



## Clinical trial results:

### 16-18F-fluor-17-estradiol PET/CT for detection of estrogen receptor positive liver metastases in breast cancer

#### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2019-002665-35  |
| Trial protocol           | DK              |
| Global end of trial date | 04 October 2024 |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 02 November 2024 |
| First version publication date | 02 November 2024 |

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 190619 |
|-----------------------|--------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04150731 |
| WHO universal trial number (UTN)   | -           |

Notes:

##### Sponsors

|                              |                                                                                          |
|------------------------------|------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Aarhus University Hospytal                                                               |
| Sponsor organisation address | Palle Juul Jensens Boulevard 99, Aarhus, Denmark, 8200                                   |
| Public contact               | Mette Abildgaard Pedersen, Aarhus University Hospital, +45 31411180, meabpe@biomed.au.dk |
| Scientific contact           | Mette Abildgaard Pedersen, Aarhus University Hospital, +45 31411180, meabpe@biomed.au.dk |

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                       | 04 October 2024 |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 04 October 2024 |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 04 October 2024 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate parametric and conventional FES-PET/CT as methods of quantification of estrogen receptor (ER) expression in patients with disseminated BC

Protection of trial subjects:

GCP trail unit Aarhus University

Background therapy: -

Evidence for comparator: -

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 23 October 2020 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | Yes             |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | Denmark: 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)                      | 6 |
| From 65 to 84 years                       | 2 |
| 85 years and over                         | 0 |

## Subject disposition

### Recruitment

Recruitment details:

At oncology department , Aarhus University Hospital

### Pre-assignment

Screening details:

Inclusion criteria: metastatic ER+, human epidermal growth factor receptor 2 negative (HER2-) BC (2) at least two liver metastases visualized on CT (3) treatment with aromatase inhibitors or chemotherapy (4) postmenopausal status.

### Period 1

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

### Arms

|                                        |                       |
|----------------------------------------|-----------------------|
| Arm title                              | FES SCAN              |
| Arm description: -                     |                       |
| Arm type                               | Experimental          |
| Investigational medicinal product name | 18F-Fluoroestradiol   |
| Investigational medicinal product code |                       |
| Other name                             |                       |
| Pharmaceutical forms                   | Infusion              |
| Routes of administration               | Intravenous bolus use |

Dosage and administration details:

200 MBq

| Number of subjects in period 1 | FES SCAN |
|--------------------------------|----------|
| Started                        | 8        |
| Completed                      | 8        |

## Baseline characteristics

### Reporting groups

|                                |               |
|--------------------------------|---------------|
| Reporting group title          | Overall trail |
| Reporting group description: - |               |

| Reporting group values                                | Overall trail | Total |  |
|-------------------------------------------------------|---------------|-------|--|
| Number of subjects                                    | 8             | 8     |  |
| 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)                                  | 6             | 6     |  |
| From 65-84 years                                      | 2             | 2     |  |
| 85 years and over                                     | 0             | 0     |  |
| Age continuous                                        |               |       |  |
| Units: years                                          |               |       |  |
| median                                                | 57            |       |  |
| full range (min-max)                                  | 41 to 74      | -     |  |
| Gender categorical                                    |               |       |  |
| Units: Subjects                                       |               |       |  |
| Female                                                | 8             | 8     |  |
| Male                                                  | 0             | 0     |  |

### Subject analysis sets

|                            |               |
|----------------------------|---------------|
| Subject analysis set title | FES uptake    |
| Subject analysis set type  | Full analysis |

Subject analysis set description:

Tumor to background FES uptake was increased with dynamic imaging compared to static imaging.

|                            |                   |
|----------------------------|-------------------|
| Subject analysis set title | FES Uptake Patlak |
| Subject analysis set type  | Full analysis     |

Subject analysis set description:

FES Uptake Patlak

| Reporting group values                                | FES uptake | FES Uptake Patlak |  |
|-------------------------------------------------------|------------|-------------------|--|
| Number of subjects                                    | 8          | 8                 |  |
| Age categorical                                       |            |                   |  |
| Units: Subjects                                       |            |                   |  |
| In utero                                              | 0          |                   |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 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)                     | 6        |  |  |
| From 65-84 years                         | 2        |  |  |
| 85 years and over                        | 0        |  |  |
| Age continuous                           |          |  |  |
| Units: years                             |          |  |  |
| median                                   | 57       |  |  |
| full range (min-max)                     | 41 to 74 |  |  |
| Gender categorical                       |          |  |  |
| Units: Subjects                          |          |  |  |
| Female                                   | 8        |  |  |
| Male                                     | 0        |  |  |

## End points

### End points reporting groups

|                                                                                               |                   |
|-----------------------------------------------------------------------------------------------|-------------------|
| Reporting group title                                                                         | FES SCAN          |
| Reporting group description: -                                                                |                   |
| Subject analysis set title                                                                    | FES uptake        |
| Subject analysis set type                                                                     | Full analysis     |
| Subject analysis set description:                                                             |                   |
| Tumor to background FES uptake was increased with dynamic imaging compared to static imaging. |                   |
| Subject analysis set title                                                                    | FES Uptake Patlak |
| Subject analysis set type                                                                     | Full analysis     |
| Subject analysis set description:                                                             |                   |
| FES Uptake Patlak                                                                             |                   |

### Primary: FES tumor to background

|                                                                                               |                         |
|-----------------------------------------------------------------------------------------------|-------------------------|
| End point title                                                                               | FES tumor to background |
| End point description:                                                                        |                         |
| Tumor to background FES uptake was increased with dynamic imaging compared to static imaging. |                         |
| End point type                                                                                | Primary                 |
| End point timeframe:                                                                          |                         |
| 2023                                                                                          |                         |

| End point values                     | FES uptake           | FES Uptake Patlak    |  |  |
|--------------------------------------|----------------------|----------------------|--|--|
| Subject group type                   | Subject analysis set | Subject analysis set |  |  |
| Number of subjects analysed          | 8                    | 8                    |  |  |
| Units: ratio                         |                      |                      |  |  |
| arithmetic mean (standard deviation) | 2.45 ( $\pm$ 0.2)    | 0 ( $\pm$ 0)         |  |  |

### Statistical analyses

|                                         |                                |
|-----------------------------------------|--------------------------------|
| Statistical analysis title              | t-test                         |
| Comparison groups                       | FES uptake v FES Uptake Patlak |
| Number of subjects included in analysis | 16                             |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | other <sup>[1]</sup>           |
| P-value                                 | < 0.05                         |
| Method                                  | t-test, 2-sided                |

Notes:

[1] - t-test

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

1 adverse event with back pain

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 22.0 |
|--------------------|------|

### Reporting groups

|                       |              |
|-----------------------|--------------|
| Reporting group title | FES exposure |
|-----------------------|--------------|

Reporting group description: -

| Serious adverse events                            | FES exposure  |  |  |
|---------------------------------------------------|---------------|--|--|
| Total subjects affected by serious adverse events |               |  |  |
| subjects affected / exposed                       | 0 / 8 (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                            | FES exposure   |  |  |
|-------------------------------------------------------|----------------|--|--|
| Total subjects affected by non-serious adverse events |                |  |  |
| subjects affected / exposed                           | 1 / 8 (12.50%) |  |  |
| Musculoskeletal and connective tissue disorders       |                |  |  |
| Back pain                                             |                |  |  |
| subjects affected / exposed                           | 1 / 8 (12.50%) |  |  |
| occurrences (all)                                     | 1              |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported