



## Clinical trial results: Efficacy of brodalumab in patients with psoriasis with failure of other anti-IL-17 treatments

### Summary

EudraCT number	2018-000097-30
Trial protocol	DK
Global end of trial date	20 April 2021

### Results information

Result version number	v1 (current)
This version publication date	27 October 2021
First version publication date	27 October 2021

### Trial information

#### Trial identification

Sponsor protocol code	2018-PSO-IL17R
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#### Additional study identifiers

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

Notes:

#### Sponsors

Sponsor organisation name	Gentofte Hospital
Sponsor organisation address	Gentofte Hospitalsvej 15, 1., Hellerup, Denmark, 2900
Public contact	Dept of Dermatology and Allergy, Herlev and Gentofte Hospital, 0045 38673204, nikolai.dyrberg.loft@regionh.dk
Scientific contact	Dept of Dermatology and Allergy, Herlev and Gentofte Hospital, 0045 38673204, nikolai.dyrberg.loft@regionh.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	10 May 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 April 2021
Global end of trial reached?	Yes
Global end of trial date	20 April 2021
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

This study will evaluate brodalumab treatment in patients with moderate-to-severe psoriasis previously treated with anti-IL-17A with primary or secondary failure of treatment.

1. Percentage of patients achieving PASI75 or an absolute PASI  $\leq 2$  after 3 months.
2. Percentage of patients achieving PASI90 after 3 months.

Protection of trial subjects:

Screening for infections prior to drug initiation, monitoring of infections and biomarkers.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 April 2018
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: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

### Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

### Arms

**Arm title** Brodalumab

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Kyntheum
Investigational medicinal product code	
Other name	Brodalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

210mg

Number of subjects in period 1	Brodalumab
Started	20
Completed	20

### Period 2

Period 2 title	4 weeks
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

**Arms**

<b>Arm title</b>	Brodalumab
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Kyntheum
Investigational medicinal product code	
Other name	Brodalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

210mg

<b>Number of subjects in period 2</b>	Brodalumab
Started	20
Completed	20

**Period 3**

Period 3 title	12 weeks
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

**Arms**

<b>Arm title</b>	Brodalumab
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Kyntheum
Investigational medicinal product code	
Other name	Brodalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

210mg

<b>Number of subjects in period 3</b>	Brodalumab
Started	20
Completed	19
Not completed	1
Lack of efficacy	1

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#### **Period 4**

Period 4 title	26 weeks
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

#### **Arms**

<b>Arm title</b>	Brodalumab
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Kyntheum
Investigational medicinal product code	
Other name	Brodalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

210mg

<b>Number of subjects in period 4</b>	Brodalumab
Started	19
Completed	14
Not completed	5
Lack of efficacy	5

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#### **Period 5**

Period 5 title	52 weeks
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

#### **Arms**

<b>Arm title</b>	Brodalumab
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Kyntheum
Investigational medicinal product code	
Other name	Brodalumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

210mg

<b>Number of subjects in period 5</b>	Brodalumab
Started	14
Completed	9
Not completed	5
Adverse event, non-fatal	2
Lack of efficacy	3

## Baseline characteristics

### Reporting groups

Reporting group title	Baseline
Reporting group description: -	

Reporting group values	Baseline	Total	
Number of subjects	20	20	
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			
50 (30-59)			
Units: years			
median	50		
inter-quartile range (Q1-Q3)	30 to 59	-	
Gender categorical			
Units: Subjects			
Female	7	7	
Male	13	13	

### Subject analysis sets

Subject analysis set title	Full
Subject analysis set type	Full analysis
Subject analysis set description: 20	

Reporting group values	Full		
Number of subjects	20		
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			

Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
50 (30-59)			
Units: years median inter-quartile range (Q1-Q3)	50 30 to 59		
Gender categorical			
Units: Subjects			
Female	7		
Male	13		

## End points

### End points reporting groups

Reporting group title	Brodalumab
Reporting group description:	-
Reporting group title	Brodalumab
Reporting group description:	-
Reporting group title	Brodalumab
Reporting group description:	-
Reporting group title	Brodalumab
Reporting group description:	-
Reporting group title	Brodalumab
Reporting group description:	-
Subject analysis set title	Full
Subject analysis set type	Full analysis
Subject analysis set description:	20

### Primary: Proportion of patients with PASI75 and/or PASI≤2 after 3 months

End point title	Proportion of patients with PASI75 and/or PASI≤2 after 3 months <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe:	3 months

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: One arm, no statistical analysis

End point values	Full			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: 14	14			

### Statistical analyses

No statistical analyses for this end point

### Primary: Proportion of patients with PASI90 after 3 months

End point title	Proportion of patients with PASI90 after 3 months <sup>[2]</sup>
End point description:	
End point type	Primary
End point timeframe:	3 months

Notes:

[2] - 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: One arm, no statistical analysis

<b>End point values</b>	Full			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: 8	8			

### **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

12 months

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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### Reporting groups

Reporting group title	Adverse events
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Reporting group description: -

<b>Serious adverse events</b>	Adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

<b>Non-serious adverse events</b>	Adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 20 (65.00%)		
Nervous system disorders			
Fatigue			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Restlessness			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis			

subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Social circumstances Traffic accident subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Gastrointestinal disorders Gastritis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Respiratory, thoracic and mediastinal disorders COVID-19 subjects affected / exposed occurrences (all)  Pneumonia subjects affected / exposed occurrences (all)  Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1  1 / 20 (5.00%) 1  6 / 20 (30.00%) 6		
Skin and subcutaneous tissue disorders Blisters subjects affected / exposed occurrences (all)  Candidiasis subjects affected / exposed occurrences (all)  Hair loss subjects affected / exposed occurrences (all)  Hyperkeratotic hand eczema subjects affected / exposed occurrences (all)  Psoriasis flare subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2  1 / 20 (5.00%) 1  1 / 20 (5.00%) 1  1 / 20 (5.00%) 1  1 / 20 (5.00%) 1		

Skin infections subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Endocrine disorders Hashimotos subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)  Back pain subjects affected / exposed occurrences (all)  PsA flare subjects affected / exposed occurrences (all)  Spondylitis subjects affected / exposed occurrences (all)  Tendonitis subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3  1 / 20 (5.00%) 1  1 / 20 (5.00%) 1  1 / 20 (5.00%) 1  1 / 20 (5.00%) 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