



Clinical trial results:

Open-label exploratory study to evaluate the effect of dupilumab on skin barrier function in Chinese patients with moderate to severe atopic dermatitis

Summary

EudraCT number	2024-000164-37
Trial protocol	Outside EU/EEA
Global end of trial date	25 January 2024

Results information

Result version number	v1 (current)
This version publication date	11 July 2024
First version publication date	11 July 2024

Trial information

Trial identification

Sponsor protocol code	LPS17250
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05624112
WHO universal trial number (UTN)	U1111-1272-6687

Notes:

Sponsors

Sponsor organisation name	Sanofi (China) Investment Co., Ltd
Sponsor organisation address	19F Tower III, Jing'an Kerry Center, 1228 Middle Yan'an Road, Shanghai, China, 200000
Public contact	Trial Transparency Team, Sanofi (China) Investment Co., Ltd, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi (China) Investment Co., Ltd, Contact-US@sanofi.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 March 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	25 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate changes in skin barrier function with transepidermal water loss (TEWL) assessed after 5 skin tape stripping (STS) in pre-defined lesional skin in participants with moderate to severe atopic dermatitis (AD) treated with dupilumab.

Protection of trial subjects:

Participants were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the participant and considering the local culture. During the course of the trial, participants were provided with individual participant cards indicating the nature of the trial the participant is participating, contact details and any information needed in the event of a medical emergency.

Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 November 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	China: 44
Worldwide total number of subjects	44
EEA total number of subjects	0

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)	11

Adults (18-64 years)	33
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at a single center in China. A total of 44 participants were screened between 25 November 2022 and 08 September 2023. There was no screening failure.

Pre-assignment

Screening details:

A total of 44 participants were enrolled in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Atopic Dermatitis Participants

Arm description:

Participants aged ≥ 12 to < 18 years and body weight of < 60 kilogram (kg) received dupilumab first dose on Day 1, followed by dupilumab second dose every second week (Q2W) for 16 weeks.

Participants aged ≥ 12 to < 18 years and body weight of ≥ 60 kg received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Participants aged ≥ 18 years received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Dupilumab
Investigational medicinal product code	
Other name	Dupixent®
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Dupilumab was administered by subcutaneous injection at sites alternating between the upper thighs, 4 quadrants of the abdomen or the upper arms, so that the same site was not injected twice during consecutive administrations.

Arm title	Healthy Participants
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Arm description:

Participants didn't receive any treatment.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Atopic Dermatitis Participants	Healthy Participants
Started	24	20
Completed	23	20
Not completed	1	0
Unspecified	1	-

Baseline characteristics

Reporting groups

Reporting group title	Atopic Dermatitis Participants
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Reporting group description:

Participants aged ≥ 12 to < 18 years and body weight of < 60 kilogram (kg) received dupilumab first dose on Day 1, followed by dupilumab second dose every second week (Q2W) for 16 weeks.

Participants aged ≥ 12 to < 18 years and body weight of ≥ 60 kg received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Participants aged ≥ 18 years received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Reporting group title	Healthy Participants
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Reporting group description:

Participants didn't receive any treatment.

Reporting group values	Atopic Dermatitis Participants	Healthy Participants	Total
Number of subjects	24	20	44
Age Categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	23.3 ± 8.98	24.5 ± 6.53	-
Gender Categorical Units: Subjects			
Female	10	8	18
Male	14	12	26

End points

End points reporting groups

Reporting group title	Atopic Dermatitis Participants
Reporting group description:	
Participants aged ≥ 12 to < 18 years and body weight of < 60 kilogram (kg) received dupilumab first dose on Day 1, followed by dupilumab second dose every second week (Q2W) for 16 weeks.	
Participants aged ≥ 12 to < 18 years and body weight of ≥ 60 kg received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.	
Participants aged ≥ 18 years received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.	
Reporting group title	Healthy Participants
Reporting group description:	
Participants didn't receive any treatment.	

Primary: Atopic Dermatitis Participants: Percent Change From Baseline in Transepidermal Water Loss After 5 Skin Tape Stripping on Lesional Skin at Week 16

End point title	Atopic Dermatitis Participants: Percent Change From Baseline in Transepidermal Water Loss After 5 Skin Tape Stripping on Lesional Skin at Week 16 ^{[1][2]}
End point description:	
The TEWL is commonly used for physiologic assessment of skin barrier function. The TEWL measurements have also been combined with skin barrier perturbation using STS to measure skin barrier function and integrity. The intent-to-treat (ITT) population included all enrolled participants, including participants who received at least 1 dose of study drug and healthy participants who had at least 1 TEWL/STS assessment performed, irrespective of compliance with the study protocol and procedures.	
End point type	Primary
End point timeframe:	
Baseline (Day 1) and Week 16	

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: As the endpoint was analyzed only in participants with atopic dermatitis reporting group, the statistical comparison can't be performed.

[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: Only participants with atopic dermatitis were analyzed for the primary endpoint.

End point values	Atopic Dermatitis Participants			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: percent change				
number (confidence interval 90%)	-45.52 (-51.32 to -29.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Atopic Dermatitis Participants: Percent Change From Baseline in Transepidermal Water Loss Before and After 10, 15, and 20 Skin Tape Stripping on Lesional Skin at Week 16

End point title	Atopic Dermatitis Participants: Percent Change From Baseline in Transepidermal Water Loss Before and After 10, 15, and 20 Skin Tape Stripping on Lesional Skin at Week 16 ^[3]
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End point description:

The TEWL is commonly used for physiologic assessment of skin barrier function. The TEWL measurements have also been combined with skin barrier perturbation using STS to measure skin barrier function and integrity. The ITT population included all enrolled participants, including participants who received at least 1 dose of study drug and healthy participants who had at least 1 TEWL/STS assessment performed, irrespective of compliance with the study protocol and procedures.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 16

Notes:

[3] - 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: Only participants with atopic dermatitis were analyzed for the secondary endpoint.

End point values	Atopic Dermatitis Participants			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: percent change				
number (confidence interval 90%)				
Before STS	-42.06 (-50.91 to -33.21)			
After 10 STS	-26.41 (-39.70 to -13.13)			
After 15 STS	-22.10 (-38.92 to -8.74)			
After 20 STS	-4.41 (-15.88 to 7.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Atopic Dermatitis Participants: Absolute Change From Baseline in Transepidermal Water Loss Before and After 10, 15, and 20 Skin Tape Stripping on Lesional Skin at Week 16

End point title	Atopic Dermatitis Participants: Absolute Change From Baseline in Transepidermal Water Loss Before and After 10, 15, and 20 Skin Tape Stripping on Lesional Skin at Week 16 ^[4]
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End point description:

The TEWL is commonly used for physiologic assessment of skin barrier function. The TEWL measurements have also been combined with skin barrier perturbation using STS to measure skin barrier function and integrity. The ITT population included all enrolled participants, including participants who received at least 1 dose of study drug and healthy participants who had at least 1 TEWL/STS assessment performed, irrespective of compliance with the study protocol and procedures.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 16

Notes:

[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: Only participants with atopic dermatitis were analyzed for the secondary endpoint.

End point values	Atopic Dermatitis Participants			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: gram per hour per meter square				
number (confidence interval 90%)				
Before STS	-23.25 (-29.13 to -17.37)			
After 10 STS	-21.27 (-30.95 to -11.59)			
After 15 STS	-18.00 (-27.88 to -8.12)			
After 20 STS	-5.98 (-14.18 to 2.22)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) data was collected from the first administration of the study drug (Day 1) up to 14 days after last administration of the study drug (maximum exposure duration: up to 16 weeks).

Adverse event reporting additional description:

Safety population included all enrolled participants, who actually received at least 1 dose of study drug or had at least 1 TEWL/STS assessment and all healthy participants who had at least 1 TEWL/STS assessment performed. TEAEs are not applicable for healthy participants because no study drug were taken.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Healthy Participants
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Reporting group description:

Participants didn't receive any treatment.

Reporting group title	Atopic Dermatitis Participants
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Reporting group description:

Participants aged ≥ 12 to < 18 years and body weight of < 60 kg received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Participants aged ≥ 12 to < 18 years and body weight of ≥ 60 kg received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Participants aged ≥ 18 years received dupilumab first dose on Day 1, followed by dupilumab second dose Q2W for 16 weeks.

Serious adverse events	Healthy Participants	Atopic Dermatitis Participants	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 24 (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: 5 %

Non-serious adverse events	Healthy Participants	Atopic Dermatitis Participants	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	8 / 24 (33.33%)	
Gastrointestinal disorders			

Abdominal Pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	2 / 24 (8.33%) 2	
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	2 / 24 (8.33%) 5	
Infections and infestations Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) Conjunctivitis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0 0 / 20 (0.00%) 0	3 / 24 (12.50%) 4 3 / 24 (12.50%) 3	

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