



Clinical trial results:

A multi-centre, randomised, double-blind placebo-controlled, Phase 2 study to investigate efficacy, safety and tolerability of SLN360 in participants with elevated lipoprotein(a) at high risk of atherosclerotic cardiovascular disease events

Summary

EudraCT number	2022-001876-32
Trial protocol	ES NL SK DK CZ
Global end of trial date	01 July 2024

Results information

Result version number	v1 (current)
This version publication date	14 June 2025
First version publication date	14 June 2025

Trial information

Trial identification

Sponsor protocol code	SLN360-002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05537571
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Silence Therapeutics plc
Sponsor organisation address	72 Hammersmith Road, London, United Kingdom, W14 8TH
Public contact	Global Regulatory, Silence Therapeutics plc, global-regulatory@silence-therapeutics.com
Scientific contact	Global Regulatory, Silence Therapeutics plc, global-regulatory@silence-therapeutics.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	16 July 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the effect of SLN360 on circulating levels of lipoprotein(a) in participants with elevated lipoprotein(a) at high risk of ASCVD events.

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation Good Clinical Practice regulations/guidelines.

Background therapy:

Participants received standard of care stable doses of lipid-modifying therapy during the trial.

Evidence for comparator: -

Actual start date of recruitment	05 December 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	Netherlands: 60
Country: Number of subjects enrolled	Slovakia: 5
Country: Number of subjects enrolled	Czechia: 11
Country: Number of subjects enrolled	Denmark: 25
Country: Number of subjects enrolled	United Kingdom: 32
Country: Number of subjects enrolled	Australia: 18
Country: Number of subjects enrolled	South Africa: 29
Worldwide total number of subjects	180
EEA total number of subjects	101

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)	92
From 65 to 84 years	88
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were screened from 05 December 2022, first randomised participant signed informed consent on 13 December 2022 and last participant was randomised 27 April 2023.

Pre-assignment

Screening details:

A total of 253 participants were screened for inclusion, 73 participants failed screening.

Pre-assignment period milestones

Number of subjects started	253 ^[1]
Number of subjects completed	180 ^[2]

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Adverse event, non-fatal: 2
Reason: Number of subjects	Consent withdrawn by subject: 1
Reason: Number of subjects	Other: 4
Reason: Number of subjects	Failure to meet randomisation criteria: 66

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The worldwide number includes enrolled participants whereas the pre-assignment period includes participants who failed screening and were not enrolled.

[2] - The number of subjects reported to be in the pre-assignment period is not consistent with the number starting period 1. It is expected that the number completing the pre-assignment period are also present in the arms in period 1.

Justification: The pre-assignment period represents the screening period, reasons for non-completion are provided. The 180 participants included in period 1 include those participants who did not fail screening and who were enrolled and randomised.

Period 1

Period 1 title	Overall trial
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

Following the completion of 36 weeks, limited members from the Sponsor team were unblinded. The nature of the treatment supply meant that the pharmacist was unblinded with appropriate unblinded oversight in place.

Arms

Are arms mutually exclusive?	No
Arm title	Placebo Q16W

Arm description:

Placebo administered subcutaneously at Weeks 0, 16 and 32 (dosing every 16 weeks [Q16W]).

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

Dosage and administration details:
Administered by subcutaneous injection.

Arm title	Placebo Q24W
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Arm description:

Placebo administered subcutaneously at Weeks 0 and 24 (dosing every 24 weeks [Q24W]). This group was stratified so that half of participants were dosed to match the SLN360 300 mg Q24W group and half were dosed to match the SLN360 450 mg Q24W group (with respect to injected volume).

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

Dosage and administration details:
Administered by subcutaneous injection.

Arm title	SLN360 300 mg Q16W
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Arm description:

SLN360 300 mg administered subcutaneously at Weeks 0, 16 and 32 (Q16W).

Arm type	Experimental
Investigational medicinal product name	Zerlasiran
Investigational medicinal product code	SLN360
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered by subcutaneous injection.

Arm title	SLN360 300 mg Q24W
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Arm description:

SLN360 300 mg administered subcutaneously at Weeks 0 and 24 (Q24W).

Arm type	Experimental
Investigational medicinal product name	Zerlasiran
Investigational medicinal product code	SLN360
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered by subcutaneous injection.

Arm title	SLN360 450 mg Q24W
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Arm description:

SLN360 450 mg administered subcutaneously at Weeks 0 and 24 (Q24W).

Arm type	Experimental
Investigational medicinal product name	Zerlasiran
Investigational medicinal product code	SLN360
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered by subcutaneous injection.

Arm title	Pooled placebo
Arm description: Pooled data from both placebo groups.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: Administered by subcutaneous injection.	

Number of subjects in period 1	Placebo Q16W	Placebo Q24W	SLN360 300 mg Q16W
Started	23	24	44
Treated	23	24	42
Completed	23	23	39
Not completed	0	1	5
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	2
Lost to follow-up	-	1	-
Hepatitis A screening result	-	-	2

Number of subjects in period 1	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Started	44	45	47
Treated	44	45	47
Completed	43	44	46
Not completed	1	1	1
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	1	1
Hepatitis A screening result	-	-	-

Period 2

Period 2 title	Treatment and follow-up
Is this the baseline period?	Yes ^[3]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

Following the completion of 36 weeks, limited members from the Sponsor team were unblinded. The

nature of the treatment supply meant that the pharmacist was unblinded with appropriate unblinded oversight in place.

Arms

Are arms mutually exclusive?	No
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Arm title	Placebo Q16W
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Arm description:

Placebo administered subcutaneously at Weeks 0, 16 and 32 (dosing every 16 weeks [Q16W]).

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

Administered by subcutaneous injection.

Arm title	Placebo Q24W
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Arm description:

Placebo administered subcutaneously at Weeks 0 and 24 (dosing every 24 weeks [Q24W]). This group was stratified so that half of participants were dosed to match the SLN360 300 mg Q24W group and half were dosed to match the SLN360 450 mg Q24W group (with respect to injected volume).

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

Administered by subcutaneous injection.

Arm title	SLN360 300 mg Q16W
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Arm description:

SLN360 300 mg administered subcutaneously at Weeks 0, 16 and 32 (Q16W).

Arm type	Experimental
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Investigational medicinal product name	Zerlasiran
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Investigational medicinal product code	SLN360
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Other name	
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Pharmaceutical forms	Solution for injection
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Routes of administration	Subcutaneous use
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Dosage and administration details:

Administered by subcutaneous injection.

Arm title	SLN360 300 mg Q24W
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Arm description:

SLN360 300 mg administered subcutaneously at Weeks 0 and 24 (Q24W).

Arm type	Experimental
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Investigational medicinal product name	Zerlasiran
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Investigational medicinal product code	SLN360
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Other name	
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Pharmaceutical forms	Solution for injection
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Routes of administration	Subcutaneous use
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Dosage and administration details:

Administered by subcutaneous injection.

Arm title	SLN360 450 mg Q24W
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Arm description:

SLN360 450 mg administered subcutaneously at Weeks 0 and 24 (Q24W).

Arm type	Experimental
Investigational medicinal product name	Zerlasiran
Investigational medicinal product code	SLN360
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection.

Arm title	Pooled placebo
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Arm description:

Pooled data from both placebo groups.

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

Dosage and administration details:

Administered by subcutaneous injection.

Notes:

[3] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Of the 180 enrolled and randomised participants, 2 participants randomised to the SLN360 300 mg Q16W group were untreated because both participants were determined to be ineligible before study drug could be administered due to hepatitis A screening results; both participants were terminated early from the study, rescreened and underwent a second randomisation, following which the participants were treated with SLN360 300 mg Q16W and SLN360 300 mg Q24W, respectively.

Number of subjects in period 2	Placebo Q16W	Placebo Q24W	SLN360 300 mg Q16W
Started	23	24	42
Completed	23	23	39
Not completed	0	1	3
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	2
Lost to follow-up	-	1	-

Number of subjects in period 2	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Started	44	45	47
Completed	43	44	46
Not completed	1	1	1
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	1	1

Baseline characteristics

Reporting groups^[1]

Reporting group title	Placebo Q16W
Reporting group description: Placebo administered subcutaneously at Weeks 0, 16 and 32 (dosing every 16 weeks [Q16W]).	
Reporting group title	Placebo Q24W
Reporting group description: Placebo administered subcutaneously at Weeks 0 and 24 (dosing every 24 weeks [Q24W]). This group was stratified so that half of participants were dosed to match the SLN360 300 mg Q24W group and half were dosed to match the SLN360 450 mg Q24W group (with respect to injected volume).	
Reporting group title	SLN360 300 mg Q16W
Reporting group description: SLN360 300 mg administered subcutaneously at Weeks 0, 16 and 32 (Q16W).	
Reporting group title	SLN360 300 mg Q24W
Reporting group description: SLN360 300 mg administered subcutaneously at Weeks 0 and 24 (Q24W).	
Reporting group title	SLN360 450 mg Q24W
Reporting group description: SLN360 450 mg administered subcutaneously at Weeks 0 and 24 (Q24W).	
Reporting group title	Pooled placebo
Reporting group description: Pooled data from both placebo groups.	

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.

Justification: The baseline data are based on the set of unique participants who were randomised and treated, this excludes 2 participant numbers that enrolled but were not treated, but were later rescreened and re-randomised / treated. The worldwide number of participants is based on all allocated participant numbers enrolled rather than unique participants.

Reporting group values	Placebo Q16W	Placebo Q24W	SLN360 300 mg Q16W
Number of subjects	23	24	42
Age categorical Units: Subjects			
Adults (18-64 years)	12	15	19
From 65-84 years	11	9	23
Age continuous Units: years			
arithmetic mean	65.0	62.1	63.1
standard deviation	± 8.79	± 9.43	± 9.81
Gender categorical Units: Subjects			
Female	5	6	11
Male	18	18	31
Ethnicity Units: Subjects			
Not Hispanic or Latino	23	24	42
Race Units: Subjects			
Asian	0	1	1
Black or African American	0	0	1

White	21	22	38
Other	2	1	2

Reporting group values	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Number of subjects	44	45	47
Age categorical Units: Subjects			
Adults (18-64 years)	23	22	27
From 65-84 years	21	23	20
Age continuous Units: years			
arithmetic mean	64.5	63.8	63.6
standard deviation	± 8.67	± 10.23	± 9.14
Gender categorical Units: Subjects			
Female	13	11	11
Male	31	34	36
Ethnicity Units: Subjects			
Not Hispanic or Latino	44	45	47
Race Units: Subjects			
Asian	2	4	1
Black or African American	0	2	0
White	36	36	43
Other	6	3	3

Reporting group values	Total		
Number of subjects	178		
Age categorical Units: Subjects			
Adults (18-64 years)	91		
From 65-84 years	87		
Age continuous Units: years			
arithmetic mean	-		
standard deviation	-		
Gender categorical Units: Subjects			
Female	46		
Male	132		
Ethnicity Units: Subjects			
Not Hispanic or Latino	178		
Race Units: Subjects			
Asian	8		
Black or African American	3		
White	153		
Other	14		

End points

End points reporting groups

Reporting group title	Placebo Q16W
Reporting group description: Placebo administered subcutaneously at Weeks 0, 16 and 32 (dosing every 16 weeks [Q16W]).	
Reporting group title	Placebo Q24W
Reporting group description: Placebo administered subcutaneously at Weeks 0 and 24 (dosing every 24 weeks [Q24W]). This group was stratified so that half of participants were dosed to match the SLN360 300 mg Q24W group and half were dosed to match the SLN360 450 mg Q24W group (with respect to injected volume).	
Reporting group title	SLN360 300 mg Q16W
Reporting group description: SLN360 300 mg administered subcutaneously at Weeks 0, 16 and 32 (Q16W).	
Reporting group title	SLN360 300 mg Q24W
Reporting group description: SLN360 300 mg administered subcutaneously at Weeks 0 and 24 (Q24W).	
Reporting group title	SLN360 450 mg Q24W
Reporting group description: SLN360 450 mg administered subcutaneously at Weeks 0 and 24 (Q24W).	
Reporting group title	Pooled placebo
Reporting group description: Pooled data from both placebo groups.	
Reporting group title	Placebo Q16W
Reporting group description: Placebo administered subcutaneously at Weeks 0, 16 and 32 (dosing every 16 weeks [Q16W]).	
Reporting group title	Placebo Q24W
Reporting group description: Placebo administered subcutaneously at Weeks 0 and 24 (dosing every 24 weeks [Q24W]). This group was stratified so that half of participants were dosed to match the SLN360 300 mg Q24W group and half were dosed to match the SLN360 450 mg Q24W group (with respect to injected volume).	
Reporting group title	SLN360 300 mg Q16W
Reporting group description: SLN360 300 mg administered subcutaneously at Weeks 0, 16 and 32 (Q16W).	
Reporting group title	SLN360 300 mg Q24W
Reporting group description: SLN360 300 mg administered subcutaneously at Weeks 0 and 24 (Q24W).	
Reporting group title	SLN360 450 mg Q24W
Reporting group description: SLN360 450 mg administered subcutaneously at Weeks 0 and 24 (Q24W).	
Reporting group title	Pooled placebo
Reporting group description: Pooled data from both placebo groups.	

Primary: Time-averaged percent change in lipoprotein(a) molar concentration from baseline to Week 36

End point title	Time-averaged percent change in lipoprotein(a) molar concentration from baseline to Week 36
End point description: In calculating the primary outcome measure, the time-averaged percent change in lipoprotein(a)	

(relative to Day 1 predose) was calculated for each participant by estimating the sum of the area under the curve with the linear trapezoidal method for all scheduled assessments from Week 4 to Week 36, inclusive, divided by the total time interval between the Week 4 and Week 36 assessments. Analysis of variance was used to test for differences between each active treatment group and the pooled placebo groups in the primary outcome measure. Time-averaged percent change in lipoprotein(a) to Week 36 was the dependent variable, and treatment group was included as the predictor variable. The least squares (LS) means, standard errors, and 2-sided 95% confidence intervals (CIs) for each treatment group and for the pairwise comparisons between the SLN360 and placebo groups were estimated.

End point type	Primary
End point timeframe:	
Week 36 relative to baseline	

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-80.5 (\pm 1.99)	-79.1 (\pm 1.94)	-83.3 (\pm 1.92)	2.3 (\pm 1.88)

Statistical analyses

Statistical analysis title	Analysis of variance for the primary endpoint
Statistical analysis description:	
Analysis of variance (ANOVA) was used to test for differences between each active treatment group and the pooled placebo groups in the primary outcome measure.	
Comparison groups	Pooled placebo v SLN360 300 mg Q16W
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-82.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-88.19
upper limit	-77.39
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the primary endpoint
Statistical analysis description:	
Analysis of variance (ANOVA) was used to test for differences between each active treatment group and the pooled placebo groups in the primary outcome measure.	
Comparison groups	SLN360 300 mg Q24W v Pooled placebo

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-81.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-86.68
upper limit	-76
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the primary endpoint
Statistical analysis description:	
Analysis of variance (ANOVA) was used to test for differences between each active treatment group and the pooled placebo groups in the primary outcome measure.	
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-85.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-90.88
upper limit	-80.26

Secondary: Time-averaged percent change in lipoprotein(a) molar concentration from baseline to Week 48	
End point title	Time-averaged percent change in lipoprotein(a) molar concentration from baseline to Week 48
End point description:	
Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.	
End point type	Secondary
End point timeframe:	
Week 48 relative to baseline	

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-81.6 (± 2.05)	-77.2 (± 2.00)	-81.5 (± 1.98)	1.5 (± 1.94)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-83.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-88.7
upper limit	-77.57
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	Pooled placebo v SLN360 300 mg Q24W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-78.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-84.18
upper limit	-73.17
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	Pooled placebo v SLN360 450 mg Q24W

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-88.43
upper limit	-77.49
Variability estimate	Standard error of the mean

Secondary: Time-averaged percent change in lipoprotein(a) molar concentration from baseline to Week 60

End point title	Time-averaged percent change in lipoprotein(a) molar concentration from baseline to Week 60
End point description:	
Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.	
End point type	Secondary
End point timeframe:	
Week 60 relative to baseline	

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-78.0 (± 2.24)	-70.7 (± 2.19)	-76.0 (± 2.16)	1.1 (± 2.11)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-79.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-85.25
upper limit	-73.1
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-71.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-77.81
upper limit	-65.8
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-77.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-83.09
upper limit	-71.15
Variability estimate	Standard error of the mean

Secondary: Time-averaged percent change in apolipoprotein(B) concentration from baseline to Week 36

End point title	Time-averaged percent change in apolipoprotein(B) concentration from baseline to Week 36
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End point description:

Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.

End point type	Secondary
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End point timeframe:

Week 36 relative to baseline

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-16.9 (± 1.93)	-13.5 (± 1.88)	-18.6 (± 1.86)	-3.6 (± 1.82)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	Pooled placebo v SLN360 300 mg Q16W
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-13.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.55
upper limit	-8.09
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-9.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.02
upper limit	-4.68
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.1
upper limit	-9.82
Variability estimate	Standard error of the mean

Secondary: Time-averaged percent change in apolipoprotein(B) concentration from baseline to Week 48

End point title	Time-averaged percent change in apolipoprotein(B) concentration from baseline to Week 48
End point description: Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.	
End point type	Secondary
End point timeframe: Week 48 relative to baseline	

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-16.4 (± 1.94)	-12.6 (± 1.90)	-18.0 (± 1.88)	-4.0 (± 1.83)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-12.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.62
upper limit	-7.08
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0013
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-8.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.85
upper limit	-3.44
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.2
upper limit	-8.84

Variability estimate	Standard error of the mean
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Secondary: Time-averaged percent change in apolipoprotein(B) concentration from baseline to Week 60

End point title	Time-averaged percent change in apolipoprotein(B) concentration from baseline to Week 60
End point description:	Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.
End point type	Secondary
End point timeframe:	Week 60 relative to baseline

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-15.0 (± 2.04)	-10.9 (± 1.99)	-16.4 (± 1.97)	-3.8 (± 1.93)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-11.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.81
upper limit	-5.73
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0106
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-7.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.64
upper limit	-1.69
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-12.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.04
upper limit	-7.15
Variability estimate	Standard error of the mean

Secondary: Time-averaged percent change in low-density lipoprotein cholesterol concentration from baseline to Week 36

End point title	Time-averaged percent change in low-density lipoprotein cholesterol concentration from baseline to Week 36
End point description:	
Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.	
End point type	Secondary
End point timeframe:	
Week 36 relative to baseline	

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-22.3 (± 8.16)	-20.1 (± 7.98)	-15.5 (± 7.89)	9.6 (± 7.72)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0051
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-31.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.07
upper limit	-9.72
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0081
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.62
upper limit	-7.81
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	Pooled placebo v SLN360 450 mg Q24W

Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0241
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-25.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.89
upper limit	-3.33
Variability estimate	Standard error of the mean

Secondary: Time-averaged percent change in low-density lipoprotein cholesterol concentration from baseline to Week 48

End point title	Time-averaged percent change in low-density lipoprotein cholesterol concentration from baseline to Week 48
End point description:	
Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.	
End point type	Secondary
End point timeframe:	
Week 48 relative to baseline	

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-20.9 (± 7.01)	-18.5 (± 6.85)	-17.0 (± 6.78)	8.9 (± 6.63)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0023
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-29.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.86
upper limit	-10.76
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0046
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-27.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.23
upper limit	-8.58
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0068
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.67
upper limit	-7.24
Variability estimate	Standard error of the mean

Secondary: Time-averaged percent change in low-density lipoprotein cholesterol concentration from baseline to Week 60

End point title	Time-averaged percent change in low-density lipoprotein cholesterol concentration from baseline to Week 60
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End point description:

Time-averaged secondary endpoints were calculated and analysed using the same conventions as the primary endpoint.

End point type	Secondary
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End point timeframe:

Week 60 relative to baseline

End point values	SLN360 300 mg Q16W	SLN360 300 mg Q24W	SLN360 450 mg Q24W	Pooled placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42	44	45	47
Units: Percentage				
least squares mean (standard error)	-19.3 (± 7.45)	-16.8 (± 7.28)	-14.7 (± 7.19)	9.3 (± 7.04)

Statistical analyses

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q16W v Pooled placebo
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0057
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-28.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.91
upper limit	-8.46
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 300 mg Q24W v Pooled placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0106
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-26.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.13
upper limit	-6.16
Variability estimate	Standard error of the mean

Statistical analysis title	Analysis of variance for the secondary endpoint
Comparison groups	SLN360 450 mg Q24W v Pooled placebo
Number of subjects included in analysis	92
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0179
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	-24.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.93
upper limit	-4.2
Variability estimate	Standard error of the mean

Adverse events

Adverse events information

Timeframe for reporting adverse events:

05 December 2022 (first participant screened) to 01 July 2024 (last participant last visit). Median duration of exposure was 24.43 weeks. Adverse event data were collected over the 60-week study period (95.6% of participants completed to week 60).

Adverse event reporting additional description:

Serious treatment-emergent and non-serious treatment-emergent adverse events are summarised for the safety population: all participants who received at least 1 dose of study drug. Safety data were summarised by actual treatment received based on the safety population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.1
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Reporting groups

Reporting group title	Placebo Q16W
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Reporting group description:

Placebo administered subcutaneously at Weeks 0, 16 and 32 (dosing every 16 weeks [Q16W]).

Reporting group title	Placebo Q24W
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Reporting group description:

Placebo administered subcutaneously at Weeks 0 and 24 (dosing every 24 weeks [Q24W]). This group was stratified so that half of participants were dosed to match the SLN360 300 mg Q24W group and half were dosed to match the SLN360 450 mg Q24W group (with respect to injected volume).

Reporting group title	SLN360 300 mg Q16W
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Reporting group description:

SLN360 300 mg administered subcutaneously at Weeks 0, 16 and 32 (Q16W).

Reporting group title	SLN360 300 mg Q24W
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Reporting group description:

SLN360 300 mg administered subcutaneously at Weeks 0 and 24 (Q24W).

Reporting group title	SLN360 450 mg Q24W
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Reporting group description:

SLN360 450 mg administered subcutaneously at Weeks 0 and 24 (Q24W).

Serious adverse events	Placebo Q16W	Placebo Q24W	SLN360 300 mg Q16W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 23 (4.35%)	3 / 24 (12.50%)	6 / 42 (14.29%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant polyp (rectal)			

subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 23 (4.35%)	0 / 24 (0.00%)	0 / 42 (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			
Acute vestibular syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 24 (4.17%)	0 / 42 (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
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
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			
Osteoarthritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyositis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
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			
Lymph node tuberculosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	1 / 42 (2.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 23 (0.00%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 23 (0.00%)	1 / 24 (4.17%)	0 / 42 (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
Urinary tract infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 24 (4.17%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	SLN360 300 mg Q24W	SLN360 450 mg Q24W	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 44 (4.55%)	5 / 45 (11.11%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant polyp (rectal)			
subjects affected / exposed	0 / 44 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 44 (2.27%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 44 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Acute vestibular syndrome			
subjects affected / exposed	0 / 44 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food poisoning			
subjects affected / exposed	1 / 44 (2.27%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 44 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyositis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Lymph node tuberculosis			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 44 (0.00%)	1 / 45 (2.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo Q16W	Placebo Q24W	SLN360 300 mg Q16W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 23 (78.26%)	22 / 24 (91.67%)	42 / 42 (100.00%)
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 24 (0.00%)	4 / 42 (9.52%)
occurrences (all)	2	0	8
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 23 (8.70%)	0 / 24 (0.00%)	0 / 42 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	2 / 23 (8.70%)	3 / 24 (12.50%)	1 / 42 (2.38%)
occurrences (all)	2	3	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 23 (4.35%)	1 / 24 (4.17%)	3 / 42 (7.14%)
occurrences (all)	1	1	3
Headache			
subjects affected / exposed	1 / 23 (4.35%)	1 / 24 (4.17%)	5 / 42 (11.90%)
occurrences (all)	1	1	5
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	2 / 23 (8.70%)	1 / 24 (4.17%)	0 / 42 (0.00%)
occurrences (all)	2	1	0
Influenza-like illness			
subjects affected / exposed	0 / 23 (0.00%)	1 / 24 (4.17%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Injection site reaction			

subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 3	2 / 24 (8.33%) 2	35 / 42 (83.33%) 71
Malaise subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 24 (4.17%) 1	6 / 42 (14.29%) 8
Non-cardiac chest pain subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	1 / 24 (4.17%) 1	0 / 42 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	2 / 24 (8.33%) 3	0 / 42 (0.00%) 0
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	2 / 24 (8.33%) 2	1 / 42 (2.38%) 2
Haemorrhoids subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 24 (0.00%) 0	0 / 42 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 2	2 / 24 (8.33%) 2	1 / 42 (2.38%) 1
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	2 / 24 (8.33%) 2	0 / 42 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 24 (0.00%) 0	3 / 42 (7.14%) 4
Back pain subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 24 (0.00%) 0	2 / 42 (4.76%) 2
Myalgia subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	1 / 24 (4.17%) 1	1 / 42 (2.38%) 2
Osteoarthritis			

subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	2 / 24 (8.33%) 2	1 / 42 (2.38%) 1
Pain in extremity subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 24 (0.00%) 0	2 / 42 (4.76%) 2
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	4 / 24 (16.67%) 4	2 / 42 (4.76%) 2
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 24 (0.00%) 0	3 / 42 (7.14%) 3
Rhinitis subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 24 (0.00%) 0	0 / 42 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	3 / 24 (12.50%) 6	6 / 42 (14.29%) 7
Urinary tract infection subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 4	0 / 24 (0.00%) 0	5 / 42 (11.90%) 6

Non-serious adverse events	SLN360 300 mg Q24W	SLN360 450 mg Q24W	
Total subjects affected by non-serious adverse events subjects affected / exposed	43 / 44 (97.73%)	42 / 45 (93.33%)	
Injury, poisoning and procedural complications Procedural pain subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1	2 / 45 (4.44%) 4	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1	2 / 45 (4.44%) 2	
Cardiac disorders Angina pectoris			

subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 2	2 / 45 (4.44%) 2	
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 44 (9.09%)	1 / 45 (2.22%)	
occurrences (all)	5	1	
Headache			
subjects affected / exposed	3 / 44 (6.82%)	6 / 45 (13.33%)	
occurrences (all)	5	8	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 44 (9.09%)	1 / 45 (2.22%)	
occurrences (all)	4	1	
Influenza-like illness			
subjects affected / exposed	1 / 44 (2.27%)	7 / 45 (15.56%)	
occurrences (all)	1	7	
Injection site reaction			
subjects affected / exposed	36 / 44 (81.82%)	37 / 45 (82.22%)	
occurrences (all)	55	109	
Malaise			
subjects affected / exposed	0 / 44 (0.00%)	4 / 45 (8.89%)	
occurrences (all)	0	5	
Non-cardiac chest pain			
subjects affected / exposed	0 / 44 (0.00%)	0 / 45 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 44 (0.00%)	2 / 45 (4.44%)	
occurrences (all)	0	2	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 44 (2.27%)	1 / 45 (2.22%)	
occurrences (all)	1	1	
Haemorrhoids			
subjects affected / exposed	0 / 44 (0.00%)	1 / 45 (2.22%)	
occurrences (all)	0	1	
Nausea			

subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1	1 / 45 (2.22%) 1	
Respiratory, thoracic and mediastinal disorders Dyspnoea subjects affected / exposed occurrences (all)	2 / 44 (4.55%) 2	0 / 45 (0.00%) 0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	4 / 44 (9.09%) 4	2 / 45 (4.44%) 2	
Back pain subjects affected / exposed occurrences (all)	2 / 44 (4.55%) 2	0 / 45 (0.00%) 0	
Myalgia subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1	7 / 45 (15.56%) 8	
Osteoarthritis subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1	0 / 45 (0.00%) 0	
Pain in extremity subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1	3 / 45 (6.67%) 3	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	6 / 44 (13.64%) 7	4 / 45 (8.89%) 4	
Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 44 (13.64%) 8	6 / 45 (13.33%) 9	
Rhinitis subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0	1 / 45 (2.22%) 1	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 44 (15.91%) 8	5 / 45 (11.11%) 5	
Urinary tract infection			

subjects affected / exposed	1 / 44 (2.27%)	3 / 45 (6.67%)	
occurrences (all)	2	4	

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/39556769>