



## Clinical trial results:

### Pilot trial to determine the efficacy of secukinumab in active non-segmental vitiligo

#### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2015-003552-48  |
| Trial protocol           | BE              |
| Global end of trial date | 16 January 2018 |

#### Results information

|                                   |                                                                                 |
|-----------------------------------|---------------------------------------------------------------------------------|
| Result version number             | v1 (current)                                                                    |
| This version publication date     | 06 June 2024                                                                    |
| First version publication date    | 06 June 2024                                                                    |
| Summary attachment (see zip file) | Final Study Report (2015-003223-53_Denosumab_Final study report_2022-04-11.pdf) |

#### Trial information

##### Trial identification

|                       |              |
|-----------------------|--------------|
| Sponsor protocol code | AGO/2015/009 |
|-----------------------|--------------|

##### Additional study identifiers

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

Notes:

#### Sponsors

|                              |                                                                         |
|------------------------------|-------------------------------------------------------------------------|
| Sponsor organisation name    | Ghent University Hospital                                               |
| Sponsor organisation address | Corneel Heymanslaan 10, Ghent, Belgium, 9000                            |
| Public contact               | Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be |
| Scientific contact           | Hiruz CTU, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be |

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                       | 22 February 2019 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 16 January 2018  |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 16 January 2018  |
| 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 investigate the capacity of a targeted anti-IL-17A treatment with secukinumab to induce repigmentation in vitiligo patients with active disease.

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring

Background therapy: -

Evidence for comparator: -

|                                                           |                 |
|-----------------------------------------------------------|-----------------|
| Actual start date of recruitment                          | 12 October 2016 |
| 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 | Belgium: 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)                      | 7 |
| From 65 to 84 years                       | 1 |
| 85 years and over                         | 0 |

## Subject disposition

### Recruitment

Recruitment details:

8 patients were recruited between 12-Oct-2016 and 16-Dec-2017. End of trial notification was dated 16-Dec-2017(last patient last visit) and submitted to EC and CA on 13-Feb-2018. There were 3 dropouts due to disease progression (for 2 patients) and unexpected stay abroad (for 1 patient).

### Pre-assignment

Screening details:

Main inclusion criteria:

- 1) Moderate to extensive vitiligo (body surface area  $\geq$  3%)
  - 2) Vitiligo patients with 'active vitiligo'.
  - 3) Vitiligo on hands and/or face
  - 4) Fitzpatrick skin type 3-6
  - 5) Impact score > 8/10 or DLQI (Dermatology Life Quality Index) >
- Patients were included correctly

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall trial (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Non-randomised - controlled    |
| Blinding used                | Not blinded                    |

Blinding implementation details:

No blinding done, all patients have received the active compound

### Arms

|                              |               |
|------------------------------|---------------|
| Are arms mutually exclusive? | No            |
| <b>Arm title</b>             | Baseline data |

Arm description:

Baseline data for the study, as the study only has 1 arm

|                                                           |              |
|-----------------------------------------------------------|--------------|
| Arm type                                                  | Baseline arm |
| No investigational medicinal product assigned in this arm |              |
| <b>Arm title</b>                                          | Active arm   |

Arm description:

Arm receiving the active product (only one arm in the study)

|                                        |                                                |
|----------------------------------------|------------------------------------------------|
| Arm type                               | Experimental                                   |
| Investigational medicinal product name | Secukinumab                                    |
| Investigational medicinal product code |                                                |
| Other name                             |                                                |
| Pharmaceutical forms                   | Suspension for injection in pre-filled syringe |
| Routes of administration               | Subcutaneous use                               |

Dosage and administration details:

Injections with secukinumab (300 mg) will be performed. The injections will be given at baseline, week 1, 2, 3, 4 and subsequent injections will be administered every 4 weeks (total of 10 injections).

| <b>Number of subjects in period 1</b> | Baseline data | Active arm |
|---------------------------------------|---------------|------------|
| Started                               | 8             | 8          |
| Completed                             | 8             | 5          |
| Not completed                         | 0             | 3          |
| Injection missed                      | -             | 1          |
| Lack of efficacy                      | -             | 2          |

## Baseline characteristics

### Reporting groups

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

| Reporting group values                                | Overall trial | Total |  |
|-------------------------------------------------------|---------------|-------|--|
| 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<br>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                                        |               |       |  |
| Units: years                                          |               |       |  |
| arithmetic mean                                       | 50            |       |  |
| full range (min-max)                                  | 30 to 70      | -     |  |
| Gender categorical                                    |               |       |  |
| Units: Subjects                                       |               |       |  |
| Female                                                | 4             | 4     |  |
| Male                                                  | 4             | 4     |  |
| Ethnic origin                                         |               |       |  |
| Units: Subjects                                       |               |       |  |
| Caucasian                                             | 5             | 5     |  |
| Asian                                                 | 1             | 1     |  |
| Indian                                                | 2             | 2     |  |
| Associated auto-immune disease                        |               |       |  |
| Units: Subjects                                       |               |       |  |
| no                                                    | 6             | 6     |  |
| thyroid                                               | 2             | 2     |  |
| Fitzpatrick skin type                                 |               |       |  |
| Units: Subjects                                       |               |       |  |
| III                                                   | 5             | 5     |  |
| IV                                                    | 1             | 1     |  |
| V-                                                    | 2             | 2     |  |
| Disease duration                                      |               |       |  |
| Units: Years                                          |               |       |  |
| arithmetic mean                                       | 16.6          |       |  |
| full range (min-max)                                  | 8 to 38       | -     |  |
| Percentage body affected                              |               |       |  |
| Units: percentage                                     |               |       |  |

|                      |               |   |  |
|----------------------|---------------|---|--|
| arithmetic mean      | 22.42         |   |  |
| full range (min-max) | 7.12 to 50.77 | - |  |

## End points

### End points reporting groups

|                                                              |               |
|--------------------------------------------------------------|---------------|
| Reporting group title                                        | Baseline data |
| Reporting group description:                                 |               |
| Baseline data for the study, as the study only has 1 arm     |               |
| Reporting group title                                        | Active arm    |
| Reporting group description:                                 |               |
| Arm receiving the active product (only one arm in the study) |               |

### Primary: Repigmentation

|                                                        |                                  |
|--------------------------------------------------------|----------------------------------|
| End point title                                        | Repigmentation <sup>[1][2]</sup> |
| End point description:                                 |                                  |
| The primary endpoint (repigmentation) was not reached. |                                  |
| End point type                                         | Primary                          |
| End point timeframe:                                   |                                  |
| N/A                                                    |                                  |

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: No statistical analysis available. The endpoint was not reached.

See attachment Final Study Report

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is not reported for the baseline arm. The baseline arm for the study was added as the study only has 1 arm.

See attachment Final Study Report

| End point values            | Active arm      |  |  |  |
|-----------------------------|-----------------|--|--|--|
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 8               |  |  |  |
| Units: number of patients   |                 |  |  |  |
| depigmentation              | 7               |  |  |  |
| limited repigmentation      | 2               |  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Improvement in Global Satisfaction

|                                         |                                                      |
|-----------------------------------------|------------------------------------------------------|
| End point title                         | Improvement in Global Satisfaction <sup>[3][4]</sup> |
| End point description:                  |                                                      |
|                                         |                                                      |
| End point type                          | Primary                                              |
| End point timeframe:                    |                                                      |
| Score using the Likert scale (5 points) |                                                      |

Notes:

[3] - 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: See attachement Final Study Report

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is not reported for the baseline arm. The baseline arm for the study was added as the study only has 1 arm.

See attachement Final Study Report

| End point values                     | Active arm      |  |  |  |
|--------------------------------------|-----------------|--|--|--|
| Subject group type                   | Reporting group |  |  |  |
| Number of subjects analysed          | 8               |  |  |  |
| Units: Global Satisfaction           |                 |  |  |  |
| arithmetic mean (standard deviation) | 0 ( $\pm$ 0)    |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Disease stability (stop of progression)

|                                                             |                                                        |
|-------------------------------------------------------------|--------------------------------------------------------|
| End point title                                             | Disease stability (stop of progression) <sup>[5]</sup> |
| End point description:                                      |                                                        |
| The secondary endpoint (disease stability) was not reached. |                                                        |
| End point type                                              | Secondary                                              |
| End point timeframe:                                        |                                                        |
| N/A                                                         |                                                        |

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is not reported for the baseline arm. The baseline arm for the study was added as the study only has 1 arm.

See attachement Final Study Report

| End point values            | Active arm      |  |  |  |
|-----------------------------|-----------------|--|--|--|
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 8               |  |  |  |
| Units: number of patients   |                 |  |  |  |
| disease progression         | 7               |  |  |  |
| disease stability           | 1               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Improvement in Dermatology Life Quality Index

|                                                            |                                                              |
|------------------------------------------------------------|--------------------------------------------------------------|
| End point title                                            | Improvement in Dermatology Life Quality Index <sup>[6]</sup> |
| End point description:                                     |                                                              |
| In none of the patients clear clinical efficacy was noted. |                                                              |



|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:  
N/A

Notes:  
[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: See attachement Final Study Report

|                             |                 |  |  |  |
|-----------------------------|-----------------|--|--|--|
| <b>End point values</b>     | Active arm      |  |  |  |
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 8               |  |  |  |
| Units: DLQI                 | 8               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

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

Timeframe for reporting adverse events:

Adverse events will be reported between the first dose administration of trial medication and the last trial related activity

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

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 21.1   |

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | Baseline data |
|-----------------------|---------------|

Reporting group description:

Baseline data for the study, as the study only has 1 arm

|                       |            |
|-----------------------|------------|
| Reporting group title | Active arm |
|-----------------------|------------|

Reporting group description:

Arm receiving the active product (only one arm in the study)

| Serious adverse events                            | Baseline data | Active arm    |  |
|---------------------------------------------------|---------------|---------------|--|
| Total subjects affected by serious adverse events |               |               |  |
| subjects affected / exposed                       | 0 / 8 (0.00%) | 0 / 8 (0.00%) |  |
| number of deaths (all causes)                     | 0             | 0             |  |
| number of deaths resulting from adverse events    | 0             | 0             |  |

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

| Non-serious adverse events                            | Baseline data | Active arm    |  |
|-------------------------------------------------------|---------------|---------------|--|
| Total subjects affected by non-serious adverse events |               |               |  |
| subjects affected / exposed                           | 0 / 8 (0.00%) | 0 / 8 (0.00%) |  |

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: No adverse events occurred during the study.

See attachment Final Study Report

## 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