Clinical trial results:
PHASE III STUDY OF [18F]PSMA-1007 VS FLUOROCHOLINE (18F) PET TO COMPARE THE DETECTION RATE OF PROSTATE CANCER LESIONS IN PATIENTS WITH BIOCHEMICAL RECURRENCE AFTER PREVIOUS DEFINITIVE TREATMENT FOR LOCALIZED PROSTATE CANCER

Summary

EudraCT number	2018-002975-16
Trial protocol	FR
Global end of trial date	08 October 2020

Results information

Result version number	v1
This version publication date	09 June 2022
First version publication date	09 June 2022

Trial information

Trial identification

Sponsor protocol code	ABX-CT-301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04102553
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ABX GmbH
Sponsor organisation address	Heinrich-Glaeser-Strasse 10-14, Radeberg, Germany, 01454
Public contact	Department of Medicinal Chemistry, ABX GmbH, info@abx.de
Scientific contact	Department of Medicinal Chemistry, ABX GmbH, info@abx.de

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	08 October 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 October 2020
Global end of trial reached?	Yes
Global end of trial date	08 October 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To show, in an independent assessment by 3 readers blinded to clinical data and tracer, the superiority of [18F]PSMA-1007 over Fluorocholine (18F) regarding the detection rate of metastatic prostate cancer lesions (patient-based analysis)

Protection of trial subjects:

In routine care

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 March 2019
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: 200
Worldwide total number of subjects	200
EEA total number of subjects	200

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)	51
From 65 to 84 years	149
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Administration of informed consent, evaluation of inclusion/exclusion criteria, medical history.

Pre-assignment period milestones

Number of subjects started	200
Number of subjects completed	200

Period 1

Period 1 title	Screening
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	[18F]PSMA-1007 and Fluorocholine (18F)

Arm description:

Patients received 2 PET scans in randomized order, either [18F]PSMA-1007 PET/CT first, followed by Fluorocholine (18F) PET/CT, or Fluorocholine (18F) PET/CT first, followed by [18F]PSMA-1007 PET/CT (1-10 days apart).

Arm type	Experimental
Investigational medicinal product name	Fluorocholine (18F)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Fluorocholine (18F) was administered with an activity of 200-400 MBq.

Investigational medicinal product name	[18F]PSMA-1007
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

[18F]PSMA-1007 was administered as a single intravenous injection of 3-4 MBq/kg (corresponding to a 210-280 MBq for a 70 kg adult).

Number of subjects in period 1	[18F]PSMA-1007 and Fluorocholine (18F)
Started	200
Completed	200

Period 2

Period 2 title	Study
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	[18F]PSMA-1007 and Fluorocholine (18F)

Arm description:

Patients received 2 PET scans in randomized order, either [18F]PSMA-1007 PET/CT first, followed by Fluorocholine (18F) PET/CT, or Fluorocholine (18F) PET/CT first, followed by [18F]PSMA-1007 PET/CT (1-10 days apart).

Arm type	Experimental
Investigational medicinal product name	Fluorocholine (18F)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Fluorocholine (18F) was administered with an activity of 200-400 MBq.

Investigational medicinal product name	[18F]PSMA-1007
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

[18F]PSMA-1007 was administered as a single intravenous injection of 3-4 MBq/kg (corresponding to a 210-280 MBq for a 70 kg adult).

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 2 is the baseline period, which refers to actual study procedure.

Number of subjects in period 2	[18F]PSMA-1007 and Fluorocholine (18F)
Started	200
study drug administration	195
Completed	190
Not completed	10
Consent withdrawn by subject	1
Physician decision	8
Protocol deviation	1

Baseline characteristics

Reporting groups

Reporting group title	Study

Reporting group description: -

Reporting group values	Study	Total	
Number of subjects	200	200	
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)	51	51	
From 65-84 years	149	149	
85 years and over	0	0	
Gender categorical Units: Subjects			
Male	200	200	
Female	0	0	

Subject analysis sets

Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients enrolled who received either study drug (including those who received Fluorocholine (18F) only)

Subject analysis set title	Intent-to-treat
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All patients who underwent both PET examinations and completed at least 4 weeks follow-up.

Reporting group values	Safety Analysis Set	Intent-to-treat	
Number of subjects	195	190	
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)	50	50	
From 65-84 years	145	140	
85 years and over	0	0	
Gender categorical Units: Subjects			
Male	195	190	
Female	0	0	

End points

End points reporting groups

Reporting group title	[18F]PSMA-1007 and Fluorocholine (18F)
Reporting group description:	
Patients received 2 PET scans in randomized order, either [18F]PSMA-1007 PET/CT first, followed by Fluorocholine (18F) PET/CT, or Fluorocholine (18F) PET/CT first, followed by [18F]PSMA-1007 PET/CT (1-10 days apart).	
Reporting group title	[18F]PSMA-1007 and Fluorocholine (18F)
Reporting group description:	
Patients received 2 PET scans in randomized order, either [18F]PSMA-1007 PET/CT first, followed by Fluorocholine (18F) PET/CT, or Fluorocholine (18F) PET/CT first, followed by [18F]PSMA-1007 PET/CT (1-10 days apart).	

Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis
Subject analysis set description:	
All patients enrolled who received either study drug (including those who received Fluorocholine (18F) only)	
Subject analysis set title	Intent-to-treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All patients who underwent both PET examinations and completed at least 4 weeks follow-up.	

Primary: Detection rate of [18F]PSMA-1007

End point title	Detection rate of [18F]PSMA-1007
End point description:	
Patient-based detection rate of all lesions compared with expert panel assessment, as determined in an independent image read with 3 readers blinded to clinical data and tracer.	
End point type	Primary
End point timeframe:	
6 months follow-up	

End point values	[18F]PSMA-1007 and Fluorocholine (18F)	Intent-to-treat		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	190	190		
Units: estimate				
number (confidence interval 95%)	0.7698 (0.7218 to 0.8178)	0.7698 (0.7218 to 0.8178)		

Statistical analyses

Statistical analysis title	Odds Ratio [18F]PSMA-1007 vs Fluorocholine (18F)
Comparison groups	[18F]PSMA-1007 and Fluorocholine (18F) v Intent-to-treat

Number of subjects included in analysis	380
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	z test
Parameter estimate	Odds ratio (OR)
Point estimate	2.606
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.9656
upper limit	3.4549

Primary: Detection rate of Fluorocholine (18F)

End point title	Detection rate of Fluorocholine (18F)
End point description:	
Patient-based detection rate of all lesions compared with expert panel assessment, as determined in an independent image read with 3 readers blinded to clinical data and tracer.	
End point type	Primary
End point timeframe:	
6 months follow-up	

End point values	[18F]PSMA-1007 and Fluorocholine (18F)	Intent-to-treat		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	190	190		
Units: estimate				
number (confidence interval 95%)	0.5651 (0.5071 to 0.6231)	0.5651 (0.5071 to 0.6231)		

Statistical analyses

Statistical analysis title	Difference in Proportions of Detection Rate
Comparison groups	[18F]PSMA-1007 and Fluorocholine (18F) v Intent-to-treat
Number of subjects included in analysis	380
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	z test
Parameter estimate	Difference in proportions
Point estimate	0.2047

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1465
upper limit	0.263

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded from the time of the first administration of study drug until 24 hours after the second PET examination. For most patients, this resulted in 1 day of safety follow-up; the maximum follow-up duration for AEs was 13 days

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	safety analysis set

Reporting group description: -

Serious adverse events	safety analysis set		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 195 (0.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	safety analysis set		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 195 (2.56%)		
Vascular disorders			
arterial hypertension			
subjects affected / exposed	1 / 195 (0.51%)		
occurrences (all)	1		
General disorders and administration site conditions			
chest discomfort			
subjects affected / exposed	1 / 195 (0.51%)		
occurrences (all)	1		
Gastrointestinal disorders			
toothache			
subjects affected / exposed	1 / 195 (0.51%)		
occurrences (all)	1		

diarrhea subjects affected / exposed occurrences (all)	 1 / 195 (0.51%) 1		
Musculoskeletal and connective tissue disorders shoulder pain subjects affected / exposed occurrences (all)	 1 / 195 (0.51%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 April 2019	Protocol version 3.0 (clarifications, typo correction)
14 October 2019	Protocol version 4.0 (description of study drug, extension of study period, typo correction)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported