



Clinical trial results:

A Non-randomised Phase II Study to Evaluate the Optimal Uptake Time of 68Ga-OPS202 as a SSTR2 Positive PET Imaging Agent in Subjects with Newly Diagnosed Breast Cancer.

Summary

EudraCT number	2018-000028-33
Trial protocol	AT
Global end of trial date	09 August 2019

Results information

Result version number	v1 (current)
This version publication date	02 August 2020
First version publication date	02 August 2020

Trial information

Trial identification

Sponsor protocol code	D-FR-01070-003
-----------------------	----------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03697551
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ipsen Pharma
Sponsor organisation address	65 quai Georges Gorse, Boulogne-Billancourt, France, 92100
Public contact	Medical Director, Ipsen Pharma, clinical.trials@ipsen.com
Scientific contact	Medical Director, Ipsen Pharma, clinical.trials@ipsen.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	06 February 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	09 August 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The co-primary objectives were to evaluate the percentage of women with newly diagnosed breast cancer who have somatostatin receptor subtype 2 (sstr2) positive lesions that were identified using gallium-68-satoreotide trizoxetan (68Ga-satoreotide trizoxetan; formerly known as 68Ga-OPS202); and to define the optimal positron emission tomography (PET) imaging time of 68Ga-satoreotide trizoxetan at 0.5, 1.0 and 2 hours post injection, based on detected lesions in adult women with sstr2 positive newly diagnosed early or advanced breast cancer.

Protection of trial subjects:

The study was conducted in compliance with independent ethics committees, informed consent regulations, the Declaration of Helsinki and International Conference on Harmonisation Good Clinical Practice Guidelines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

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)	3
From 65 to 84 years	1

85 years and over	0
-------------------	---

Subject disposition

Recruitment

Recruitment details:

Female subjects with newly diagnosed breast cancer who had a sstr2 positive lesion were recruited to this study from 22 October 2018, and the last subject last visit was on 6 February 2019. The study was terminated early on 9 August 2019.

Pre-assignment

Screening details:

Six subjects were screened and 4 subjects were eligible to receive 68Ga-satoreotide trizoxetan as a sstr2 positive PET imaging agent. The screening period was up to 14 days prior to the 68Ga-satoreotide trizoxetan administration on Day 1, with a follow-up visit at Day 14 for safety evaluation.

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	68Ga-Satoreotide Trizoxetan
-----------	-----------------------------

Arm description:

Subjects received a single dose of 68Ga-satoreotide trizoxetan on Day 1.

Arm type	Experimental
Investigational medicinal product name	68Ga-satoreotide trizoxetan
Investigational medicinal product code	
Other name	68Ga-OPS202; 68Ga-IPN01070
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

It was planned for subjects to receive a single dose of 68Ga-satoreotide trizoxetan which consisted of a peptide mass of up to 45 micrograms, with a radioactivity range of 150-200 megabecquerel (per protocol), administered as a slow intravenous bolus injected over 1 minute.

Number of subjects in period 1	68Ga-Satoreotide Trizoxetan
Started	4
Completed	4

Baseline characteristics

Reporting groups

Reporting group title	68Ga-Satoreotide Trizoxetan
-----------------------	-----------------------------

Reporting group description:

Subjects received a single dose of 68Ga-satoreotide trizoxetan on Day 1.

Reporting group values	68Ga-Satoreotide Trizoxetan	Total	
Number of subjects	4	4	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	51.8 ± 14.9	-	
Gender categorical Units: Subjects			
Female	4	4	
Male	0	0	

End points

End points reporting groups

Reporting group title	68Ga-Satoreotide Trizoxetan
Reporting group description:	
Subjects received a single dose of 68Ga-satoreotide trizoxetan on Day 1.	

Primary: Percentage of Subjects with Sufficiently Avid Lesion(s) Identified as sstr2 Positive Lesions (Co-Primary Endpoint)

End point title	Percentage of Subjects with Sufficiently Avid Lesion(s) Identified as sstr2 Positive Lesions (Co-Primary Endpoint) ^[1]
End point description:	
The percentage of subjects with sufficiently avid lesion(s) to be identified as a sstr2 positive lesion using 68Ga-satoreotide trizoxetan was to be determined.	
End point type	Primary
End point timeframe:	
At 0.5, 1.0 and 2.0 hours post injection on Day 1.	

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: The study was stopped prematurely, prior to the generation of data sufficient to conduct formal statistical analyses. Consequently, statistical analyses as described in the protocol were not conducted.

End point values	68Ga-Satoreotide Trizoxetan			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[2]			
Units: Percentage of subjects				

Notes:

[2] - No data was analysed for this endpoint due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Primary: Differences in the Number of Lesions Detected by 68Ga-satoreotide trizoxetan Between the 3 PET Acquisition Timepoints in Primary Breast Lesions (Co-Primary Endpoint)

End point title	Differences in the Number of Lesions Detected by 68Ga-satoreotide trizoxetan Between the 3 PET Acquisition Timepoints in Primary Breast Lesions (Co-Primary Endpoint) ^[3]
End point description:	
The differences in the number of lesions detected by 68Ga-satoreotide trizoxetan between the 3 PET acquisition timepoints, and reader interpretation was to be determined.	
End point type	Primary
End point timeframe:	
0.5, 1.0 and 2.0 hours post injection on Day 1	

Notes:

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

Justification: The study was stopped prematurely, prior to the generation of data sufficient to conduct formal statistical analyses. Consequently, statistical analyses as described in the protocol were not conducted.

End point values	68Ga-Satoreotide Trizoxetan			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[4]			
Units: Number of lesions				

Notes:

[4] - No data was analysed for this endpoint due to early termination of the study.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Treatment emergent adverse events were monitored from Day 1 up to Day 14 (+/- 3 days) (2 weeks).

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	20.1
--------------------	------

Reporting groups

Reporting group title	68Ga-Satoreotide Trizoxetan
-----------------------	-----------------------------

Reporting group description:

Subjects received a single dose of 68Ga-satoreotide trizoxetan on Day 1.

Serious adverse events	68Ga-Satoreotide Trizoxetan		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	68Ga-Satoreotide Trizoxetan		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No serious and no non-serious adverse events were reported for this study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 June 2018	To modify the restrictions on the minimum number of subjects per tumour stage, to update the version of the National Cancer Institute-Common Terminology Criteria for Adverse Events to be used, to update the pharmacovigilance contact details and to add instructions on spillage of the product, to make clarifications and to correct typographical errors.
14 September 2018	To correct a typo in the exclusion criterion which defined previous cancer of subjects not eligible for the study.

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 study was terminated early on 9 August 2019 due to recruitment challenges and the potential overlap with another Ipsen study, and not due to safety concerns.

Notes: