



## Clinical trial results:

### A Phase 2a, Proof-of-Concept, Open-Label Study to Evaluate the Pharmacodynamics, Pharmacokinetics, and Safety of Obicetrapib in Patients with Early Alzheimer's Disease (Hetero/Homozygote APOE4 Carriers)

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2021-002687-41 |
| Trial protocol           | NL             |
| Global end of trial date | 01 June 2023   |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 06 April 2025 |
| First version publication date | 06 April 2025 |

#### Trial information

##### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | TA-8995-AD-1 |
|-----------------------|--------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT05161715 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                                              |
|------------------------------|----------------------------------------------------------------------------------------------|
| Sponsor organisation name    | NewAmsterdam Pharma BV                                                                       |
| Sponsor organisation address | Gooimeer 2-35, DC Naarden, Netherlands, 1411                                                 |
| Public contact               | Study Director, NewAmsterdam Pharma BV, 31 352062971, study.director@newamsterdampharma.com  |
| Scientific contact           | Study Director, NewAmsterdam Pharma BV, +31 352062971, study.director@newamsterdampharma.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                       | 24 August 2024 |
| Is this the analysis of the primary completion data? | Yes            |
| Primary completion date                              | 09 May 2023    |
| Global end of trial reached?                         | Yes            |
| Global end of trial date                             | 01 June 2023   |
| Was the trial ended prematurely?                     | No             |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the pharmacodynamics (PD) (apolipoproteins/lipid particles and cholesterol efflux) of obicetrapib in cerebrospinal fluid (CSF) and plasma (apolipoproteins/lipid particles) in patients with early Alzheimer's Disease (AD) (hetero/homozygote APOE4 carriers).

The exploratory objectives of this study are to evaluate:

- other PD markers of obicetrapib (additional lipoproteins, neurodegeneration, and inflammation) in patients with early AD.
- the cognitive effects of obicetrapib in patients with early AD.
- the pharmacokinetics (PK) of obicetrapib in patients with early AD.

The safety objective of this study is to evaluate the safety and tolerability of obicetrapib in patients with early AD.

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki and with all applicable laws and regulations of the locale and country where the study was conducted, and in compliance with Good Clinical Practice Guidelines.

Background therapy: -

Evidence for comparator: -

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 12 January 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 | Netherlands: 13 |
| Worldwide total number of subjects   | 13              |
| EEA total number of subjects         | 13              |

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)                     | 8 |
| From 65 to 84 years                      | 5 |
| 85 years and over                        | 0 |

## Subject disposition

### Recruitment

Recruitment details:

13 participants were randomized

### Pre-assignment

Screening details:

18 participants were screened

### Period 1

|                              |                         |
|------------------------------|-------------------------|
| Period 1 title               | Overall Study           |
| Is this the baseline period? | Yes                     |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

### Arms

|           |             |
|-----------|-------------|
| Arm title | Obicetrapib |
|-----------|-------------|

Arm description:

Obicetrapib (10 mg)

|                                        |                         |
|----------------------------------------|-------------------------|
| Arm type                               | Experimental            |
| Investigational medicinal product name | Obicetrapib 5 mg tablet |
| Investigational medicinal product code |                         |
| Other name                             |                         |
| Pharmaceutical forms                   | Tablet                  |
| Routes of administration               | Oral use                |

Dosage and administration details:

Once daily 2 x 5 mg obicetrapib tablet

| Number of subjects in period 1 | Obicetrapib |
|--------------------------------|-------------|
| Started                        | 13          |
| Completed                      | 13          |

### Period 2

|                              |                |
|------------------------------|----------------|
| Period 2 title               | Overall Study  |
| Is this the baseline period? | No             |
| Allocation method            | Not applicable |
| Blinding used                | Not blinded    |

### Arms

|                                        |                         |
|----------------------------------------|-------------------------|
| <b>Arm title</b>                       | Obicetrapib             |
| Arm description:                       |                         |
| Obicetrapib (10 mg)                    |                         |
| Arm type                               | Experimental            |
| Investigational medicinal product name | Obicetrapib 5 mg tablet |
| Investigational medicinal product code |                         |
| Other name                             |                         |
| Pharmaceutical forms                   | Tablet                  |
| Routes of administration               | Oral use                |
| Dosage and administration details:     |                         |
| Once daily 2 x 5 mg obicetrapib tablet |                         |

|                                       |             |
|---------------------------------------|-------------|
| <b>Number of subjects in period 2</b> | Obicetrapib |
| Started                               | 13          |
| Completed                             | 13          |

## Baseline characteristics

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | Obicetrapib |
|-----------------------|-------------|

Reporting group description:

Obicetrapib (10 mg)

| Reporting group values                                                                           | Obicetrapib | Total |  |
|--------------------------------------------------------------------------------------------------|-------------|-------|--|
| Number of subjects                                                                               | 13          | 13    |  |
| Age categorical                                                                                  |             |       |  |
| Units: Subjects                                                                                  |             |       |  |
| In utero                                                                                         |             | 0     |  |
| Preterm newborn infants (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)                                                                             |             | 0     |  |
| From 65-84 years                                                                                 |             | 0     |  |
| 85 years and over                                                                                |             | 0     |  |
| Age continuous                                                                                   |             |       |  |
| Baseline Population is defined as all participants who received at least one dose of study drug. |             |       |  |
| Units: years                                                                                     |             |       |  |
| arithmetic mean                                                                                  | 64.5        |       |  |
| standard deviation                                                                               | ± 6.2       | -     |  |
| Gender categorical                                                                               |             |       |  |
| Baseline Population is defined as all participants who received at least one dose of study drug. |             |       |  |
| Units: Subjects                                                                                  |             |       |  |
| Female                                                                                           | 12          | 12    |  |
| Male                                                                                             | 1           | 1     |  |

## End points

### End points reporting groups

|                                                                                                  |                     |
|--------------------------------------------------------------------------------------------------|---------------------|
| Reporting group title                                                                            | Obicetrapib         |
| Reporting group description:                                                                     |                     |
| Obicetrapib (10 mg)                                                                              |                     |
| Reporting group title                                                                            | Obicetrapib         |
| Reporting group description:                                                                     |                     |
| Obicetrapib (10 mg)                                                                              |                     |
| Subject analysis set title                                                                       | Baseline Population |
| Subject analysis set type                                                                        | Intention-to-treat  |
| Subject analysis set description:                                                                |                     |
| Baseline Population is defined as all participants who received at least one dose of study drug. |                     |

### Primary: 1. Mean Percent Change in Apolipoprotein A-I (ApoA-I) In Cerebrospinal Fluid (CSF)

|                                                                                   |                                                                                    |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| End point title                                                                   | 1. Mean Percent Change in Apolipoprotein A-I (ApoA-I) In Cerebrospinal Fluid (CSF) |
| End point description:                                                            |                                                                                    |
| Mean percent change from screening (V1) to end of treatment (V6) in ApoA-I in CSF |                                                                                    |
| End point type                                                                    | Primary                                                                            |
| End point timeframe:                                                              |                                                                                    |
| 24 weeks                                                                          |                                                                                    |

| End point values                              | Obicetrapib       | Obicetrapib       |  |  |
|-----------------------------------------------|-------------------|-------------------|--|--|
| Subject group type                            | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed                   | 12 <sup>[1]</sup> | 12 <sup>[2]</sup> |  |  |
| Units: Percentage Change from Screening Visit |                   |                   |  |  |
| arithmetic mean (standard deviation)          | -8.4 (± 13.6)     | -8.4 (± 13.6)     |  |  |

Notes:

[1] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

[2] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

### Statistical analyses

|                                         |                           |
|-----------------------------------------|---------------------------|
| Statistical analysis title              | Statistical Analysis      |
| Comparison groups                       | Obicetrapib v Obicetrapib |
| Number of subjects included in analysis | 24                        |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | superiority               |
| P-value                                 | = 0.425 <sup>[3]</sup>    |
| Method                                  | Wilcoxon (Mann-Whitney)   |

Notes:

[3] - No multiple testing correction was performed

### Primary: 2. Mean Percent Change in Apolipoprotein A-I (ApoA-I) in Plasma

|                 |                                                          |
|-----------------|----------------------------------------------------------|
| End point title | 2. Mean Percent Change in Apolipoprotein A-I (ApoA-I) in |
|-----------------|----------------------------------------------------------|

|                                                                            |         |
|----------------------------------------------------------------------------|---------|
|                                                                            | Plasma  |
| End point description:                                                     |         |
| Mean percent change in ApoA-I in plasma from baseline (V2) to week 24 (V6) |         |
| End point type                                                             | Primary |
| End point timeframe:                                                       |         |
| 24 weeks                                                                   |         |

| End point values                     | Obicetrapib       | Obicetrapib     |  |  |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type                   | Reporting group   | Reporting group |  |  |
| Number of subjects analysed          | 13 <sup>[4]</sup> | 13              |  |  |
| Units: Percent Change from Baseline  |                   |                 |  |  |
| arithmetic mean (standard deviation) | 37.5 (± 25.2)     | 37.5 (± 25.2)   |  |  |

Notes:

[4] - For the PD endpoints in plasma, analyses were conducted on all 13 patients.

### Statistical analyses

| Statistical analysis title              | Statistical Analysis       |
|-----------------------------------------|----------------------------|
| Comparison groups                       | Obicetrapib v Obicetrapib  |
| Number of subjects included in analysis | 26                         |
| Analysis specification                  | Pre-specified              |
| Analysis type                           | superiority <sup>[5]</sup> |
| P-value                                 | = 0.0002                   |
| Method                                  | Wilcoxon (Mann-Whitney)    |

Notes:

[5] - No multiple testing correction was performed

### Primary: 3. Mean Percent Change in Apolipoprotein-E (ApoE) in Cerebrospinal Fluid (CSF)

|                                                                          |                                                                                |
|--------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| End point title                                                          | 3. Mean Percent Change in Apolipoprotein-E (ApoE) in Cerebrospinal Fluid (CSF) |
| End point description:                                                   |                                                                                |
| Mean percent change from screening (V1) to end of treatment (V6) in ApoE |                                                                                |
| End point type                                                           | Primary                                                                        |
| End point timeframe:                                                     |                                                                                |
| 24 weeks                                                                 |                                                                                |

| End point values                     | Obicetrapib       | Obicetrapib       |  |  |
|--------------------------------------|-------------------|-------------------|--|--|
| Subject group type                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed          | 12 <sup>[6]</sup> | 12 <sup>[7]</sup> |  |  |
| Units: Percent Change from Baseline  |                   |                   |  |  |
| arithmetic mean (standard deviation) | 3.9 (± 10.3)      | 3.9 (± 10.3)      |  |  |

Notes:

[6] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

[7] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

### Statistical analyses

| Statistical analysis title              | Statistical Analysis      |
|-----------------------------------------|---------------------------|
| Comparison groups                       | Obicetrapib v Obicetrapib |
| Number of subjects included in analysis | 24                        |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | superiority               |
| P-value                                 | = 0.0424 <sup>[8]</sup>   |
| Method                                  | Wilcoxon (Mann-Whitney)   |

Notes:

[8] - No multiple testing correction was performed

### Primary: 4. Mean Percent Change in Apolipoprotein-E (ApoE) in Plasma

|                                                                          |                                                             |
|--------------------------------------------------------------------------|-------------------------------------------------------------|
| End point title                                                          | 4. Mean Percent Change in Apolipoprotein-E (ApoE) in Plasma |
| End point description:                                                   |                                                             |
| Mean percent change from baseline (V2) to week 24 (V6) in plasma in ApoE |                                                             |
| End point type                                                           | Primary                                                     |
| End point timeframe:                                                     |                                                             |
| 24 weeks                                                                 |                                                             |

| End point values                     | Obicetrapib       | Obicetrapib     |  |  |
|--------------------------------------|-------------------|-----------------|--|--|
| Subject group type                   | Reporting group   | Reporting group |  |  |
| Number of subjects analysed          | 13 <sup>[9]</sup> | 13              |  |  |
| Units: Percent Change from Baseline  |                   |                 |  |  |
| arithmetic mean (standard deviation) | 47.8 (± 46.9)     | 47.8 (± 46.9)   |  |  |

Notes:

[9] - For the PD endpoints in plasma, analyses were conducted on all 13 patients.

### Statistical analyses

| Statistical analysis title              | Statistical Analysis      |
|-----------------------------------------|---------------------------|
| Comparison groups                       | Obicetrapib v Obicetrapib |
| Number of subjects included in analysis | 26                        |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | superiority               |
| P-value                                 | = 0.001 <sup>[10]</sup>   |
| Method                                  | Wilcoxon (Mann-Whitney)   |

Notes:

[10] - No multiple testing correction was performed

**Primary: 5. Small HDL (s-HDL) Particle Concentration in Cerebrospinal Fluid (CSF) at Baseline**

|                 |                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------|
| End point title | 5. Small HDL (s-HDL) Particle Concentration in Cerebrospinal Fluid (CSF) at Baseline <sup>[11]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------|

End point description:

Small high-density lipoprotein (s-HDL) particle concentration in cerebrospinal fluid (CSF) measured by Ion Mobility Assay (<https://doi.org/10.1002/alz.12649>)

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

End point timeframe:

At Baseline

Notes:

[11] - 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: Average relative abundance was reported and statistical analysis was not performed. Small high-density lipoprotein (s-HDL) particle concentration in CSF measured by Ion Mobility Assay (<https://doi.org/10.1002/alz.12649>)

|                                      |                    |  |  |  |
|--------------------------------------|--------------------|--|--|--|
| <b>End point values</b>              | Obicetrapib        |  |  |  |
| Subject group type                   | Reporting group    |  |  |  |
| Number of subjects analysed          | 12 <sup>[12]</sup> |  |  |  |
| Units: Average relative abundance    |                    |  |  |  |
| arithmetic mean (standard deviation) | 0.542 (± 0.138)    |  |  |  |

Notes:

[12] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

**Statistical analyses**

No statistical analyses for this end point

**Primary: 6. Small HDL (s-HDL) Particle Concentration in Cerebrospinal Fluid (CSF) at Week 24**

|                 |                                                                                                     |
|-----------------|-----------------------------------------------------------------------------------------------------|
| End point title | 6. Small HDL (s-HDL) Particle Concentration in Cerebrospinal Fluid (CSF) at Week 24 <sup>[13]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------|

End point description:

Small high-density lipoprotein (s-HDL) particle concentration in CSF measured by Ion Mobility Assay (<https://doi.org/10.1002/alz.12649>)

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

End point timeframe:

At Week 24

Notes:

[13] - 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: Average relative abundance was reported and statistical analysis was not performed. Small high-density lipoprotein (s-HDL) particle concentration in CSF measured by Ion Mobility Assay (<https://doi.org/10.1002/alz.12649>)

|                                      |                    |  |  |  |
|--------------------------------------|--------------------|--|--|--|
| <b>End point values</b>              | Obicetrapib        |  |  |  |
| Subject group type                   | Reporting group    |  |  |  |
| Number of subjects analysed          | 12 <sup>[14]</sup> |  |  |  |
| Units: Average Relative Abundance    |                    |  |  |  |
| arithmetic mean (standard deviation) | 0.542 (± 0.106)    |  |  |  |

Notes:

[14] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

## Statistical analyses

No statistical analyses for this end point

### Primary: 7. Small HDL (s-HDL) Particle Concentration in Plasma at Baseline

|                 |                                                                                   |
|-----------------|-----------------------------------------------------------------------------------|
| End point title | 7. Small HDL (s-HDL) Particle Concentration in Plasma at Baseline <sup>[15]</sup> |
|-----------------|-----------------------------------------------------------------------------------|

End point description:

Small high-density lipoprotein (s-HDL) particle concentration plasma measured by Ion Mobility Assay.

For more information on the measurement used please refer to this article:

<https://doi.org/10.1002/alz.12649>

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

End point timeframe:

At Baseline

Notes:

[15] - 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: Due to a non-optimal sample preparation procedure, a number of the samples allocated for the small HDL-C particle analysis were lost and therefore no samples were assessed for this measure.

| End point values                     | Obicetrapib       |  |  |  |
|--------------------------------------|-------------------|--|--|--|
| Subject group type                   | Reporting group   |  |  |  |
| Number of subjects analysed          | 0 <sup>[16]</sup> |  |  |  |
| Units: Average Relative Abundance    |                   |  |  |  |
| arithmetic mean (standard deviation) | ( )               |  |  |  |

Notes:

[16] - Due to a non-optimal sample prep, samples were not able to be assessed for this measure.

## Statistical analyses

No statistical analyses for this end point

### Primary: 8. Small HDL (s-HDL) Particle Concentration in Plasma at Week 24

|                 |                                                                                  |
|-----------------|----------------------------------------------------------------------------------|
| End point title | 8. Small HDL (s-HDL) Particle Concentration in Plasma at Week 24 <sup>[17]</sup> |
|-----------------|----------------------------------------------------------------------------------|

End point description:

Small high-density lipoprotein (s-HDL) particle concentration in plasma measured by Ion Mobility Assay at Week 24

For more information on the measurement used please refer to this article:

<https://doi.org/10.1002/alz.12649>

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

End point timeframe:

At Week 24

Notes:

[17] - 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: Due to a non-optimal sample preparation procedure, a number of the samples allocated for the small HDL-C particle analysis were lost and therefore no samples were assessed for this measure.

| End point values                     | Obicetrapib       |  |  |  |
|--------------------------------------|-------------------|--|--|--|
| Subject group type                   | Reporting group   |  |  |  |
| Number of subjects analysed          | 0 <sup>[18]</sup> |  |  |  |
| Units: Average Relative Abundance    |                   |  |  |  |
| arithmetic mean (standard deviation) | ( )               |  |  |  |

Notes:

[18] - Due to a non-optimal sample prep, samples were not able to be assessed for this measure.

## Statistical analyses

No statistical analyses for this end point

## Primary: 9. Mean Percent Change in Cholesterol Efflux Capacity in Cerebrospinal Fluid (CSF)

|                                                                                               |                                                                                    |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| End point title                                                                               | 9. Mean Percent Change in Cholesterol Efflux Capacity in Cerebrospinal Fluid (CSF) |
| End point description:                                                                        |                                                                                    |
| Mean percent change in cholesterol efflux capacity in CSF from screening (V1) to week 24 (V6) |                                                                                    |
| End point type                                                                                | Primary                                                                            |
| End point timeframe:                                                                          |                                                                                    |
| 24 Weeks                                                                                      |                                                                                    |

| End point values                     | Obicetrapib        | Obicetrapib        |  |  |
|--------------------------------------|--------------------|--------------------|--|--|
| Subject group type                   | Reporting group    | Reporting group    |  |  |
| Number of subjects analysed          | 12 <sup>[19]</sup> | 12 <sup>[20]</sup> |  |  |
| Units: Percent Change from Screening |                    |                    |  |  |
| arithmetic mean (standard deviation) | 1.9 (± 24.1)       | 1.9 (± 24.1)       |  |  |

Notes:

[19] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

[20] - Lumbar puncture was not possible for 1 patient at EOT (Day 168, Visit 6); hence n=12 for CSF

## Statistical analyses

|                                         |                           |
|-----------------------------------------|---------------------------|
| Statistical analysis title              | Statistical Analysis      |
| Comparison groups                       | Obicetrapib v Obicetrapib |
| Number of subjects included in analysis | 24                        |
| Analysis specification                  | Pre-specified             |
| Analysis type                           | superiority               |
| P-value                                 | = 0.556 <sup>[21]</sup>   |
| Method                                  | Wilcoxon (Mann-Whitney)   |

Notes:

[21] - No multiple testing correction was performed

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug through Week 24.5

Adverse event reporting additional description:

Safety Population included all participants who received at least 1 dose of any study drug.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | Obicetrapib |
|-----------------------|-------------|

Reporting group description:

Obicetrapib (10 mg)

| Serious adverse events                            | Obicetrapib    |  |  |
|---------------------------------------------------|----------------|--|--|
| Total subjects affected by serious adverse events |                |  |  |
| subjects affected / exposed                       | 0 / 13 (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                                          | Obicetrapib     |  |  |
|---------------------------------------------------------------------|-----------------|--|--|
| Total subjects affected by non-serious adverse events               |                 |  |  |
| subjects affected / exposed                                         | 9 / 13 (69.23%) |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                 |  |  |
| basal cell carcinoma face                                           |                 |  |  |
| subjects affected / exposed                                         | 1 / 13 (7.69%)  |  |  |
| occurrences (all)                                                   | 1               |  |  |
| General disorders and administration site conditions                |                 |  |  |
| unilateral leg swelling                                             |                 |  |  |
| subjects affected / exposed                                         | 1 / 13 (7.69%)  |  |  |
| occurrences (all)                                                   | 1               |  |  |
| Respiratory, thoracic and mediastinal disorders                     |                 |  |  |

|                                                                                                                                                                                                                                                                         |                                                                           |  |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|--|--|
| Productive cough<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                    | 1 / 13 (7.69%)<br>1                                                       |  |  |
| Investigations<br>weight loss<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                       | 1 / 13 (7.69%)<br>1                                                       |  |  |
| Injury, poisoning and procedural complications<br>Fall<br>subjects affected / exposed<br>occurrences (all)<br><br>Lumbar puncture headache<br>subjects affected / exposed<br>occurrences (all)<br><br>rib contusion<br>subjects affected / exposed<br>occurrences (all) | 1 / 13 (7.69%)<br>1<br><br>1 / 13 (7.69%)<br>1<br><br>1 / 13 (7.69%)<br>1 |  |  |
| Cardiac disorders<br>Angina pectoris<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                | 1 / 13 (7.69%)<br>1                                                       |  |  |
| Nervous system disorders<br>headache<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                | 2 / 13 (15.38%)<br>2                                                      |  |  |
| Blood and lymphatic system disorders<br>Normocytic anaemia<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                          | 1 / 13 (7.69%)<br>1                                                       |  |  |
| Ear and labyrinth disorders<br>benign paroxysmal positional vertigo<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                 | 1 / 13 (7.69%)<br>1                                                       |  |  |
| Gastrointestinal disorders<br>Constipation<br>subjects affected / exposed<br>occurrences (all)<br><br>loose stool                                                                                                                                                       | 1 / 13 (7.69%)<br>1                                                       |  |  |

|                                                                                                                       |                     |  |  |
|-----------------------------------------------------------------------------------------------------------------------|---------------------|--|--|
| subjects affected / exposed<br>occurrences (all)                                                                      | 1 / 13 (7.69%)<br>1 |  |  |
| obstipation<br>subjects affected / exposed<br>occurrences (all)                                                       | 1 / 13 (7.69%)<br>1 |  |  |
| reflux esophagitis<br>subjects affected / exposed<br>occurrences (all)                                                | 1 / 13 (7.69%)<br>1 |  |  |
| Skin and subcutaneous tissue disorders<br>hair loss<br>subjects affected / exposed<br>occurrences (all)               | 1 / 13 (7.69%)<br>1 |  |  |
| Musculoskeletal and connective tissue disorders<br>hand arthritis<br>subjects affected / exposed<br>occurrences (all) | 1 / 13 (7.69%)<br>1 |  |  |
| Lateral epicondylitis<br>subjects affected / exposed<br>occurrences (all)                                             | 1 / 13 (7.69%)<br>1 |  |  |
| low back pain<br>subjects affected / exposed<br>occurrences (all)                                                     | 1 / 13 (7.69%)<br>1 |  |  |
| lumbago<br>subjects affected / exposed<br>occurrences (all)                                                           | 1 / 13 (7.69%)<br>1 |  |  |
| Infections and infestations<br>COVID-19<br>subjects affected / exposed<br>occurrences (all)                           | 1 / 13 (7.69%)<br>1 |  |  |
| Gastroenteritis<br>subjects affected / exposed<br>occurrences (all)                                                   | 1 / 13 (7.69%)<br>1 |  |  |
| Herpes zoster<br>subjects affected / exposed<br>occurrences (all)                                                     | 1 / 13 (7.69%)<br>1 |  |  |
| Laryngitis                                                                                                            |                     |  |  |

|                                                                                                         |                     |  |  |
|---------------------------------------------------------------------------------------------------------|---------------------|--|--|
| subjects affected / exposed<br>occurrences (all)                                                        | 1 / 13 (7.69%)<br>1 |  |  |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)                   | 1 / 13 (7.69%)<br>1 |  |  |
| Metabolism and nutrition disorders<br>Hyponatraemia<br>subjects affected / exposed<br>occurrences (all) | 1 / 13 (7.69%)<br>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