



## Clinical trial results:

**PARPi-PANC - A multicentric, single arm, phase II trial assessing the efficacy of niraparib as first line therapy for patients with metastatic homologous repair-deficient pancreatic cancer**

### Summary

|                          |                   |
|--------------------------|-------------------|
| EudraCT number           | 2021-003042-20    |
| Trial protocol           | FR                |
| Global end of trial date | 06 September 2024 |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 28 June 2026 |
| First version publication date | 28 June 2026 |

### Trial information

#### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | ET21-169 |
|-----------------------|----------|

#### Additional study identifiers

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

Notes:

### Sponsors

|                              |                                                                   |
|------------------------------|-------------------------------------------------------------------|
| Sponsor organisation name    | Centre Léon Bérard                                                |
| Sponsor organisation address | 28 Rue Laënnec, Lyon, France,                                     |
| Public contact               | DRCI - Phases précoces, Centre Léon Bérard, +33 (0)4 26 55 68 24, |
| Scientific contact           | DRCI - Phases précoces, Centre Léon Bérard, +33 (0)4 26 55 68 24, |

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:

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**Results analysis stage**

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|                                                      |                   |
|------------------------------------------------------|-------------------|
| Analysis stage                                       | Final             |
| Date of interim/final analysis                       | 09 February 2026  |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 06 September 2024 |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 06 September 2024 |
| Was the trial ended prematurely?                     | Yes               |

Notes:

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**General information about the trial**

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Main objective of the trial:

To assess the efficacy of niraparib in patients with HR-deficient pancreatic cancer.

Protection of trial subjects:

No study-related procedure will be performed without prior written informed consent obtained from the patient. The investigator will inform the patient about the study treatment, its objectives, and its design, provide the patient information leaflet and informed consent form, answer any questions the patient may have, and ensure that the patient understands the potential risks and benefits of participating in the study before signing the informed consent form.

Background therapy: -

Evidence for comparator: -

|                                                           |                   |
|-----------------------------------------------------------|-------------------|
| Actual start date of recruitment                          | 12 September 2023 |
| Long term follow-up planned                               | No                |
| Independent data monitoring committee (IDMC) involvement? | Yes               |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |           |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | France: 2 |
| Worldwide total number of subjects   | 2         |
| EEA total number of subjects         | 2         |

Notes:

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**Subjects enrolled per age group**

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|                                           |   |
|-------------------------------------------|---|
| 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)                      | 1 |
| From 65 to 84 years                       | 1 |
| 85 years and over                         | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Inform the patient about the treatments, objectives, outcome and any ancillary studies, answer their questions and sign the informed consent with them after a reflection period . Check the eligibility criteria list and perform the exams (e.g. Physical examination, baseline signs and symptoms...)

### Period 1

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

### Arms

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Single Arm |
|------------------|------------|

Arm description:

Niraparib as first line therapy for patients with metastatic homologous repair-deficient pancreatic cancer. Only patients with mutation and/or rearrangement leading to inactivation in at least one of the following genes BARD1, BRCA1, BRCA2, BRIP1, FANCA, FANCD2, FANCL, MRE11, NBN, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L are eligible.

|                                        |              |
|----------------------------------------|--------------|
| Arm type                               | Experimental |
| Investigational medicinal product name | Niraparib    |
| Investigational medicinal product code |              |
| Other name                             |              |
| Pharmaceutical forms                   | Capsule      |
| Routes of administration               | Oral use     |

Dosage and administration details:

Per Os at approximately the same time every day, with or without a meal. Capsules should be swallowed whole with water. The capsules should not be chewed or crushed. Bedtime administration may be a potential method for managing nausea. Per Os at approximately the same time every day, with or without a meal. Capsules should be swallowed whole with water. The capsules should not be chewed or crushed. Bedtime administration may be a potential method for managing nausea. 300 mg/d, continuously for patients with TB >1.5- 3 ULN and/or ASAT/ALAT ≤5ULN. Or 200mg/d initial dosing for patients with TB >1.5 ULN and up to 3ULN and/or ASAT/ALAT > 2.5 ULN and up to 5 ULN with increase to 300mg if 1) liver safety lab tests improve to Grade 1 according to NCI criteria (based on total bilirubin and AST/ALT) with bilirubin <1.5ULN) and 2) no grade >1 related AE are reported.

|                                       |            |
|---------------------------------------|------------|
| <b>Number of subjects in period 1</b> | Single Arm |
| Started                               | 2          |
| Completed                             | 2          |

## Baseline characteristics

### Reporting groups

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | Overall study period |
|-----------------------|----------------------|

Reporting group description: -

| Reporting group values                                | Overall study period | Total |  |
|-------------------------------------------------------|----------------------|-------|--|
| Number of subjects                                    | 2                    | 2     |  |
| Age categorical                                       |                      |       |  |
| Units: Subjects                                       |                      |       |  |
| In utero                                              | 0                    | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                    | 0     |  |
| Newborns (0-27 days)                                  | 0                    | 0     |  |
| Infants and toddlers (28 days-23<br>months)           | 0                    | 0     |  |
| Children (2-11 years)                                 | 0                    | 0     |  |
| Adolescents (12-17 years)                             | 0                    | 0     |  |
| Adults (18-64 years)                                  | 1                    | 1     |  |
| From 65-84 years                                      | 1                    | 1     |  |
| 85 years and over                                     | 0                    | 0     |  |
| Age continuous                                        |                      |       |  |
| Units: years                                          |                      |       |  |
| median                                                | 66                   |       |  |
| full range (min-max)                                  | 56 to 76             | -     |  |
| Gender categorical                                    |                      |       |  |
| Units: Subjects                                       |                      |       |  |
| Female                                                | 1                    | 1     |  |
| Male                                                  | 1                    | 1     |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                        |            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                  | Single Arm |
| Reporting group description:<br>Niraparib as first line therapy for patients with metastatic homologous repair-deficient pancreatic cancer. Only patients with mutation and/or rearrangement leading to inactivation in at least one of the following genes BARD1, BRCA1, BRCA2, BRIP1, FANCA, FANCD2, FANCL, MRE11, NBN, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D, RAD54L are eligible. |            |

### Primary: Objective response rate

|                        |                                        |
|------------------------|----------------------------------------|
| End point title        | Objective response rate <sup>[1]</sup> |
| End point description: |                                        |

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

The primary endpoint is the ORR after 16 weeks of treatment (ORR-16W) defined as the rate of patients with CR or PR as per RECIST V1.1.

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: Only two patients were included, and the sponsor decided to prematurely terminate the study. Consequently, no analysis was performed.

| End point values            | Single Arm       |  |  |  |
|-----------------------------|------------------|--|--|--|
| Subject group type          | Reporting group  |  |  |  |
| Number of subjects analysed | 2 <sup>[2]</sup> |  |  |  |
| Units: number               |                  |  |  |  |
| No evaluate                 | 2                |  |  |  |

Notes:

[2] - Trial ended prematurely, no analysis.

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

The investigator collects (spontaneous patient report or questioning) and immediately notifies the sponsor of all SAEs, in a written report, whether or not they are deemed to be attributable to research and which occur during the study.

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 24     |

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

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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: Only one adverse event was reported for this study: grade 3 vomiting related to treatment

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date              | Amendment                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20 September 2022 | The addition of specific details regarding home blood pressure monitoring by the patient on days 8, 22, 8, and 22 impacts the information sheet.<br>The addition of instructions and a record of these home blood pressure measurements in the home monitoring logbook.                                                                                                                                |
| 13 March 2023     | The removal of the requirement for biallelic inactivation of one of the homologous recombination genes (criterion I3 & study design).<br>The ability to document an alteration of one of the homologous recombination genes using liquid biopsy (addition of a mandatory blood sample for screening, study design). Collection of an archived tumor sample remains required for the ancillary program. |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported