Clinical trial results:
Phase II/III study for evaluation of the diagnostic performance of [18F] CTT1057 PET imaging for the detection of PSMA positive tumors using histopathology as a standard of truth (GuideView)

Summary

EudraCT number	2020-003958-67
Trial protocol	FR ES IT
Global end of trial date	24 November 2023

Results information

Result version number	v1
This version publication date	09 November 2024
First version publication date	09 November 2024

Trial information

Trial identification

Sponsor protocol code	CAAA405A12302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04838626
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, 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	24 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 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 patient-level sensitivity of vidoflufolastat (18F)
- Evaluate the region-level specificity of vidoflufolastat (18F)

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com for complete trial results.

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	07 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: 45
Country: Number of subjects enrolled	Italy: 54
Country: Number of subjects enrolled	Spain: 80
Country: Number of subjects enrolled	Switzerland: 12
Country: Number of subjects enrolled	United States: 4
Worldwide total number of subjects	195
EEA total number of subjects	179

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)	92
From 65 to 84 years	103
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

195 patients were enrolled. 184 participants received vidoflufolastat (18F) and 184 underwent PET/CT. 173 patients completed the study and 184 patients completed treatment.

Pre-assignment

Screening details:

A total of 195 participants were enrolled. 184 participants completed the study treatment phase (PET imaging completed)

Period 1

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

Arms

Arm title	PET/CT imaging with vidoflufolastat (18F).

Arm description:

Single intravenous dose of approximately 370 Mega-Becquerel (MBq) on Day 1 and subsequent PET/CT scan

Arm type	Experimental
Investigational medicinal product name	vidoflufolastat (18F)
Investigational medicinal product code	AAA405
Other name	[18F]CTT1057
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Single intravenous dose of approximately 370 Mega-Becquerel (MBq) on Day 1 and subsequent PET/CT scan

Number of subjects in period 1	PET/CT imaging with vidoflufolastat (18F).
Started	195
Completed	173
Not completed	22
Physician decision	6
Consent withdrawn by subject	9
Adverse event, non-fatal	2
Technical Problems	2
Protocol deviation	3

Baseline characteristics

Reporting groups	
Reporting group title	PET/CT imaging with vidoflufolastat (18F).
Reporting group description:	
Single intravenous dose of approximately 370 Mega-Becquerel (MBq) on Day 1 and subsequent PET/CT scan	

Reporting group values	PET/CT imaging with vidoflufolastat (18F).	Total	
Number of subjects	195	195	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	92	92	
From 65-84 years	103	103	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	64.5		
standard deviation	± 6.41	-	
Sex: Female, Male Units: Participants			
Female	0	0	
Male	195	195	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	192	192	
More than one race	0	0	
Unknown or Not Reported	2	2	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	56	56	
Not Hispanic or Latino	122	122	
Unknown or Not Reported	17	17	

End points

End points reporting groups

Reporting group title	PET/CT imaging with vidoflufolastat (18F).
Reporting group description: Single intravenous dose of approximately 370 Mega-Becquerel (MBq) on Day 1 and subsequent PET/CT scan	
Subject analysis set title	Central Reader 1
Subject analysis set type	Per protocol
Subject analysis set description: Central Reading Center 1	
Subject analysis set title	Central Reader 2
Subject analysis set type	Per protocol
Subject analysis set description: Central Reading Center 2	
Subject analysis set title	Central Reader 3
Subject analysis set type	Per protocol
Subject analysis set description: Central Reading Center 3	
Subject analysis set title	Central Reader 1
Subject analysis set type	Per protocol
Subject analysis set description: Central Reading Center 1	
Subject analysis set title	Central Reader 2
Subject analysis set type	Per protocol
Subject analysis set description: Central Reading Center 2	
Subject analysis set title	Central Reader 3
Subject analysis set type	Per protocol
Subject analysis set description: Central Reading Center 3	
Subject analysis set title	Central Reader 1
Subject analysis set type	Per protocol
Subject analysis set description: Central Reader 1	
Subject analysis set title	Central Reader 2
Subject analysis set type	Per protocol
Subject analysis set description: Central Reader 2	
Subject analysis set title	Central Reader 3
Subject analysis set type	Per protocol
Subject analysis set description: Central Reader 3	

Primary: Patient-level sensitivity of vidoflufolastat (18F) - % Sensitivity

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

End point description:

Sensitivity of vidoflufolastat (18F) Positron Emission Tomography (PET) imaging, considering Prostate Specific Membrane Antigen (PSMA) positive patients as those who show at least one pathological vidoflufolastat (18F) uptake either in the primary tumor and/or metastatic Pelvic Lymph Node (PLN) regions, with anatomically localized correspondence with the Standard of Truth (SoT).

End point type	Primary

End point timeframe:

vidoflufolastat (18F)7 PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

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: Not applicable for a single treatment arm study.

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Sensitivity				
number (confidence interval 95%)	88.8 (83.00 to 93.09)	88.2 (82.32 to 92.62)	86.8 (80.74 to 91.56)	

Statistical analyses

No statistical analyses for this end point

Primary: Region-level specificity of vidoflufolastat (18F) - % Specificity

End point title	Region-level specificity of vidoflufolastat (18F) - % Specificity[2]

End point description:

Specificity of vidoflufolastat (18F) PET imaging, defined as proportion of PLN regions that test negative for lymph nodes on vidoflufolastat (18F) among those that are lymph node negative on the SoT.

End point type	Primary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

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: Not applicable for a single treatment arm study.

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Specificity				
number (confidence interval 95%)	97.1 (92.74 to 99.20)	97.1 (92.74 to 99.20)	97.1 (92.74 to 99.20)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Specificity of vidoflufolastat (18F) PET imaging, considering PSMA negative patients as those who do not show any pathological vidoflufolastat (18F) uptake either in the primary tumor or PLNs and will be confirmed not having primary tumor or metastatic PLNs with the SoT

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Specificity				
number (confidence interval 95%)	0.0 (0.0 to 70.76)	33.3 (0.84 to 90.57)	20.0 (0.51 to 71.64)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Proportion of patients who are both vidoflufolastat (18F) and SoT negative (true negatives (TN)) among those who test negative on vidoflufolastat (18F) (TN+ false negatives (FN))

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Negative Predictive Value				
number (confidence interval 95%)	0.0 (0.0 to 17.65)	4.8 (0.12 to 23.82)	4.3 (0.11 to 21.95)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Proportion of patients who are both vidoflufolastat (18F) and SoT positive (true positives (TP) among those who test positive on vidoflufolastat (18F) (TP+ false positives (FP))

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Positive Predictive Value				
number (confidence interval 95%)	98.0 (94.38 to 99.59)	98.7 (95.30 to 99.84)	97.3 (93.27 to 99.26)	

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:

Proportion of patients that are SoT and vidoflufolastat (18F) positive (TP) and negative (TN) among all patients in Efficacy Analysis Set (EFF) (TP+TN+FP+FN)

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Negative Predictive Value				
number (confidence interval 95%)	87.2 (81.28 to 91.81)	87.2 (81.28 to 91.81)	84.9 (78.64 to 89.88)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region-level Sensitivity of vidoflufolastat (18F) - % Sensitivity	
End point title	Region-level Sensitivity of vidoflufolastat (18F) - % Sensitivity
End point description:	
Proportion of PLN regions that test positive on both vidoflufolastat (18F) and SoT (TP) among those that are SoT positive (TP+FN)	
End point type	Secondary
End point timeframe:	
vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan	

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Sensitivity				
number (confidence interval 95%)	20.6 (8.70 to 37.90)	23.5 (10.75 to 41.17)	20.6 (8.70 to 37.90)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region-level positive predictive value of vidoflufolastat (18F)	
End point title	Region-level positive predictive value of vidoflufolastat (18F)
End point description:	
Proportion of Pelvic Lymph Node (PLN) regions that are Standard of Truth (SoT) and vidoflufolastat (18F) positive (TP) among those regions that test positive on vidoflufolastat (18F) (TP+False Positive (FP))	
End point type	Secondary
End point timeframe:	
vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan	

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Positive Predictive Value				
number (confidence interval 95%)	63.6 (30.79 to 89.07)	66.7 (34.89 to 90.08)	63.6 (30.79 to 89.07)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Proportion of PLN regions that are SoT and vidoflufolastat (18F) negative (TN) among those regions that test negative on vidoflufolastat (18F) (TN+FN)

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Negative Predictive Value				
number (confidence interval 95%)	83.2 (76.55 to 88.65)	83.8 (77.10 to 89.10)	83.2 (76.55 to 88.65)	

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:

Proportion of PLN regions that are SoT and vidoflufolastat (18F) positive (TP) and negative (TN) among all PLN regions assessed vidoflufolastat (18F)(TP+TN+FP+FN)

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Negative Predictive Value				
number (confidence interval 95%)	82.0 (75.40 to 87.41)	82.6 (76.05 to 87.91)	82.0 (75.40 to 87.41)	

Statistical analyses

No statistical analyses for this end point

Secondary: Region-level sensitivity of vidoflufolastat (18F) scan with standard of truth excluding Pelvic Lymph Node (PLN) metastasis < 2 mm

End point title	Region-level sensitivity of vidoflufolastat (18F) scan with standard of truth excluding Pelvic Lymph Node (PLN) metastasis < 2 mm

End point description:

Sensitivity of vidoflufolastat (18F) PET imaging in the PLN region, excluding from the analysis those lymph nodes showing metastasis <2mm (micro-metastasis)

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	172	172	172	
Units: % Negative Predictive Value				
number (confidence interval 95%)	26.9 (11.57 to 47.79)	30.8 (14.33 to 51.79)	26.9 (11.57 to 47.79)	

Statistical analyses

No statistical analyses for this end point

Secondary: Detection of distant metastasis of vidoflufolastat (18F) scan - Participants with at least one distant metastatic lesion (%)

End point title	Detection of distant metastasis of vidoflufolastat (18F) scan - Participants with at least one distant metastatic lesion (%)

End point description:

Number of distant metastasis identified at PET/CT scan in all patients, and percentage of patients with at least one distant metastatic lesion (extra-PLN, visceral or skeletal)identified by PET scan in all patients with an evaluable vidoflufolastat (18F) PET/CT scan.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	184	184	184	
Units: Participants	7	11	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Overview of adverse events

End point title	Overview of adverse events

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.

AEs = Adverse Events

End point type	Secondary

End point timeframe:

Adverse Events are reported from the single dose of study treatment administration until 14 days afterwards, for a maximum time frame of approx. 14 days.

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	184			
Units: Participants				
Adverse events	24			
Treatment-related Adverse events	1			
Serious adverse events	2			
Serious adverse events Treatment-related	0			
Fatal serious adverse events	0			
Fatal serious adverse events Treatment-related	0			
AEs leading to dose adjustment / interruption	0			
Adverse events requiring additional therapy	5			

Statistical analyses

No statistical analyses for this end point

Secondary: vidoflufolastat (18F) scan inter-reader variability - Number of scans

agreed	
End point title	vidoflufolastat (18F) scan inter-reader variability - Number of scans agreed

End point description:

Scan inter-reader variability is defined the agreement rate among reader determination of vidoflufolastat (18F) images.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	184			
Units: Participants				
Number of scans agreed by all three readers	163			
Number of scans agreed by two readers	21			

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:

Scan inter-reader variability is defined the agreement rate among reader determination of vidoflufolastat (18F) images.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	184			
Units: % variability				
number (confidence interval 95%)	63.9 (55.52 to 72.20)			

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:

Scan intra-reader variability is defined as the within-reader agreement rate of vidoflufolastat (18F) images.

End point type	Secondary

End point timeframe:

vidoflufolastat (18F) PET imaging acquired at Day 1 assessed against histopathology as Standard of Truth (SoT) obtained during surgery within 6 weeks from vidoflufolastat (18F) scan

End point values	Central Reader 1	Central Reader 2	Central Reader 3	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	20	20	
Units: variability (%)				
number (confidence interval 95%)	100 (100 to 100)	100 (100 to 100)	89.4 (69.04 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time of maximum observed blood concentration occurrence (Tmax) of vidoflufolastat (18F)

End point title	Time of maximum observed blood concentration occurrence (Tmax) of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post injection)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: kBq/mL				
median (full range (min-max))	0.0333 (0.0167 to 0.0833)			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed maximum blood concentration (Cmax) of vidoflufolastat (18F)

End point title	Observed maximum blood concentration (Cmax) of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post injection)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: kBq/mL				
arithmetic mean (standard deviation)	49.0 (± 19.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the vidoflufolastat (18F) concentration-time curve from time zero to the time of last quantifiable concentration (AUClast)

End point title	Area under the vidoflufolastat (18F) concentration-time curve from time zero to the time of last quantifiable concentration (AUClast)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post injection)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: h*kBq/mL				
arithmetic mean (standard deviation)	47.9 (± 11.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration-time curve from time zero (pre-dose) extrapolated to infinite time (AUCinf) of vidoflufolastat (18F)

End point title	Area under the concentration-time curve from time zero (pre-dose) extrapolated to infinite time (AUCinf) of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post infusion)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: h*kBq/mL				
arithmetic mean (standard deviation)	50.0 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Half-Life Lambda z of vidoflufolastat (18F)

End point title	Half-Life Lambda z of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post injection)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: hours				
arithmetic mean (standard deviation)	1.34 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of distribution during the terminal phase following intravenous elimination (Vz) of vidoflufolastat (18F)

End point title	Volume of distribution during the terminal phase following intravenous elimination (Vz) of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post injection)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Liters				
arithmetic mean (standard deviation)	14.9 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Urinary excretion of radioactivity expressed as a percentage of injected activity (%IA) of vidoflufolastat (18F)

End point title	Urinary excretion of radioactivity expressed as a percentage of injected activity (%IA) of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (pre-injection/0 hour, 0 hour (injection) - T (image acquisition starting time), T (image acquisition starting time) to 3 hours, 3 hours to 5 hours post imaging)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: Hours				
arithmetic mean (standard deviation)				
0 HRS INJECTION/PRE-INJECTION	0.000821 (± 0.00120)			
0 HRS (INJECTION) - T (IMAGE STARTING TIME)	15.8 (± 11.9)			
IMAGE ACQUISITION STARTING TIME T - 3 H	11.9 (± 8.30)			
3 H - 5 H	10.5 (± 8.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Total systemic clearance for intravenous administration (CL) of vidoflufolastat (18F)

End point title	Total systemic clearance for intravenous administration (CL) of vidoflufolastat (18F)

End point description:

End point type	Secondary

End point timeframe:

Day 1 (0, 0-5, 15, 30, 60, 120, 180-240, 300 minutes post injection)

End point values	PET/CT imaging with vidoflufolastat (18F).			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: L/h				
arithmetic mean (standard deviation)	7.70 (± 999)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse Events are reported from the single dose of study treatment administration until 14 days afterwards, for a maximum time frame of approx. 14 days.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups	
Reporting group title	All Subjects
Reporting group description:	
All Subjects	

Serious adverse events	All Subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 184 (1.09%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Sepsis syndrome			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	All Subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 184 (12.50%)		
Investigations			

Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Amylase increased			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	5 / 184 (2.72%)		
occurrences (all)	5		
Nervous system disorders			
Presyncope			
subjects affected / exposed	2 / 184 (1.09%)		
occurrences (all)	2		
Neuropathy peripheral			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	2 / 184 (1.09%)		
occurrences (all)	2		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Feeling hot			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	1 / 184 (0.54%)		
occurrences (all)	1		

Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1 1 / 184 (0.54%) 1		
Reproductive system and breast disorders Scrotal oedema subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1		
Skin and subcutaneous tissue disorders Skin discolouration subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1 1 / 184 (0.54%) 1		
Renal and urinary disorders Urinary incontinence subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1		
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1		
Infections and infestations Oral herpes subjects affected / exposed occurrences (all) COVID-19 subjects affected / exposed occurrences (all)	 1 / 184 (0.54%) 1 1 / 184 (0.54%) 1		

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 update the inclusion criterion on the definition of high-risk prostate cancer per D'Amico classification to also include participants with clinical stage T2c or higher at initial diagnosis (instead of T2c only) as they were also considered high-risk per D'Amico classification. Other clarifications and corrections of discrepancies or errors were implemented across the protocol.

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.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com for complete trial results.

Notes: