



Clinical trial results:

An Open-label Extension Study to Evaluate the Long-term Safety and Tolerability of Daxdilimab (HZN-7734) in Subjects with Systemic Lupus Erythematosus (RECAST SLE OLE)

Summary

EudraCT number	2022-000855-35
Trial protocol	GR ES PL
Global end of trial date	31 October 2023

Results information

Result version number	v1 (current)
This version publication date	07 September 2024
First version publication date	07 September 2024

Trial information

Trial identification

Sponsor protocol code	HZNP-DAX-204
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05430854
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	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, 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	31 October 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 October 2023
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 long-term safety and tolerability of 200 mg every 12 weeks (Q12W) daxdilimab.

Protection of trial subjects:

This study was conducted in accordance with the protocol and with the following:

- Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and the Council for International Organizations of Medical Sciences international ethical guidelines.
- Applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines.
- Applicable laws and regulations.

The protocol, protocol amendments, informed consent form, Investigator's brochure, and other relevant documents (e.g., advertisements) were submitted to an Institutional Review Board/Independent Ethics Committee (IRB/IEC) by the Investigator and reviewed and approved by the IRB/IEC before the study was initiated. Any protocol amendments required IRB/IEC approval before implementation, except for changes needed to eliminate an immediate hazard to study subjects. Both protocols and substantial amendments required health authority approval prior to initiation, except for changes needed to eliminate an immediate hazard. The Investigator was responsible for providing written summaries of the study status to the IRB/IEC annually or more frequently, notifying the IRB/IEC of Serious Adverse Events (SAEs) or other significant safety findings, and ensuring study conduct and compliance with 21 CFR, International Council for Harmonisation (ICH) guidelines, IRB/IEC requirements, European regulation 536/2014 for clinical studies, European Medical Device Regulation 2017/745 for clinical device research, and all other applicable local regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2022
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	Argentina: 30
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	India: 16
Country: Number of subjects enrolled	Mexico: 26
Country: Number of subjects enrolled	Poland: 29
Country: Number of subjects enrolled	Serbia: 13
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	United States: 32

Worldwide total number of subjects	155
EEA total number of subjects	34

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)	150
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This was an open-label extension (OLE) of study VIB7734.P2.S1 (NCT04925934). Eligible participants were enrolled after the completion of the VIB7734.P2.S1 study. 155 participants were enrolled at 54 centers in the United States, Argentina, Greece, India, Mexico, Poland, Serbia, Spain and Taiwan from 01 June 2022 to 31 October 2023.

Pre-assignment

Screening details:

155 participants were enrolled and received study drug.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)

Arm description:

Participants who received placebo in the parent study received daxdilimab 200 mg subcutaneous (SC) injection Q12W in this OLE Study.

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:

SC Q12W

Arm title	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg Q12W
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Arm description:

Participants who received 200 mg Q4W in the parent study received daxdilimab 200 mg SC injection Q12W in this OLE Study.

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:

SC Q12W

Arm title	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W
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Arm description:

Participants who received 200 mg Q12W in the parent study, and received daxdilimab 200 mg Q12W in this OLE Study.

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:

SC Q12W

Number of subjects in period 1	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W
Started	47	57	51
Completed	8	4	5
Not completed	39	53	46
Consent withdrawn by subject	-	3	-
Trial terminated by Sponsor	39	50	46

Baseline characteristics

Reporting groups

Reporting group title	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)
Reporting group description: Participants who received placebo in the parent study received daxdilimab 200 mg subcutaneous (SC) injection Q12W in this OLE Study.	
Reporting group title	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg Q12W
Reporting group description: Participants who received 200 mg Q4W in the parent study received daxdilimab 200 mg SC injection Q12W in this OLE Study.	
Reporting group title	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W
Reporting group description: Participants who received 200 mg Q12W in the parent study, and received daxdilimab 200 mg Q12W in this OLE Study.	

Reporting group values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W
Number of subjects	47	57	51
Age Categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	41.3 ± 10.3	44.8 ± 12.8	45.9 ± 11.2
Gender Categorical Units: Subjects			
Female	44	52	46
Male	3	5	5
Race Units: Subjects			
American Indian or Alaskan Native	1	2	0
Asian	7	5	8
Black or African American	3	5	6
White	35	39	35
Other	1	6	2
Ethnicity Units: Subjects			
Hispanic or Latino	19	24	16
Not Hispanic or Latino	28	33	35

Reporting group values	Total		
Number of subjects	155		
Age Categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	-		
Gender Categorical Units: Subjects			
Female	142		
Male	13		
Race Units: Subjects			
American Indian or Alaskan Native	3		
Asian	20		
Black or African American	14		
White	109		
Other	9		
Ethnicity Units: Subjects			
Hispanic or Latino	59		
Not Hispanic or Latino	96		

End points

End points reporting groups

Reporting group title	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)
Reporting group description: Participants who received placebo in the parent study received daxdilimab 200 mg subcutaneous (SC) injection Q12W in this OLE Study.	
Reporting group title	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg Q12W
Reporting group description: Participants who received 200 mg Q4W in the parent study received daxdilimab 200 mg SC injection Q12W in this OLE Study.	
Reporting group title	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W
Reporting group description: Participants who received 200 mg Q12W in the parent study, and received daxdilimab 200 mg Q12W in this OLE Study.	

Primary: Number of Participants Who Experienced Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Participants Who Experienced Treatment-emergent Adverse Events (TEAEs) ^[1]
End point description: An adverse event (AE) is any untoward medical occurrence in a participant administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of an IP, whether or not considered related to the IP. A TEAE is defined as any AE with an onset date on or after the first dose date in the OLE study. OLE Safety Analysis Set: all participants who received at least 1 dose of daxdilimab in the OLE study.	
End point type	Primary
End point timeframe: Up to approximately 56 weeks	

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 additional statistical analysis was pre-specified for this endpoint.

End point values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	57	51	
Units: Participants	25	31	31	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who Experienced Serious Adverse Events (SAEs)

End point title	Number of Participants who Experienced Serious Adverse Events (SAEs) ^[2]
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End point description:

An AE is considered "serious" if, in the view of either the Investigator or Sponsor, it results in any of the following outcomes: - Death - A life-threatening AE - Inpatient hospitalization or prolongation of existing hospitalization - Persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions - A congenital abnormality/birth defect - Important medical events judged to jeopardize the participant(s). OLE Safety Analysis Set: all participants who received at least 1 dose of daxdilimab in the OLE study.

End point type	Primary
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End point timeframe:

Up to approximately 56 weeks

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: No additional statistical analysis was pre-specified for this endpoint.

End point values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	57	51	
Units: Participants	3	5	5	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who Experienced AEs of Special Interest (AESI)

End point title	Number of Participants who Experienced AEs of Special Interest (AESI) ^[3]
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End point description:

An AESI is an AE of scientific and medical interest specific to understanding of the IP and may require close monitoring and collection of additional information by the Investigator. In this study, AESIs were: - Hypersensitivity reaction, including anaphylaxis - Severe (Grade 3 or higher) viral infections/reactivations - Opportunistic infections - Malignancy (except non-melanoma skin cancer). OLE Safety Analysis Set: all participants who received at least 1 dose of daxdilimab in the OLE study.

End point type	Primary
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End point timeframe:

Up to approximately 56 weeks

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: No additional statistical analysis was pre-specified for this endpoint.

End point values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	57	51	
Units: Participants				

Participants with at least 1 AESI	1	2	1	
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Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Daxdilimab

End point title	Serum Concentration of Daxdilimab
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End point description:

Serum concentration of daxdilimab refers to the amount of daxdilimab present in the blood serum at a given time. Blood samples were collected via venipuncture at the specified time frames. Week 0 corresponds to the last day of the treatment period in the parent study and Day 1 of the treatment period in the OLE study. PK Analysis Set: all participants who received any dose of daxdilimab in OLE study and had at least 1 measurable PK concentration post dose. Number analyzed represents the number of participants with available data at that time point.

End point type	Secondary
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End point timeframe:

Week 0 (Week 0 = Day 1), Week 12, Week 24, Week 36, Week 48, Week 56

End point values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg	Daxdilimab 200 mg Q12W/ Daxdilimab 200 mg Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	57	51	
Units: ug/mL				
arithmetic mean (standard deviation)				
Week 0 (N = 0, 55, 50)	0 (± 0)	5.527 (± 4.412)	0.458 (± 0.614)	
Week 12 (N = 47, 57, 51)	0.291 (± 0.390)	0.502 (± 0.740)	0.400 (± 0.520)	
Week 24 (N = 47, 56, 50)	0.414 (± 0.575)	0.398 (± 0.531)	0.437 (± 0.437)	
Week 36 (N = 27, 26, 25)	0.508 (± 0.616)	0.464 (± 0.467)	1.002 (± 1.404)	
Week 48 (N = 11, 10, 11)	0.813 (± 1.044)	0.380 (± 0.395)	0.815 (± 0.759)	
Week 56 (N = 5, 2, 5)	0.399 (± 0.251)	0.146 (± 0.009)	0.997 (± 0.898)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Plasmacytoid Dendritic Cell (pDCs) Count

End point title	Change From Baseline in Plasmacytoid Dendritic Cell (pDCs) Count
End point description:	
PDCs count refers to the number of pDCs present in a blood sample. Blood samples were collected via venipuncture at the specified time frames. Week 0 corresponds to the last day of the treatment period in the parent study and Day 1 of the treatment period in the OLE study. OLE Safety Analysis Set: all participants who received at least 1 dose of daxdilimab in the OLE study. The overall number of participants analyzed represents the number of participants contributing data to any individual timepoint within the table.	
End point type	Secondary
End point timeframe:	
Week 0 (Week 0 = Day 1), Week 12, Week 24, Week 36, Week 48, Week 56	

End point values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	36	33	
Units: Percentage change in pDCs count arithmetic mean (standard deviation)				
Week 0 (N = 24, 32, 30)	70.59 (± 225.39)	-58.37 (± 36.19)	-30.40 (± 50.67)	
Week 12 (N = 23, 36, 33)	1.33 (± 142.08)	13.57 (± 158.14)	-21.25 (± 66.97)	
Week 24 (N = 22, 33, 29)	-14.39 (± 164.63)	-24.98 (± 79.85)	-19.86 (± 77.23)	
Week 36 (N = 12, 12, 15)	13.64 (± 255.67)	-41.36 (± 41.29)	-51.11 (± 35.28)	
Week 48 (N = 8, 5, 6)	-49.47 (± 34.54)	-58.65 (± 43.33)	-4.44 (± 74.93)	
Week 56 (N = 3, 2, 3)	-75.22 (± 14.11)	-43.13 (± 49.49)	4.15 (± 96.43)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Expressing Anti-drug Antibodies (ADA)

End point title	Number of Participants Expressing Anti-drug Antibodies (ADA)
End point description:	
ADA incidence is the number of the participants with ADA positive post-Baseline only or boosted their preexisting ADA during the trial. Persistent positive was defined as ADA positive at ≥ 2 post-Baseline assessments (with ≥ 16 weeks between first and last positive) or positive at last post-Baseline assessment. Transient positive was defined as ADA post-Baseline positive but did not fulfill the criteria of persistent positive. Analysis Set: all participants who received at least 1 dose of daxdilimab in parent study or OLE study.	
End point type	Secondary
End point timeframe:	
Up to approximately 56 weeks	

End point values	Placebo/Daxdilimab 200 mg Every 12 Weeks (Q12W)	Daxdilimab 200 mg Every 4 Weeks (Q4W)/Daxdilimab 200 mg	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	57	51	
Units: Participants				
ADA Incidence	7	6	4	
ADA not detected	34	48	44	
Only Baseline positive	0	3	0	
Only post-Baseline positive	6	3	3	
Both Baseline and post-Baseline positive	7	3	2	
Persistent positive	4	3	2	
Transient positive	9	3	3	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 56 weeks

Adverse event reporting additional description:

Serious and other AEs is reported for the OLE Safety Analysis Set: all participants who received at least 1 dose of daxdilimab in the OLE study. All-cause mortality is reported for all participants enrolled/randomized in the study.

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	Placebo/Daxdilimab 200 mg Q12W
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Reporting group description:

Participants who received placebo in the parent study received daxdilimab 200 mg SC injection Q12W in this OLE Study.

Reporting group title	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W
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Reporting group description:

Participants who received 200 mg Q12W in the parent study received daxdilimab 200 mg SC injection Q12W in this OLE Study.

Reporting group title	Daxdilimab 200 mg Q4W in Parent Study
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Reporting group description:

Participants who received 200 mg Q4W in the parent study received daxdilimab 200 mg SC injection Q12W in this OLE Study.

Serious adverse events	Placebo/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q4W in Parent Study
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 47 (6.38%)	5 / 51 (9.80%)	5 / 57 (8.77%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 47 (2.13%)	0 / 51 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 47 (0.00%)	1 / 51 (1.96%)	0 / 57 (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

Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 51 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 47 (0.00%)	1 / 51 (1.96%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 51 (1.96%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 51 (1.96%)	0 / 57 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glomerulonephritis minimal lesion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc disorder			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Cytomegalovirus nephritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 51 (1.96%)	0 / 57 (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
Dengue fever			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 51 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 51 (0.00%)	0 / 57 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q12W/Daxdilimab 200 mg Q12W	Daxdilimab 200 mg Q4W in Parent Study
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 47 (25.53%)	19 / 51 (37.25%)	19 / 57 (33.33%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 47 (8.51%)	2 / 51 (3.92%)	1 / 57 (1.75%)
occurrences (all)	4	2	1
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 47 (6.38%)	1 / 51 (1.96%)	3 / 57 (5.26%)
occurrences (all)	4	1	3

Blood and lymphatic system disorders Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	3 / 51 (5.88%) 5	0 / 57 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	4 / 51 (7.84%) 6	1 / 57 (1.75%) 1
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0 0 / 47 (0.00%) 0	0 / 51 (0.00%) 0 3 / 51 (5.88%) 3	3 / 57 (5.26%) 3 2 / 57 (3.51%) 2
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Osteoarthritis subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1 2 / 47 (4.26%) 2	3 / 51 (5.88%) 3 1 / 51 (1.96%) 1	2 / 57 (3.51%) 2 4 / 57 (7.02%) 4
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Sinusitis subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	4 / 47 (8.51%) 4 1 / 47 (2.13%) 1 1 / 47 (2.13%) 1 1 / 47 (2.13%) 1	2 / 51 (3.92%) 2 1 / 51 (1.96%) 1 3 / 51 (5.88%) 3 5 / 51 (9.80%) 6	0 / 57 (0.00%) 0 3 / 57 (5.26%) 3 2 / 57 (3.51%) 2 0 / 57 (0.00%) 0

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