Clinical trial results:
A prospective, international, multi-centre, open-label,single-arm phase II study investigating the predictive value of [68Ga]Ga-PentixaFor PET imaging in primary and isolated secondary CNS lymphoma patients

Summary

EudraCT number	2021-001711-85
Trial protocol	FR DK NL
Global end of trial date	29 March 2023

Results information

Result version number	v1 (current)
This version publication date	17 March 2024
First version publication date	17 March 2024
Summary attachment (see zip file)	A prospective, international, multi-centre, open-label, single-arm phase II study investigating the predictive value of [68Ga]Ga-PentixaFor PET imaging in primary and isolated secondary CNS lymphoma p (phase II study investigating the predictive value of [68Ga]Ga-PentixaFor PET imaging in

Trial information

Trial identification

Sponsor protocol code	PTF202

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05222269
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pentixapharm AG
Sponsor organisation address	Bismarckstrasse 13, Würzburg, Germany, 97080
Public contact	Elisa Galvez, PIVOTAL, +34 664111890, elisa.galvez@pivotalcr.com
Scientific contact	Anja Zehnder, Pentixapharm AG, +49 931 99136075, anja.zehnder@pentixapharm.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	21 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 January 2023
Global end of trial reached?	Yes
Global end of trial date	29 March 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the negative predictive value (NPV) of [68Ga]Ga-PentixaFor (PTF)-PET at interim examination (after 6 ± 2 weeks of induction chemotherapy) for progression-free survival (PFS).

Protection of trial subjects:

-This study was conducted in accordance with the study protocol, the ethical principles that have their origins in the Declaration of Helsinki and also in agreement with the International Conference on Harmonisation (ICH) guidelines on Good Clinical Practice (GCP), as well as all other applicable country and regional legal and regulatory requirements.
-Investigators were trained to conduct this study in accordance with the study protocol and ICH GCP guidelines. Written commitments were obtained from investigators to comply with GCP and to conduct the study in accordance with the protocol. The investigators were responsible for ensuring that this protocol, the site's ICF, and other information that will be presented to potential subjects were reviewed and approved by the appropriate IRB/IEC prior to enrolment of any study subject.
-Study-related data will be used by the sponsor in accordance with local data protection law.
-All local and national radiation protection rules and regulations applicable to the use IMP and the conduct of clinical trials were adhered in this trial.
-The Informed Consent forms were designed following the Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Background therapy: -

Evidence for comparator:

No comparator

Actual start date of recruitment	25 October 2022
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	Denmark: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	0
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Adult patients of either sex with histologically confirmed primary or secondary CNSL based on cytology/flow cytometry of cerebrospinal fluid (CSF) or brain biopsy will be recruited. Their disease must be previously untreated and located exclusively in the CNS,
Approximately 50 patients were planned in USA and EU

Pre-assignment

Screening details:

The screening phase will last for a maximum of 14 days.
Patients withdrawn from the study up to Visit 3 of the study will be replaced.

Pre-assignment period milestones

Number of subjects started	2[1]
Number of subjects completed	1

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Inclusion criteria not met: 1

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: We have equaled the pre-assignment period with the screening period (two patients), and only one of those patients met the I/E criteria. Hence only one patient was recruited.

Period 1

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

Arms

Arm title	Whole approved population

Arm description: -

Arm type	Experimental
Investigational medicinal product name	[68Ga]Ga-PentixaFor
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Infusion , Injection

Dosage and administration details:

In a volume of approximately 10 ml. A single dose is drawn from this solution according to the desired activity (150±50 MBq) and is to be administered to the patient as a bolus injection at a rate of approximately 10 ml per minute, with a resulting bolus duration of approximately 1 minute.

Number of subjects in period 1	Whole approved population
Started	1
Completed	1

Baseline characteristics

Reporting groups

Reporting group title	Whole approved population

Reporting group description: -

Reporting group values	Whole approved population	Total	
Number of subjects	1	1	
Age categorical			
Subjects from 18 years or above			
Units: Subjects			
Adults (18-64 years)	0	0	
From 65-84 years	1	1	
85 years and over	0	0	
Age continuous			
Units: years			
median	69		
full range (min-max)	69 to 69	-	
Gender categorical			
Units: Subjects			
Female	0	0	
Male	1	1	
Other	0	0	

Subject analysis sets

Subject analysis set title	Whole approved population
Subject analysis set type	Full analysis

Subject analysis set description:

The primary analysis of efficacy and safety will be based on the full analysis set (FAS) which will be defined as all enrolled patients who received at least one PTF administration.

Reporting group values	Whole approved population		
Number of subjects	1		
Age categorical			
Subjects from 18 years or above			
Units: Subjects			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
median	69		
full range (min-max)	69 to 69*		
Gender categorical			
Units: Subjects			
Female	0		
Male	1		

Other	0		

End points

End points reporting groups

Reporting group title	Whole approved population
Reporting group description: -	
Subject analysis set title	Whole approved population
Subject analysis set type	Full analysis

Subject analysis set description:

The primary analysis of efficacy and safety will be based on the full analysis set (FAS) which will be defined as all enrolled patients who received at least one PTF administration.

Primary: NPV of [68Ga]Ga-PentixaFor (PTF)-PET for PFS

End point title	NPV of [68Ga]Ga-PentixaFor (PTF)-PET for PFS[1]

End point description:

Negative predictive value (NPV) of PTF-PET at interim examination (after 6 ± 2 weeks of induction chemotherapy) for progression-free survival (PFS)

End point type	Primary

End point timeframe:

4-8 weeks

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: Only a percentage of patients who have not progressed was planned as the primary end point. It was planned with a 95% IC. This was mainly descriptive

End point values	Whole approved population			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: percentage				
number (not applicable)	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From 25/Oct/2022 to 25-Jan-23

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Patients fulfilling I/E criteria who signed ICF

Reporting group description: -

Serious adverse events	Patients fulfilling I/E criteria who signed ICF		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pulmonary oedema			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Patients fulfilling I/E criteria who signed ICF		
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 1 (100.00%)		
Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all)	 1 / 1 (100.00%) 1		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	 1 / 1 (100.00%) 1		
Infections and infestations Fungal infection subjects affected / exposed occurrences (all)	 1 / 1 (100.00%) 1		
Metabolism and nutrition disorders Hypomagnesaemia subjects affected / exposed occurrences (all) Weight decreased subjects affected / exposed occurrences (all) Hyperkalaemia subjects affected / exposed occurrences (all)	 1 / 1 (100.00%) 1 1 / 1 (100.00%) 1 1 / 1 (100.00%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported