Clinical trial results:
A 24-Week, Worldwide, Multicenter, Double-Blind, Randomized, Parallel, Placebo-Controlled Study to Assess the Efficacy and Tolerability of Anacetrapib When Added to Ongoing Statin Therapy With or Without Other Lipid Modifying Medication(s) in Patients with Hypercholesterolemia or Low HDL-C

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2012-003110-14
Trial protocol	NL GB DE HU ES SK BG RO
Global end of trial date	29 October 2014

Results information

Result version number	v1 (current)
This version publication date	26 February 2016
First version publication date	26 February 2016

Trial information

Trial identification

Sponsor protocol code	MK-0859-021

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01717300
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 October 2014
Global end of trial reached?	Yes
Global end of trial date	29 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study will evaluate the effects of 2 different dose levels of anacetrapib on low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C) in participants with hypercholesterolemia when added to an existing statin-modifying therapy.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 November 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 22
Country: Number of subjects enrolled	Canada: 16
Country: Number of subjects enrolled	Germany: 17
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	United Kingdom: 24
Country: Number of subjects enrolled	Hungary: 32
Country: Number of subjects enrolled	Israel: 38
Country: Number of subjects enrolled	Netherlands: 28
Country: Number of subjects enrolled	Poland: 19
Country: Number of subjects enrolled	Puerto Rico: 20
Country: Number of subjects enrolled	Romania: 26
Country: Number of subjects enrolled	Slovakia: 47
Country: Number of subjects enrolled	United States: 155
Worldwide total number of subjects	459
EEA total number of subjects	230

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)	289
From 65 to 84 years	170
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were to complete a 2-week placebo run-in, a 24-week treatment period, and a 12-week safety follow-up.

Pre-assignment

Screening details:

Adult participants, with hypercholesterolemia or low HDL-C who had been treated with an appropriate statin dose with or without other lipid-modifying therapy (LMT) for at least 6 weeks and had not met their LDL-C goal. Additionally, participants on statin with or without other LMT with low HDL-C and LDL-C at goal were eligible to participate.

Period 1

Period 1 title	Treatment 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	Anacetrapib 25 mg

Arm description:

One tablet of anacetrapib 25 mg and one tablet of placebo taken once daily with a meal for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Anacetrapib
Investigational medicinal product code	
Other name	MK-0859
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet once daily with a meal for 24 weeks

Investigational medicinal product name	Placebo to match anacetrapib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One or two placebo tablets once daily for 24 weeks

Arm title	Anacetrapib 100 mg

Arm description:

One tablet of anacetrapib 100 mg and one tablet of placebo taken once daily with a meal for 24 weeks

Arm type	Experimental
Investigational medicinal product name	Anacetrapib
Investigational medicinal product code	
Other name	MK-0859
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One tablet once daily with a meal for 24 weeks

Investigational medicinal product name	Placebo to match anacetrapib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One or two placebo tablets once daily for 24 weeks

Arm title	Placebo

Arm description:

Two matching placebo tablets once daily with a meal for 24 weeks

Arm type	Placebo
Investigational medicinal product name	Placebo to match anacetrapib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

One or two placebo tablets once daily for 24 weeks

Number of subjects in period 1	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo
Started	152	153	154
Completed	136	140	140
Not completed	16	13	14
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	7	7	3
Physician decision	-	-	1
Adverse event, non-fatal	5	4	9
Non-compliance with study drug	-	-	1
Lost to follow-up	-	1	-
Protocol deviation	3	1	-

Period 2

Period 2 title	Follow-up
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes

Arm title	Anacetrapib 25 mg-Follow up

Arm description:

Participants who completed treatment period and participants who were discontinued during treatment period (non-completers) who were administered anacetrapib 25 mg in treatment period and entered Follow-up period. No study drug was administered during Follow-up Period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Anacetrapib 100 mg-Follow-up

Arm description:

Participants who completed treatment period and participants who were discontinued during treatment period (non-completers) who were administered anacetrapib 100 mg in treatment period and entered Follow-up period. No study drug was administered during Follow-up Period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo-Follow-up

Arm description:

Participants who completed treatment period and participants who were discontinued during treatment period (non-completers) who were administered placebo in treatment period and entered Follow-up period. No study drug was administered during Follow-up Period.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	Anacetrapib 25 mg-Follow up	Anacetrapib 100 mg-Follow-up	Placebo-Follow-up
Started	136	140	140
Completed	144	148	152
Not completed	1	4	1
Adverse event, serious fatal	-	2	-
Consent withdrawn by subject	-	1	-
Physician decision	-	-	1
Adverse event, non-fatal	1	-	-
Lost to follow-up	-	1	-
Joined	9	12	13
Non-completers from Treatment Period	9	12	13

Baseline characteristics

Reporting groups	
Reporting group title	Anacetrapib 25 mg
Reporting group description:	
One tablet of anacetrapib 25 mg and one tablet of placebo taken once daily with a meal for 24 weeks	
Reporting group title	Anacetrapib 100 mg
Reporting group description:	
One tablet of anacetrapib 100 mg and one tablet of placebo taken once daily with a meal for 24 weeks	
Reporting group title	Placebo
Reporting group description:	
Two matching placebo tablets once daily with a meal for 24 weeks	

Reporting group values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo
Number of subjects	152	153	154
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	61.9	58.7	60.3
standard deviation	± 9.1	± 9.6	± 8.9
Gender Categorical Units: Subjects			
Female	102	101	108
Male	50	52	46

Reporting group values	Total		
Number of subjects	459		
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	311		
Male	148		

End points

End points reporting groups

Reporting group title	Anacetrapib 25 mg
Reporting group description:	
One tablet of anacetrapib 25 mg and one tablet of placebo taken once daily with a meal for 24 weeks	
Reporting group title	Anacetrapib 100 mg
Reporting group description:	
One tablet of anacetrapib 100 mg and one tablet of placebo taken once daily with a meal for 24 weeks	
Reporting group title	Placebo
Reporting group description:	
Two matching placebo tablets once daily with a meal for 24 weeks	
Reporting group title	Anacetrapib 25 mg-Follow up
Reporting group description:	
Participants who completed treatment period and participants who were discontinued during treatment period (non-completers) who were administered anacetrapib 25 mg in treatment period and entered Follow-up period. No study drug was administered during Follow-up Period.	
Reporting group title	Anacetrapib 100 mg-Follow-up
Reporting group description:	
Participants who completed treatment period and participants who were discontinued during treatment period (non-completers) who were administered anacetrapib 100 mg in treatment period and entered Follow-up period. No study drug was administered during Follow-up Period.	
Reporting group title	Placebo-Follow-up
Reporting group description:	
Participants who completed treatment period and participants who were discontinued during treatment period (non-completers) who were administered placebo in treatment period and entered Follow-up period. No study drug was administered during Follow-up Period.	
Subject analysis set title	Anacetrapib 25 mg- Efficacy Population
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants who received at least 1 dose of study treatment had baseline data and at least 1 post-dose observation for the analysis endpoint.	
Subject analysis set title	Anacetrapib 100 mg- Efficacy Population
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants who received at least 1 dose of study treatment had baseline data and at least 1 post-dose observation for the analysis endpoint.	
Subject analysis set title	Placebo - Efficacy Population
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants who received at least 1 dose of study treatment had baseline data and at least 1 post-dose observation for the analysis endpoint.	

Primary: Percentage Change From Baseline in LDL-C - Treatment Period

End point title	Percentage Change From Baseline in LDL-C - Treatment Period
End point description:	
LDL-C levels measured at baseline and after 24 weeks of treatment using beta quantification method	
End point type	Primary
End point timeframe:	
Baseline and Week 24	

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	126	133	133	
Units: Percentage Change				
least squares mean (confidence interval 95%)	-21.9 (-27.9 to -15.9)	-28 (-33.7 to -22.3)	0.9 (-4.9 to 6.7)	

Statistical analyses

Statistical analysis title	Comparison of Percentage Change from Baseline

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, statin stratum and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Mean
Point estimate	-22.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.4
upper limit	-15.1

Statistical analysis title	Comparison of Percentage Change from Baseline

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, statin stratum and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population

Number of subjects included in analysis	266
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Mean
Point estimate	-28.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.4
upper limit	-21.3

Statistical analysis title	Comparison of Percent Change from Baseline

Statistical analysis description:

Between group comparison of percent change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, statin stratum and the interaction of time by treatment. Analysis population defined as participants who receive at least 1 dose of study treatment and have baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population
Number of subjects included in analysis	259
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.118
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.7
upper limit	-1.6

Primary: Percentage Change From Baseline in HDL-C - Treatment Period

End point title	Percentage Change From Baseline in HDL-C - Treatment Period

End point description:

HDL-C levels measured at baseline and after 24 weeks of treatment

End point type	Primary

End point timeframe:

Baseline and Week 24

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	136	138	140	
Units: Percentage Change				
least squares mean (confidence interval 95%)	69.4 (62.4 to 76.3)	98.6 (91.7 to 105.4)	3.9 (-2.9 to 10.7)	

Statistical analyses

Statistical analysis title	Comparison of Percentage Change from Baseline

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, statin stratum and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population
Number of subjects included in analysis	274
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Mean
Point estimate	65.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	56
upper limit	75

Statistical analysis title	Comparison of Percentage Change from Baseline

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, statin stratum and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Mean
Point estimate	94.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	85.2
upper limit	104

Primary: Percentage of Participants With Any Adverse Event (AE) - Treatment Period

End point title	Percentage of Participants With Any Adverse Event (AE) - Treatment Period

End point description:

An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry ofthe body temporally associated with the use of the study drug, whether or not considered related to theuse of the drug. Any worsening of a preexisting condition which is temporally associated with the use ofthe study drug is also an AE.

End point type	Primary

End point timeframe:

Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	35.5	39.9	39	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.2
upper limit	7.4

Statistical analysis title	Difference in Percentages Between Groups

Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10
upper limit	11.8

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	305
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	15.1

Primary: Percentage of Participants With Any Drug-related AE - Treatment Period

End point title	Percentage of Participants With Any Drug-related AE - Treatment Period

End point description:

An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the drug. Any worsening of a preexisting condition which is temporally associated with the use of the study drug is also an AE. AEs reported by the investigator as definitely, probably, or possibly related to study drug were considered drug-related.

End point type	Primary

End point timeframe:

Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	2	8.5	5.2	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	9.5

Primary: Percentage of Participants With Any Serious Adverse Event (SAE) - Treatment Period

End point title	Percentage of Participants With Any Serious Adverse Event (SAE) - Treatment Period

End point description:

An AE or suspected adverse reaction is considered an SAE if it results in any of the following outcomes: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal lifefunctions, or a congenital anomaly/birth defect.

End point type	Primary

End point timeframe:

Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	5.3	4.6	5.2	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentage
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	5.5

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.9
upper limit	4.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	305
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.1
upper limit	4.6

Primary: Percentage of Participants With Any Drug-related SAE - Treatment Period

End point title	Percentage of Participants With Any Drug-related SAE - Treatment Period

End point description:

An AE or suspected adverse reaction is considered an SAE if it results in any of the following outcomes: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. SAEs reported by the investigator as definitely, probably or possibly related to study were considered to be drug-related.

End point type	Primary

End point timeframe:

Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	0	0	0	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.5

Primary: Percentage of Participants With Any AE Leading to Discontinuation of Treatment - Treatment Period

End point title	Percentage of Participants With Any AE Leading to Discontinuation of Treatment - Treatment Period

End point description:

An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study drug, whether or not considered related to the use of the drug. Any worsening of a preexisting condition which is temporally associated with the use of the study drug is also an AE. Adverse Events that were reported as the cause for discontinuation of the study drug were recorded.

End point type	Primary

End point timeframe:
Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	3.3	2.6	5.8	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.9
upper limit	2.4

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	1.5

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg

Number of subjects included in analysis	305
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen & Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.2
upper limit	3.7

Primary: Percentage of Participants With Elevations in Sitting Systolic Blood Pressure (SiSBP) ≥ 10 mm Hg - Treatment Period

End point title	Percentage of Participants With Elevations in Sitting Systolic Blood Pressure (SiSBP) ≥ 10 mm Hg - Treatment Period

End point description:

Participants had SBP assessed while sitting at baseline and throughout the 24 week treatment period. Participants who had a SiSBP reading that was ≥ 10 mm Hg higher than their baseline SiSBP for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	153	
Units: Percentage of Participants				
number (not applicable)	37.4	33.3	39.9	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.663
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-2.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.4
upper limit	8.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.236
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.2
upper limit	4.3

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.46
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.8
upper limit	6.7

Primary: Percentage of Participants With Elevations in SiSBP ≥ 15 mm Hg - Treatment Period

End point title	Percentage of Participants With Elevations in SiSBP ≥ 15 mm Hg - Treatment Period

End point description:

Participants had SBP assessed while in sitting position at baseline and throughout the 24 week treatment period. Participants who had a SiSBP reading that was ≥ 15 mm Hg higher than their baseline SiSBP for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:
up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	153	
Units: Percentage of Participants				
number (not applicable)	19	19.6	22.2	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.498
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4
upper limit	6.1

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.575
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	6.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.902
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	9.6

Primary: Percentage of Participants With Elevations in Sitting Diastolic Blood Pressure (SiDBP) ≥ 10 mm Hg - Treatment Period

End point title	Percentage of Participants With Elevations in Sitting Diastolic Blood Pressure (SiDBP) ≥ 10 mm Hg - Treatment Period

End point description:

Participants had DBP assessed while in sitting position at baseline and throughout the 24 week treatment period. Participants who had a SiDBP reading that was ≥ 10 mm Hg higher than their baseline SiDBP for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	153	153	
Units: Percentage of Participants				
number (not applicable)	15.6	15.7	19.6	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.369
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.7
upper limit	4.8

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.369
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	4.7

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.992
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.4
upper limit	8.4

Primary: Percentage of Participants With Sodium Levels > Upper Limit of Normal (ULN) - Treatment Period

End point title	Percentage of Participants With Sodium Levels > Upper Limit of Normal (ULN) - Treatment Period

End point description:

Participants had sodium levels assessed throughout the 24 week treatment period. Participants who had any sodium level that was > the ULN of 145 mEq/L were recorded.

End point type	Primary

End point timeframe:
Up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Participants				
number (not applicable)	5.5	11.8	15	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.007
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-9.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.7
upper limit	-2.8

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.402
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	4.5

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.054
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	13

Primary: Percentage of Participants With Chloride Levels > ULN - Treatment Period

End point title	Percentage of Participants With Chloride Levels > ULN - Treatment Period

End point description:

Participants had chloride levels assessed throughout the 24 week treatment period. Participants who had any chloride level that was > the ULN of 110 mEq/L were recorded.

End point type	Primary

End point timeframe:

up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Participants				
number (not applicable)	0	0.7	0.7	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Group
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.329
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	3.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	3

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.329
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	1.9

Primary: Percentage of Participants With Potassium Levels < Lower limit of Normal (LLN) - Treatment Period

End point title	Percentage of Participants With Potassium Levels < Lower limit of Normal (LLN) - Treatment Period

End point description:

Participants had potassium levels assessed throughout the 24 week treatment period. Participants who had any potassium level that was < the ULN of 3.5 mEq/L were recorded.

End point type	Primary

End point timeframe:
up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Participants				
number (not applicable)	1.4	3.9	2.6	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.444
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.3
upper limit	2.5

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.521
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.172
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	2.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	7.1

Primary: Percentage of Participants With Bicarbonate Levels > ULN - Treatment Period

End point title	Percentage of Participants With Bicarbonate Levels > ULN - Treatment Period
End point description:	
Participants had bicarbonate levels assessed throughout the 24 week treatment period. Participants who had any bicarbonate level that was > the ULN of 33 mEq/L were recorded.	
End point type	Primary
End point timeframe:	
up to 24 weeks	

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Particpants				
number (not applicable)	0	0	0	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.5

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	2.5

Primary: Percentage of Participants With Consecutive Elevations in Alanine Aminotransferase (ALT) and/or Aspartate Aminotransferase (AST) of ≥3 X ULN

End point title	Percentage of Participants With Consecutive Elevations in Alanine Aminotransferase (ALT) and/or Aspartate Aminotransferase (AST) of ≥3 X ULN

End point description:

Participants had AST and ALT levels assessed throughout the 24 week treatment period. Participants who had 2 consecutive assessments of either AST or ALT that were 3 x ULN or greater were recorded.

The AST UNLs for males and females were 43 U/L and 36 U/L, respectively. The ALT UNLs for males and females were 40 U/L and 33 U/L, respectively.

End point type	Primary
End point timeframe:	
up to 24 weeks	

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Participants				
number (not applicable)	0	0	0.7	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.329
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	1.9

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.317
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	1.8

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	2.5

Primary: Percentage of Participants With Creatine Kinase (CK) ≥10 x ULN - Treatment Period

End point title	Percentage of Participants With Creatine Kinase (CK) ≥10 x ULN - Treatment Period

End point description:

Participants had CK assessed throughout the 24 week treatment period. Participants who had any CK level that was ≥10 x ULN were recorded. The UNLs for males and females were 207 U/L and 169 U/L, respectively.

End point type	Primary

End point timeframe:

up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Participants				
number (not applicable)	0	0.7	0	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo

Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.317
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	3.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.329
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	3.6

Primary: Percentage of Participants With CK ≥10 x ULN With Muscle Symptoms -

Treatment Period	
End point title	Percentage of Participants With CK ≥10 x ULN With Muscle Symptoms - Treatment Period

End point description:

Participants had CK assessed throughout the 24 week treatment period. Participants who had any CK level that was ≥10 x ULN and had associated muscle spasms present within +/- 7 days were recorded. The UNLs for males and females were 207 U/L and 169 U/L, respectively.

End point type	Primary

End point timeframe:

up to 24 week

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	153	153	
Units: Percentage of Participants				
number (not applicable)	0	0	0	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Placebo v Anacetrapib 25 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	2.5

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	299
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	2.5

Primary: Percentage of Participants with an Adjudicated Cardiovascular (CV) SAE - Treatment Period

End point title	Percentage of Participants with an Adjudicated Cardiovascular (CV) SAE - Treatment Period

End point description:

An AE or suspected adverse reaction is was considered an SAE if it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. All events were adjudicated by an expert committee independent of the Sponsor. Participants that experienced adjudicated SAEs of CV death, Non-fatal stroke, non-fatal myocardial infarction, or unstable angina were recorded.

End point type	Primary

End point timeframe:

up to 24 weeks

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	5.3	3.3	1.3	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.12
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	8.3

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo
Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.469
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	5.7

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	305
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.389
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.2
upper limit	2.9

Primary: Percentage of Participants Who Died From Any Cause - Treatment Period	
End point title	Percentage of Participants Who Died From Any Cause - Treatment Period
End point description:	
Participants who died from any cause were recorded. All deaths were adjudicated by an expert committee independent of the Sponsor.	
End point type	Primary
End point timeframe:	
up to 24 weeks	

End point values	Anacetrapib 25 mg	Anacetrapib 100 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	152	153	154	
Units: Percentage of Participants				
number (not applicable)	0.7	0.7	0	

Statistical analyses

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 25 mg v Placebo
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.314
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	3.6

Statistical analysis title	Difference in Percentages Between Groups
Comparison groups	Anacetrapib 100 mg v Placebo

Number of subjects included in analysis	307
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.316
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	3.6

Statistical analysis title	Miettinen and Nurminen
Comparison groups	Anacetrapib 25 mg v Anacetrapib 100 mg
Number of subjects included in analysis	305
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.996
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	3

Secondary: Percent Change From Baseline in Non-HDL-C- Treatment Period	
End point title	Percent Change From Baseline in Non-HDL-C- Treatment Period
End point description:	
Non-HDL-C levels measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	133	138	137	
Units: Percentage Change				
least squares mean (confidence interval 95%)	-18.5 (-23.6 to -13.4)	-24.5 (-29.4 to -19.6)	5.7 (0.7 to 10.7)	

Statistical analyses

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal
Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	270
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-24.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.6
upper limit	-17.8

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-30.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.5
upper limit	-23.9

Statistical analysis title	Difference in Least Squares Mean Change
Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population
Number of subjects included in analysis	271
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.067
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.3
upper limit	0.4

Secondary: Percent Change From Baseline in Apolipoprotein B (Apo B) - Treatment Period

End point title	Percent Change From Baseline in Apolipoprotein B (Apo B) - Treatment Period
End point description:	
Apo B levels measured at baseline and after 24 weeks of treatment	
End point type	Secondary
End point timeframe:	
up to 24 weeks	

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131	137	136	
Units: Percentage Change				
least squares mean (confidence interval 95%)	-16.1 (-20.1 to -12.1)	-17.1 (-20.9 to -13.2)	1.8 (-2.1 to 5.7)	

Statistical analyses

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment

and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	267
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-17.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.1
upper limit	-12.7

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-18.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24
upper limit	-13.7

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population

Number of subjects included in analysis	268
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.712
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.2
upper limit	4.2

Secondary: Percent Change From Baseline in Apolipoprotein A1 (Apo-A1) - Treatment Period

End point title	Percent Change From Baseline in Apolipoprotein A1 (Apo-A1) - Treatment Period
End point description:	
Apo A-1 levels measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe:	
up to 24 weeks	

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	131	137	136	
Units: Percentage Change				
least squares mean (confidence interval 95%)	26.2 (22.4 to 29.9)	33.2 (29.5 to 36.9)	3.4 (-0.3 to 7.1)	

Statistical analyses

Statistical analysis title	Difference in Least Squares Mean Change
Statistical analysis description:	
Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.	
Comparison groups	Anacetrapib 25 mg- Efficacy Population v Placebo - Efficacy Population

Number of subjects included in analysis	267
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	22.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.9
upper limit	27.6

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	29.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	25
upper limit	34.6

Statistical analysis title	Difference in Least Squares Mean Change

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population
Number of subjects included in analysis	268
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	7

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	11.9

Secondary: Percent Change From Baseline in Lipoprotein(a) (Lp[a]) - Treatment Period

End point title	Percent Change From Baseline in Lipoprotein(a) (Lp[a]) - Treatment Period
End point description: Lp(a) levels measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe: up to 24 weeks	

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	137	147	144	
Units: Percentage Change				
least squares mean (confidence interval 95%)	-19.8 (-26 to -13.7)	-29.5 (-36 to -23)	-0.1 (-3.7 to 3.5)	

Statistical analyses

Statistical analysis title	Difference in Median Change
Statistical analysis description: Between group comparison of percent change from baseline performed using Hodges-Lehmann estimate of the median difference between treatments with a corresponding distribution-free CI based on Wilcoxon's rank sum test. Analysis population defined as participants who receive at least 1 dose of study treatment and have baseline and at least 1 post-randomization observation for the analysis endpoint.	
Comparison groups	Anacetrapib 25 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	281
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	-22.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.4
upper limit	-16.8

Statistical analysis title	Difference in Median Change

Statistical analysis description:

Between group comparison of percent change from baseline performed using Hodges-Lehmann estimate of the median difference between treatments with a corresponding distribution-free CI based on Wilcoxon's rank sum test. Analysis population defined as participants who receive at least 1 dose of study treatment and have baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	291
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	-32.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.2
upper limit	-26.2

Statistical analysis title	Difference in Median Change

Statistical analysis description:

Between group comparison of percent change from baseline performed using Hodges-Lehmann estimate of the median difference between treatments with a corresponding distribution-free CI based on Wilcoxon's rank sum test. Analysis population defined as participants who receive at least 1 dose of study treatment and have baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population
Number of subjects included in analysis	284
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)
Point estimate	-8.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.3
upper limit	-1.9

Secondary: Percent Change From Baseline in High-density Lipoprotein-cholesterol (HDL-C) in Participants with Low HDL-C at LDL-C Goal After 24 Weeks - Treatment Period

End point title	Percent Change From Baseline in High-density Lipoprotein-cholesterol (HDL-C) in Participants with Low HDL-C at LDL-C Goal After 24 Weeks - Treatment Period

End point description:

HDL-C levels measured at baseline and after 24 weeks of treatment among participants who were at their LDL-C goal at baseline (as per their coronary heart disease risk category) with low HDL-C

End point type	Secondary

End point timeframe:

Baseline and Week 24

End point values	Anacetrapib 25 mg- Efficacy Population	Anacetrapib 100 mg- Efficacy Population	Placebo - Efficacy Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	29	23	23	
Units: Percentage Change				
least squares mean (confidence interval 95%)	87.5 (70.1 to 105)	105.3 (85.8 to 124.7)	10.1 (-8.7 to 28.8)	

Statistical analyses

Statistical analysis title	Difference in Least Squares Mean Changes

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who were at their
LDL-C goal at baseline (as per their coronary heart disease risk category) with low HDL-C, received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	77.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.8
upper limit	103.1

Statistical analysis title	Difference in Least Squares Mean Changes

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who were at their LDL-C goal at baseline (as per their coronary heart disease risk category) with low HDL-C, received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 100 mg- Efficacy Population v Placebo - Efficacy Population
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	95.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.2
upper limit	122.2

Statistical analysis title	Difference in Least Squares Mean Changes

Statistical analysis description:

Between group comparison of percentage change from baseline performed using Constrained Longitudinal Data Analysis (cLDA) model with terms for treatment, time, and the interaction of time by treatment. Analysis population defined as participants who were at their LDL-C goal at baseline (as per their coronary heart disease risk category) with low HDL-C, received at least 1 dose of study treatment and had baseline and at least 1 post-randomization observation for the analysis endpoint.

Comparison groups	Anacetrapib 25 mg- Efficacy Population v Anacetrapib 100 mg- Efficacy Population
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.179
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least Squares Means
Point estimate	17.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	43.8

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: up to 36 weeks	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	Anacetrapib 25 mg
Reporting group description: Participants who received at least 1 dose of Anacetrapib 25 mg	
Reporting group title	Placebo
Reporting group description: Participants who received at least 1 dose of placebo.	
Reporting group title	Anacetrapib 100 mg
Reporting group description: Participants who received at least 1 dose of Anacetrapib 100 mg	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: None of the reported non-serious adverse events exceeded the 5% cut-off in any of the treatment arms.

Serious adverse events	Anacetrapib 25 mg	Placebo	Anacetrapib 100 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 152 (5.26%)	8 / 154 (5.19%)	7 / 153 (4.58%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung cancer metastatic			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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
Hypotension			

subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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
Intermittent claudication			
subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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
Peripheral embolism			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	2 / 152 (1.32%)	0 / 154 (0.00%)	0 / 153 (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
Atrial fibrillation			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	2 / 153 (1.31%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			

subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
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			
Cerebrovascular accident			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Ischaemic stroke			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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			
Coronary artery restenosis			
subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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			
Acute pulmonary oedema			

subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Acute respiratory failure			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	1 / 152 (0.66%)	1 / 154 (0.65%)	0 / 153 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
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			
Abscess limb			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Cellulitis			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	1 / 153 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Pneumonia			
subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 152 (0.00%)	1 / 154 (0.65%)	0 / 153 (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
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 152 (0.66%)	0 / 154 (0.00%)	0 / 153 (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

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

Non-serious adverse events	Anacetrapib 25 mg	Placebo	Anacetrapib 100 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 152 (0.00%)	0 / 154 (0.00%)	0 / 153 (0.00%)

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 January 2013	Provided new data on the pharmacokinetic properties of anacetrapib and related changes to eligibility criteria and study procedures. Most notably, removed women of child-bearing potential from Inclusion Criteria and removed Inclusion Criteria regarding pregnancy and breast-feeding.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported