Clinical trial results:
A Phase II, Randomized, Placebo-Controlled, Double-Blind Study of the Safety and Efficacy of MPSK3169A in Patients with Coronary Heart Disease or High Risk of Coronary Heart Disease

Summary

EudraCT number	2012-000191-41
Trial protocol	HU DE CZ SK
Global end of trial date	22 July 2013

Results information

Result version number	v1 (current)
This version publication date	04 March 2016
First version publication date	04 March 2016

Trial information

Trial identification

Sponsor protocol code	GC28210

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01609140
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, CH-4070, Basel, Switzerland,
Public contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.com
Scientific contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.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	19 September 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 July 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and efficacy of MPSK3169A on top of standard-of-care (SOC) statin in participants with a low-density lipoprotein cholesterol (LDLc) of 90−250 milligrams per deciliter (mg/dL) and either coronary heart disease (CHD) or a CHD risk equivalent.

Protection of trial subjects:

Efforts to minimize risk included the following: judicious eligibility of participants who may benefit from LDLc lowering because of a combination of high cardiovascular risk and LDLc levels well above the goal of 70 mg/dL, use of SOC statin therapy for all participants, regular safety evaluations overseen by the investigator, study overseen by an internal monitoring committee (IMC), and the use of a minimum threshold of LDLc below which MPSK3169A would be withheld. This study was conducted in full conformance with the International Conference on Harmonisation (ICH) E6 guideline for Good Clinical Practice (GCP) and the principles of the Declaration of Helsinki or the laws and regulations of the country in which the research was conducted, whichever afforded the greater protection to the individual.

Background therapy:

All participants regardless of treatment assignment received SOC treatment with statins. The type and dose of statin therapy was not changed during the run-in, treatment, or follow-up periods of the study.

Evidence for comparator: -

Actual start date of recruitment	21 May 2012
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	Norway: 21
Country: Number of subjects enrolled	Slovakia: 10
Country: Number of subjects enrolled	Czech Republic: 9
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Hungary: 13
Country: Number of subjects enrolled	Canada: 44
Country: Number of subjects enrolled	New Zealand: 9
Country: Number of subjects enrolled	South Africa: 4
Country: Number of subjects enrolled	United States: 137
Worldwide total number of subjects	248
EEA total number of subjects	54

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)	125
From 65 to 84 years	123
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants who met all of the eligibility criteria except the inclusion criterion pertaining to statins and other lipid-modifying therapies entered run-in period of 6 weeks until they were on stable SOC statin therapy for at least 4 weeks, and were off prohibited lipid-modifying therapies for at least 4 weeks (or 6 weeks in the case of fibrates).

Period 1

Period 1 title	Treatment Period (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	MPSK3169A 400 mg once every 4 weeks (Q4W)

Arm description:

Participants received 400 mg of MPSK3169A Q4W subcutaneously for approximately 24 weeks.

Arm type	Experimental
Investigational medicinal product name	MPSK3169A
Investigational medicinal product code	RO6801831
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants in the study received subcutaneous doses of MPSK3169A or matching placebo every four weeks.

Arm title	MPSK3169A 200 mg Q8W

Arm description:

Participants received 200 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.

Arm type	Experimental
Investigational medicinal product name	MPSK3169A
Investigational medicinal product code	RO6801831
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants in the study received subcutaneous doses of MPSK3169A or matching placebo every four weeks.

Arm title	MPSK3169A 400 mg Q8W

Arm description:

Participants received 400 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.

Arm type	Experimental

Investigational medicinal product name	MPSK3169A
Investigational medicinal product code	RO6801831
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants in the study received subcutaneous doses of MPSK3169A or matching placebo every four weeks.

Arm title	MPSK3169A 800 mg Q8W

Arm description:

Participants received 800 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.

Arm type	Experimental
Investigational medicinal product name	MPSK3169A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants in the study received subcutaneous doses of MPSK3169A or matching placebo every four weeks.

Arm title	MPSK3169A 800 mg Q12W

Arm description:

Participants received 800 mg of MPSK3169A Q12W subcutaneously for approximately 24 weeks.

Arm type	Experimental
Investigational medicinal product name	MPSK3169A
Investigational medicinal product code	RO6801831
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

All participants in the study received subcutaneous doses of MPSK3169A or matching placebo every four weeks.

Arm title	Placebo

Arm description:

Participants received matching placebo injections subcutaneously for approximately 24 weeks.

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

Dosage and administration details:

All participants in the study received subcutaneous doses of matching placebo every four weeks.

Number of subjects in period 1	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W
Started	57	23	30
Completed	52	23	28
Not completed	5	0	2
Consent withdrawn by subject	1	-	1
Death	-	-	-
Randomized on calculated LDL only, not Direct	-	-	-
Adverse event	1	-	-
Participant moved out of state	1	-	-
Lost to follow-up	-	-	1
Participant stopped study drug	1	-	-
Physician/Subject Unblinding	-	-	-
Protocol deviation	1	-	-

Number of subjects in period 1	MPSK3169A 800 mg Q8W	MPSK3169A 800 mg Q12W	Placebo
Started	51	23	64
Completed	46	23	57
Not completed	5	0	7
Consent withdrawn by subject	2	-	3
Death	-	-	1
Randomized on calculated LDL only, not Direct	1	-	-
Adverse event	-	-	1
Participant moved out of state	-	-	-
Lost to follow-up	-	-	-
Participant stopped study drug	-	-	-
Physician/Subject Unblinding	-	-	1
Protocol deviation	2	-	1

Baseline characteristics

Reporting groups	
Reporting group title	MPSK3169A 400 mg once every 4 weeks (Q4W)
Reporting group description:	
Participants received 400 mg of MPSK3169A Q4W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 200 mg Q8W
Reporting group description:	
Participants received 200 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 400 mg Q8W
Reporting group description:	
Participants received 400 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 800 mg Q8W
Reporting group description:	
Participants received 800 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 800 mg Q12W
Reporting group description:	
Participants received 800 mg of MPSK3169A Q12W subcutaneously for approximately 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo injections subcutaneously for approximately 24 weeks.	

Reporting group values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W
Number of subjects	57	23	30
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	65.6	63.3	62.8
standard deviation	± 8.5	± 10	± 8.1
Gender categorical Units: Subjects			
Female	24	8	16
Male	33	15	14

Reporting group values	MPSK3169A 800 mg Q8W	MPSK3169A 800 mg Q12W	Placebo
Number of subjects	51	23	64
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	63.9	63.8	63.1
standard deviation	± 8.9	± 7.2	± 7.8

Gender categorical Units: Subjects			
Female	25	10	24
Male	26	13	40

Reporting group values	Total		
Number of subjects	248		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	107		
Male	141		

End points

End points reporting groups

Reporting group title	MPSK3169A 400 mg once every 4 weeks (Q4W)
Reporting group description:	
Participants received 400 mg of MPSK3169A Q4W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 200 mg Q8W
Reporting group description:	
Participants received 200 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 400 mg Q8W
Reporting group description:	
Participants received 400 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 800 mg Q8W
Reporting group description:	
Participants received 800 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 800 mg Q12W
Reporting group description:	
Participants received 800 mg of MPSK3169A Q12W subcutaneously for approximately 24 weeks.	
Reporting group title	Placebo
Reporting group description:	
Participants received matching placebo injections subcutaneously for approximately 24 weeks.	

Primary: Absolute Change From Baseline in LDLc Concentration at Day 169

End point title	Absolute Change From Baseline in LDLc Concentration at Day 169
End point description:	
Modified Intent to Treat (mITT) population included participants who were randomized and received at least 1 dose of study drug. Participants with baseline measurement and post baseline measurement of LDLc concentration at Day 169 were included in the analysis of this end point.	
End point type	Primary
End point timeframe:	
Baseline, Day 169	

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45[1]	21[2]	28[3]	44[4]
Units: milligram(s)/deciliter				
arithmetic mean (standard deviation)	-72.7 (± 24.6)	-13.6 (± 26.1)	-33.4 (± 32.5)	-55.8 (± 29.9)

Notes:

[1] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[2] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[3] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[4] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[5]	59[6]		
Units: milligram(s)/deciliter				
arithmetic mean (standard deviation)	-23.9 (± 25.7)	-10.6 (± 24.8)		

Notes:

[5] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[6] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

Statistical analyses

Statistical analysis title	Statistical analysis I

Statistical analysis description:

This analysis was performed on Day 169. Least squares (LS) mean difference, 95% confidence intervals (CIs) and p−values were based on an analysis of covariance model adjusted for baseline LDLc (less than [<] 120 mg/dL, greater than or equal to [≥] 120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.7
upper limit	71.9
Variability estimate	Standard error of the mean
Dispersion value	5.1

Statistical analysis title	Statistical analysis II

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7885
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	1.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	14.6
Variability estimate	Standard error of the mean
Dispersion value	6.5

Statistical analysis title	Statistical analysis III

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=87.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0005
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	21
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.3
upper limit	32.7
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis IV

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	43.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.3
upper limit	53.6

Variability estimate	Standard error of the mean
Dispersion value	5.2

Statistical analysis title	Statistical analysis V

Statistical analysis description:

Differences from Pbo are the difference between LS means with the standard error. P−values are adjusted for baseline LDLc (<120 mg/dL, >=120 mg/dL) and diabetes status (yes,no) and not adjusted for multiple testing. Number of subjects included in analysis=78.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0579
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	26.2
Variability estimate	Standard error of the mean
Dispersion value	6.8

Secondary: Absolute Change From Baseline in LDLc Concentration for Each Arm at the Nadir for That Arm

End point title	Absolute Change From Baseline in LDLc Concentration for Each Arm at the Nadir for That Arm

End point description:

Nadir is defined as the planned visit, up to day 169, with the greatest mean decrease within a treatment group. mITT population participants with baseline measurement and at least 1 postbaseline measurement of LDLc concentration were included in the analysis of this end point.

End point type	Secondary

End point timeframe:

Baseline, up to Day 169 (Nadir)

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50[7]	20[8]	27[9]	46[10]
Units: milligram(s)/deciliter				
arithmetic mean (standard deviation)	-84.8 (± 29.9)	-70.6 (± 18.1)	-82.9 (± 28.4)	-86 (± 26)

Notes:

[7] - Includes participants who were evaluable with non-missing LDLc values at baseline and up to Day 169.
[8] - Includes participants who were evaluable with non-missing LDLc values at baseline and up to Day 169.
[9] - Includes participants who were evaluable with non-missing LDLc values at baseline and up to Day 169.
[10] - Includes participants who were evaluable with non-missing LDLc values at baseline and up to Day 169.

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22[11]	61[12]		
Units: milligram(s)/deciliter				
arithmetic mean (standard deviation)	-87.6 (± 32.1)	-11.4 (± 19.8)		

Notes:

[11] - Includes participants who were evaluable with non-missing LDLc values at baseline and up to Day 169.
[12] - Includes participants who were evaluable with non-missing LDLc values at baseline and up to Day 169.

Statistical analyses

Statistical analysis title	Statistical analysis I

Statistical analysis description:

This analysis was performed at nadir timepoint. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	72.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	64
upper limit	81.3
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis II

Statistical analysis description:

This analysis was performed at nadir timepoint. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	44.4
upper limit	67.4
Variability estimate	Standard error of the mean
Dispersion value	5.8

Statistical analysis title	Statistical analysis III

Statistical analysis description:

This analysis was performed at nadir timepoint. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	67.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.1
upper limit	77.9
Variability estimate	Standard error of the mean
Dispersion value	5.3

Statistical analysis title	Statistical analysis IV

Statistical analysis description:

This analysis was performed at nadir timepoint. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	70.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.8
upper limit	79.4
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis V

Statistical analysis description:

This analysis was performed at nadir timepoint. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	73.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.8
upper limit	85
Variability estimate	Standard error of the mean
Dispersion value	5.6

Secondary: Average Change from Baseline in LDLc Concentration Weighted By the Number of Weeks Between Consecutive LDLc Measurements at Day 169

End point title	Average Change from Baseline in LDLc Concentration Weighted By the Number of Weeks Between Consecutive LDLc Measurements at Day 169

End point description:

This outcome was calculated by dividing the average change from baseline of LDLc concentration by average number of weeks of study treatment. mITTpopulation participants with baseline and post baseline measurement of LDLc concentration at Day 169 were included in the analysis of this end point.

End point type	Secondary

End point timeframe:

Baseline, Day 169

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44[13]	21[14]	28[15]	43[16]
Units: mg/dL/week				
arithmetic mean (standard deviation)	-79.3 (± 25)	-36.7 (± 17.4)	-60.9 (± 22.3)	-74.5 (± 21)

Notes:

[13] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[14] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[15] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[16] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[17]	59[18]		
Units: mg/dL/week				
arithmetic mean (standard deviation)	-61.9 (± 18.2)	-9.6 (± 19.1)		

Notes:

[17] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[18] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

Statistical analyses

Statistical analysis title	Statistical analysis I

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	68.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.1
upper limit	76
Variability estimate	Standard error of the mean
Dispersion value	3.8

	Statistical analysis II

Statistical analysis title	

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	25.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	16
upper limit	34.9
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis III

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=87.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	48.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.2
upper limit	57.3
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis IV

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=102.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	62.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.7
upper limit	69.7
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis V

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=78.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.9
upper limit	61.5
Variability estimate	Standard error of the mean
Dispersion value	5

Secondary: Average Percentage Change from Baseline in LDLc Concentration Weighted By the Number of Weeks Between Consecutive LDLc Measurements at Day 169

End point title	Average Percentage Change from Baseline in LDLc Concentration Weighted By the Number of Weeks Between Consecutive LDLc Measurements at Day 169

End point description:

mITT population participants with baseline and post baseline measurement of LDLc concentration at Day 169 were included in the analysis of this end point.

End point type	Secondary

End point timeframe:

Baseline, Day 169

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44[19]	21[20]	28[21]	43[22]
Units: percentage change/week				
arithmetic mean (standard deviation)	-63.9 (± 14.2)	-29.3 (± 12.6)	-46 (± 10.5)	-59.6 (± 14.5)

Notes:

[19] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[20] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[21] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[22] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19[23]	59[24]		
Units: percentage change/week				
arithmetic mean (standard deviation)	-48.8 (± 9.5)	-7.1 (± 15.5)		

Notes:

[23] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

[24] - Includes participants who were evaluable with non-missing LDLc values at baseline and Day 169.

Statistical analyses

Statistical analysis title	Statistical analysis I

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	56.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.1
upper limit	62
Variability estimate	Standard error of the mean
Dispersion value	2.8

	Statistical analysis II

Statistical analysis title	

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	22
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.1
upper limit	28.9
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis III

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=87.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	38.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.2
upper limit	44.8
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis IV

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=102.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	52.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.6
upper limit	57.6
Variability estimate	Standard error of the mean
Dispersion value	2.8

Statistical analysis title	Statistical analysis V

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=78.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	41.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.4
upper limit	48.8
Variability estimate	Standard error of the mean
Dispersion value	3.6

Secondary: Percentage Change from Baseline in LDLc Concentration for Each Arm at Day 169 and at the Nadir for That Arm

End point title	Percentage Change from Baseline in LDLc Concentration for Each Arm at Day 169 and at the Nadir for That Arm

End point description:

Nadir is defined as the planned visit, up to day 169, with the greatest mean decrease within a treatment group. mITT population participants with baseline and post baseline measurement of LDLc concentration at Day 169 were included in the analysis of this end point. "n" value indicates the number of participants evaluable at a specified timepoint for a particular treatment arm.

End point type	Secondary

End point timeframe:

Baseline, Day 169, up to Day 169 (Nadir)

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50[25]	21[26]	28[27]	46[28]
Units: percentage change				
arithmetic mean (standard deviation)				
% change from baseline in LDL-c at Day 169	-58.7 (± 14.9)	-10.5 (± 18.1)	-23.3 (± 20.5)	-44.3 (± 21.1)
% change from baseline in LDL-c at nadir	-69.6 (± 17.3)	-57.7 (± 15.6)	-64.4 (± 15)	-68.7 (± 17.1)

Notes:

[25] - n=45 on Day 169 and n=50 at nadir.

[26] - n=21 on Day 169 and n=20 at nadir.

[27] - n=28 on Day 169 and n=27 at nadir.

[28] - n=44 on Day 169 and n=46 at nadir.

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22[29]	61[30]		
Units: percentage change				
arithmetic mean (standard deviation)				
% change from baseline in LDL-c at Day 169	-16.1 (± 19.4)	-7.7 (± 20.3)		
% change from baseline in LDL-c at nadir	-66.1 (± 14.9)	-9 (± 16.4)		

Notes:

[29] - n=19 on Day 169 and n=22 at nadir.

[30] - n=59 on Day 169 and n=61 at nadir.

Statistical analyses

Statistical analysis title	Statistical analysis I

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.5
upper limit	58.5

Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis II

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6097
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	2.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	12.1
Variability estimate	Standard error of the mean
Dispersion value	4.9

Statistical analysis title	Statistical analysis III

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=87.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0007
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.4
upper limit	23.9
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis IV

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	36.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.6
upper limit	43.8
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis V

Statistical analysis description:

This analysis was performed on Day 169. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=78.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1027
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	8.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	18.2
Variability estimate	Standard error of the mean
Dispersion value	5

Statistical analysis title	Statistical analysis VI

Statistical analysis description:

This analysis was performed at Nadir timepoint. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	59.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.5
upper limit	66
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis VII

Statistical analysis description:

This analysis was performed at Nadir timepoint. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	48.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.9
upper limit	56.5
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis VIII

Statistical analysis description:

This analysis was performed at Nadir timepoint. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo

Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	54.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.9
upper limit	61.9
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis IX

Statistical analysis description:

This analysis was performed at Nadir timepoint. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	58.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.4
upper limit	65.1
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis X

Statistical analysis description:

This analysis was performed at Nadir timepoint. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	56.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.5
upper limit	64.6
Variability estimate	Standard error of the mean
Dispersion value	4.1

Secondary: Absolute Change From Baseline (CFB) in LDLc Concentration at all Other TimePoints

End point title	Absolute Change From Baseline (CFB) in LDLc Concentration at all Other TimePoints

End point description:

mITT population participants with baseline and at least 1 post baseline measurement of LDLc concentration were included in the analysis of this end point. "n" value indicates the number of participants evaluable at a specified timepoint for a particular treatment arm.

End point type	Secondary

End point timeframe:

Baseline, Days 8, 15, 22, 29, 43, 57, 71, 85, 99, 113, 120, 141, and 155

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	23	28	49
Units: mg/dL				
arithmetic mean (standard deviation)				
Day 8 (n=50,23,25,43,22,60)	-65.8 (± 18.4)	-61.6 (± 20.7)	-70 (± 25.1)	-68.6 (± 24.2)
Day 15 (n=50,23,28,44,20,61)	-78.1 (± 24.7)	-65.4 (± 24.3)	-79.8 (± 27.5)	-82.5 (± 21.9)
Day 22 (n=47,23,28,47,23,61)	-81 (± 25)	-61.4 (± 21)	-83.1 (± 29.8)	-85 (± 22.3)
Day 29 (n=49,23,28,49,21,63)	-74.6 (± 27.1)	-44.4 (± 22.5)	-76.1 (± 28.4)	-82.8 (± 25.8)
Day 43 (n=50,22,26,46,23,61)	-84.8 (± 29.9)	-24.7 (± 18.5)	-65 (± 30.6)	-74.2 (± 25.1)
Day 57 (n=53,23,28,48,22,58)	-76.3 (± 30.9)	-13.3 (± 25.3)	-34.9 (± 30.2)	-59 (± 23.5)
Day 71 (n=53,20,27,46,22,59)	-84.2 (± 29.4)	-70.6 (± 18.1)	-82.9 (± 28.4)	-86 (± 26)
Day 85 (n=53,23,28,47,22,61)	-74.7 (± 35.2)	-50.7 (± 21.1)	-73.8 (± 28.3)	-81.4 (± 24.7)
Day 99 (n=50,23,28,44,20,57)	-81 (± 29.6)	-20.8 (± 25)	-57.9 (± 23.5)	-71.8 (± 25.4)
Day 113 (n=48,23,27,45,22,58)	-75.3 (± 28.9)	-14.3 (± 25.7)	-36.5 (± 32.2)	-55.6 (± 29.4)
Day 120 (n=47,23,27,44,22,58)	-81.6 (± 26.4)	-59.6 (± 20.3)	-72.2 (± 28.6)	-80.6 (± 24.7)
Day 141 (n=48,22,27,46,21,57)	-72.4 (± 31.4)	-45.4 (± 23.3)	-74.2 (± 21.8)	-81.4 (± 26.5)

Day 155 (n=47,22,28,42,22,58)	-79.1 (± 29.9)	-21.6 (± 23.6)	-55.7 (± 25.2)	-75.7 (± 23.5)

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	63		
Units: mg/dL				
arithmetic mean (standard deviation)				
Day 8 (n=50,23,25,43,22,60)	-67.6 (± 21.6)	-8.8 (± 17.9)		
Day 15 (n=50,23,28,44,20,61)	-80.6 (± 25)	-11.4 (± 19.8)		
Day 22 (n=47,23,28,47,23,61)	-83.8 (± 31.4)	-9 (± 21.5)		
Day 29 (n=49,23,28,49,21,63)	-85.4 (± 33.3)	-7.6 (± 22.8)		
Day 43 (n=50,22,26,46,23,61)	-75.6 (± 35)	-7.8 (± 22.1)		
Day 57 (n=53,23,28,48,22,58)	-68.6 (± 24.7)	-6.1 (± 24.8)		
Day 71 (n=53,20,27,46,22,59)	-40.1 (± 27.8)	-9.1 (± 22.1)		
Day 85 (n=53,23,28,47,22,61)	-24.8 (± 25.4)	-11.9 (± 26.5)		
Day 99 (n=50,23,28,44,20,57)	-86.5 (± 28)	-7.9 (± 23.5)		
Day 113 (n=48,23,27,45,22,58)	-87.6 (± 32.1)	-9.8 (± 22.1)		
Day 120 (n=47,23,27,44,22,58)	-85.1 (± 31.6)	-8 (± 24.4)		
Day 141 (n=48,22,27,46,21,57)	-67.9 (± 27.2)	-10.4 (± 24.4)		
Day 155 (n=47,22,28,42,22,58)	-43.8 (± 28.6)	-12.9 (± 22.2)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=110.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	54.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.8
upper limit	61.7
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.1
upper limit	60.7
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDL-c (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	57.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.1
upper limit	66.4
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p-values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status

(yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	56.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.6
upper limit	63.9
Variability estimate	Standard error of the mean
Dispersion value	3.9

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	56.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.7
upper limit	65.7
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	65.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.4
upper limit	74.1
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	53
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.4
upper limit	63.5
Variability estimate	Standard error of the mean
Dispersion value	5.3

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	64.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	55
upper limit	74.8
Variability estimate	Standard error of the mean
Dispersion value	5

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	69
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.4
upper limit	77.5
Variability estimate	Standard error of the mean
Dispersion value	4.3

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	66.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.7
upper limit	77.9
Variability estimate	Standard error of the mean
Dispersion value	5.6

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=108.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	70.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.2
upper limit	79.5
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.5
upper limit	62.1
Variability estimate	Standard error of the mean
Dispersion value	5.5

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	71
Confidence interval	
level	95 %
sides	2-sided
lower limit	60.9
upper limit	81.1
Variability estimate	Standard error of the mean
Dispersion value	5.1

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=108.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	73.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.6
upper limit	81.8
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	72.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.8
upper limit	83.5
Variability estimate	Standard error of the mean
Dispersion value	5.5

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=112.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	67.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.1
upper limit	76.3
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 17

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	36.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.7
upper limit	47.7
Variability estimate	Standard error of the mean
Dispersion value	5.8

Statistical analysis title	Statistical analysis 18

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=91.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	66.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.3
upper limit	76.9
Variability estimate	Standard error of the mean
Dispersion value	5.5

Statistical analysis title	Statistical analysis 19

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=112.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	73.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.6
upper limit	82.7
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 20

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	76.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.5
upper limit	88.4
Variability estimate	Standard error of the mean
Dispersion value	6.1

Statistical analysis title	Statistical analysis 21

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	78.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.8
upper limit	87.7
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 22

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0017
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	15.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.5
upper limit	27.7
Variability estimate	Standard error of the mean
Dispersion value	6.1

Statistical analysis title	Statistical analysis 23

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=87.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	53.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.7
upper limit	64.8
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 24

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	64.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.1
upper limit	74.3
Variability estimate	Standard error of the mean
Dispersion value	4.9

Statistical analysis title	Statistical analysis 25

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	66.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.4
upper limit	78.3
Variability estimate	Standard error of the mean
Dispersion value	6.1

Statistical analysis title	Statistical analysis 26

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	71.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.1
upper limit	81.2
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 27

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2596
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	19.2
Variability estimate	Standard error of the mean
Dispersion value	6.2

Statistical analysis title	Statistical analysis 28

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	27.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.3
upper limit	39.3
Variability estimate	Standard error of the mean
Dispersion value	5.8

Statistical analysis title	Statistical analysis 29

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=106.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	52.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.5
upper limit	62
Variability estimate	Standard error of the mean
Dispersion value	4.9

Statistical analysis title	Statistical analysis 30

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.2
upper limit	74.1
Variability estimate	Standard error of the mean
Dispersion value	6.3

Statistical analysis title	Statistical analysis 31

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=112.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	74
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.1
upper limit	82.9
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis 32

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=79.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	58.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.7
upper limit	70.8
Variability estimate	Standard error of the mean
Dispersion value	6.1

Statistical analysis title	Statistical analysis 33

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	70.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.7
upper limit	81.5
Variability estimate	Standard error of the mean
Dispersion value	5.5

Statistical analysis title	Statistical analysis 34

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	73.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.4
upper limit	82.9
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 35

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	29.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.5
upper limit	40.8
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 36

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	62.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.8
upper limit	72
Variability estimate	Standard error of the mean
Dispersion value	4.9

Statistical analysis title	Statistical analysis 37

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	37.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.3
upper limit	50.1
Variability estimate	Standard error of the mean
Dispersion value	6.3

Statistical analysis title	Statistical analysis 38

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	MPSK3169A 400 mg Q8W v Placebo

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	58.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.1
upper limit	70.4
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 39

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=108.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	67.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.3
upper limit	77.2
Variability estimate	Standard error of the mean
Dispersion value	5

Statistical analysis title	Statistical analysis 40

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0795
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	11.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	23.9
Variability estimate	Standard error of the mean
Dispersion value	6.4

Statistical analysis title	Statistical analysis 41

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	72.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.9
upper limit	81.4
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 42

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	11.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	23.5
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 43

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	46.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.7
upper limit	57.8
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 44

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=101.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	60.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.7
upper limit	69.9
Variability estimate	Standard error of the mean
Dispersion value	4.9

Statistical analysis title	Statistical analysis 45

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=77.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	77
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.7
upper limit	89.3
Variability estimate	Standard error of the mean
Dispersion value	6.2

Statistical analysis title	Statistical analysis 46

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=106.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	64.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.5
upper limit	75
Variability estimate	Standard error of the mean
Dispersion value	5.2

Statistical analysis title	Statistical analysis 47

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5761
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.2
upper limit	16.5
Variability estimate	Standard error of the mean
Dispersion value	6.5

Statistical analysis title	Statistical analysis 48

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	23.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.3
upper limit	35.8
Variability estimate	Standard error of the mean
Dispersion value	6.2

Statistical analysis title	Statistical analysis 49

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	42.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.4
upper limit	53.4
Variability estimate	Standard error of the mean
Dispersion value	5.3

Statistical analysis title	Statistical analysis 50

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	76.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.3
upper limit	89.5
Variability estimate	Standard error of the mean
Dispersion value	6.6

Statistical analysis title	Statistical analysis 51

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	71.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.3
upper limit	80.8
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 52

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	50.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.5
upper limit	61.6
Variability estimate	Standard error of the mean
Dispersion value	5.8

Statistical analysis title	Statistical analysis 53

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	60.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.4
upper limit	71.4
Variability estimate	Standard error of the mean
Dispersion value	5.6

Statistical analysis title	Statistical analysis 54

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=102.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	68.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.1
upper limit	78.1
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 55

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	74.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.2
upper limit	86.6
Variability estimate	Standard error of the mean
Dispersion value	6

Statistical analysis title	Statistical analysis 56

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.4
upper limit	70.8
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 57

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=79.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	34.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	23
upper limit	46.2
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 58

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	60.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.1
upper limit	71.8
Variability estimate	Standard error of the mean
Dispersion value	5.5

Statistical analysis title	Statistical analysis 59

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	67.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.6
upper limit	77.2
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 60

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=78.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.7
upper limit	67.3
Variability estimate	Standard error of the mean
Dispersion value	6

Statistical analysis title	Statistical analysis 61

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	65.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.8
upper limit	74.8
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 62

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1512
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	8.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	19.6
Variability estimate	Standard error of the mean
Dispersion value	5.7

Statistical analysis title	Statistical analysis 63

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	40
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.5
upper limit	50.5
Variability estimate	Standard error of the mean
Dispersion value	5.3

Statistical analysis title	Statistical analysis 64

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=100.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	60.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.3
upper limit	69.8
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 65

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	29.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.2
upper limit	40.9
Variability estimate	Standard error of the mean
Dispersion value	5.8

Secondary: Percentage Change From Baseline (%CFB) in LDLc Concentration at all Other Time Points

End point title	Percentage Change From Baseline (%CFB) in LDLc Concentration at all Other Time Points

End point description:

mITT population participants with baseline and at least 1 post baseline measurement of LDLc concentration were included in the analysis of this end point. "n" value indicates the number of participants evaluable at a specified timepoint for a particular treatment arm.

End point type	Secondary

End point timeframe:

Baseline, Days 8, 15, 22, 29, 43, 57, 71, 85, 99, 113, 120, 141, and 155

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	23	28	49
Units: percentage change				
arithmetic mean (standard deviation)				
Day 8 (n=50,23,25,43,22,60)	-55.9 (± 16.1)	-52.1 (± 19.2)	-53.3 (± 18.6)	-55.9 (± 18.7)
Day 15 (n=50,23,28,44,20,61)	-65.6 (± 17.9)	-54.6 (± 18.6)	-60.4 (± 16.2)	-67.4 (± 16.8)
Day 22 (n=47,23,28,47,23,61)	-66.1 (± 14)	-50.9 (± 16.2)	-62.3 (± 13.4)	-68.3 (± 15.1)
Day 29 (n=49,23,28,49,21,63)	-60 (± 17.2)	-36.5 (± 16.3)	-56.8 (± 14.6)	-66.4 (± 16.7)
Day 43 (n=50,22,26,46,23,61)	-69.6 (± 17.3)	-20 (± 15.1)	-46.2 (± 14.2)	-59.7 (± 16.4)
Day 57 (n=53,23,28,48,22,58)	-62.5 (± 20.2)	-10.1 (± 19)	-24.8 (± 17.8)	-48 (± 17.3)
Day 71 (n=53,20,27,46,22,59)	-69.5 (± 18.5)	-57.7 (± 15.6)	-64.4 (± 15)	-68.7 (± 17.1)
Day 85 (n=53,23,28,47,22,61)	-60.6 (± 24.9)	-41.9 (± 17.5)	-55.7 (± 13.3)	-65.5 (± 15.7)
Day 99 (n=50,23,28,44,20,57)	-66.6 (± 19.8)	-17.2 (± 18.3)	-44.1 (± 15.6)	-57.8 (± 18)
Day 113 (n=48,23,27,45,22,58)	-61.7 (± 19.3)	-10.9 (± 19)	-25.5 (± 18.5)	-45.4 (± 22)
Day 120 (n=47,23,27,44,22,58)	-66.7 (± 15.9)	-49.1 (± 16.2)	-56.7 (± 17.2)	-65.7 (± 17.8)
Day 141 (n=48,22,27,46,21,57)	-58.9 (± 22.7)	-36.7 (± 16.8)	-57.6 (± 12.7)	-65 (± 17.1)
Day 155 (n=47,22,28,42,22,58)	-64.6 (± 20.8)	-16.9 (± 18.7)	-42.5 (± 15.5)	-61 (± 16.3)

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	63		
Units: percentage change				
arithmetic mean (standard deviation)				
Day 8 (n=50,23,25,43,22,60)	-53.4 (± 18.5)	-6.7 (± 14.9)		
Day 15 (n=50,23,28,44,20,61)	-62.2 (± 16.9)	-9 (± 16.4)		
Day 22 (n=47,23,28,47,23,61)	-64 (± 20.1)	-6.5 (± 18.5)		
Day 29 (n=49,23,28,49,21,63)	-64.5 (± 18.1)	-5.6 (± 18.9)		
Day 43 (n=50,22,26,46,23,61)	-57.3 (± 21.1)	-6.3 (± 18.7)		
Day 57 (n=53,23,28,48,22,58)	-52 (± 15.7)	-3.9 (± 20.8)		
Day 71 (n=53,20,27,46,22,59)	-29.6 (± 19.2)	-6.2 (± 17.7)		
Day 85 (n=53,23,28,47,22,61)	-16.8 (± 17.1)	-9 (± 20.5)		
Day 99 (n=50,23,28,44,20,57)	-66.8 (± 18.4)	-5.3 (± 19.7)		
Day 113 (n=48,23,27,45,22,58)	-66.1 (± 14.9)	-7.4 (± 18.3)		
Day 120 (n=47,23,27,44,22,58)	-63.9 (± 13.5)	-5.7 (± 20.6)		
Day 141 (n=48,22,27,46,21,57)	-50.9 (± 14.2)	-7.7 (± 19.2)		
Day 155 (n=47,22,28,42,22,58)	-31.7 (± 16.2)	-9.7 (± 17.6)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=110.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	47.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	41
upper limit	54
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	45.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.9
upper limit	53.3
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	46
Confidence interval	
level	95 %
sides	2-sided
lower limit	38
upper limit	54
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	MPSK3169A 800 mg Q8W v Placebo
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	48.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.5
upper limit	55
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

This analysis was performed on Day 8. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	45.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.4
upper limit	54.1
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.4
upper limit	62.3
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	45.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.4
upper limit	53.8
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.7
upper limit	59.2
Variability estimate	Standard error of the mean
Dispersion value	3.9

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	58.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.5
upper limit	64.9
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

This analysis was performed on Day 15. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	53.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	44.5
upper limit	61.9
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=108.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	59
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.7
upper limit	65.3
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	44.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.4
upper limit	52.2
Variability estimate	Standard error of the mean
Dispersion value	4

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	48
upper limit	62.8
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=108.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.2
upper limit	67.8
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

This analysis was performed on Day 22. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	57.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.2
upper limit	65.1
Variability estimate	Standard error of the mean
Dispersion value	4

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=112.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	54.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.8
upper limit	61
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 17

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	30.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.5
upper limit	39.2
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 18

Statistical analysis description:

Statistical analysis 18
This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no).). Number of subjects included in analysis=91.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.2
upper limit	58.8
Variability estimate	Standard error of the mean
Dispersion value	4

Statistical analysis title	Statistical analysis 19

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=112.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	60.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.1
upper limit	67.3
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 20

Statistical analysis description:

This analysis was performed on Day 29. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	58.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.1
upper limit	67.5
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 21

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	63.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.2
upper limit	70.5
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 22

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0019
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	13.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.1
upper limit	22.2
Variability estimate	Standard error of the mean
Dispersion value	4.3

Statistical analysis title	Statistical analysis 23

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=87.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	39.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.6
upper limit	47.9
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 24

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	53.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.7
upper limit	60.3
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 25

Statistical analysis description:

This analysis was performed on Day 43. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.6
upper limit	59.6
Variability estimate	Standard error of the mean
Dispersion value	4.3

Statistical analysis title	Statistical analysis 26

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=111.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	59.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.1
upper limit	66.6
Variability estimate	Standard error of the mean
Dispersion value	3.7

Statistical analysis title	Statistical analysis 27

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1812
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	15.5
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 28

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	21.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.6
upper limit	30
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 29

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=106.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	44.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.1
upper limit	51.8
Variability estimate	Standard error of the mean
Dispersion value	3.7

Statistical analysis title	Statistical analysis 30

Statistical analysis description:

This analysis was performed on Day 57. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	48.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	39
upper limit	57.8
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 31

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=112.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	62.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.8
upper limit	69
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 32

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=79.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.2
upper limit	60
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis 33

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	57.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.2
upper limit	65.3
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 34

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.8
upper limit	68.5
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis 35

Statistical analysis description:

This analysis was performed on Day 71. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	22.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.2
upper limit	31.5
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 36

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	44
upper limit	58.5
Variability estimate	Standard error of the mean
Dispersion value	3.7

Statistical analysis title	Statistical analysis 37

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	32.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.3
upper limit	42
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 38

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	45.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.1
upper limit	54.7
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis 39

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=108.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.3
upper limit	63.3
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 40

Statistical analysis description:

This analysis was performed on Day 85. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1312
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	7.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.2
upper limit	16.9
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 41

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.9
upper limit	68.3
Variability estimate	Standard error of the mean
Dispersion value	3.7

Statistical analysis title	Statistical analysis 42

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0115
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	11.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.7
upper limit	20.9
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 43

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	38.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.8
upper limit	47
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 44

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=101.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	52
Confidence interval	
level	95 %
sides	2-sided
lower limit	44.4
upper limit	59.5
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 45

Statistical analysis description:

This analysis was performed on Day 99. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=77.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	61.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.7
upper limit	70.9
Variability estimate	Standard error of the mean
Dispersion value	4.9

Statistical analysis title	Statistical analysis 46

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	54.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.7
upper limit	61.6
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 47

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4651
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	3.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	12.8
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 48

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	17.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.9
upper limit	26.7
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis 49

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	37.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	30
upper limit	45.2
Variability estimate	Standard error of the mean
Dispersion value	3.9

Statistical analysis title	Statistical analysis 50

Statistical analysis description:

This analysis was performed on Day 113. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	58.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.1
upper limit	68
Variability estimate	Standard error of the mean
Dispersion value	4.8

Statistical analysis title	Statistical analysis 51

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	60.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.4
upper limit	67.2
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis 52

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	43.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.8
upper limit	51.9
Variability estimate	Standard error of the mean
Dispersion value	4.3

Statistical analysis title	Statistical analysis 53

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	50.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.2
upper limit	58.5
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 54

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=102.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	59.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.4
upper limit	66.4
Variability estimate	Standard error of the mean
Dispersion value	3.6

Statistical analysis title	Statistical analysis 55

Statistical analysis description:

This analysis was performed on Day 120. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	57.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.1
upper limit	66.6
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 56

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	50.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.8
upper limit	58.1
Variability estimate	Standard error of the mean
Dispersion value	3.6

Statistical analysis title	Statistical analysis 57

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=79.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	28.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.9
upper limit	38
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 58

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=84.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	49.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.8
upper limit	57.8
Variability estimate	Standard error of the mean
Dispersion value	4.3

Statistical analysis title	Statistical analysis 59

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=103.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	56.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.4
upper limit	63.9
Variability estimate	Standard error of the mean
Dispersion value	3.7

Statistical analysis title	Statistical analysis 60

Statistical analysis description:

This analysis was performed on Day 141. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=78.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	42.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.5
upper limit	51.9
Variability estimate	Standard error of the mean
Dispersion value	4.7

Statistical analysis title	Statistical analysis 61

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=105.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55
Confidence interval	
level	95 %
sides	2-sided
lower limit	48
upper limit	62
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis 62

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1094
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	7.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	15.9
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 63

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=86.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	91
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	32.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.2
upper limit	40.5
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 64

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=100.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	112
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.8
upper limit	58.2
Variability estimate	Standard error of the mean
Dispersion value	3.6

Statistical analysis title	Statistical analysis 65

Statistical analysis description:

This analysis was performed on Day 155. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDL−c (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=80.

Comparison groups	MPSK3169A 800 mg Q12W v Placebo

Number of subjects included in analysis	86
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	21.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.1
upper limit	30.6
Variability estimate	Standard error of the mean
Dispersion value	4.5

Secondary: Absolute CFB in Total Cholesterol (TC), Non-High Density Lipoprotein (Non-HDL-c), and Apolipoprotein B (ApoB) at Day 169 and at Nadir

End point title	Absolute CFB in Total Cholesterol (TC), Non-High Density Lipoprotein (Non-HDL-c), and Apolipoprotein B (ApoB) at Day 169 and at Nadir

End point description:

Nadir is defined as the planned visit, up to day 169, with the greatest mean decrease within a treatment group. mITT population participants with baseline and at least 1 post baseline measurement of TC, non-HDLc and ApoB levels were included in the analysis of this end point. "n" value indicates the number of participants evaluable at a specified timepoint for a particular treatment arm.

End point type	Secondary

End point timeframe:

Baseline, Day 169, up to Day 169 (Nadir)

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	23	28	47
Units: mg/dL				
arithmetic mean (standard deviation)				
CFB in TC at Day 169 (n=47,23,28,44,21,60)	-75.4 (± 28.2)	-12.1 (± 26.9)	-33.6 (± 38.8)	-56.9 (± 35.6)
CFB in TC at nadir (n=52,23,27,47,20,62)	-92.1 (± 33.2)	-70.4 (± 21.4)	-84.7 (± 29.4)	-92.3 (± 31)
CFB in non-HDLc at Day 169 (n=47,23,28,44,21,60)	-78.6 (± 28.3)	-13.1 (± 28.7)	-34.9 (± 35.4)	-59.7 (± 38.1)
CFB in non-HDL-c at nadir (n=51,23,27,47,20,62)	-95.5 (± 33.6)	-74.4 (± 18.7)	-88.7 (± 31.2)	-94.5 (± 30.6)
CFB in ApoB at Day 169 (n=47,23,28,44,21,60)	-48.5 (± 19.2)	-5 (± 18.2)	-18.5 (± 20)	-37.1 (± 22.5)
CFB in ApoB at nadir (n=52,23,27,47,20,62)	-59.5 (± 21.3)	-44.6 (± 14.8)	-53.4 (± 18.6)	-59.5 (± 18.5)

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	62		
Units: mg/dL				
arithmetic mean (standard deviation)				
CFB in TC at Day 169 (n=47,23,28,44,21,60)	-27.3 (± 25.9)	-11.5 (± 29.7)		
CFB in TC at nadir (n=52,23,27,47,20,62)	-93.6 (± 27.5)	-10.4 (± 23.2)		
CFB in non-HDLc at Day 169 (n=47,23,28,44,21,60)	-27.9 (± 27)	-11 (± 28.6)		
CFB in non-HDL-c at nadir (n=51,23,27,47,20,62)	-95.4 (± 30.1)	-10.7 (± 23.2)		
CFB in ApoB at Day 169 (n=47,23,28,44,21,60)	-15.8 (± 15.4)	-5.8 (± 16.1)		
CFB in ApoB at nadir (n=52,23,27,47,20,62)	-59.2 (± 21.1)	-5.9 (± 14.1)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	63.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.4
upper limit	74.8
Variability estimate	Standard error of the mean
Dispersion value	5.9

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	MPSK3169A 200 mg Q8W v Placebo
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9833
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.7
upper limit	14.4
Variability estimate	Standard error of the mean
Dispersion value	7.4

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0047
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	19.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.2
upper limit	33.6
Variability estimate	Standard error of the mean
Dispersion value	7

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	43.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.3
upper limit	55.2
Variability estimate	Standard error of the mean
Dispersion value	6

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0488
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	30.3
Variability estimate	Standard error of the mean
Dispersion value	7.7

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	81.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	71.3
upper limit	91.4
Variability estimate	Standard error of the mean
Dispersion value	5.1

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	59.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.3
upper limit	72
Variability estimate	Standard error of the mean
Dispersion value	6.5

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	71.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.2
upper limit	83.7
Variability estimate	Standard error of the mean
Dispersion value	6.2

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=109.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	79.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	69
upper limit	89.5
Variability estimate	Standard error of the mean
Dispersion value	5.2

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	81.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.3
upper limit	95.4
Variability estimate	Standard error of the mean
Dispersion value	6.9

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	67.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	55.6
upper limit	79.1
Variability estimate	Standard error of the mean
Dispersion value	6

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8377
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.1
upper limit	16.2
Variability estimate	Standard error of the mean
Dispersion value	7.4

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0017
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	22.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.4
upper limit	36
Variability estimate	Standard error of the mean
Dispersion value	7

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	47
Confidence interval	
level	95 %
sides	2-sided
lower limit	35
upper limit	59
Variability estimate	Standard error of the mean
Dispersion value	6.1

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.334
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	16.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	31.7
Variability estimate	Standard error of the mean
Dispersion value	7.7

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	84.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	74.3
upper limit	94.6
Variability estimate	Standard error of the mean
Dispersion value	5.2

Statistical analysis title	Statistical analysis 17

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	62.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.9
upper limit	75.8
Variability estimate	Standard error of the mean
Dispersion value	6.6

Statistical analysis title	Statistical analysis 18

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	75.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.9
upper limit	87.5
Variability estimate	Standard error of the mean
Dispersion value	6.3

Statistical analysis title	Statistical analysis 19

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=109.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	81.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.9
upper limit	91.5
Variability estimate	Standard error of the mean
Dispersion value	5.2

Statistical analysis title	Statistical analysis 20

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	83.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.7
upper limit	97.2
Variability estimate	Standard error of the mean
Dispersion value	6.9

Statistical analysis title	Statistical analysis 21

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	42.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.4
upper limit	49.6
Variability estimate	Standard error of the mean
Dispersion value	3.6

Statistical analysis title	Statistical analysis 22

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.786
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	7.6
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis 23

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.4
upper limit	20.1
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 24

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	30.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.1
upper limit	37.6
Variability estimate	Standard error of the mean
Dispersion value	3.7

Statistical analysis title	Statistical analysis 25

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0381
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	9.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	18.9
Variability estimate	Standard error of the mean
Dispersion value	4.6

Statistical analysis title	Statistical analysis 26

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	53.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.8
upper limit	59.7
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 27

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	38.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.9
upper limit	46.5
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 28

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	45.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.8
upper limit	53.7
Variability estimate	Standard error of the mean
Dispersion value	4

Statistical analysis title	Statistical analysis 29

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=109.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	52
Confidence interval	
level	95 %
sides	2-sided
lower limit	45.4
upper limit	58.6
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 30

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	52.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.7
upper limit	61.2
Variability estimate	Standard error of the mean
Dispersion value	4.4

Secondary: Percentage CFB in TC, Non-HDL-c, and ApoB at Day 169 and At Nadir

End point title	Percentage CFB in TC, Non-HDL-c, and ApoB at Day 169 and At Nadir

End point description:

Nadir is defined as the planned visit, up to day 169, with the greatest mean decrease within a treatment group. mITT population participants with baseline and at least 1 post baseline measurement of TC, non-HDLc and ApoB levels were included in the analysis of this end point. "n" value indicates the number of participants evaluable at a specified timepoint for a particular treatment arm.

End point type	Secondary

End point timeframe:

Baseline, Day 169, up to Day 169 (nadir)

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	23	28	47
Units: percentage change				
arithmetic mean (standard deviation)				
% CFB in TC at Day 169 (n=47,23,28,44,21,60)	-37 (± 11.7)	-5.8 (± 12.5)	-14.6 (± 15.9)	-27.3 (± 15.9)
% CFB in TC at nadir (n=52,23,27,47,20,62)	-45.5 (± 13)	-35.9 (± 11.2)	-40.8 (± 10.4)	-44.2 (± 12.2)
% CFB in non-HDLc at Day 169 (n=47,23,28,44,21,60)	-51.5 (± 14.7)	-8.4 (± 17.4)	-20.4 (± 19.1)	-38.3 (± 21.1)
% CFB in non-HDL-c at nadir (n=51,23,27,47,20,62)	-63.1 (± 15.6)	-50.8 (± 12.9)	-57.1 (± 15)	-60.1 (± 13.3)
% CFB in ApoB at Day 169 (n=47,23,28,44,21,60)	-46.7 (± 16.5)	-5 (± 15.7)	-16.6 (± 17.7)	-35.6 (± 18.7)
% CFB in ApoB at nadir (n=52,23,27,47,20,62)	-58.1 (± 16)	-45.1 (± 14.1)	-51.9 (± 13.7)	-56.6 (± 13.1)

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	62		
Units: percentage change				
arithmetic mean (standard deviation)				
% CFB in TC at Day 169 (n=47,23,28,44,21,60)	-12.2 (± 10.8)	-5.5 (± 14.3)		
% CFB in TC at nadir (n=52,23,27,47,20,62)	-45.9 (± 12.3)	-5.2 (± 11.8)		
% CFB in non-HDLc at Day 169 (n=47,23,28,44,21,60)	-15.8 (± 14)	-6.8 (± 18.4)		
% CFB in non-HDL-c at nadir (n=51,23,27,47,20,62)	-60.8 (± 16.1)	-7.3 (± 14.8)		
% CFB in ApoB at Day 169 (n=47,23,28,44,21,60)	-13.3 (± 12.2)	-5 (± 16)		
% CFB in ApoB at nadir (n=52,23,27,47,20,62)	-55.7 (± 17.2)	-5.7 (± 13.5)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	31.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	26
upper limit	36.6
Variability estimate	Standard error of the mean
Dispersion value	2.7

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9878
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	6.7
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0077
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	8.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.3
upper limit	14.8
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	21.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.8
upper limit	26.6
Variability estimate	Standard error of the mean
Dispersion value	2.8

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

This analysis was performed for TC parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0643
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	13.3
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	39.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.4
upper limit	44.4
Variability estimate	Standard error of the mean
Dispersion value	2.3

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	30.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.8
upper limit	36.3
Variability estimate	Standard error of the mean
Dispersion value	2.9

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	34.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.4
upper limit	40.4
Variability estimate	Standard error of the mean
Dispersion value	2.8

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=109.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	38.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.8
upper limit	43
Variability estimate	Standard error of the mean
Dispersion value	2.3

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

This analysis was performed for TC parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	40.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.4
upper limit	46.6
Variability estimate	Standard error of the mean
Dispersion value	3.1

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	MPSK3169A 400 mg once every 4 weeks (Q4W) v Placebo
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	44.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.9
upper limit	51.8
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7274
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	10.2
Variability estimate	Standard error of the mean
Dispersion value	4.4

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0012
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.4
upper limit	21.6
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	31.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.3
upper limit	38.4
Variability estimate	Standard error of the mean
Dispersion value	3.6

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

This analysis was performed for non-HDLc parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0472
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	18
Variability estimate	Standard error of the mean
Dispersion value	4.5

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	55.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.7
upper limit	60.7
Variability estimate	Standard error of the mean
Dispersion value	2.8

Statistical analysis title	Statistical analysis 17

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	43.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.4
upper limit	50.5
Variability estimate	Standard error of the mean
Dispersion value	3.6

Statistical analysis title	Statistical analysis 18

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	49.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.5
upper limit	55.9
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 19

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=109.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	52.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.7
upper limit	58
Variability estimate	Standard error of the mean
Dispersion value	2.9

Statistical analysis title	Statistical analysis 20

Statistical analysis description:

This analysis was performed for non-HDLc parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	53.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	45.9
upper limit	60.8
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 21

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=107.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	41.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.3
upper limit	48.1
Variability estimate	Standard error of the mean
Dispersion value	3.2

Statistical analysis title	Statistical analysis 22

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=83.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9891
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	7.9
Variability estimate	Standard error of the mean
Dispersion value	4.1

Statistical analysis title	Statistical analysis 23

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=88.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0034
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	11.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.8
upper limit	18.8
Variability estimate	Standard error of the mean
Dispersion value	3.8

Statistical analysis title	Statistical analysis 24

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=104.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	30.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.8
upper limit	36.9
Variability estimate	Standard error of the mean
Dispersion value	3.3

Statistical analysis title	Statistical analysis 25

Statistical analysis description:

This analysis was performed for Apo-B parameter on Day 169. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=81.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0501
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	8.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	16.5
Variability estimate	Standard error of the mean
Dispersion value	4.2

Statistical analysis title	Statistical analysis 26

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=114.

Comparison groups	Placebo v MPSK3169A 400 mg once every 4 weeks (Q4W)

Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	51.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.3
upper limit	57.1
Variability estimate	Standard error of the mean
Dispersion value	2.7

Statistical analysis title	Statistical analysis 27

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=85.

Comparison groups	Placebo v MPSK3169A 200 mg Q8W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	39.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.3
upper limit	46.1
Variability estimate	Standard error of the mean
Dispersion value	3.5

Statistical analysis title	Statistical analysis 28

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=89.

Comparison groups	Placebo v MPSK3169A 400 mg Q8W

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	45.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	38.8
upper limit	52
Variability estimate	Standard error of the mean
Dispersion value	3.4

Statistical analysis title	Statistical analysis 29

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=109.

Comparison groups	Placebo v MPSK3169A 800 mg Q8W
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	50.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	44.8
upper limit	55.9
Variability estimate	Standard error of the mean
Dispersion value	2.8

Statistical analysis title	Statistical analysis 30

Statistical analysis description:

This analysis was performed for Apo-B parameter at nadir. LS mean difference, 95% CIs and p−values were based on an analysis of covariance model adjusted for baseline LDLc (<120 mg/dL, ≥120 mg/dL) and diabetes status (yes, no). Number of subjects included in analysis=82.

Comparison groups	Placebo v MPSK3169A 800 mg Q12W

Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	49.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.5
upper limit	57.1
Variability estimate	Standard error of the mean
Dispersion value	3.7

Secondary: Number of Participants With Anti-Therapeutic Antibodies Directed Against MPSK3169A

End point title	Number of Participants With Anti-Therapeutic Antibodies Directed Against MPSK3169A

End point description:

mITT population was considered for the analysis of this end point.

End point type	Secondary

End point timeframe:

From baseline up to Day 169

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	23	30	51
Units: participants	0	0	0	1

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	64		
Units: participants	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Median Serum Concentrations of MPSK3169A Following Multiple Dose Administration

End point title	Median Serum Concentrations of MPSK3169A Following Multiple Dose Administration

End point description:

Non-measurable minimum value of a full range was reported as '-99999'. If the median and full ranges were not measurable, they were reported as 99999 (Full range: -99999 to 99999). Pharmacokinetic (PK) evaluable population included all randomized participants who received at least 1 injection of MPSK3169A and had evaluable PK data. "n" value indicates the number of participants evaluable at a specified timepoint for a particular treatment arm.

End point type	Secondary

End point timeframe:

Days 1, 8, 15, 29, 57, 85, 113, 120, 141, 169, 197, and 225; and at early termination or unscheduled visit (Unsch/Disc)

End point values	MPSK3169A 400 mg once every 4 weeks (Q4W)	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W	MPSK3169A 800 mg Q8W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	57	23	30	50
Units: micrograms per milliliter (mcg/mL)				
median (full range (min-max))				
Day 1 (n=57,23,30,50,23,2)	0.77 (-99999 to 15.3)	0.53 (-99999 to 2.97)	0.72 (-99999 to 6.31)	1.92 (0.36 to 11)
Day 8 (n=57,23,30,50,23,3)	32 (-99999 to 50)	14.3 (3.58 to 24.8)	31.6 (16.6 to 59.2)	68.95 (37.4 to 164)
Day 15 (n=55,22,30,49,22,3)	23.1 (-99999 to 38.2)	8.48 (2.91 to 17.3)	23.6 (2.86 to 44.4)	52.9 (34.5 to 130)
Day 29 (n=54,23,28,49,23,3)	9.6 (-99999 to 21.9)	2.83 (0.48 to 7.51)	10.65 (0.57 to 28.5)	29 (1.07 to 87.4)
Day 57 (n=56,23,29,49,23,3)	10.3 (-99999 to 33.6)	0.24 (-99999 to 1.1)	0.98 (-99999 to 4.48)	4.46 (0.39 to 41)
Day 85 (n=56,23,29,49,23,5)	11.5 (-99999 to 105)	3.19 (0.16 to 65.5)	11.1 (1.41 to 21.3)	22.5 (-99999 to 57.6)
Day 113 (n=53,23,29,48,21,3)	10.9 (-99999 to 42.8)	0.14 (-99999 to 1.22)	1.08 (-99999 to 5.53)	4.36 (0.12 to 21.6)
Day 120 (n=55,23,28,48,23,2)	32.9 (-99999 to 112)	10.7 (-99999 to 22.7)	28.1 (11.6 to 66.5)	60.05 (-99999 to 130)
Day 141 (n=54,23,29,48,22,2)	10.46 (-99999 to 42.9)	2.73 (-99999 to 9.16)	8.74 (0.73 to 27.3)	27.7 (-99999 to 120)
Day 169 (n=49,23,28,46,23,23)	9.78 (-99999 to 40.4)	0.24 (-99999 to 1.27)	0.78 (-99999 to 8.79)	4.16 (-99999 to 34.7)
Day 197 (n=51,20,29,45,21,22)	0.99 (-99999 to 15.8)	0.18 (-99999 to 0.21)	0.25 (-99999 to 0.82)	0.41 (-99999 to 18.7)
Day 225 (n=51,22,28,45,23,16)	0.28 (-99999 to 8.39)	99999 (-99999 to 99999)	0.7 (-99999 to 1.26)	0.76 (-99999 to 6.04)
Unsch/Disc (n=58,24,30,49,23,25)	2.14 (-99999 to 16.4)	99999 (-99999 to 99999)	7.23 (-99999 to 13.7)	0.24 (-99999 to 14.9)

End point values	MPSK3169A 800 mg Q12W	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	25		
Units: micrograms per milliliter (mcg/mL)				
median (full range (min-max))				
Day 1 (n=57,23,30,50,23,2)	2.25 (-99999 to 12.8)	99999 (-99999 to 99999)		
Day 8 (n=57,23,30,50,23,3)	63.9 (-99999 to 180)	99999 (-99999 to 99999)		
Day 15 (n=55,22,30,49,22,3)	54.25 (-99999 to 87.1)	99999 (-99999 to 99999)		
Day 29 (n=54,23,28,49,23,3)	31.4 (-99999 to 58.7)	19.7 (-99999 to 19.7)		
Day 57 (n=56,23,29,49,23,3)	3.27 (-99999 to 16.7)	99999 (-99999 to 99999)		
Day 85 (n=56,23,29,49,23,5)	0.37 (-99999 to 26)	99999 (-99999 to 99999)		
Day 113 (n=53,23,29,48,21,3)	20.4 (-99999 to 64.6)	99999 (99999 to 99999)		
Day 120 (n=55,23,28,48,23,2)	17.1 (-99999 to 34.5)	99999 (-99999 to 99999)		
Day 141 (n=54,23,29,48,22,2)	6.52 (-99999 to 21.3)	99999 (-99999 to 99999)		
Day 169 (n=49,23,28,46,23,23)	0.3 (-99999 to 3.21)	0.11 (-99999 to 0.11)		
Day 197 (n=51,20,29,45,21,22)	0.38 (-99999 to 10)	4.61 (-99999 to 4.61)		
Day 225 (n=51,22,28,45,23,16)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Unsch/Disc (n=58,24,30,49,23,25)	0.48 (-99999 to 0.48)	99999 (-99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 112 days after last dose (approximately 40 weeks)	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	16
Reporting groups	
Reporting group title	MPSK3169A 400 mg Q4W
Reporting group description: Participants received 400 mg of MPSK3169A Q4W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 200 mg Q8W
Reporting group description: Participants received 200 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 400 mg Q8W
Reporting group description: Participants received 400 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 800 mg Q8W
Reporting group description: Participants received 800 mg of MPSK3169A Q8W subcutaneously for approximately 24 weeks.	
Reporting group title	MPSK3169A 800 mg Q12W
Reporting group description: Participants received 800 mg of MPSK3169A Q12W subcutaneously for approximately 24 weeks.	
Reporting group title	Placebo
Reporting group description: Participants received matching placebo injections subcutaneously for approximately 24 weeks.	

Serious adverse events	MPSK3169A 400 mg Q4W	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 57 (12.28%)	3 / 23 (13.04%)	0 / 30 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Urinary bladder adenoma			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Lung adenocarcinoma			

subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Prostate cancer			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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			
Hypotension			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Pulmonary embolism			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Dyspnoea			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Psychiatric disorders			
Depression			

subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Investigations			
International normalised ratio increased			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Hip fracture			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Concussion			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Pelvic fracture			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Thermal burn			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Humerus fracture			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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

Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	2 / 57 (3.51%)	2 / 23 (8.70%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Coronary artery disease			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Cardiac failure acute			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Atrial flutter			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Mitral valve incompetence			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Nervous system disorders			

Ischaemic stroke			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Carotid artery disease			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Syncope			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	0 / 30 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Renal failure acute			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Haematuria			

subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	0 / 30 (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
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonella sepsis			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (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

Serious adverse events	MPSK3169A 800 mg Q8W	MPSK3169A 800 mg Q12W	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 50 (10.00%)	3 / 23 (13.04%)	8 / 64 (12.50%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Urinary bladder adenoma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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			
Chest pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (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
Pulmonary embolism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Dyspnoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (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
Investigations			
International normalised ratio increased			

subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (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
Hip fracture			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (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
Concussion			
subjects affected / exposed	0 / 50 (0.00%)	1 / 23 (4.35%)	0 / 64 (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
Pelvic fracture			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (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
Thermal burn			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Humerus fracture			
subjects affected / exposed	0 / 50 (0.00%)	1 / 23 (4.35%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Angina unstable			
subjects affected / exposed	0 / 50 (0.00%)	1 / 23 (4.35%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (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
Cardiac failure acute			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Atrial flutter			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Mitral valve incompetence			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Carotid artery disease			

subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Syncope			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	1 / 50 (2.00%)	0 / 23 (0.00%)	0 / 64 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Endocrine disorders			
Goitre			

subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
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			
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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
Salmonella sepsis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (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

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

Non-serious adverse events	MPSK3169A 400 mg Q4W	MPSK3169A 200 mg Q8W	MPSK3169A 400 mg Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 57 (75.44%)	13 / 23 (56.52%)	22 / 30 (73.33%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	5	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Fall			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Excoriation			
subjects affected / exposed	3 / 57 (5.26%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	4	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	6 / 57 (10.53%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	6	1	0
Hypotension			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 57 (10.53%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences (all)	9	1	2
Dizziness			
subjects affected / exposed	1 / 57 (1.75%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Syncope			
subjects affected / exposed	3 / 57 (5.26%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	3	1	0
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	11 / 57 (19.30%)	1 / 23 (4.35%)	7 / 30 (23.33%)
occurrences (all)	47	4	25
Injection site bruising			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	3 / 30 (10.00%)
occurrences (all)	2	0	3
Injection site pain			
subjects affected / exposed	6 / 57 (10.53%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	14	0	1
Injection site haemorrhage			
subjects affected / exposed	3 / 57 (5.26%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	3	0	4
Oedema peripheral			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Fatigue			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Injection site swelling			

subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 57 (5.26%)	2 / 23 (8.70%)	0 / 30 (0.00%)
occurrences (all)	3	6	0
Nausea			
subjects affected / exposed	6 / 57 (10.53%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	8	0	1
Constipation			
subjects affected / exposed	0 / 57 (0.00%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	2 / 30 (6.67%)
occurrences (all)	0	1	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 57 (5.26%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
Depression			
subjects affected / exposed	2 / 57 (3.51%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 57 (5.26%)	1 / 23 (4.35%)	4 / 30 (13.33%)
occurrences (all)	3	1	5
Arthralgia			

subjects affected / exposed	4 / 57 (7.02%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	4	1	1
Muscle spasms			
subjects affected / exposed	3 / 57 (5.26%)	2 / 23 (8.70%)	1 / 30 (3.33%)
occurrences (all)	3	2	1
Myalgia			
subjects affected / exposed	3 / 57 (5.26%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	3	0	2
Pain in extremity			
subjects affected / exposed	4 / 57 (7.02%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	4	0	4
Musculoskeletal pain			
subjects affected / exposed	0 / 57 (0.00%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 57 (10.53%)	3 / 23 (13.04%)	3 / 30 (10.00%)
occurrences (all)	6	3	3
Upper respiratory tract infection			
subjects affected / exposed	8 / 57 (14.04%)	2 / 23 (8.70%)	2 / 30 (6.67%)
occurrences (all)	11	2	3
Urinary tract infection			
subjects affected / exposed	5 / 57 (8.77%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	7	0	2
Bronchitis			
subjects affected / exposed	2 / 57 (3.51%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
Sinusitis			
subjects affected / exposed	2 / 57 (3.51%)	1 / 23 (4.35%)	1 / 30 (3.33%)
occurrences (all)	2	1	3
Influenza			
subjects affected / exposed	3 / 57 (5.26%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	3	1	0
Gastroenteritis			
subjects affected / exposed	1 / 57 (1.75%)	2 / 23 (8.70%)	2 / 30 (6.67%)
occurrences (all)	1	2	2

Viral infection			
subjects affected / exposed	1 / 57 (1.75%)	0 / 23 (0.00%)	2 / 30 (6.67%)
occurrences (all)	2	0	2
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	2 / 57 (3.51%)	1 / 23 (4.35%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
Hypokalaemia			
subjects affected / exposed	4 / 57 (7.02%)	0 / 23 (0.00%)	0 / 30 (0.00%)
occurrences (all)	4	0	0

Non-serious adverse events	MPSK3169A 800 mg Q8W	MPSK3169A 800 mg Q12W	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 50 (66.00%)	19 / 23 (82.61%)	50 / 64 (78.13%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 50 (6.00%)	1 / 23 (4.35%)	1 / 64 (1.56%)
occurrences (all)	3	1	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 50 (6.00%)	2 / 23 (8.70%)	3 / 64 (4.69%)
occurrences (all)	3	2	3
Fall			
subjects affected / exposed	1 / 50 (2.00%)	2 / 23 (8.70%)	1 / 64 (1.56%)
occurrences (all)	1	2	1
Excoriation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 50 (8.00%)	0 / 23 (0.00%)	2 / 64 (3.13%)
occurrences (all)	5	0	2
Hypotension			
subjects affected / exposed	4 / 50 (8.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences (all)	5	0	1
Nervous system disorders			

Headache			
subjects affected / exposed	6 / 50 (12.00%)	1 / 23 (4.35%)	5 / 64 (7.81%)
occurrences (all)	10	1	6
Dizziness			
subjects affected / exposed	7 / 50 (14.00%)	0 / 23 (0.00%)	3 / 64 (4.69%)
occurrences (all)	10	0	3
Syncope			
subjects affected / exposed	0 / 50 (0.00%)	1 / 23 (4.35%)	0 / 64 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	6 / 50 (12.00%)	5 / 23 (21.74%)	4 / 64 (6.25%)
occurrences (all)	44	29	11
Injection site bruising			
subjects affected / exposed	3 / 50 (6.00%)	3 / 23 (13.04%)	2 / 64 (3.13%)
occurrences (all)	4	3	4
Injection site pain			
subjects affected / exposed	2 / 50 (4.00%)	1 / 23 (4.35%)	2 / 64 (3.13%)
occurrences (all)	3	1	5
Injection site haemorrhage			
subjects affected / exposed	2 / 50 (4.00%)	1 / 23 (4.35%)	1 / 64 (1.56%)
occurrences (all)	3	3	1
Oedema peripheral			
subjects affected / exposed	1 / 50 (2.00%)	2 / 23 (8.70%)	3 / 64 (4.69%)
occurrences (all)	1	2	3
Fatigue			
subjects affected / exposed	2 / 50 (4.00%)	0 / 23 (0.00%)	5 / 64 (7.81%)
occurrences (all)	6	0	6
Injection site swelling			
subjects affected / exposed	0 / 50 (0.00%)	3 / 23 (13.04%)	1 / 64 (1.56%)
occurrences (all)	0	4	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 50 (0.00%)	2 / 23 (8.70%)	1 / 64 (1.56%)
occurrences (all)	0	2	1
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	5 / 50 (10.00%)	3 / 23 (13.04%)	5 / 64 (7.81%)
occurrences (all)	7	6	5
Nausea			
subjects affected / exposed	2 / 50 (4.00%)	2 / 23 (8.70%)	7 / 64 (10.94%)
occurrences (all)	2	2	8
Constipation			
subjects affected / exposed	2 / 50 (4.00%)	0 / 23 (0.00%)	4 / 64 (6.25%)
occurrences (all)	3	0	4
Abdominal pain upper			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 50 (6.00%)	1 / 23 (4.35%)	6 / 64 (9.38%)
occurrences (all)	3	1	6
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 50 (2.00%)	1 / 23 (4.35%)	0 / 64 (0.00%)
occurrences (all)	1	1	0
Depression			
subjects affected / exposed	0 / 50 (0.00%)	1 / 23 (4.35%)	4 / 64 (6.25%)
occurrences (all)	0	1	4
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	5 / 50 (10.00%)	3 / 23 (13.04%)	4 / 64 (6.25%)
occurrences (all)	6	4	4
Arthralgia			
subjects affected / exposed	2 / 50 (4.00%)	2 / 23 (8.70%)	2 / 64 (3.13%)
occurrences (all)	2	2	2
Muscle spasms			
subjects affected / exposed	2 / 50 (4.00%)	0 / 23 (0.00%)	3 / 64 (4.69%)
occurrences (all)	4	0	3
Myalgia			
subjects affected / exposed	3 / 50 (6.00%)	0 / 23 (0.00%)	1 / 64 (1.56%)
occurrences (all)	3	0	1

Pain in extremity			
subjects affected / exposed	0 / 50 (0.00%)	1 / 23 (4.35%)	2 / 64 (3.13%)
occurrences (all)	0	1	2
Musculoskeletal pain			
subjects affected / exposed	4 / 50 (8.00%)	0 / 23 (0.00%)	2 / 64 (3.13%)
occurrences (all)	4	0	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 50 (16.00%)	5 / 23 (21.74%)	10 / 64 (15.63%)
occurrences (all)	8	5	13
Upper respiratory tract infection			
subjects affected / exposed	6 / 50 (12.00%)	6 / 23 (26.09%)	9 / 64 (14.06%)
occurrences (all)	8	7	9
Urinary tract infection			
subjects affected / exposed	3 / 50 (6.00%)	1 / 23 (4.35%)	3 / 64 (4.69%)
occurrences (all)	3	5	3
Bronchitis			
subjects affected / exposed	2 / 50 (4.00%)	3 / 23 (13.04%)	6 / 64 (9.38%)
occurrences (all)	3	3	6
Sinusitis			
subjects affected / exposed	2 / 50 (4.00%)	1 / 23 (4.35%)	4 / 64 (6.25%)
occurrences (all)	2	2	4
Influenza			
subjects affected / exposed	1 / 50 (2.00%)	2 / 23 (8.70%)	2 / 64 (3.13%)
occurrences (all)	1	2	2
Gastroenteritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	2 / 64 (3.13%)
occurrences (all)	0	0	2
Viral infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 23 (0.00%)	0 / 64 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	3 / 50 (6.00%)	1 / 23 (4.35%)	1 / 64 (1.56%)
occurrences (all)	3	1	1
Hypokalaemia			

subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	1 / 23 (4.35%) 1	0 / 64 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 March 2012	The protocol was amended to provide 'Method of treatment assignment and blinding' that was inadvertently omitted during protocol publication.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported