



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 | | |
|-------|---|--|--|

| |
|--|
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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