Clinical trial results:
Evaluation of the suitability of PD L 506 for intraoperative visualisation of palpable and nonpalpable breast cancer tissue

Summary

EudraCT number	2009-016842-22
Trial protocol	DE
Global end of trial date	20 December 2012

Results information

Result version number	v1 (current)
This version publication date	24 September 2022
First version publication date	24 September 2022

Trial information

Trial identification

Sponsor protocol code	NCT01110954

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01110954
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	photonamic GmbH & Co. KG
Sponsor organisation address	Eggerstedter Weg 12, Pinneberg, Germany, 25421
Public contact	Clinical Project Management Department, photonamic GmbH & Co. KG, +49 41017853953, m.stocker@photonamic.de
Scientific contact	Clinical Project Management Department, photonamic GmbH & Co. KG, +49 41017853953, m.stocker@photonamic.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	13 November 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 July 2012
Global end of trial reached?	Yes
Global end of trial date	20 December 2012
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The study is composed of two consecutive study steps. Only if Step 1 is successfully completed, Step 2 will be performed.

Primary Study Aims:
•Step 1: Assessment and quantitative determination of PPIX fluorescence in palpable breast cancer tissues after oral administration of PD L 506 for implementation of the technical setting serving as prerequisite for Step 2.
•Step 2: Assessment and quantitative determination of PPIX fluorescence in nonpalpable breast cancer tissue after oral administration of one of two different doses of PD L 506.

Protection of trial subjects:

Application of a sun blocker applied to face, neck and decollete of the patients shortly before surgery in order to avoid phototoxicity during surgery.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 May 2010
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	Germany: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	8
Number of subjects completed	7

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 1

Period 1

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

Arms

Arm title	Fluorescence Assessment
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	5-Aminolevulinic Acid Hydrochloride
Investigational medicinal product code	PD L 506
Other name	
Pharmaceutical forms	Powder for oral solution
Routes of administration	Oral use

Dosage and administration details:

For preparing the oral solution for one patient the powder of two vials had to be dissolved in 100 ml tap water. The calculated volume of the PD L 506 -solution was measured and transferred into an appropriate glass-container.

Number of subjects in period 1[1]	Fluorescence Assessment
Started	7
Completed	7

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: One patient withdrew her consent the same day she gave it.

Baseline characteristics

Reporting groups

Reporting group title	Study

Reporting group description: -

Reporting group values	Study	Total	
Number of subjects	7	7	
Age categorical Units: Subjects			
Adults (18-64 years)	3	3	
From 65-84 years	4	4	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	67.1		
standard deviation	± 5.1	-	
Gender categorical Units: Subjects			
Female	7	7	
Male	0	0	
Side of Breast Cancer Units: Subjects			
Both	1	1	
Left	2	2	
Right	4	4	
Breast Side under Study Units: Subjects			
Right	5	5	
Left	2	2	
Palpable/Non-Palpable Units: Subjects			
Palpable	6	6	
Non-Palpable	1	1	
Weight Units: kg			
arithmetic mean	64.3		
standard deviation	± 4.7	-	
Height Units: cm			
arithmetic mean	161.0		
standard deviation	± 4.3	-	

Subject analysis sets

Subject analysis set title	Per Protocol
Subject analysis set type	Per protocol

Subject analysis set description:

The per protocol population consisted of all patients who completed the study according to the protocol.

Subject analysis set title	Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety population includes all patients who received the study medication.

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

Subject analysis set description:

Patients who received the study medication according to study protocol.

Reporting group values	Per Protocol	Safety	Intention to treat
Number of subjects	3	7	7
Age categorical Units: Subjects			
Adults (18-64 years)	1	3	3
From 65-84 years	2	4	4
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	69.7	67.1	67.1
standard deviation	± 5.7	± 5.1	± 5.1
Gender categorical Units: Subjects			
Female	3	7	7
Male	0	0	0
Side of Breast Cancer Units: Subjects			
Both	1	1	1
Left	1	2	2
Right	1	4	4
Breast Side under Study Units: Subjects			
Right	2	5	5
Left	1	2	2
Palpable/Non-Palpable Units: Subjects			
Palpable	3	6	6
Non-Palpable	0	1	1
Weight Units: kg			
arithmetic mean	67.3	64.3	64.3
standard deviation	± 5.2	± 4.7	± 4.7
Height Units: cm			
arithmetic mean	162.7	161.0	161.0
standard deviation	± 3.4	± 4.3	± 4.3

End points

End points reporting groups

Reporting group title	Fluorescence Assessment
Reporting group description: -	
Subject analysis set title	Per Protocol
Subject analysis set type	Per protocol
Subject analysis set description:	
The per protocol population consisted of all patients who completed the study according to the protocol.	
Subject analysis set title	Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety population includes all patients who received the study medication.	
Subject analysis set title	Intention to treat
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Patients who received the study medication according to study protocol.	

Primary: Qualitative assessment of PPIX fluorescence in breast cancer tissues by the investigator

End point title	Qualitative assessment of PPIX fluorescence in breast cancer tissues by the investigator[1]
End point description:	
End point type	Primary
End point timeframe:	
Immediately after excision of the primary tumour	
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 statistical analyses were planned for this endpoint.	

End point values	Per Protocol	Intention to treat		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	7		
Units: Fluorescence Impression				
none	3	4		
weak	0	2		
strong	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Severity of Adverse Events

End point title	Severity of Adverse Events
End point description:	

End point type	Secondary

End point timeframe:

From Day 0 till 7 or 28 days after surgery, respectively.

End point values	Safety			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: Number of Adverse Events per category				
Mild	7			
Moderate	3			
Severe	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From Day 0 to day 7 or 28, respectively, after study termination.	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4

Reporting groups	
Reporting group title	Safety

Reporting group description: -

Serious adverse events	Safety		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (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	Safety		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)		
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 7 (42.86%)		
occurrences (all)	3		
Creatinine urine increased			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Alanine aminotransferase increased			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Gamma-glutamyltransferase increased			

subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Blood bilirubin increased			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 February 2010	Primary tumour resection procedure for both Steps was amended as requested by the Ethics Committee as the clinical study protocol in its final version dated December 28, 2009 did not contain information on how to proceed in case of fluorescence in the tumour cavity after resection of the tumour.
26 July 2012	Change of Principal Investigator.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported