



Clinical trial results:

A randomised, double-blind, placebo-controlled, trial to evaluate the efficacy of brodalumab monotherapy on vascular and systemic inflammation by 18F-FDG-PET/CT in subjects with moderate-to-severe plaque-type psoriasis who are candidates for systemic therapy

Summary

EudraCT number	2017-003697-14
Trial protocol	DK
Global end of trial date	02 July 2025

Results information

Result version number	v1 (current)
This version publication date	18 July 2025
First version publication date	18 July 2025
Summary attachment (see zip file)	PSOPET2.Summary.2025 (PSOPET2.summary.results.EudraCT.2025.pdf)

Trial information

Trial identification

Sponsor protocol code	PsoPET2
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 67, Aarhus N, Denmark, 8200
Public contact	Secretary M. Larsen, Aarhus University Hospital, 45 7846 1856, annebreg@rm.dk
Scientific contact	Secretary M. Larsen, Aarhus University Hospital, 45 7846 1856, annebreg@rm.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	02 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2025
Global end of trial reached?	Yes
Global end of trial date	02 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the change in aortic wall inflammation from baseline to week 16 in brodalumab treated psoriasis subjects compared to placebo.

Protection of trial subjects:

none

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2017
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	Denmark: 37
Worldwide total number of subjects	37
EEA total number of subjects	37

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)	37
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	37
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Number of subjects completed	37
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Period 1

Period 1 title	Overall Trial (overall period)
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Is this the baseline period?	Yes
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Allocation method	Randomised - controlled
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Blinding used	Double blind
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Roles blinded	Subject, Investigator, Monitor, Data analyst
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Arms

Are arms mutually exclusive?	Yes
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Arm title	Brodalumab
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Arm description: -

Arm type	Active comparator
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Investigational medicinal product name	Brodalumab
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Concentrate and solvent for solution for injection
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Routes of administration	Subcutaneous use
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Dosage and administration details:

Inj Brodalumab 210 mg s.c. week 0, week 1 and week 2 and from there every 2. week.

Arm title	Placebo
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Arm description: -

Arm type	Placebo
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Investigational medicinal product name	NaCl
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Concentrate and solvent for solution for injection
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Routes of administration	Subcutaneous use
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Dosage and administration details:

NaCl 1 ml s.c. at 0, week 1 and week 2 and from then every 2. week

Number of subjects in period 1	Brodalumab	Placebo
Started	18	19
Completed	18	19

Baseline characteristics

End points

End points reporting groups

Reporting group title	Brodalumab
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	PSOPET2
Subject analysis set type	Per protocol
Subject analysis set description:	
Per protocol	

Primary: Aorta inflammation

End point title	Aorta inflammation ^[1]
End point description:	

End point type	Primary
End point timeframe:	
Baseline to week 16	

Notes:

[1] - 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: In process by statistics

End point values	Brodalumab	PSOPET2		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18	37		
Units: TBRmax				
number (not applicable)	18	37		

Statistical analyses

Statistical analysis title	In process by statistics
Comparison groups	Brodalumab v PSOPET2
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	other
P-value	< 5
Method	Fisher exact

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

During trial with study medication.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Frequency threshold for reporting non-serious adverse events: 4 %

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: Correct

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported