



## 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
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##### 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 (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			
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
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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
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

### Reporting groups

Reporting group title	Baseline data
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Reporting group description:

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

Reporting group title	Active arm
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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 attachement 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