



Clinical trial results:

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study Evaluating the Efficacy and Safety of Daxdilimab in Adult Participants with Active Proliferative Lupus Nephritis

Summary

EudraCT number	2022-001377-31
Trial protocol	ES HR
Global end of trial date	04 January 2024

Results information

Result version number	v1 (current)
This version publication date	29 December 2024
First version publication date	29 December 2024

Trial information

Trial identification

Sponsor protocol code	HZNP-DAX-203
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05540665
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, United States,
Public contact	Amgen (EUROPE) GmbH, IHQ Medical Info-Clinical Trials, MedInfoInternational@amgen.com
Scientific contact	Amgen (EUROPE) GmbH, IHQ Medical Info-Clinical Trials, MedInfoInternational@amgen.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 January 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate the efficacy of daxdilimab in combination with standard-of-care (SOC) compared to placebo in combination with SOC in participants with active, proliferative Lupus nephritis (LN).

Protection of trial subjects:

The trial was conducted in accordance with the protocol, International Council for Harmonisation (ICH) Good Clinical Practice (GCP), and applicable local regulations. The Principal Investigator assured that no planned deviations from, or changes to, the protocol took place without prior agreement from the Sponsor and documented approval from the institutional review board (IRB)/research ethics board (REB), except where necessary to eliminate immediate hazards to the trial participants. All personnel involved in the conduct of this study completed ICH GCP training.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 April 2023
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 4
Country: Number of subjects enrolled	Brazil: 2
Country: Number of subjects enrolled	Malaysia: 3
Country: Number of subjects enrolled	Philippines: 1
Country: Number of subjects enrolled	Poland: 1
Country: Number of subjects enrolled	Serbia: 5
Country: Number of subjects enrolled	Thailand: 3
Worldwide total number of subjects	19
EEA total number of subjects	1

Notes:

Subjects enrolled per age group

In utero	0
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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)	19
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with active proliferative LN were recruited from centers in Argentina, Brazil, Malaysia, the Philippines, Poland, Serbia, and Thailand between April 2023 and January 2024, when the study was terminated.

Pre-assignment

Screening details:

Participants were randomized in a 1:1:1 ratio to receive either daxdilimab 300 mg or 100 mg subcutaneously (SC) or placebo SC in addition to standard of care (SOC) background therapy for a Treatment Period of about 104 weeks. Participants were followed up for 12 weeks following last dose of investigational product (IP).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants were randomized to receive placebo SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. Thereafter, placebo was administered every 4 weeks (Q4W) through Week 52. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved either partial renal response (PRR) or complete renal response (CRR) at both Weeks 48 and 52 would have continued to receive placebo at Week 64 and every 12 weeks (Q12W) through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at either Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and then Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.

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

Dosage and administration details:

SC injection

Arm title	Daxdilimab 100 mg
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Arm description:

Participants were randomized to receive daxdilimab 100 mg SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 100 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.

Arm type	Experimental
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Investigational medicinal product name	Daxdilimab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
100 mg SC injection	
Arm title	Daxdilimab 300 mg

Arm description:

Participants were randomized to receive daxdilimab 300 mg SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.

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

Dosage and administration details:

300 mg SC injection

Number of subjects in period 1	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg
Started	6	6	7
Completed	0	0	0
Not completed	6	6	7
Study terminated by sponsor	6	6	7

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: Participants were randomized to receive placebo SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. Thereafter, placebo was administered every 4 weeks (Q4W) through Week 52. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved either partial renal response (PRR) or complete renal response (CRR) at both Weeks 48 and 52 would have continued to receive placebo at Week 64 and every 12 weeks (Q12W) through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at either Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and then Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.	
Reporting group title	Daxdilimab 100 mg
Reporting group description: Participants were randomized to receive daxdilimab 100 mg SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 100 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.	
Reporting group title	Daxdilimab 300 mg
Reporting group description: Participants were randomized to receive daxdilimab 300 mg SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.	

Reporting group values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg
Number of subjects	6	6	7
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	6	7
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	37.2	31.5	30.3
standard deviation	± 5.91	± 10.97	± 6.47

Gender Categorical			
Units: Subjects			
Female	6	6	5
Male	0	0	2
Race			
Units: Subjects			
Asian	1	4	2
White	5	2	5
Ethnicity			
Units: Subjects			
Hispanic or Latino	3	0	3
Not Hispanic or Latino	3	6	4

Reporting group values	Total		
Number of subjects	19		
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)	19		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical			
Units: Subjects			
Female	17		
Male	2		
Race			
Units: Subjects			
Asian	7		
White	12		
Ethnicity			
Units: Subjects			
Hispanic or Latino	6		
Not Hispanic or Latino	13		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants were randomized to receive placebo SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. Thereafter, placebo was administered every 4 weeks (Q4W) through Week 52. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved either partial renal response (PRR) or complete renal response (CRR) at both Weeks 48 and 52 would have continued to receive placebo at Week 64 and every 12 weeks (Q12W) through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at either Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and then Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.	
Reporting group title	Daxdilimab 100 mg
Reporting group description:	
Participants were randomized to receive daxdilimab 100 mg SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 100 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.	
Reporting group title	Daxdilimab 300 mg
Reporting group description:	
Participants were randomized to receive daxdilimab 300 mg SC in addition to SOC background therapy at Day 1, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.	

Primary: Percentage of Participants who Achieved CRR at Week 48 Through Week 52

End point title	Percentage of Participants who Achieved CRR at Week 48 Through Week 52 ^[1]
End point description:	
CRR was defined as meeting all of the following:	
<ul style="list-style-type: none">• Estimated glomerular filtration rate (eGFR) ≥ 60 mL/min/1.73 m² or no worse than 15% below Baseline• 24-hour urine protein to creatinine ratio (UPCR) ≤ 0.5 mg/mg• No discontinuation of trial intervention or use of restricted medication beyond the protocol-allowed threshold before assessment	
End point type	Primary
End point timeframe:	
Week 48 to Week 52	
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 was pre-specified for this endpoint.	

End point values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[2]	0 ^[3]	0 ^[4]	
Units: Percentage of Participants				

Notes:

[2] - Due to early termination data were not collected.

[3] - Due to early termination data were not collected.

[4] - Due to early termination data were not collected.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in eGFR at Week 52

End point title	Change From Baseline in eGFR at Week 52
End point description: Change over time in the levels of eGRF present in the blood. Due to early termination data were not collected.	
End point type	Secondary
End point timeframe: Baseline and Week 52	

End point values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[5]	0 ^[6]	0 ^[7]	
Units: mL/min/1.73 m ²				
arithmetic mean (standard deviation)				
Baseline	()	()	()	
Week 52 (N = 0, 0, 0)	()	()	()	

Notes:

[5] - Due to early termination data were not collected.

[6] - Due to early termination data were not collected.

[7] - Due to early termination data were not collected.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Overall Renal Response (ORR) at Week 48 Through Week 52

End point title	Percentage of Participants who Achieved Overall Renal Response (ORR) at Week 48 Through Week 52
End point description: CRR was defined as meeting all of the following: <ul style="list-style-type: none"> EGFR \geq 60 mL/min/1.73 m² or no worse than 15% below Baseline 24-hour UPCR \leq 0.5 mg/mg No discontinuation of trial intervention or use of restricted medication beyond the protocol-allowed threshold before assessment 	

PRR was defined as meeting all of the following:

- EGFR \geq 60 mL/min/1.73 m² or no worse than 15% below Baseline

- Improvement in 24-hour UPCR:
 - For participants with a Baseline UPCR ≤ 3.0 mg/mg: < 1.0 mg/mg
 - For participants with a Baseline UPCR > 3.0 mg/mg: $> 50\%$ improvement from baseline and ≤ 3.0 mg/mg
- No discontinuation of trial intervention or use of restricted medication beyond the protocol-allowed threshold before assessment

End point type	Secondary
End point timeframe:	
Week 48 to Week 52	

End point values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[8]	0 ^[9]	0 ^[10]	
Units: Percentage of Participants				

Notes:

[8] - Due to early termination data were not collected.

[9] - Due to early termination data were not collected.

[10] - Due to early termination data were not collected.

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Participants Achieving a Decrease in Daily Oral Corticosteroid (OCS) Dose of ≤ 2.5 mg Prednisone-Equivalent by Week 24 Maintained Through Week 52

End point title	Proportion of Participants Achieving a Decrease in Daily Oral Corticosteroid (OCS) Dose of ≤ 2.5 mg Prednisone-Equivalent by Week 24 Maintained Through Week 52
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End point description:

Sustained reduction of OCS dose:

- Prednisone-equivalent dose ≤ 2.5 mg/day by Week 24 and not exceeding this dose through Week 52 and
- No discontinuation of trial intervention or use of restricted medication beyond the protocol-allowed threshold before assessment

End point type	Secondary
End point timeframe:	
Week 24 to Week 52	

End point values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[11]	0 ^[12]	0 ^[13]	
Units: Percentage of Participants				

Notes:

[11] - Due to early termination data were not collected.

[12] - Due to early termination data were not collected.

[13] - Due to early termination data were not collected.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Daxdilimab

End point title	Serum Concentration of Daxdilimab ^[14]
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End point description:

Levels of daxdilimab present in the blood serum at different time points.

Pharmacokinetic (PK) Analysis Set: all participants who received any dose of daxdilimab and had at least 1 quantifiable PK observation following the initial dose. Value of "99999" indicates that the Standard deviation (SD) was not calculated due to the low level of observations.

End point type	Secondary
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End point timeframe:

Week 0 pre-dose, and 6 hours post-dose; Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, and Week 36

Notes:

[14] - 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: This endpoint is specific to IP arms only.

End point values	Daxdilimab 100 mg	Daxdilimab 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: ng/mL				
arithmetic mean (standard deviation)				
Week 0 pre-dose (N = 7, 6, 0)	7.80 (± 0.00)	7.80 (± 0.00)		
Week 0 post-dose (N = 7, 6, 0)	689.07 (± 498.40)	3854.29 (± 3312.12)		
Week 2 (N = 7, 6, 0)	4996.67 (± 1732.21)	17610.00 (± 10382.53)		
Week 4 (N = 7, 6, 0)	8531.67 (± 3993.99)	22171.43 (± 9187.26)		
Week 8 (N = 7, 6, 0)	3533.33 (± 1727.54)	10330.00 (± 4167.07)		
Week 12 (N = 6, 5, 0)	2988.00 (± 1223.83)	10201.67 (± 4619.64)		
Week 16 (N = 2, 3, 0)	1080.33 (± 1020.32)	5051.50 (± 6644.68)		
Week 20 (N = 6, 3, 0)	240.83 (± 184.66)	2003.00 (± 3907.13)		
Week 24 (N = 1, 2, 0)	93.85 (± 94.96)	9660.00 (± 99999)		
Week 36 (N = 1, 0, 0)	0 (± 0)	1040.00 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Detectable Anti-Drug Antibodies (ADA) Against Daxdilimab

End point title	Number of Participants with Detectable Anti-Drug Antibodies
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End point description:

Assessed via blood test at multiple time points throughout the duration of the study.

End point type Secondary

End point timeframe:

Up to approximately 36 weeks

End point values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Participants				
ADA Negative	6	6	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who experienced Treatment-emergent Adverse Events (TEAEs)

End point title Number of Participants who experienced Treatment-emergent Adverse Events (TEAEs)

End point description:

An AE was any untoward medical occurrence in a participant or clinical subject who was administered a pharmaceutical product, which may or may not have been causally related to the treatment. A serious AE (SAE) was any AE resulting in death, life-threatening situations, inpatient hospitalization or its prolongation, persistent/significant disability/incapacity, congenital abnormality/birth defect, or other significant medical events that may have jeopardized the participant or required medical/surgical intervention to prevent the outcomes listed above. Treatment-emergent AEs of special interest (AESI) included hypersensitivity reactions (e.g., anaphylaxis), severe viral infections/reactivations (Common Terminology for Adverse Events [CTCAE] Grade 3+), herpes zoster, opportunistic infections, and malignancies.

End point type Secondary

End point timeframe:

Up to approximately 36 weeks

End point values	Placebo	Daxdilimab 100 mg	Daxdilimab 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	7	
Units: Participants				
All TEAEs	2	2	5	
All SAEs	0	0	1	
All ≥ Grade 3 AESI	0	0	0	
Fatal AEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 36 weeks

Adverse event reporting additional description:

All-cause mortality is reported for all participants randomized in the study. Serious adverse events and other adverse events are reported for all participants who received at least one dose of trial drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Daxdilimab 100 mg
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Reporting group description:

Participants were randomized to receive daxdilimab 100 mg SC at baseline, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 100 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.

Reporting group title	Daxdilimab 300 mg
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Reporting group description:

Participants were randomized to receive daxdilimab 300 mg SC at baseline, Week 2, and Week 4. From Week 8 through Week 52, daxdilimab was administered Q4W. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved PRR or CRR at both Weeks 48 and 52 would have continued to receive daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.

Reporting group title	Placebo
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Reporting group description:

Participants were randomized to receive placebo SC at baseline, Week 2, and Week 4. Thereafter, placebo was administered Q4W through Week 52. At Week 64, dosing would have been adjusted based on renal response criteria: participants who achieved either partial renal response (PRR) or complete renal response (CRR) at both Weeks 48 and 52 would have continued to receive placebo at Week 64 and every 12 weeks (Q12W) through Week 104 (last dose at Week 100), in addition to SOC therapy. Participants who didn't achieve PRR or CRR at either Week 48 or 52 would have received daxdilimab 300 mg at Week 64 and then Q12W through Week 104 (last dose at Week 100), in addition to SOC therapy. However, the study was terminated prior to any participants reaching Week 64.

Reporting group title	Total
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Reporting group description: -

Reporting group title	Daxdilimab Total
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Reporting group description:

All participants who were exposed to daxdilimab.

Serious adverse events	Daxdilimab 100 mg	Daxdilimab 300 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Infections and infestations			
Gastrointestinal infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Total	Daxdilimab Total	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Infections and infestations			
Gastrointestinal infection			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Daxdilimab 100 mg	Daxdilimab 300 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	5 / 7 (71.43%)	2 / 6 (33.33%)
Investigations			
Urinary sediment abnormal			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Rhinitis allergic subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all) Butterfly rash subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Rash erythematous subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1 1 / 6 (16.67%) 1 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0	0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 1 / 7 (14.29%) 1 1 / 7 (14.29%) 1	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0
Endocrine disorders Cushingoid subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0
Infections and infestations Influenza subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 1 / 6 (16.67%) 1	0 / 7 (0.00%) 0 0 / 7 (0.00%) 0	1 / 6 (16.67%) 1 0 / 6 (0.00%) 0
Metabolism and nutrition disorders			

Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Non-serious adverse events	Total	Daxdilimab Total	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 19 (47.37%)	7 / 13 (53.85%)	
Investigations			
Urinary sediment abnormal			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Abdominal pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Butterfly rash			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Rash			
subjects affected / exposed	1 / 19 (5.26%)	1 / 13 (7.69%)	
occurrences (all)	1	1	
Rash erythematous			

subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 13 (7.69%) 1	
Endocrine disorders Cushingoid subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 13 (7.69%) 1	
Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	1 / 13 (7.69%) 1	
Infections and infestations Influenza subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1 1 / 19 (5.26%) 1	0 / 13 (0.00%) 0 1 / 13 (7.69%) 1	
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1	0 / 13 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 May 2022	<ul style="list-style-type: none">- Updated eligibility criteria to clarify eligibility for participants unable to understand the informed consent form; the use of digital pathology images for adjudication of diagnosis; to clarify review of screening data.- Updated exploratory objectives and endpoints .- Updated clinical safety laboratory tests for consistency with eligibility criteria and clinical evaluation.- Clarified details in the schedule of assessments.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated early following a sponsor decision.

Notes: