)	100 (39.76 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overview of Adverse Events (AEs) and Treatment Emergent Adverse Events (TEAEs)

End point title	Overview of Adverse Events (AEs) and Treatment Emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) is any untoward medical occurrence (e.g. any unfavorable and unintended sign [including abnormal laboratory findings], symptom or disease) in a subject or clinical investigation subject.

End point type	Secondary

End point timeframe:

From first dosing (Day 1) up to 14 days post dosing

End point values	Vidoflufolastat (18F) Safety Set (F-SAF)	Gallium (68Ga) gozetotide safety Set (Ga-SAF)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	171	178		
Units: Participants				
Adverse Events (AEs)	20	16		
Treatment-related AEs	6	2		
Serious Adverse Events (SAEs)	1	0		
Treatment-related SAEs	0	0		
Fatal serious AEs	0	0		
Treatment-related fatal AEs	0	0		
AEs leading to treatment discontinuation	0	0		
Treatment-related AEs leading to treatment discont	0	0		
AEs leading to dose adjustment / interruption	0	0		
AEs requiring additional therapy	2	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Vidoflufolastat (18F) scan inter-reader variability

End point title	Vidoflufolastat (18F) scan inter-reader variability

End point description:

Inter-reader variability is defined as the agreement among three readers determination of vidoflufolastat (18F) images.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Vidoflufolastat (18F) Safety Set (F-SAF)			
Subject group type	Subject analysis set			
Number of subjects analysed	171			
Units: % agreement				
number (confidence interval 95%)	65.5 (56.84 to 74.15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Vidoflufolastat (18F) scan intra-reader variability

End point title	Vidoflufolastat (18F) scan intra-reader variability

End point description:

Intra-reader variability is defined as the within-reader agreement for two different time points of vidoflufolastat (18F) images.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 1	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	19	19	19	
Units: % agreement				
number (confidence interval 95%)	100 (100 to 100)	61.2 (10.39 to 100)	100 (100 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concordance between vidoflufolastat (18F) and gallium (68GA) gozetotide for detection of lesions at lesion level using central reads (Overall)

End point title	Concordance between vidoflufolastat (18F) and gallium (68GA) gozetotide for detection of lesions at lesion level using central reads (Overall)

End point description:

Concordance between vidoflufolastat (18F) and gallium (68Ga) gozetotide for detection of PSMA-positive lesions (location and number) using central reads.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 or Day 15 assessed against Composite Truth Standard (CTS) obtained within 8 weeks (before or after) of 18F-CTT PET scan or during follow-up (up to 90 days after radiotherapy for PSA level assessment)

End point values	Vidoflufolastat (18F) Safety Set (F-SAF) Central Reader 1	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 2	Vidoflufolastat (18F) Safety Set (F-SAF) - Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	171	171	171	
Units: Percentage of lesions				
number (confidence interval 95%)	49.4 (39.78 to 59.00)	50.9 (40.65 to 61.04)	54.3 (43.47 to 64.77)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change in patient management plans attributed to the vidoflufolastat (18F) PET/CT scan

End point title	Change in patient management plans attributed to the vidoflufolastat (18F) PET/CT scan

End point description:

Change in patient management plans attributed to the PET/CT scan is defined as the percentage of participants who underwent a change in intended treatment plan attributed to the vidoflufolastat (18F) PET/CT scan as assessed by pre and post imaging questionnaires.

End point type	Secondary

End point timeframe:

From randomization up to 14 days after obtaining the results of the vidoflufolastat (18F) PET imaging

End point values	Vidoflufolastat (18F) Safety Set (F-SAF)			
Subject group type	Subject analysis set			
Number of subjects analysed	171			
Units: participants	61			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse Events (AEs) were collected from first dosing (Day 1) up to 14 days post dosing.	
Adverse event reporting additional description:	
Any sign or symptom that occurs during the conduct of the trial and safety follow-up.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups	
Reporting group title	Gallium (68Ga) gozetotide safety Set (Ga-SAF)
Reporting group description:	
Ga-SAF included all participants who received Gallium (68Ga) gozetotide.	
Reporting group title	Vidoflufolastat (18F) Safety Set (F-SAF)
Reporting group description:	
F-SAF included all participants who received the investigational treatment (i.e. vidoflufolastat (18F)).	

Serious adverse events	Gallium (68Ga) gozetotide safety Set (Ga-SAF)	Vidoflufolastat (18F) Safety Set (F-SAF)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Gallium (68Ga) gozetotide safety Set (Ga-SAF)	Vidoflufolastat (18F) Safety Set (F-SAF)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 178 (8.99%)	20 / 171 (11.70%)	
Vascular disorders			

Hypertensive crisis			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Hypertension			
subjects affected / exposed	2 / 178 (1.12%)	0 / 171 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
Thirst			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Malaise			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Injection site warmth			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Asthenia			
subjects affected / exposed	0 / 178 (0.00%)	5 / 171 (2.92%)	
occurrences (all)	0	5	
Respiratory, thoracic and mediastinal disorders			
Tachypnoea			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Rhinitis allergic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Apathy			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Investigations			
Amylase increased			

subjects affected / exposed	0 / 178 (0.00%)	2 / 171 (1.17%)	
occurrences (all)	0	2	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 178 (0.56%)	1 / 171 (0.58%)	
occurrences (all)	1	1	
Lipase increased			
subjects affected / exposed	0 / 178 (0.00%)	3 / 171 (1.75%)	
occurrences (all)	0	3	
Injury, poisoning and procedural complications			
Wound			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Tendon rupture			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Muscle strain			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	1 / 178 (0.56%)	1 / 171 (0.58%)	
occurrences (all)	1	1	
Neuropathy peripheral			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Cognitive disorder			

subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Abdominal pain			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Paraesthesia oral			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Flatulence			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 178 (0.56%)	0 / 171 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Renal pain			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	0 / 178 (0.00%)	1 / 171 (0.58%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue			

disorders Muscle spasms subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all)	 0 / 178 (0.00%) 0 1 / 178 (0.56%) 1	 1 / 171 (0.58%) 1 0 / 171 (0.00%) 0	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	 1 / 178 (0.56%) 1	 2 / 171 (1.17%) 2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 December 2021	The main purpose of the amendment was to clarify the inclusion criterion on PSA level requirements for confirmation of BCR following RT and following RP to avoid misinterpretation and ensure full alignment with the published definitions for BCR per AUA and ASTRO-Phoenix guidelines and with the targeted study population (participants who had BCR following initial definitive therapy). The amendment also clarified that participants with prior salvage RT or salvage surgery were not eligible for the study to ensure alignment with the targeted participant population.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The cohort was mainly European and White, with only 1 site in the US. Low subject numbers in some subgroups precluded analysis. Composite Truth Standard Level 1 was usable from only a small proportion of subjects in this study.

Notes: