Clinical trial results:
A Randomized, Placebo-controlled, Double-blind, Multicenter Study to Assess the Efficacy and Safety of Nipocalimab in Adults with Primary Sjogren's Syndrome (pSS)

Summary

EudraCT number	2021-000665-32
Trial protocol	DE ES IT PL PT NL FR
Global end of trial date	29 November 2023

Results information

Result version number	v2 (current)
This version publication date	23 October 2025
First version publication date	10 November 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	CR109062

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04968912
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.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	29 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the efficacy of nipocalimab versus placebo in subjects with primary Sjogren's syndrome (pSS).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 September 2021
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	Germany: 30
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Japan: 7
Country: Number of subjects enrolled	Poland: 90
Country: Number of subjects enrolled	Portugal: 1
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	United States: 25
Worldwide total number of subjects	163
EEA total number of subjects	127

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)	147
From 65 to 84 years	16
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 163 subjects were enrolled, randomised (1:1:1 ratio) in this study and treated with either nipocalimab or placebo. Out of 163 subjects, 136 subjects completed the study.

Period 1

Period 1 title	Overall Study (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	Group 1: Placebo IV

Arm description:

Subjects received placebo intravenous (IV) infusion every 2 weeks (q2w) from Week 0 through Week 22 along with standard of care treatments (SOC).

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received placebo q2w from Week 0 through Week 22 along with SOC.

Arm title	Group 2: Nipocalimab 5 mg/kg IV

Arm description:

Subjects received nipocalimab 5 milligrams per kilogram (mg/kg) IV infusion q2w from Week 0 through Week 22 along with SOC.

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	
Other name	JNJ-80202135
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received nipocalimab 5 mg/kg q2w from Week 0 through Week 22 along with SOC.

Arm title	Group 3: Nipocalimab 15 mg/kg IV

Arm description:

Subjects received nipocalimab 15 mg/kg IV infusion q2w from Week 0 through Week 22 along with SOC.

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	
Other name	JNJ-80202135
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received nipocalimab 15 mg/kg q2w from Week 0 through Week 22 along with SOC.

Number of subjects in period 1	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV
Started	56	53	54
Completed	46	46	44
Not completed	10	7	10
Consent withdrawn by subject	7	4	7
Unspecified	-	1	2
No longer clinically benefited	1	1	-
Lost to follow-up	2	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: Placebo IV
Reporting group description:	
Subjects received placebo intravenous (IV) infusion every 2 weeks (q2w) from Week 0 through Week 22 along with standard of care treatments (SOC).	
Reporting group title	Group 2: Nipocalimab 5 mg/kg IV
Reporting group description:	
Subjects received nipocalimab 5 milligrams per kilogram (mg/kg) IV infusion q2w from Week 0 through Week 22 along with SOC.	
Reporting group title	Group 3: Nipocalimab 15 mg/kg IV
Reporting group description:	
Subjects received nipocalimab 15 mg/kg IV infusion q2w from Week 0 through Week 22 along with SOC.	

Reporting group values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV
Number of subjects	56	53	54
Age categorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	50	49	48
From 65 to 84 years	6	4	6
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	47.3	48.3	48.6
standard deviation	± 12.6	± 11.83	± 12.07
Title for Gender Units: subjects			
Female	52	49	50
Male	4	4	4

Reporting group values	Total		
Number of subjects	163		
Age categorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	147		
From 65 to 84 years	16		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		

Title for Gender Units: subjects			
Female	151		
Male	12		

End points

End points reporting groups

Reporting group title	Group 1: Placebo IV
Reporting group description:	
Subjects received placebo intravenous (IV) infusion every 2 weeks (q2w) from Week 0 through Week 22 along with standard of care treatments (SOC).	
Reporting group title	Group 2: Nipocalimab 5 mg/kg IV
Reporting group description:	
Subjects received nipocalimab 5 milligrams per kilogram (mg/kg) IV infusion q2w from Week 0 through Week 22 along with SOC.	
Reporting group title	Group 3: Nipocalimab 15 mg/kg IV
Reporting group description:	
Subjects received nipocalimab 15 mg/kg IV infusion q2w from Week 0 through Week 22 along with SOC.	

Primary: Change From Baseline in Clinical European League Against Rheumatism (EULAR) Sjögren's Syndrome Disease Activity Index (clinESSDAI) Score at Week 24

End point title	Change From Baseline in Clinical European League Against Rheumatism (EULAR) Sjögren's Syndrome Disease Activity Index (clinESSDAI) Score at Week 24

End point description:

In clinESSDAI, physician scores the systemic disease activity level on 11 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, and hematological), with each domain activity in 3 to 4 levels (no, low, moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). Each domain was assigned a weight between 1 and 7, and domain score was multiplied by domain weight. A higher score indicates worsening of the disease. Sum of the weighted domain scores is the overall score, which can range from 0 to 135. The full analysis set (FAS) included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Here, 'N' (number of subjects analysed) signifies subjects who were evaluable for this endpoint.

End point type	Primary
End point timeframe:	
Baseline, Week 24	

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	42	40	
Units: Scores on a scale				
arithmetic mean (standard deviation)	-3.3 (± 4.72)	-3.8 (± 3.22)	-6.7 (± 4.50)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods

were 53 and 54.

Comparison groups	Group 3: Nipocalimab 15 mg/kg IV v Group 1: Placebo IV
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.65
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.03
upper limit	-1.28

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.

Comparison groups	Group 2: Nipocalimab 5 mg/kg IV v Group 1: Placebo IV
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.681
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.34
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.71
upper limit	1.03

Secondary: Change From Baseline in EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) Score at Week 24

End point title	Change From Baseline in EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) Score at Week 24

End point description:

Change from baseline in ESSPRI score at Week 24 was reported. The ESSPRI was a patient-reported assessment of the severity of dryness, fatigue, and pain associated with primary sogrens syndrome. Subjects were asked to rate the severity of dryness, fatigue and pain over the past 2 weeks on a numeric rating scale (NRS), ranging from 0 "no symptom" to 10 "maximal imaginable" symptoms (dryness, fatigue, pain). Each domain was scored on scale of 0 to 10 (0 =no symptom at all and 10 = worst symptom imaginable). A total score was calculated as the mean of the 3 individual domain scores, where all domains carry the same weight. Minimum score can be 0 and maximum score can be 10, where higher ESSPRI scores indicated more severe symptoms. The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Here, 'N' (number of subjects analysed) signifies subjects who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	43	41	
Units: Scores on a scale				
arithmetic mean (standard deviation)	-1.8 (± 2.01)	-1.2 (± 1.90)	-2.3 (± 1.74)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Improvement of Greater Than or Equal to (>=)4 Points From Baseline in EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) Score (Minimal Clinically Important Improvement) at Week 24

End point title	Percentage of Subjects With Improvement of Greater Than or Equal to (>=)4 Points From Baseline in EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) Score (Minimal Clinically Important Improvement) at Week 24

End point description:

ESSDAI was a validated tool used in clinical studies to measure systemic disease activity in subjects with primary Sjogren's syndrome. In ESSDAI, physician scores the systemic disease activity level on 12 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, hematological, and biological), with each domain activity in 3 to 4 levels (no, low, moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). Each domain was assigned a weight between 1 and 6, and domain score was multiplied by domain weight. Sum of the weighted domain scores is the overall score, which can range from 0 to 123. A higher score indicates worsening of disease. FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Percentage of subjects				
number (not applicable)	28.6	34.0	46.3	

Statistical analyses

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 54.

Comparison groups	Group 3: Nipocalimab 15 mg/kg IV v Group 1: Placebo IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.138
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	17.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.8
upper limit	32.7

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.

Comparison groups	Group 1: Placebo IV v Group 2: Nipocalimab 5 mg/kg IV
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.648
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	5.4
Confidence interval	
level	90 %
sides	2-sided
lower limit	-9.2
upper limit	20

Secondary: Percentage of Subjects With Improvement of >=4 Points From Baseline in clinESSDAI Score (Minimal Clinically Important Improvement) at Week 24

End point title	Percentage of Subjects With Improvement of >=4 Points From Baseline in clinESSDAI Score (Minimal Clinically Important Improvement) at Week 24

End point description:

Percentage of subjects with improvement of >= 4 points from baseline in clinESSDAI score (minimal clinically important improvement) at Week 24 were reported. In clinESSDAI, physician scores the systemic disease activity level on 11 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, and hematological), with each domain activity in 3 to 4 levels (no, low,

moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). A higher score indicates worsening of the disease. Each domain is assigned a weight between 1 and 7, and the domain score is multiplied by the domain weight. Sum of the weighted domain scores is the overall score, which can range from 0 to 135. FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Percentage of Subjects				
number (not applicable)	33.9	37.7	51.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 54.

Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.138
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	17.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.6
upper limit	33.2

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.

Comparison groups	Group 1: Placebo IV v Group 2: Nipocalimab 5 mg/kg IV

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.766
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	3.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-11.3
upper limit	18.9

Secondary: Number of Subjects With Improvement of Greater Than or Equal to (>=)4 Points From Baseline in ESSDAI Score (Minimal Clinically Important Improvement) at Week 24

End point title	Number of Subjects With Improvement of Greater Than or Equal to (>=)4 Points From Baseline in ESSDAI Score (Minimal Clinically Important Improvement) at Week 24

End point description:

ESSDAI was a validated tool used in clinical studies to measure systemic disease activity in subjects with primary Sjogren's syndrome. In ESSDAI, physician scores the systemic disease activity level on 12 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, hematological, and biological), with each domain activity in 3 to 4 levels (no, low, moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). Each domain was assigned a weight between 1 and 6, and domain score was multiplied by domain weight. Sum of the weighted domain scores is the overall score, which can range from 0 to 123. A higher score indicates worsening of disease. FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	16	18	25	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With ESSPRI Response Defined as a Decrease of one Point or a Decrease of >= 15 Percent (%) in the ESSPRI Score From Baseline (Minimal Clinically Important Improvement) at Week 24

End point title	Percentage of Subjects With ESSPRI Response Defined as a Decrease of one Point or a Decrease of >= 15 Percent (%) in the ESSPRI Score From Baseline (Minimal Clinically Important Improvement) at Week 24

End point description:

Percentage of subjects with ESSPRI response defined as a decrease of one point or a decrease of >= 15% from baseline (minimal clinically important improvement) at Week 24 was reported. The ESSPRI was a patient-reported assessment of the severity of dryness, fatigue, and pain associated with primary sjogren's syndrome. Subjects were asked to rate the severity of dryness, fatigue and pain over the past 2 weeks on a NRS, ranging from 0 "no symptom" to 10 "maximal imaginable" symptoms (dryness, fatigue, pain). Each domain was scored on scale of 0 to 10 (0 =no symptom at all and 10 = worst symptom imaginable). A total score was calculated as the mean of the 3 individual domain scores, where all domains carry the same weight. Minimum score can be 0 and maximum score can be 10, where higher ESSPRI scores indicated more severe symptoms. The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Percentage of Subjects				
number (not applicable)	50.0	39.6	55.6	

Statistical analyses

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 54.

Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.788
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	5.6
Confidence interval	
level	90 %
sides	2-sided
lower limit	-10.1
upper limit	21.2

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.

Comparison groups	Group 1: Placebo IV v Group 2: Nipocalimab 5 mg/kg IV
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.28
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	-10.4
Confidence interval	
level	90 %
sides	2-sided
lower limit	-26
upper limit	5.2

Secondary: Number of Subjects With Improvement of >=4 Points From Baseline in clinESSDAI Score (Minimal Clinically Important Improvement) at Week 24

End point title	Number of Subjects With Improvement of >=4 Points From Baseline in clinESSDAI Score (Minimal Clinically Important Improvement) at Week 24

End point description:

Number of subjects with improvement of >= 4 points from baseline in clinESSDAI score (minimal clinically important improvement) at Week 24 were reported. In clinESSDAI, physician scores the systemic disease activity level on 11 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, and hematological), with each domain activity in 3 to 4 levels (no, low, moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). A higher score indicates worsening of the disease. Each domain is assigned a weight between 1 and 7, and the domain score is multiplied by the domain weight. Sum of the weighted domain scores is the overall score, which can range from 0 to 135. FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	19	20	28	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With ESSPRI Response Defined as a Decrease of one Point or a Decrease of >= 15 % in the ESSPRI Score From Baseline (Minimal Clinically Important Improvement) at Week 24

End point title	Number of Subjects With ESSPRI Response Defined as a Decrease of one Point or a Decrease of >= 15 % in the ESSPRI Score From Baseline (Minimal Clinically Important Improvement) at Week 24

End point description:

Number of subjects with ESSPRI response defined as a decrease of one point or a decrease of >= 15% from baseline (minimal clinically important improvement) at Week 24 was reported. The ESSPRI was a patient-reported assessment of the severity of dryness, fatigue, and pain associated with primary sjogren's syndrome. Subjects were asked to rate the severity of dryness, fatigue and pain over the past 2 weeks on a NRS, ranging from 0 "no symptom" to 10 "maximal imaginable" symptoms (dryness, fatigue, pain). Each domain was scored on scale of 0 to 10 (0 =no symptom at all and 10 = worst symptom imaginable). A total score was calculated as the mean of the 3 individual domain scores, where all domains carry the same weight. Minimum score can be 0 and maximum score can be 10, where higher ESSPRI scores indicated more severe symptoms. The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	28	21	30	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Disease Response According to the Sjögren's Tool for Assessing Response (STAR) Composite Score at Week 24

End point title	Percentage of Subjects With Disease Response According to the Sjögren's Tool for Assessing Response (STAR) Composite Score at Week 24

End point description:

Percentage of subjects with disease response according to the STAR composite score at Week 24 was reported. A STAR response is defined as a composite score of >=5 points in the 5 STAR domains, with weighting in parentheses: i) decrease of >=3 in clinESSDAI score (3), ii) decrease of >=1 point or >=15% from baseline in ESSPRI score (3), iii) abnormal Schirmer's test at baseline and an increase of >=5 millimetre (mm), or normal Schirmer's test at baseline and no change to abnormal, or abnormal ocular staining score at baseline and a decrease of >=2 points, or normal ocular staining score at baseline and no change to abnormal (1), iv) increase of >=25% in unstimulated whole saliva or any increase if score is 0 at baseline (1), v) decrease of >=25% in rheumatoid factor or decrease of >=10% in immunoglobulin G (IgG) (1). The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Percentage of Subjects				
number (not applicable)	39.3	50.9	63.0	

Statistical analyses

Statistical analysis title	Statistical Analysis 10
Statistical analysis description:	
Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 54.	
Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	23.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	8.4
upper limit	38.9

Statistical analysis title	Statistical Analysis 9
Statistical analysis description:	
Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.	
Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.218
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	11.7

Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.9
upper limit	27.2

Secondary: Number of Subjects With Disease Response According to the STAR Composite Score at Week 24

End point title	Number of Subjects With Disease Response According to the STAR Composite Score at Week 24

End point description:

Number of subjects with disease response according to the STAR composite score at Week 24 was reported. A STAR response is defined as a composite score of >=5 points in the 5 STAR domains, with weighting in parentheses: i) decrease of >=3 in clinESSDAI score (3), ii) decrease of >=1 point or >=15% from baseline in ESSPRI score (3), iii) abnormal Schirmer's test at baseline and an increase of >=5 millimetre (mm), or normal Schirmer's test at baseline and no change to abnormal, or abnormal ocular staining score at baseline and a decrease of >=2 points, or normal ocular staining score at baseline and no change to abnormal (1), iv) increase of >=25% in unstimulated whole saliva or any increase if score is 0 at baseline (1), v) decrease of >=25% in rheumatoid factor or decrease of >=10% in immunoglobulin G (IgG) (1). The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Number	22	27	34	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With an Improvement in DAL by >= 1 Level in at Least One clinESSDAI or ESSDAI Domain at Week 24

End point title	Number of Subjects With an Improvement in DAL by >= 1 Level in at Least One clinESSDAI or ESSDAI Domain at Week 24

End point description:

Number of subjectS with improvement in DAL by >= 1 level in at least one clinESSDAI or ESSDAI domain at Week 24 was reported. In clinESSDAI, physician scores systemic disease activity level on 11 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, and hematological), with each domain activity in 3 to 4 levels (no, low, moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). A higher score indicates worsening of the disease. Each domain is assigned a weight between 1 and 7, and the domain score is multiplied by domain weight. Sum of the weighted domain scores is overall score, which can range from 0 to 135. FAS

included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	19	28	29	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With an Improvement in Disease Activity Level (DAL) by >= 1 Level in at Least One clinESSDAI or ESSDAI Domain at Week 24

End point title	Percentage of Subjects With an Improvement in Disease Activity Level (DAL) by >= 1 Level in at Least One clinESSDAI or ESSDAI Domain at Week 24

End point description:

Percentage of subjects with improvement in DAL by >= 1 level in at least one clinESSDAI or ESSDAI domain at Week 24 was reported. In clinESSDAI, physician scores systemic disease activity level on 11 organ-specific domains (constitutional, lymphadenopathy and lymphoma, articular, muscular, cutaneous, glandular, pulmonary, renal, peripheral nervous system, central nervous system, and hematological), with each domain activity in 3 to 4 levels (no, low, moderate, high) according to their severity (0 = no disease activity; 3 or 4 = high disease activity). A higher score indicates worsening of the disease. Each domain is assigned a weight between 1 and 7, and the domain score is multiplied by domain weight. Sum of the weighted domain scores is overall score, which can range from 0 to 135. FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Percentage of Subjects				
number (not applicable)	33.9	52.8	53.7	

Statistical analyses

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 54.

Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.046
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	19.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	4.5
upper limit	35

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.

Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	18.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	3.6
upper limit	34.2

Secondary: Percentage of Subjects With Improvement From Baseline in >= 3 of 5 Composite of Relevant Endpoints for Sjögren's Syndrome (CRESS) Categories at Week 24

End point title	Percentage of Subjects With Improvement From Baseline in >= 3 of 5 Composite of Relevant Endpoints for Sjögren's Syndrome (CRESS) Categories at Week 24

End point description:

Percentage of subjects with Improvement from baseline in >= 3 of 5 CRESS categories at week 24 was reported. CRESS was a composite tool that incorporates measures of disease activity (clinESSDAI), symptoms (ESSPRI), glandular function and systemic inflammation to assess disease activity. A CRESS response was defined as a response in >=3 of the following 5 categories: i) clinESSDAI score <5 (low

disease activity), ii) decrease of >=1 point or >=15% from baseline in ESSPRI score, iii) abnormal Schirmer's test at baseline (<=5 mm) and an increase of >=5 mm, or normal Schirmer's test at baseline and no change to abnormal, iv) increase of >=25% in unstimulated whole saliva or any increase if score is 0 at baseline, v) decrease of >=25% in rheumatoid factor or decrease of >=10% in IgG. The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

at Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Percentage of Subjects				
number (not applicable)	17.9	43.4	48.1	

Statistical analyses

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 54.

Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	30.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	16.3
upper limit	44.3

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

Subjects analysed for both the treatments as per assigned treatment sequence in respective periods were 56 and 53.

Comparison groups	Group 1: Placebo IV v Group 3: Nipocalimab 15 mg/kg IV

Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in proportion
Point estimate	25.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	11.5
upper limit	39.5

Secondary: Number of Subjects With Improvement From Baseline in >= 3 of 5 CRESS Categories at Week 24

End point title	Number of Subjects With Improvement From Baseline in >= 3 of 5 CRESS Categories at Week 24

End point description:

Number of subjects with Improvement from baseline in >= 3 of 5 CRESS categories at week 24 was reported. CRESS was a composite tool that incorporates measures of disease activity (clinESSDAI), symptoms (ESSPRI), glandular function and systemic inflammation to assess disease activity. A CRESS response was defined as a response in >=3 of the following 5 categories: i) clinESSDAI score <5 (low disease activity), ii) decrease of >=1 point or >=15% from baseline in ESSPRI score, iii) abnormal Schirmer's test at baseline (<=5 mm) and an increase of >=5 mm, or normal Schirmer's test at baseline and no change to abnormal, iv) increase of >=25% in unstimulated whole saliva or any increase if score is 0 at baseline, v) decrease of >=25% in rheumatoid factor or decrease of >=10% in IgG. The FAS included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	10	23	26	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events of Special Interests (AESIs)

End point title	Number of Subjects With Adverse Events of Special Interests (AESIs)

End point description:

Number of subjects with AESIs were reported. AEs was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. Treatment-emergent adverse events associated with the following situations are considered as AESIs: severe infections, severe hypoalbuminemia. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Post first administration of study intervention (Week 0) up to 30 weeks

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	1	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-emergent Serious Adverse Events (SAEs)

End point title	Number of Subjects With Treatment-emergent Serious Adverse Events (SAEs)

End point description:

Treatment-emergent SAEs were defined as SAEs with onset or worsening on or after date of first dose of study treatment. An AE is any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. A SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/ incapacity; congenital anomaly or any situation deemed medically important by the investigator. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

post first administration of study intervention (Week 0) up to 30 weeks

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	3	4	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Subjects With Treatment-emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non investigational) product. An AE does not necessarily have a causal relationship with the pharmaceutical/biological agent under study. TEAEs were defined as AEs with onset or worsening on or after date of first dose of study treatment. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Post first administration of study intervention (Week 0) up to 30 weeks

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	35	42	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With TEAEs Leading to Treatment Discontinuation

End point title	Number of Subjects With TEAEs Leading to Treatment Discontinuation

End point description:

Number of subjects with TEAEs leading to treatment discontinuation were reported. AEs was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. TEAEs are defined as AEs with onset or worsening on or after date of first dose of study treatment. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.

End point type	Secondary

End point timeframe:

Post first administration of study intervention (Week 0) up to 30 weeks

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects	2	3	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Abnormalities in Vital Signs

End point title	Number of Subjects With Clinically Significant Abnormalities in Vital Signs

End point description:

Number of subject with clinically significant abnormalities in vital signs were reported. Vital sign parameters including temperature (less than [<]36 and greater than [>] 38), pulse rate (<=50 beats per minute [bpm] and with >=15 bpm decrease from baseline and >=120 bpm and with >=15 bpm increase from baseline), and blood pressure (systolic blood pressure [SBP]: <=90 millimeters of mercury [mmHg] and with >=20 mmHg decrease from baseline and diastolic blood pressure [DBP]: <=50 mmHg and with >=15 mmHg decrease from baseline and >=100 mmHg and with >=15 mmHg increase from baseline). The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Only those categories in which at least 1 subject had data were reported.

End point type	Secondary

End point timeframe:

post first administration of study intervention (Week 0) up to 30 weeks

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Subjects				
Pulse: =<50 bpm and with =>15 bpm	0	1	0	
Pulse:>=120 bpm and with >=15 bpm	0	0	0	
SBP: <=90 mmHg and with >=20 mmHg	3	1	1	
SBP: >=160 mmHg and with >=20 mmHg	0	0	2	
DBP: <=50 mmHg and with >=15 mmHg	1	1	0	
DBP: >=100 mmHg and with >=15 mmHg	0	0	1	
Temperature: <36	5	4	6	
Temperature: > 38	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Abnormalities in Laboratory Parameters

End point title	Number of Subjects With Clinically Significant Abnormalities in Laboratory Parameters

End point description:

Laboratory parameters included hematology (platelet count [platelets: decrease >20% and value <100 (fraction 1)], red blood cell count, hemoglobin, hematocrit, white blood cell count with differential [lymphocytes: decrease >20% and value <0.08], [leukocytes: decrease >10% and value <2.5], [neutrophils: increase >30% and value >0.90], [eosinophils: increase >20% and value >0.10]), serum chemistry (phosphate [decrease >10% and value <0.6), lipid panel (high-density lipoprotein [HDL] and low-density lipoprotein [LDL], creatine kinase: increase >20% and value >960, cholesterol: value >=6.2), urinalysis, and blood coagulation. Safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Here, W: denotes week, N: number of subjects evaluable, and n: number of subjects evaluable for each arm at specific time points. Only those categories in which at least 1 subject had data were reported.

End point type	Secondary

End point timeframe:

Weeks 2, 4, 8, 12, 16, 20, 24, and Week 30/final safety follow-up visit

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	51	50	
Units: Subjects				
W 2: Lymphocytes(n=55, 50, 50)	1	0	0	
W 2: Platelets (n=54, 50, 50)	1	0	0	
W4: Phosphate(n=54, 51, 49)	0	0	1	
W 4: Cholesterol: Value >=6.2 (n=53, 51, 49)	2	1	1	
W4: HDL Cholesterol- Value >=2.1 (n= 53, 49, 49)	1	3	7	
W4: LDL Cholesterol-Value >=4.1(n=53, 49, 49)	0	0	1	
W4:Leukocytes (n=53, 51, 50)	1	0	0	
W8: Cholesterol:Value >=6.2 (n=54, 48, 47)	1	2	1	
W8: HDL Cholesterol:Value >=2.1(n=53, 48, 46)	2	4	7	
W8:LDL Cholesterol: Value >=4.1(n=53, 48, 46)	0	2	1	
W8: Neutrophils (n=53, 48, 47)	0	1	0	
W8:Lymphocytes(n=53,48, 47)	0	2	0	

W12:HDL Cholesterol:Value >=2.1 (n=50, 46, 46)	1	3	6	
W12:HDL Cholesterol: Value <1.0 (n=50, 46, 46)	0	1	0	
W12:Neutrophils (n=48, 44, 43)	0	0	1	
W12:Lymphocytes (n=48,44,43)	0	1	1	
W16: Leukocytes (n=48, 43,44)	2	0	1	
W24:HDL Cholesterol:Value >=2.1 (n=49, 46, 48)	2	4	6	
W24: LDL Cholesterol-Value >=4.1(n=49, 45, 48)	0	2	0	
W24: Eosinophils (n=49, 47, 46)	1	0	0	
W24: Creatine Kinase (n=50,48,49)	0	1	0	
W24: Cholesterol (n=50, 46, 49)	0	1	0	
W30: Leukocytes (n=45, 46,46)	0	1	0	
W30: Eosinophils (n=45, 46, 46)	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Nipocalimab Concentration Over Time

End point title	Serum Nipocalimab Concentration Over Time[1]

End point description:

Serum concentrations of nipocalimab over time in subjects receiving active study intervention will be reported. The pharmacokinetics (PK) analysis set was defined as all randomised subjects who had received at least 1 complete dose of nipocalimab and have at least 1 valid post-dose blood sample drawn for PK analysis. This endpoint was planned to be analysed for specified arms only. Here, N: number of subjects evaluable for this endpoint and n: number of subjects evaluable for each arm at specific time points.

End point type	Secondary

End point timeframe:

Weeks 0, 2, 4, 8, 12, 16, 20, 24, and Week 30/final safety follow-up pre dose and post dose

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: The data was planned to be analysed for specified baseline arms only.

End point values	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	53	54		
Units: micrograms per millilitre				
arithmetic mean (standard deviation)				
Week 0, predose (n= 53, 52)	0.000 (± 0.0036)	0.001 (± 0.0079)		
Week 0, postdose (n= 53, 54)	108.132 (± 41.1048)	354.926 (± 129.2114)		
Week 2, predose (n= 48, 50)	0.001 (± 0.0066)	0.004 (± 0.0145)		
Week 2, postdose (n= 47, 50)	98.569 (± 48.0806)	340.360 (± 130.4009)		

Week 4, predose (n= 44, 43)	0.001 (± 0.0046)	0.001 (± 0.0067)		
Week 8, predose (n= 34, 39)	0.002 (± 0.0082)	0.001 (± 0.0031)		
Week 8, postdose (n= 34, 38)	109.944 (± 38.2894)	345.526 (± 130.7682)		
Week 12, predose (n= 26, 32)	0.020 (± 0.1018)	0.003 (± 0.0119)		
Week 12, postdose (n= 26, 32)	107.112 (± 35.8943)	331.531 (± 187.7316)		
Week 16, predose (n= 22, 25)	0.000 (± 0.0000)	0.004 (± 0.0069)		
Week 24/final efficacy (n= 16, 19)	0.001 (± 0.0026)	0.003 (± 0.0070)		
Week 30/final safety follow-up visit (n= 16, 19)	0.002 (± 0.0066)	0.000 (± 0.0000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in C-reactive Protein (CRP)

End point title	Change From Baseline in C-reactive Protein (CRP)

End point description:

Change from baseline in biomarkers CRP were reported. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Here, N: number of subjects evaluable for this endpoint and n: number of subjects evaluable for each arm at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, 6, 8, 10, 12, 16, 20, 24, and Week 30/final safety follow-up visit

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Milligrams per litre				
arithmetic mean (standard deviation)				
Week 2 (n=55, 51, 51)	1.513 (± 7.6158)	0.520 (± 6.8520)	0.939 (± 5.5131)	
Week 4 (n=54, 50, 49)	-0.243 (± 2.1402)	0.238 (± 7.1198)	0.302 (± 1.9397)	
Week 6 (n=53, 47, 49)	-0.279 (± 2.2463)	-0.285 (± 6.7629)	-0.090 (± 2.1916)	
Week 8 (n=53, 49, 47)	0.026 (± 3.3460)	0.361 (± 2.3499)	-0.121 (± 1.3529)	
Week 10 (n=51, 45, 45)	1.751 (± 1.8643)	2.242 (± 5.1090)	1.304 (± 1.3120)	
Week 12 (n=50, 46, 46)	0.918 (± 4.9796)	0.765 (± 3.2934)	0.139 (± 2.0962)	
Week 16 (n=48, 44, 44)	-0.154 (± 2.1477)	-0.927 (± 7.6604)	0.107 (± 1.5903)	

Week 20 (n=46, 46, 43)	0.735 (± 6.3374)	1.020 (± 5.4001)	0.267 (± 2.9934)	
Week 24/ final efficacy visit (n=50, 48, 47)	1.524 (± 9.4589)	1.515 (± 6.6511)	0.200 (± 1.9106)	
Week 30/ final safety follow-up (n=46, 44, 46)	0.789 (± 3.8812)	-0.716 (± 6.1862)	-0.176 (± 1.4461)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Erythrocyte Sedimentation Rate (ESR)

End point title	Change From Baseline in Erythrocyte Sedimentation Rate (ESR)

End point description:

Change from baseline in biomarkers ESR were reported. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Here, N: number of subjects evaluable for this endpoint and n: number of subjects evaluable for each arm at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, 8, 12, 16, 20, 24, and Week 30/final safety follow-up visit

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: Millimetres per hour				
arithmetic mean (standard deviation)				
Week 2 (n= 54, 50, 49)	-0.037 (± 14.8768)	0.100 (± 11.4682)	-6.816 (± 14.6283)	
Week 4 (n= 53, 50, 49)	-1.340 (± 13.7448)	-1.640 (± 12.3813)	-9.327 (± 16.4929)	
Week 8 (n= 52, 46, 44)	10.602 (± 54.9277)	-0.005 (± 114.9206)	-28.010 (± 35.4705)	
Week 12 (n= 49, 44, 46)	-1.163 (± 17.9691)	-7.932 (± 17.5544)	-11.217 (± 14.6271)	
Week 16 (n= 47, 44, 40)	-5.213 (± 16.6053)	-7.225 (± 14.7691)	-12.500 (± 15.5616)	
Week 20 (n= 44, 44, 41)	-9.523 (± 21.9741)	-5.273 (± 16.7726)	-12.390 (± 15.4659)	
Week 24/ final efficacy visit (n=51, 46, 49)	-6.118 (± 19.5332)	-5.261 (± 18.1322)	-9.653 (± 16.5951)	
Week 30/ final safety follow-up (n= 46, 44, 45)	-7.478 (± 20.4958)	-2.909 (± 17.3498)	-6.978 (± 19.1115)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Total Immunoglobulin [Ig]G, IgG1, IgG2, IgG3, IgG4

End point title	Change From Baseline in Total Immunoglobulin [Ig]G, IgG1, IgG2, IgG3, IgG4

End point description:

Change from baseline in total immunoglobulin [Ig]G, IgG1, IgG2, IgG3, IgG4 were reported. The pharmacodynamic (PD) analysis set was defined as subjects who had received at least 1 dose (partial or complete) of nipocalimab and have at least 1 valid post-dose blood sample drawn for PD analysis. Here, N: number of subjects evaluable for this endpoint and n: number of subjects evaluable for each arm at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, 8, 12, 16, 20, 24, and Week 30/final safety follow-up visit

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	51	51	
Units: Grams per litre				
arithmetic mean (standard deviation)				
IgG: Week 2 (n=55, 51, 51)	-0.293 (± 2.5034)	-3.570 (± 1.5226)	-7.712 (± 3.2346)	
IgG: Week 4 (n=53, 50, 50)	-0.274 (± 2.6898)	-4.612 (± 1.7211)	-8.904 (± 3.3077)	
IgG: Week 8 (n=52, 43, 45)	-0.126 (± 2.6075)	-5.114 (± 1.7088)	-9.578 (± 4.1409)	
IgG: Week 12 (n=45, 38, 38)	-0.051 (± 2.6476)	-5.231 (± 1.8415)	-9.899 (± 4.3507)	
IgG: Week 16 (n=41, 34, 34)	-0.211 (± 2.9717)	-5.224 (± 2.0568)	-9.340 (± 4.3346)	
IgG: Week 20 (n=39, 32, 32)	-0.217 (± 2.6829)	-4.942 (± 2.2000)	-9.976 (± 5.2069)	
IgG: Week 24/final efficacy (n=35, 31, 30)	-0.171 (± 3.5555)	-4.360 (± 2.8371)	-9.467 (± 5.4390)	
IgG: Week 30 /final safety (n=35, 30 30)	-0.421 (± 4.0162)	-0.015 (± 2.3388)	-0.688 (± 4.9730)	
IgG1: Week 2 (n=55, 51, 51)	-0.422 (± 2.4279)	-2.590 (± 1.1672)	-5.720 (± 2.6621)	
IgG1: Week 4 (n=52, 50, 50)	-0.256 (± 2.8110)	-3.364 (± 1.8922)	-6.300 (± 2.7080)	
IgG1: Week 8 (n=52, 44, 46)	-0.316 (± 2.4727)	-3.444 (± 2.2316)	-6.728 (± 3.0146)	
IgG1: Week 12 (n=44, 38, 38)	-0.388 (± 2.6534)	-3.587 (± 2.7108)	-6.997 (± 2.8712)	
IgG1: Week 16 (n=41, 34, 34)	-0.155 (± 2.7970)	-3.391 (± 2.7162)	-6.678 (± 3.3193)	
IgG1: Week 20 (n=39, 32, 32)	-0.027 (± 2.9349)	-3.547 (± 4.3021)	-7.106 (± 3.1650)	
IgG1: Week 24/final efficacy (n=35, 31, 30)	-0.273 (± 3.4443)	-2.807 (± 3.8918)	-6.854 (± 3.3401)	
IgG1: Week 30 /final safety (n=35, 29, 30)	-0.567 (± 3.8984)	-0.203 (± 3.9916)	-0.642 (± 4.0439)	

IgG2: Week 2 (n=55, 51, 51)	0.011 (± 0.5523)	-0.478 (± 0.5438)	-1.208 (± 0.8527)	
IgG2: Week 4 (n=52, 50, 50)	0.058 (± 0.5328)	-0.657 (± 0.6511)	-1.471 (± 1.0384)	
IgG2: Week 8 (n=52, 44, 46)	-0.025 (± 0.5082)	-0.897 (± 0.6258)	-1.735 (± 1.0015)	
IgG2: Week 12 (n=44, 38, 38)	0.071 (± 0.4862)	-0.893 (± 0.6425)	-1.698 (± 1.0102)	
IgG2: Week 16 (n=41, 34, 34)	0.060 (± 0.5388)	-0.878 (± 0.7311)	-1.655 (± 1.0935)	
IgG2: Week 20 (n=39, 32, 32)	0.043 (± 0.5881)	-0.843 (± 0.7219)	-1.725 (± 1.0670)	
IgG2: Week 24/final efficacy (n=35, 31, 30)	0.013 (± 0.6359)	-0.786 (± 0.8167)	-1.720 (± 1.0577)	
IgG2: Week 30 /final safety (n=35, 29, 30)	0.151 (± 0.6005)	-0.242 (± 0.6325)	-0.600 (± 0.7790)	
IgG3: Week 2 (n=55, 51, 51)	-0.021 (± 0.1003)	-0.133 (± 0.1004)	-0.224 (± 0.1398)	
IgG3: Week 4 (n=52, 50, 50)	-0.010 (± 0.1030)	-0.148 (± 0.1113)	-0.217 (± 0.1539)	
IgG3: Week 8 (n=52, 44, 46)	-0.013 (± 0.0987)	-0.152 (± 0.1266)	-0.217 (± 0.1438)	
IgG3: Week 12 (n=44, 38, 38)	-0.002 (± 0.1175)	-0.146 (± 0.1316)	-0.231 (± 0.1396)	
IgG3: Week 16 (n=41, 34, 34)	-0.001 (± 0.1234)	-0.145 (± 0.1111)	-0.219 (± 0.1584)	
IgG3: Week 20 (n=39, 32, 32)	0.003 (± 0.1355)	-0.127 (± 0.1705)	-0.236 (± 0.1477)	
IgG3: Week 24/final efficacy (n=35, 31, 30)	-0.006 (± 0.1459)	-0.105 (± 0.1671)	-0.246 (± 0.1656)	
IgG3: Week 30 /final safety (n=35, 29, 30)	-0.004 (± 0.1334)	-0.012 (± 0.0964)	-0.015 (± 0.0979)	
IgG4: Week 2 (n=55, 51, 51)	-0.028 (± 0.1631)	-0.158 (± 0.4306)	-0.242 (± 0.2717)	
IgG4: Week 4 (n=52, 50, 50)	-0.001 (± 0.0606)	-0.175 (± 0.4426)	-0.292 (± 0.3429)	
IgG4: Week 8 (n=52, 44, 46)	-0.018 (± 0.1231)	-0.207 (± 0.4708)	-0.302 (± 0.3568)	
IgG4: Week 12 (n=44, 38, 38)	-0.003 (± 0.1137)	-0.226 (± 0.5036)	-0.317 (± 0.3557)	
IgG4: Week 16 (n=41, 34, 34)	-0.010 (± 0.1075)	-0.229 (± 0.5302)	-0.279 (± 0.2811)	
IgG4: Week 20 (n=39, 32, 32)	-0.010 (± 0.0923)	-0.227 (± 0.5416)	-0.307 (± 0.3435)	
IgG4: Week 24/final efficacy (n=35, 31, 30)	-0.004 (± 0.0803)	-0.207 (± 0.5828)	-0.308 (± 0.3133)	
IgG4: Week 30 /final safety (n=35, 29, 30)	-0.008 (± 0.1341)	-0.111 (± 0.5936)	-0.025 (± 0.1846)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Autoantibodies : Anti-Sjogren's Syndrome Related Antigen A (anti-Ro/SSA), Anti-Sjogren's Syndrome Related Antigen B (anti-La/SSB), and Anti-Ro52/TRIM21

End point title	Change From Baseline in Autoantibodies : Anti-Sjogren's Syndrome Related Antigen A (anti-Ro/SSA), Anti-Sjogren's

	Syndrome Related Antigen B (anti-La/SSB), and Anti-Ro52/TRIM21

End point description:

Change from baseline in autoantibodies included anti-Ro/SSA, anti-La/SSB, and anti-Ro52/tripartite motif-containing protein 21 (Anti-Ro52/TRIM21) were reported. The PD analysis set was defined as subjects who had received at least 1 dose (partial or complete) of nipocalimab and have at least 1 valid post-dose blood sample drawn for PD analysis. Here, N: number of subjects evaluable for this endpoint and n: number of subjects evaluable for each arm at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, 8, 12, 16, 20, 24, and Week 30/final safety follow-up visit

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: CU				
median (inter-quartile range (Q1-Q3))				
Anti-Ro60/SSA: Week 2 (n=51, 48, 49)	-3.80 (-2480.00 to 893.30)	-3327.70 (-10728.60 to -1492.30)	-6838.30 (-20472.00 to -469.00)	
Anti-Ro60/SSA: Week 4 (n=50, 47, 48)	90.80 (-87.90 to 3520.00)	-5628.70 (-12174.20 to -2884.60)	-8682.45 (-22604.00 to -882.15)	
Anti-Ro60/SSA: Week 8 (n=49, 40, 44)	15.10 (-1480.00 to 1392.00)	-6952.90 (-11828.00 to -2864.25)	-11398.15 (-22522.35 to -925.20)	
Anti-Ro60/SSA: Week 16 (n=38, 33, 32)	41.25 (-2340.20 to 3792.00)	-5424.00 (-8576.00 to -3201.10)	-8511.15 (-20066.55 to -1637.40)	
Anti-Ro60/SSA: Week 24/final (n=33, 29, 28)	56.70 (-1787.10 to 2398.90)	-5702.50 (-13240.00 to -804.00)	-8384.40 (-18053.85 to -619.55)	
Anti-Ro60/SSA: Week 30 /final (n=32, 28, 27)	-13.80 (-3208.15 to 2681.85)	-73.60 (-2270.60 to 773.25)	-39.90 (-2006.70 to 5976.00)	
Anti-Ro52/TRIM21: Week 2 (n=51, 49, 50)	-0.50 (-181.60 to 26.00)	-490.80 (-1877.50 to -107.40)	-496.30 (-1988.40 to 0.00)	
Anti-Ro52/TRIM21: Week 4 (n=50, 48, 49)	-0.45 (-170.20 to 24.40)	-762.50 (-2876.90 to -277.25)	-523.90 (-2412.50 to -24.70)	
Anti-Ro52/TRIM21: Week 8 (n=49, 41, 45)	-1.30 (-880.30 to 7.00)	-732.60 (-1943.40 to -272.80)	-611.40 (-3042.30 to 0.00)	
Anti-Ro52/TRIM21: Week 16 (n=38, 34, 33)	-0.05 (-430.60 to 253.80)	-581.90 (-1741.30 to -249.10)	-592.10 (-2494.10 to -21.90)	
Anti-Ro52/TRIM21: Week 24/final (n=33, 30, 29)	0.60 (-36.90 to 1098.10)	-525.95 (-1488.90 to -29.20)	-493.20 (-1397.60 to 0.00)	
Anti-Ro52/TRIM21: Week 30 /final (n=32, 29, 28)	0.00 (-1031.80 to 184.40)	0.90 (-233.80 to 768.00)	0.00 (-167.75 to 507.75)	
Anti-La/SSB: Week 2 (n= 54, 50, 50)	0.00 (-3.70 to 6.00)	-19.40 (-134.90 to -3.20)	-25.30 (-346.10 to -2.60)	

Anti-La/SSB: Week 4 (n=53, 49, 49)	0.00 (-3.80 to 10.20)	-33.80 (-179.70 to -6.70)	-38.90 (-369.90 to -6.00)	
Anti-La/SSB: Week 8 (n=52, 42, 45)	-0.15 (-18.45 to 7.00)	-27.25 (-122.40 to -5.40)	-44.60 (-507.90 to -5.20)	
Anti-La/SSB: Week 16 (n=41, 35, 33)	0.00 (-3.60 to 56.50)	-28.10 (-323.30 to -1.30)	-46.50 (-530.50 to -9.20)	
Anti-La/SSB: Week 24/final (n=36, 31, 29)	1.10 (-5.35 to 53.10)	-22.30 (-318.20 to 0.00)	-40.80 (-2861.40 to -6.20)	
Anti-La/SSB: Week 30 /final (n=35, 30, 28)	0.00 (-19.30 to 29.00)	-1.40 (-29.60 to 6.80)	-3.65 (-43.25 to 0.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Autoantibodies: Rheumatoid Factor (RF)

End point title	Change From Baseline in Autoantibodies: Rheumatoid Factor (RF)

End point description:

Change from baseline in autoantibodies included RF were reported. The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention. Here, N: number of subjects evaluable for this endpoint and n: number of subjects evaluable for each arm at specific time points.

End point type	Secondary

End point timeframe:

Baseline, Weeks 2, 4, 8, 12, 16, 20, 24, and Week 30/final safety follow-up visit

End point values	Group 1: Placebo IV	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	53	54	
Units: international unit per millilitre				
median (inter-quartile range (Q1-Q3))				
RF: Week 2 (n=55, 51, 51)	-0.500 (-2.200 to 0.000)	-1.700 (-4.500 to 0.000)	-3.600 (-9.500 to 0.000)	
RF: Week 4 (n=54, 50, 47)	-0.150 (-2.500 to 0.400)	-3.300 (-6.600 to -0.600)	-5.400 (-14.500 to -0.500)	
RF: Week 8 (n=53, 49, 45)	-0.100 (-1.600 to 1.000)	-3.200 (-6.000 to 0.000)	-4.400 (-14.100 to 0.000)	
RF: Week 12 (n=49, 45, 46)	0.000 (-1.500 to 3.400)	-2.700 (-4.700 to 0.000)	-5.650 (-16.800 to -0.500)	
RF: Week 16 (n=48, 44, 43)	0.000 (-2.250 to 2.350)	-3.450 (-6.900 to 0.000)	-6.000 (-18.600 to -0.500)	

RF: Week 20 (n=46, 46, 43)	0.000 (-3.000 to 2.500)	-2.900 (-5.900 to 0.000)	-6.900 (-18.600 to 0.000)	
RF: Week 24/final efficacy visit (n=50, 48, 47)	0.000 (-1.700 to 1.400)	-2.850 (-5.950 to 0.000)	-4.400 (-16.000 to 0.000)	
RF: Week 30 /final safety(n=46, 44, 46)	0.000 (-3.300 to 1.700)	0.000 (-1.800 to 3.450)	0.000 (-1.800 to 1.600)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Anti-drug Antibodies (ADAs) to Nipocalimab

End point title	Number of Subjects with Anti-drug Antibodies (ADAs) to Nipocalimab[2]

End point description:

Number of subjects with ADA to nipocalimab were reported. The presence of ADA to nipocalimab in serum was determined by a sensitive and drug-tolerant electrochemiluminescence immunoassay (ECLIA) method. Immunogenicity analysis set included all randomised subjects who received at least 1 dose (partial or complete) of nipocalimab and had appropriate samples for ADA detection. This endpoint was planned to be analysed for specified arms only.

End point type	Secondary

End point timeframe:

Baseline (Week 0) up to Week 30/final safety follow-up visit

Notes:

[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: The data was planned to be analysed for specified baseline arms only.

End point values	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	52		
Units: Subjects	46	41		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Neutralising Antibodies (NAbs) to Nipocalimab

End point title	Number of Subjects with Neutralising Antibodies (NAbs) to Nipocalimab[3]

End point description:

Number of subjects with NAbs were reported. Neutralising antibodies to nipocalimab were assessed using a non-cell based competitive ligand binding ECLIA assay. Immunogenicity analysis set included all randomised subjects who received at least 1 dose (partial or complete) of nipocalimab and had appropriate samples for ADA detection. This endpoint was planned to be analysed for specified arms only.

End point type	Secondary

End point timeframe:

Baseline (Week 0) up to Week 30/final safety follow-up visit

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: The data was planned to be analysed for specified baseline arms only.

End point values	Group 2: Nipocalimab 5 mg/kg IV	Group 3: Nipocalimab 15 mg/kg IV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	52		
Units: Subjects	33	28		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From baseline (Week 0) up to 30 Weeks	
Adverse event reporting additional description:	
The safety analysis set included all randomised subjects who had received at least 1 dose (partial or complete) of any study intervention.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups	
Reporting group title	Group 1: Placebo IV
Reporting group description:	
Subjects received placebo intravenous (IV) infusion every 2 weeks (q2w) from Week 0 through Week 22 along with standard of care treatments (SOC)	
Reporting group title	Group 3: Nipocalimab 15 mg/kg IV
Reporting group description:	
Subjects received nipocalimab 15 mg/kg IV infusion q2w from Week 0 through Week 22 along with SOC.	
Reporting group title	Group 2: Nipocalimab 5 mg/kg IV
Reporting group description:	
Subjects received nipocalimab 5 milligrams per kilogram (mg/kg) IV infusion q2w from Week 0 through Week 22 along with SOC.	

Serious adverse events	Group 1: Placebo IV	Group 3: Nipocalimab 15 mg/kg IV	Group 2: Nipocalimab 5 mg/kg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 56 (5.36%)	4 / 54 (7.41%)	4 / 53 (7.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	0 / 53 (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
Pregnancy, puerperium and perinatal conditions			
Anembryonic Gestation			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	0 / 53 (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
Immune system disorders			

Anaphylactic Reaction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	0 / 53 (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
Pulmonary Mass			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	0 / 53 (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
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
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			
Sjogren's Syndrome			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	0 / 53 (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
Infections and infestations			
Acute Sinusitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 54 (0.00%)	0 / 53 (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
Appendicitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			

subjects affected / exposed	0 / 56 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital Herpes Simplex			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	0 / 53 (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

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

Non-serious adverse events	Group 1: Placebo IV	Group 3: Nipocalimab 15 mg/kg IV	Group 2: Nipocalimab 5 mg/kg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 56 (39.29%)	32 / 54 (59.26%)	35 / 53 (66.04%)
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 56 (14.29%)	6 / 54 (11.11%)	4 / 53 (7.55%)
occurrences (all)	12	7	6
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 56 (10.71%)	6 / 54 (11.11%)	3 / 53 (5.66%)
occurrences (all)	9	9	4
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 56 (1.79%)	3 / 54 (5.56%)	0 / 53 (0.00%)
occurrences (all)	1	3	0
Abdominal Pain Upper			
subjects affected / exposed	2 / 56 (3.57%)	1 / 54 (1.85%)	4 / 53 (7.55%)
occurrences (all)	2	1	5
Diarrhoea			
subjects affected / exposed	2 / 56 (3.57%)	8 / 54 (14.81%)	3 / 53 (5.66%)
occurrences (all)	2	10	3
Nausea			
subjects affected / exposed	2 / 56 (3.57%)	6 / 54 (11.11%)	0 / 53 (0.00%)
occurrences (all)	4	9	0
Vomiting			

subjects affected / exposed	1 / 56 (1.79%)	3 / 54 (5.56%)	0 / 53 (0.00%)
occurrences (all)	1	3	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	1 / 56 (1.79%)	1 / 54 (1.85%)	3 / 53 (5.66%)
occurrences (all)	2	1	3
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 54 (0.00%)	3 / 53 (5.66%)
occurrences (all)	0	0	4
Rash			
subjects affected / exposed	0 / 56 (0.00%)	3 / 54 (5.56%)	1 / 53 (1.89%)
occurrences (all)	0	5	1
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	2 / 56 (3.57%)	1 / 54 (1.85%)	3 / 53 (5.66%)
occurrences (all)	2	1	3
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	3 / 56 (5.36%)	1 / 54 (1.85%)	4 / 53 (7.55%)
occurrences (all)	3	1	4
Covid-19			
subjects affected / exposed	3 / 56 (5.36%)	3 / 54 (5.56%)	7 / 53 (13.21%)
occurrences (all)	3	4	7
Cystitis			
subjects affected / exposed	3 / 56 (5.36%)	1 / 54 (1.85%)	3 / 53 (5.66%)
occurrences (all)	3	1	5
Nasopharyngitis			
subjects affected / exposed	4 / 56 (7.14%)	7 / 54 (12.96%)	4 / 53 (7.55%)
occurrences (all)	4	9	5
Oral Herpes			
subjects affected / exposed	0 / 56 (0.00%)	1 / 54 (1.85%)	3 / 53 (5.66%)
occurrences (all)	0	1	3
Upper Respiratory Tract Infection			
subjects affected / exposed	4 / 56 (7.14%)	3 / 54 (5.56%)	6 / 53 (11.32%)
occurrences (all)	4	3	6

Urinary Tract Infection subjects affected / exposed occurrences (all)	3 / 56 (5.36%) 4	3 / 54 (5.56%) 3	4 / 53 (7.55%) 5

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 May 2021	The purpose of this amendment was to include additional safety criteria related to hypogammaglobulinemia, hyperlipidemia, and anaphylaxis; to update the use of oral contraceptives; and to clarify the use of NSAIDs prior to study visits involving joint counts or pain assessments.
04 February 2022	The purpose of this amendment was to amend eligibility criteria to include a broader population of Sjögren's disease patients.
20 July 2022	The purpose of this amendment was to revise the inclusion criterion and secondary endpoint (Sjogren's Syndrome Responder Index response) that depends on erythrocyte sedimentation rate (ESR) as key laboratory supplies required for the ESR test that meet European Union Conformité Européene CE marking requirements for laboratory tests were no longer commercially available. In addition, a new secondary endpoint (Sjögren's Tool for Assessing Response) was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported