Clinical trial results:
A Double-blind, Randomized, Placebo and Ezetimibe Controlled, Multicenter Study to Evaluate Safety, Tolerability and Efficacy of AMG 145 on LDL-C in Combination With Statin Therapy in Subjects With Primary Hypercholesterolemia and Mixed Dyslipidemia

Summary

EudraCT number	2012-001363-70
Trial protocol	BE ES HU NL IT CZ SE DK GB DE
Global end of trial date	04 December 2013

Results information

Result version number	v1 (current)
This version publication date	20 June 2016
First version publication date	06 August 2015

Trial information

Trial identification

Sponsor protocol code	20110115

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01763866
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen, Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States, 91320
Public contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com
Scientific contact	IHQ Medical Info-Clinical Trials, Amgen (EUROPE) GmbH, MedInfoInternational@amgen.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	04 December 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 December 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the effect of 12 weeks of evolocumab administered subcutaneously every 2 weeks (Q2W) and monthly (QM) when used in combination with a statin, compared with placebo, on percent change from baseline in low-density lipoprotein cholesterol (LDL-C) in patients with primary hypercholesterolemia and mixed dyslipidemia.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations and guidelines, and Food and Drug Administration (FDA) regulations, and guidelines set forth in 21 CFR Parts 11, 50, 54, 56, and 312.
All subjects provided written informed consent before undergoing any study-related procedures, including screening procedures.
The study protocol, amendments, and the informed consent form (ICF) were reviewed by the Institutional Review Boards (IRBs) and Independent Ethics Committees (IECs). No subjects were recruited into the study and no investigational product (IP) was shipped until the IRB/IEC gave written approval of the protocol and ICF and Amgen received copies of these approvals.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 January 2013
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	United States: 558
Country: Number of subjects enrolled	Belgium: 38
Country: Number of subjects enrolled	Canada: 176
Country: Number of subjects enrolled	Czech Republic: 238
Country: Number of subjects enrolled	Denmark: 137
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Germany: 123
Country: Number of subjects enrolled	Hungary: 64
Country: Number of subjects enrolled	Italy: 53
Country: Number of subjects enrolled	Netherlands: 40
Country: Number of subjects enrolled	Russian Federation: 122
Country: Number of subjects enrolled	Spain: 21
Country: Number of subjects enrolled	Sweden: 35
Country: Number of subjects enrolled	Switzerland: 24

Country: Number of subjects enrolled	United Kingdom: 200
Country: Number of subjects enrolled	Australia: 47
Country: Number of subjects enrolled	Hong Kong: 7
Worldwide total number of subjects	1899
EEA total number of subjects	965

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)	1226
From 65 to 84 years	673
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients aged 18 to 80 years with a screening LDL-C level of ≥ 150 mg/dL (no statin at screening), ≥ 100 mg/dL (nonintensive statin at screening), or ≥ 80 mg/dL (intensive statin at screening) and fasting triglyceride levels of 400 mg/dL or less.
First patient enrolled on 15 January2013; Last patient enrolled on 10 July 2013.

Pre-assignment

Screening details:

A total of 2067 patients were first randomized to 1 of the 5 open-label statin cohorts (atorvastatin 10 mg or 80 mg, rosuvastatin 5 mg or 40 mg, or simvastatin 40 mg), and 1899 were randomized to investigational product.
Randomization into the statin dose cohorts was stratified by entry statin therapy and by use of certain concomitant medications.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	A10 PBO Q2W

Arm description:

Participants received atorvastatin 10 mg once daily during the 4 week lipid stabilization period and then in combination with placebo (PBO) subcutaneous injection once every 2 weeks (Q2W) and placebo tablets once daily for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

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

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A10 PBO QM

Arm description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month (QM) and placebo tablets once a day for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

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

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A10 EZE (Q2W)

Arm description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe (EZE) orally once a day for up to 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Ezetimibe
Investigational medicinal product code	Zetia
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A10 EZE (QM)
Arm description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Arm type	Active comparator
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered by subcutaneous injection	
Investigational medicinal product name	Ezetimibe
Investigational medicinal product code	Zetia
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Administered orally once daily	
Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
Administered orally once a day	
Arm title	A10 EvoMab Q2W
Arm description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab (EvoMab) by subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered by subcutaneous injection	
Investigational medicinal product name	Placebo to Ezetimibe
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Administered orally once daily	
Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A10 EvoMab QM

Arm description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

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

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A80 PBO Q2W

Arm description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

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

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A80 PBO QM

Arm description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month and placebo tablets once a day for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

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

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A80 EZE (Q2W)

Arm description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe orally once a day for up to 12 weeks.

Arm type	Active comparator
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Ezetimibe
Investigational medicinal product code	Zetia
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:	
Administered orally once daily	
Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
Administered orally once a day	
Arm title	A80 EZE (QM)
Arm description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Arm type	Active comparator
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered by subcutaneous injection	
Investigational medicinal product name	Ezetimibe
Investigational medicinal product code	Zetia
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Administered orally once daily	
Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
Administered orally once a day	
Arm title	A80 EvoMab Q2W
Arm description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.	
Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered by subcutaneous injection	
Investigational medicinal product name	Placebo to Ezetimibe
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	A80 EvoMab QM

Arm description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

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

Dosage and administration details:

Administered orally once daily

Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R5 PBO Q2W

Arm description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R5 PBO QM

Arm description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R5 EvoMab Q2W

Arm description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R5 EvoMab QM

Arm description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Arm type	Experimental

Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R40 PBO Q2W

Arm description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R40 PBO QM

Arm description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R40 EvoMab Q2W

Arm description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	R40 EvoMab QM

Arm description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Rosuvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	S40 PBO Q2W

Arm description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Simvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	S40 PBO QM

Arm description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo to Evolocumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Simvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	S40 EvoMab Q2W

Arm description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Arm type	Experimental
Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered by subcutaneous injection

Investigational medicinal product name	Simvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered orally once a day

Arm title	S40 EvoMab QM

Arm description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Arm type	Experimental

Investigational medicinal product name	Evolocumab
Investigational medicinal product code	AMG 145
Other name	Repatha
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered by subcutaneous injection

Investigational medicinal product name	Simvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:
Administered orally once a day

Number of subjects in period 1	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)
Started	56	55	56
Received Treatment	56	55	56
Completed	54	54	51
Not completed	2	1	5
Consent withdrawn by subject	2	1	4
Death	-	-	-
Lost to follow-up	-	-	-
Decision by sponsor	-	-	1

Number of subjects in period 1	A10 EZE (QM)	A10 EvoMab Q2W	A10 EvoMab QM
Started	55	110	110
Received Treatment	55	110	110
Completed	55	108	107
Not completed	0	2	3
Consent withdrawn by subject	-	-	3
Death	-	-	-
Lost to follow-up	-	-	-
Decision by sponsor	-	2	-

Number of subjects in period 1	A80 PBO Q2W	A80 PBO QM	A80 EZE (Q2W)
Started	55	55	56
Received Treatment	55	55	56
Completed	48	55	53
Not completed	7	0	3
Consent withdrawn by subject	4	-	1
Death	-	-	-

Lost to follow-up	1	-	-
Decision by sponsor	2	-	2

Number of subjects in period 1	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Started	54	110	110
Received Treatment	54	109	110
Completed	53	102	108
Not completed	1	8	2
Consent withdrawn by subject	1	2	2
Death	-	-	-
Lost to follow-up	-	-	-
Decision by sponsor	-	6	-

Number of subjects in period 1	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W
Started	58	57	114
Received Treatment	58	57	113
Completed	54	57	102
Not completed	4	0	12
Consent withdrawn by subject	2	-	6
Death	-	-	-
Lost to follow-up	1	-	1
Decision by sponsor	1	-	5

Number of subjects in period 1	R5 EvoMab QM	R40 PBO Q2W	R40 PBO QM
Started	115	56	56
Received Treatment	115	56	55
Completed	112	55	55
Not completed	3	1	1
Consent withdrawn by subject	3	-	1
Death	-	1	-
Lost to follow-up	-	-	-
Decision by sponsor	-	-	-

Number of subjects in period 1	R40 EvoMab Q2W	R40 EvoMab QM	S40 PBO Q2W
Started	111	112	56
Received Treatment	111	112	56
Completed	105	110	52
Not completed	6	2	4
Consent withdrawn by subject	1	1	2
Death	-	-	-
Lost to follow-up	1	1	-
Decision by sponsor	4	-	2

Number of subjects in period 1	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Started	55	112	115
Received Treatment	55	112	115
Completed	54	109	113
Not completed	1	3	2
Consent withdrawn by subject	1	2	1
Death	-	-	-
Lost to follow-up	-	-	1
Decision by sponsor	-	1	-

Reporting groups	
Reporting group title	A10 PBO Q2W
Reporting group description:	
Participants received atorvastatin 10 mg once daily during the 4 week lipid stabilization period and then in combination with placebo (PBO) subcutaneous injection once every 2 weeks (Q2W) and placebo tablets once daily for up to 12 weeks.	
Reporting group title	A10 PBO QM
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month (QM) and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A10 EZE (Q2W)
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe (EZE) orally once a day for up to 12 weeks.	
Reporting group title	A10 EZE (QM)
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Reporting group title	A10 EvoMab Q2W
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab (EvoMab) by subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A10 EvoMab QM
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A80 PBO Q2W
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A80 PBO QM
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A80 EZE (Q2W)
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Reporting group title	A80 EZE (QM)
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Reporting group title	A80 EvoMab Q2W
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks and placebo	

tablets once a day for up to 12 weeks.

Reporting group title	A80 EvoMab QM

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.

Reporting group title	R5 PBO Q2W

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R5 PBO QM

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	R5 EvoMab Q2W

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R5 EvoMab QM

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group title	R40 PBO Q2W

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R40 PBO QM

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	R40 EvoMab Q2W

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R40 EvoMab QM

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group title	S40 PBO Q2W

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	S40 PBO QM

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	S40 EvoMab Q2W

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	S40 EvoMab QM

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)
Number of subjects	56	55	56
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	58.3	62.2	61
standard deviation	± 10.5	± 10.4	± 9
Gender, Male/Female Units: participants			
Female	24	28	29
Male	32	27	27
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	3	2	2
Not Hispanic or Latino	53	53	54
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	2
Black or African American	3	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	52	55	53
Other	0	0	0
Mixed Race	0	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	18	19	10
Non-intensive statin use	20	25	30
No statin use	18	11	16
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	123	123.7	126.8
standard deviation	± 46.6	± 47.9	± 49.6
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	149.1	147.7	153.8
standard deviation	± 46.9	± 51.4	± 53.2
Apolipoprotein B Concentration			
Data are provided for the full analysis set			

Units: mg/dL			
arithmetic mean	95.3	95.3	101.3
standard deviation	± 26	± 29.6	± 31.2
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	3.988	3.859	4.112
standard deviation	± 1.154	± 1.396	± 1.311
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.666	0.647	0.692
standard deviation	± 0.216	± 0.266	± 0.243
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	31.5	41	37
inter-quartile range (Q1-Q3)	13 to 87.5	15 to 106	9.5 to 190
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	112	108	129.5
inter-quartile range (Q1-Q3)	83 to 176	83 to 145	94 to 151.5
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	22	22	25.5
inter-quartile range (Q1-Q3)	17 to 35	17 to 29	19 to 30
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	54.1	57.9	54.1
standard deviation	± 16.6	± 18.4	± 17.2

Reporting group values	A10 EZE (QM)	A10 EvoMab Q2W	A10 EvoMab QM
Number of subjects	55	110	110
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	60.6	58.3	59.6
standard deviation	± 9.2	± 8.4	± 11.1
Gender, Male/Female Units: participants			
Female	28	56	44
Male	27	54	66
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	5	2

Not Hispanic or Latino	54	105	108
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	3	4
Black or African American	2	9	4
Native Hawaiian or Other Pacific Islander	0	0	0
White	52	97	101
Other	0	1	0
Mixed Race	0	0	1
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	14	28	35
Non-intensive statin use	21	52	40
No statin use	20	30	35
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	119.3	124.2	126.1
standard deviation	± 28.1	± 43.4	± 50.4
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	148.3	152.3	154.3
standard deviation	± 36.8	± 45.6	± 53.1
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	94.6	99.7	97.3
standard deviation	± 20.4	± 26.4	± 28.9
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	4.002	3.98	4.1
standard deviation	± 1.1	± 1.224	± 1.636
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.64	0.663	0.659
standard deviation	± 0.169	± 0.217	± 0.249
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	33	27	49
inter-quartile range (Q1-Q3)	8 to 163	8 to 120	11 to 169
Triglyceride Concentration			

Data are provided for the full analysis set			
Units: mg/dL			
median	119	135	119
inter-quartile range (Q1-Q3)	87 to 168	99 to 189	84 to 161
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	24	27	24
inter-quartile range (Q1-Q3)	17 to 33	20 to 38	17 to 32
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	52.7	56	56.1
standard deviation	± 13.7	± 17.9	± 17.8

Reporting group values	A80 PBO Q2W	A80 PBO QM	A80 EZE (Q2W)
Number of subjects	55	55	56
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	57.1	58.8	60.5
standard deviation	± 9.9	± 11.5	± 10.2
Gender, Male/Female			
Units: participants			
Female	22	24	24
Male	33	31	32
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	5	5	4
Not Hispanic or Latino	50	50	52
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Black or African American	1	2	3
Native Hawaiian or Other Pacific Islander	0	1	0
White	51	52	53
Other	2	0	0
Mixed Race	0	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	15	12	21
Non-intensive statin use	22	27	22
No statin use	18	16	13

Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	100.3	94.7	98.7
standard deviation	± 36.2	± 31.9	± 34
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	124.2	116.5	124.8
standard deviation	± 39.3	± 35.7	± 35.4
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	81.1	80.1	85.3
standard deviation	± 22.1	± 21.4	± 23.1
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	3.704	3.461	3.748
standard deviation	± 1.26	± 1.093	± 1.099
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.603	0.571	0.64
standard deviation	± 0.221	± 0.189	± 0.234
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	53	50	25
inter-quartile range (Q1-Q3)	15 to 177	13 to 152	12 to 108
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	104	104	133
inter-quartile range (Q1-Q3)	82 to 142	76 to 124	89 to 155
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	21	21	26.5
inter-quartile range (Q1-Q3)	16 to 28	15 to 25	18 to 31
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	50.6	50.9	48.7
standard deviation	± 15.6	± 13	± 12.6

Reporting group values	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Number of subjects	54	110	110

Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	61.1	59.7	60.1
standard deviation	± 8.9	± 10.2	± 10.2
Gender, Male/Female Units: participants			
Female	28	44	48
Male	26	66	62
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	4	5	7
Not Hispanic or Latino	50	105	103
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	1	1
Black or African American	4	3	4
Native Hawaiian or Other Pacific Islander	1	0	0
White	46	105	105
Other	0	1	0
Mixed Race	0	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	11	34	35
Non-intensive statin use	21	47	46
No statin use	22	29	29
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	92.3	94.2	93.8
standard deviation	± 19.3	± 34.8	± 32.3
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	118.4	120.2	117.2
standard deviation	± 25.5	± 42.3	± 36.3
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	78.7	79.9	77.9
standard deviation	± 16.9	± 25.1	± 21.5
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			

Units: ratio			
arithmetic mean	3.54	3.696	3.462
standard deviation	± 1.1	± 1.371	± 1
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.56	0.593	0.562
standard deviation	± 0.157	± 0.227	± 0.171
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	61.5	32	24.5
inter-quartile range (Q1-Q3)	12 to 192	11.5 to 135.5	8 to 93
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	109	104	106.5
inter-quartile range (Q1-Q3)	80 to 171	81 to 163	79 to 137
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	22	21	21
inter-quartile range (Q1-Q3)	16 to 34	16 to 33	16 to 27
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	51.6	48.5	50.8
standard deviation	± 15.1	± 12.9	± 13.5

Reporting group values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W
Number of subjects	58	57	114
Age categorical Units: Subjects			

Age Continuous Units: years			
arithmetic mean	61.2	59.6	58.9
standard deviation	± 9.1	± 9.2	± 11.2
Gender, Male/Female Units: participants			
Female	35	27	52
Male	23	30	62
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	2	4	6
Not Hispanic or Latino	56	53	108
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2

Black or African American	2	1	7
Native Hawaiian or Other Pacific Islander	0	0	0
White	56	56	104
Other	0	0	1
Mixed Race	0	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	13	13	33
Non-intensive statin use	25	28	49
No statin use	20	16	32
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	115.6	119.9	118.7
standard deviation	± 39.8	± 39.1	± 40.9
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	141.1	148.3	146.6
standard deviation	± 41.6	± 43.3	± 43.2
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	93.1	95.9	95.4
standard deviation	± 27.3	± 25.2	± 27
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	4.044	3.891	3.915
standard deviation	± 1.685	± 1.234	± 1.216
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.661	0.636	0.64
standard deviation	± 0.273	± 0.207	± 0.249
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	34	35	38
inter-quartile range (Q1-Q3)	8 to 158	14 to 156.5	11 to 165
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	112.5	134	116
inter-quartile range (Q1-Q3)	89 to 148	86 to 184	90 to 168
Very Low Density Lipoprotein			

Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	22.5	27	23
inter-quartile range (Q1-Q3)	18 to 30	17 to 37	18 to 34
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	52.1	55.5	54.5
standard deviation	± 14.9	± 16	± 15

Reporting group values	R5 EvoMab QM	R40 PBO Q2W	R40 PBO QM
Number of subjects	115	56	56
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	59.3	60.2	58.3
standard deviation	± 10.5	± 8.7	± 11.3
Gender, Male/Female			
Units: participants			
Female	51	21	27
Male	64	35	29
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	3	2	3
Not Hispanic or Latino	112	54	53
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Black or African American	5	0	3
Native Hawaiian or Other Pacific Islander	1	0	0
White	107	55	52
Other	1	0	1
Mixed Race	0	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	38	13	13
Non-intensive statin use	42	23	22
No statin use	35	20	21
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	122.9	77.4	102.9
standard deviation	± 42	± 20.9	± 49.3

Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	152	103.9	128.7
standard deviation	± 46.4	± 25.7	± 53.4
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	97.2	71	84.8
standard deviation	± 26.9	± 16.6	± 29.7
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	4.178	3.086	3.547
standard deviation	± 1.932	± 0.728	± 1.355
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.676	0.479	0.562
standard deviation	± 0.341	± 0.129	± 0.217
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	32	28.5	33
inter-quartile range (Q1-Q3)	9 to 172	7 to 171	11 to 148
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	121	128	116
inter-quartile range (Q1-Q3)	93 to 161	91.5 to 162	78 to 160
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	24	26	23
inter-quartile range (Q1-Q3)	19 to 32	18.5 to 32.5	16 to 32
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	54	52.8	56
standard deviation	± 16	± 12.9	± 18.7

Reporting group values	R40 EvoMab Q2W	R40 EvoMab QM	S40 PBO Q2W
Number of subjects	111	112	56
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	59.5	59.6	61.9

standard deviation	± 9.2	± 9	± 9.7

Gender, Male/Female Units: participants			
Female	43	52	32
Male	68	60	24
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	6	5	1
Not Hispanic or Latino	105	107	55
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	3
Black or African American	5	3	3
Native Hawaiian or Other Pacific Islander	0	0	1
White	105	109	49
Other	0	0	0
Mixed Race	1	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	33	37	19
Non-intensive statin use	50	44	21
No statin use	28	31	16
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	88.5	88.5	110.3
standard deviation	± 31.5	± 31.3	± 28
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	113.5	114.3	138.4
standard deviation	± 36	± 34.7	± 29.3
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	77.4	78.7	91.6
standard deviation	± 22.3	± 23.1	± 18.4
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	3.413	3.307	3.733
standard deviation	± 1.355	± 1.061	± 1.079
Apolipoprotein B/Apolipoprotein A1			

Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.538	0.536	0.611
standard deviation	± 0.227	± 0.193	± 0.179
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	41	49.5	36.5
inter-quartile range (Q1-Q3)	10 to 183	11 to 184.5	17.5 to 140.5
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	102	119.5	124
inter-quartile range (Q1-Q3)	79 to 151	87 to 149.5	90 to 173
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	20	24	25
inter-quartile range (Q1-Q3)	16 to 30	17 to 30	18 to 34.5
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	53.2	53.8	55
standard deviation	± 16.4	± 14.6	± 14.2

Reporting group values	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Number of subjects	55	112	115
Age categorical			
Units: Subjects			
Age Continuous			
Units: years			
arithmetic mean	61.5	59.7	61.5
standard deviation	± 10.3	± 9.2	± 9.6
Gender, Male/Female			
Units: participants			
Female	28	45	59
Male	27	67	56
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	2	3	5
Not Hispanic or Latino	53	109	110
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	1	0
Black or African American	1	4	5
Native Hawaiian or Other Pacific Islander	0	0	0
White	54	106	110

Other	0	0	0
Mixed Race	0	0	0
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	13	31	34
Non-intensive statin use	26	45	48
No statin use	16	36	33
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean	108.6	114.9	123.7
standard deviation	± 30.9	± 34.5	± 48.5
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			
arithmetic mean	135.7	146.8	151.2
standard deviation	± 38.4	± 41.8	± 51.5
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
arithmetic mean	89.8	94.2	96.5
standard deviation	± 20.7	± 24	± 27.5
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	3.595	4.196	3.924
standard deviation	± 1.345	± 1.436	± 1.42
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio			
arithmetic mean	0.581	0.657	0.639
standard deviation	± 0.174	± 0.193	± 0.224
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L			
median	28	32.5	37
inter-quartile range (Q1-Q3)	13 to 180	13 to 157	11 to 141
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	106	129	110
inter-quartile range (Q1-Q3)	87 to 139	91.5 to 195	84 to 161
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL			
median	21	26	22

inter-quartile range (Q1-Q3)	17 to 26	18.5 to 39	17 to 32
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL			
arithmetic mean	59.9	49.7	57.3
standard deviation	± 21.8	± 12.6	± 17.4

Reporting group values	Total		
Number of subjects	1899		
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: participants			
Female	871		
Male	1028		
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	87		
Not Hispanic or Latino	1812		
Race/Ethnicity, Customized			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	25		
Black or African American	75		
Native Hawaiian or Other Pacific Islander	4		
White	1785		
Other	7		
Mixed Race	2		
Stratification Factor: Entry Statin Therapy			
Intensive statin use was defined as daily atorvastatin (40mg or greater), rosuvastatin (20mg or greater), simvastatin (80 mg), or any statin plus ezetimibe.			
Units: Subjects			
Intensive statin use	542		
Non-intensive statin use	796		
No statin use	561		
Low-Density Lipoprotein Cholesterol (LDL-C) Concentration			
Data are provided for the full analysis set (all participants randomized to investigational product (IP) who received at least 1 dose of IP (subcutaneously or orally).			
Units: mg/dL			
arithmetic mean			
standard deviation	-		
Non-High-Density Lipoprotein Cholesterol (non-HDL-C) Concentration			
Data are provided for the full analysis set.			
Units: mg/dL			

arithmetic mean standard deviation	- 		
Apolipoprotein B Concentration			
Data are provided for the full analysis set			
Units: mg/dL arithmetic mean standard deviation	- 		
Total Cholesterol/HDL-C Ratio			
Data are provided for the full analysis set			
Units: ratio arithmetic mean standard deviation	- 		
Apolipoprotein B/Apolipoprotein A1 Ratio			
Data are provided for the full analysis set			
Units: ratio arithmetic mean standard deviation	- 		
Lipoprotein(a) Concentration			
Data are provided for the full analysis set			
Units: nmol/L median inter-quartile range (Q1-Q3)	- 		
Triglyceride Concentration			
Data are provided for the full analysis set			
Units: mg/dL median inter-quartile range (Q1-Q3)	- 		
Very Low Density Lipoprotein Cholesterol (VLDL-C) Concentration			
Data are provided for the full analysis set			
Units: mg/dL median inter-quartile range (Q1-Q3)	- 		
HDL-C Concentration			
Data are provided for the full anlaysis set			
Units: mg/dL arithmetic mean standard deviation	- 		

End points reporting groups

Reporting group title	A10 PBO Q2W
Reporting group description:	
Participants received atorvastatin 10 mg once daily during the 4 week lipid stabilization period and then in combination with placebo (PBO) subcutaneous injection once every 2 weeks (Q2W) and placebo tablets once daily for up to 12 weeks.	
Reporting group title	A10 PBO QM
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month (QM) and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A10 EZE (Q2W)
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe (EZE) orally once a day for up to 12 weeks.	
Reporting group title	A10 EZE (QM)
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Reporting group title	A10 EvoMab Q2W
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab (EvoMab) by subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A10 EvoMab QM
Reporting group description:	
Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A80 PBO Q2W
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A80 PBO QM
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month and placebo tablets once a day for up to 12 weeks.	
Reporting group title	A80 EZE (Q2W)
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Reporting group title	A80 EZE (QM)
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.	
Reporting group title	A80 EvoMab Q2W
Reporting group description:	
Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks and placebo	

tablets once a day for up to 12 weeks.

Reporting group title	A80 EvoMab QM

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.

Reporting group title	R5 PBO Q2W

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R5 PBO QM

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	R5 EvoMab Q2W

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R5 EvoMab QM

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group title	R40 PBO Q2W

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R40 PBO QM

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	R40 EvoMab Q2W

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R40 EvoMab QM

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group title	S40 PBO Q2W

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	S40 PBO QM

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	S40 EvoMab Q2W

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	S40 EvoMab QM

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Primary: Percent Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 12

End point title	Percent Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 12

End point description:

Calculated LDL-C was determined based on the Friedewald equation.
Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Primary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	9.86 (± 2.53)	0.97 (± 2.82)	-21.96 (± 2.63)	-17.08 (± 2.78)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-61.56 (± 1.81)	-58.19 (± 1.99)	14.49 (± 4.42)	11.83 (± 3.85)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-14.6 (± 4.29)	-19.8 (± 3.85)	-61.8 (± 3.04)	-58.68 (± 2.74)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				

least squares mean (standard error)	8.12 (± 2.68)	5.1 (± 2.62)	-60.09 (± 1.94)	-59.4 (± 1.87)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	9.42 (± 3.6)	2.59 (± 4.3)	-58.89 (± 2.58)	-52.4 (± 2.98)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	4.7 (± 3.61)	3.4 (± 4.94)	-65.86 (± 3.05)	-57.02 (± 3.93)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 EvoMab Q2W v A10 PBO Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [1]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-71.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-77.55
upper limit	-65.29
Variability estimate	Standard error of the mean
Dispersion value	3.11

Notes:

[1] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.94
upper limit	-52.38
Variability estimate	Standard error of the mean
Dispersion value	3.44

Notes:

[2] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-39.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.81
upper limit	-33.4
Variability estimate	Standard error of the mean
Dispersion value	3.15

Notes:

[3] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 EZE (QM) v A10 EvoMab QM

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-41.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.83
upper limit	-34.37
Variability estimate	Standard error of the mean
Dispersion value	3.41

Notes:

[4] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-76.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-86.87
upper limit	-65.72
Variability estimate	Standard error of the mean
Dispersion value	5.36

Notes:

[5] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 PBO QM v A80 EvoMab QM

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [6]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-70.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-79.81
upper limit	-61.2
Variability estimate	Standard error of the mean
Dispersion value	4.72

Notes:

[6] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [7]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-47.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.54
upper limit	-36.86
Variability estimate	Standard error of the mean
Dispersion value	5.24

Notes:

[7] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 EZE (QM) v A80 EvoMab QM

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [8]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-38.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.21
upper limit	-29.56
Variability estimate	Standard error of the mean
Dispersion value	4.73

Notes:

[8] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [9]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-68.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-74.72
upper limit	-61.7
Variability estimate	Standard error of the mean
Dispersion value	3.3

Notes:

[9] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R5 PBO QM v R5 EvoMab QM

Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [10]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-64.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-70.84
upper limit	-58.14
Variability estimate	Standard error of the mean
Dispersion value	3.21

Notes:

[10] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [11]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-68.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-77.04
upper limit	-59.57
Variability estimate	Standard error of the mean
Dispersion value	4.42

Notes:

[11] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R40 PBO QM v R40 EvoMab QM

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [12]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-54.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.31
upper limit	-44.65
Variability estimate	Standard error of the mean
Dispersion value	5.23

Notes:

[12] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [13]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-70.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-76.72
upper limit	-64.41
Variability estimate	Standard error of the mean
Dispersion value	3.12

Notes:

[13] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the percent change from Baseline at Week 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	S40 PBO QM v S40 EvoMab QM

Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [14]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-60.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.11
upper limit	-51.72
Variability estimate	Standard error of the mean
Dispersion value	4.41

Notes:

[14] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Primary: Mean Percent Change From Baseline in LDL-C at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in LDL-C at Weeks 10 and 12

End point description:

Calculated LDL-C was determined based on the Friedewald equation.
Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Primary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	8.54 (± 2.24)	0.35 (± 2.6)	-23.88 (± 2.34)	-18.98 (± 2.57)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-61.41 (± 1.61)	-62.47 (± 1.83)	13.12 (± 3.99)	9.76 (± 3.39)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-16.85 (± 3.88)	-21.25 (± 3.42)	-61.8 (± 2.77)	-65.05 (± 2.42)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	7.55 (± 2.39)	2.79 (± 2.5)	-59.33 (± 1.74)	-63.79 (± 1.76)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	6.57 (± 3.11)	-0.02 (± 3.51)	-59.08 (± 2.23)	-62.94 (± 2.44)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	3.26 (± 3.4)	6 (± 4.8)	-66.17 (± 2.93)	-62.45 (± 3.85)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [15]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-69.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-75.38
upper limit	-64.51
Variability estimate	Standard error of the mean
Dispersion value	2.76

Notes:

[15] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [16]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-62.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.06
upper limit	-56.57
Variability estimate	Standard error of the mean
Dispersion value	3.17

Notes:

[16] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [17]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.03
upper limit	-32.03
Variability estimate	Standard error of the mean
Dispersion value	2.79

Notes:

[17] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [18]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-43.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-49.7
upper limit	-37.28
Variability estimate	Standard error of the mean
Dispersion value	3.15

Notes:

[18] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [19]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-74.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-84.49
upper limit	-65.35
Variability estimate	Standard error of the mean
Dispersion value	4.85

Notes:

[19] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [20]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-74.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-83
upper limit	-66.62
Variability estimate	Standard error of the mean
Dispersion value	4.15

Notes:

[20] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [21]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.32
upper limit	-35.57
Variability estimate	Standard error of the mean
Dispersion value	4.75

Notes:

[21] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)

Statistical analysis description:

The null hypothesis was that there was no mean difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and ezetimibe, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [22]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-43.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.06
upper limit	-35.55
Variability estimate	Standard error of the mean
Dispersion value	4.19

Notes:

[22] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W

Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [23]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-66.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-72.67
upper limit	-61.08
Variability estimate	Standard error of the mean
Dispersion value	2.93

Notes:

[23] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [24]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-66.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-72.6
upper limit	-60.56
Variability estimate	Standard error of the mean
Dispersion value	3.05

Notes:

[24] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [25]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-65.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-73.19
upper limit	-58.12
Variability estimate	Standard error of the mean
Dispersion value	3.81

Notes:

[25] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [26]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-62.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-71.37
upper limit	-54.46
Variability estimate	Standard error of the mean
Dispersion value	4.27

Notes:

[26] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W

Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [27]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-69.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-74.86
upper limit	-64.01
Variability estimate	Standard error of the mean
Dispersion value	2.74

Notes:

[27] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM

Statistical analysis description:

The null hypothesis was that there was no difference in the mean percent change from Baseline at Weeks 10 and 12 in LDL-C between evolocumab and placebo, and the alternative hypothesis was that a mean difference did exist.

Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [28]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-68.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-76.68
upper limit	-60.22
Variability estimate	Standard error of the mean
Dispersion value	4.17

Notes:

[28] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Change From Baseline in LDL-C at Weeks 10 and 12

End point title	Mean Change From Baseline in LDL-C at Weeks 10 and 12

End point description:

Calculated LDL-C was determined based on the Friedewald equation.
Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: mg/dL				
least squares mean (standard error)	6.8 (± 3.7)	-0.4 (± 4.4)	-32.4 (± 3.8)	-25.1 (± 4.3)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: mg/dL				
least squares mean (standard error)	-76.8 (± 2.7)	-80.1 (± 3.1)	11 (± 5)	5.5 (± 3.7)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: mg/dL				
least squares mean (standard error)	-13 (± 4.9)	-21.3 (± 3.7)	-58.8 (± 3.5)	-60.1 (± 2.6)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: mg/dL				
least squares mean (standard error)	6.5 (± 3.5)	0.1 (± 4.2)	-68.9 (± 2.5)	-77.8 (± 3)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: mg/dL				
least squares mean (standard error)	3.4 (± 3)	-4.8 (± 4.2)	-52.3 (± 2.2)	-55.3 (± 2.9)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: mg/dL				
least squares mean (standard error)	-5.7 (± 5.2)	1.7 (± 6.5)	-83.8 (± 4.5)	-78.4 (± 5.1)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [29]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-83.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-92.6
upper limit	-74.6
Variability estimate	Standard error of the mean
Dispersion value	4.5

Notes:

[29] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [30]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-79.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-90.2
upper limit	-69.2
Variability estimate	Standard error of the mean
Dispersion value	5.3

Notes:

[30] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [31]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.4
upper limit	-35.3
Variability estimate	Standard error of the mean
Dispersion value	4.4

Notes:

[31] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [32]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.4
upper limit	-44.6
Variability estimate	Standard error of the mean
Dispersion value	5.3

Notes:

[32] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [33]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-69.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-81.9
upper limit	-57.8
Variability estimate	Standard error of the mean
Dispersion value	6.1

Notes:

[33] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [34]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-65.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-74.5
upper limit	-56.7
Variability estimate	Standard error of the mean
Dispersion value	4.5

Notes:

[34] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.001 [35]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-45.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.7
upper limit	-33.9
Variability estimate	Standard error of the mean
Dispersion value	6

Notes:

[35] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [36]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-38.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.8
upper limit	-29.9
Variability estimate	Standard error of the mean
Dispersion value	4.5

Notes:

[36] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [37]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-75.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-83.9
upper limit	-67
Variability estimate	Standard error of the mean
Dispersion value	4.3

Notes:

[37] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [38]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-77.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-88
upper limit	-67.8
Variability estimate	Standard error of the mean
Dispersion value	5.1

Notes:

[38] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [39]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-55.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.1
upper limit	-48.4
Variability estimate	Standard error of the mean
Dispersion value	3.7

Notes:

[39] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [40]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-50.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.6
upper limit	-40.6
Variability estimate	Standard error of the mean
Dispersion value	5.1

Notes:

[40] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [41]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-78.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-86.2
upper limit	-70
Variability estimate	Standard error of the mean
Dispersion value	4.1

Notes:

[41] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [42]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-80.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-91.7
upper limit	-68.6
Variability estimate	Standard error of the mean
Dispersion value	5.8

Notes:

[42] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Change From Baseline in LDL-C at Week 12

End point title	Change From Baseline in LDL-C at Week 12

End point description:

Calculated LDL-C was determined based on the Friedewald equation.
Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: mg/dL				
least squares mean (standard error)	8.6 (± 4)	0.8 (± 4.5)	-30.1 (± 4.1)	-23.3 (± 4.5)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: mg/dL				
least squares mean (standard error)	-77 (± 2.9)	-75.1 (± 3.2)	12.7 (± 5.3)	7 (± 4.1)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: mg/dL				
least squares mean (standard error)	-9.9 (± 5.2)	-19.5 (± 4.1)	-59 (± 3.7)	-54.8 (± 2.9)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: mg/dL				
least squares mean (standard error)	7.8 (± 3.8)	2.4 (± 4.4)	-69.2 (± 2.7)	-73.3 (± 3.1)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: mg/dL				
least squares mean (standard error)	5.1 (± 3.2)	-2 (± 4.7)	-52.1 (± 2.3)	-46.7 (± 3.3)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: mg/dL				
least squares mean (standard error)	-4.5 (± 5.3)	-0.6 (± 6.6)	-83.5 (± 4.6)	-72.5 (± 5.2)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [43]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-85.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-95.2
upper limit	-75.9
Variability estimate	Standard error of the mean
Dispersion value	4.9

Notes:

[43] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [44]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-75.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-86.8
upper limit	-64.9
Variability estimate	Standard error of the mean
Dispersion value	5.5

Notes:

[44] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [45]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-46.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-56.6
upper limit	-37.1
Variability estimate	Standard error of the mean
Dispersion value	4.9

Notes:

[45] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [46]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-51.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-62.6
upper limit	-40.9
Variability estimate	Standard error of the mean
Dispersion value	5.5

Notes:

[46] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [47]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-71.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-84.4
upper limit	-59
Variability estimate	Standard error of the mean
Dispersion value	6.4

Notes:

[47] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [48]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-61.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-71.6
upper limit	-52
Variability estimate	Standard error of the mean
Dispersion value	5

Notes:

[48] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [49]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.5
upper limit	-36.6
Variability estimate	Standard error of the mean
Dispersion value	6.3

Notes:

[49] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [50]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-35.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.2
upper limit	-25.5
Variability estimate	Standard error of the mean
Dispersion value	5

Notes:

[50] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [51]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-77.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-86.2
upper limit	-67.9
Variability estimate	Standard error of the mean
Dispersion value	4.6

Notes:

[51] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [52]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-75.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-86.3
upper limit	-65.3
Variability estimate	Standard error of the mean
Dispersion value	5.3

Notes:

[52] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [53]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.1
upper limit	-49.4
Variability estimate	Standard error of the mean
Dispersion value	4

Notes:

[53] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [54]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.9
upper limit	-33.4
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[54] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [55]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-87.5
upper limit	-70.4
Variability estimate	Standard error of the mean
Dispersion value	4.3

Notes:

[55] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [56]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-71.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-83.8
upper limit	-60
Variability estimate	Standard error of the mean
Dispersion value	6

Notes:

[56] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in Non-High-Density Lipoprotein Cholesterol (non-HDL-C) at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in Non-High-Density Lipoprotein Cholesterol (non-HDL-C) at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.8 (± 2.07)	1.28 (± 2.44)	-20.71 (± 2.15)	-16.56 (± 2.41)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-53.48 (± 1.48)	-56.09 (± 1.71)	10.74 (± 3.59)	8.45 (± 3.13)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-16.19 (± 3.49)	-18.79 (± 3.16)	-54.44 (± 2.49)	-56.31 (± 2.23)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	7.02 (± 2.11)	3.73 (± 2.32)	-52.59 (± 1.54)	-55.47 (± 1.64)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	6.19 (± 2.61)	1.58 (± 2.9)	-52.08 (± 1.88)	-55.72 (± 2.01)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	0.74 (± 3.23)	6.81 (± 4.35)	-59.33 (± 2.79)	-56.01 (± 3.49)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [57]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-60.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.29
upper limit	-55.27
Variability estimate	Standard error of the mean
Dispersion value	2.54

Notes:

[57] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [58]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.23
upper limit	-51.51
Variability estimate	Standard error of the mean
Dispersion value	2.97

Notes:

[58] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [59]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.84
upper limit	-27.7
Variability estimate	Standard error of the mean
Dispersion value	2.57

Notes:

[59] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [60]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-39.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.34
upper limit	-33.71
Variability estimate	Standard error of the mean
Dispersion value	2.95

Notes:

[60] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [61]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-65.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-73.78
upper limit	-56.56
Variability estimate	Standard error of the mean
Dispersion value	4.37

Notes:

[61] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [62]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-64.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-72.32
upper limit	-57.19
Variability estimate	Standard error of the mean
Dispersion value	3.84

Notes:

[62] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001 [63]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-38.25

Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.68
upper limit	-29.81
Variability estimate	Standard error of the mean
Dispersion value	4.28

Notes:

[63] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [64]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.15
upper limit	-29.9
Variability estimate	Standard error of the mean
Dispersion value	3.87

Notes:

[64] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [65]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.73
upper limit	-54.48
Variability estimate	Standard error of the mean
Dispersion value	2.6

Notes:

[65] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [66]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.8
upper limit	-53.6
Variability estimate	Standard error of the mean
Dispersion value	2.83

Notes:

[66] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [67]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-58.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.6
upper limit	-51.94
Variability estimate	Standard error of the mean
Dispersion value	3.2

Notes:

[67] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [68]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.31

Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.29
upper limit	-50.32
Variability estimate	Standard error of the mean
Dispersion value	3.53

Notes:

[68] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [69]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-60.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.18
upper limit	-54.94
Variability estimate	Standard error of the mean
Dispersion value	2.59

Notes:

[69] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [70]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-62.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-70.22
upper limit	-55.42
Variability estimate	Standard error of the mean
Dispersion value	3.75

Notes:

[70] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in non-HDL-C at Week 12

End point title	Percent Change From Baseline in non-HDL-C at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	8.25 (± 2.32)	2.43 (± 2.69)	-18.27 (± 2.4)	-14.78 (± 2.65)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-53.39 (± 1.66)	-52.2 (± 1.9)	11.79 (± 3.87)	9.95 (± 3.51)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-14.34 (± 3.75)	-17.26 (± 3.52)	-54.84 (± 2.66)	-50.05 (± 2.5)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	7.92 (± 2.4)	5.85 (± 2.42)	-52.04 (± 1.74)	-51.57 (± 1.72)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	8.61 (± 3.04)	3.35 (± 3.53)	-50.97 (± 2.18)	-46.42 (± 2.45)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	1.89 (± 3.38)	5.66 (± 4.53)	-59.02 (± 2.87)	-50.96 (± 3.6)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [71]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-61.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-67.25
upper limit	-56.03
Variability estimate	Standard error of the mean
Dispersion value	2.84

Notes:

[71] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [72]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-54.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.4
upper limit	-48.46
Variability estimate	Standard error of the mean
Dispersion value	3.28

Notes:

[72] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [73]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-35.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.79
upper limit	-29.44
Variability estimate	Standard error of the mean
Dispersion value	2.88

Notes:

[73] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [74]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.15
upper limit	-31.3
Variability estimate	Standard error of the mean
Dispersion value	3.26

Notes:

[74] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [75]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-66.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-75.88
upper limit	-57.39
Variability estimate	Standard error of the mean
Dispersion value	4.69

Notes:

[75] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [76]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-60.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-68.49
upper limit	-51.52
Variability estimate	Standard error of the mean
Dispersion value	4.3

Notes:

[76] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [77]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-40.51

Confidence interval	
level	95 %
sides	2-sided
lower limit	-49.55
upper limit	-31.47
Variability estimate	Standard error of the mean
Dispersion value	4.59

Notes:

[77] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [78]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.3
upper limit	-24.28
Variability estimate	Standard error of the mean
Dispersion value	4.32

Notes:

[78] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [79]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.78
upper limit	-54.13
Variability estimate	Standard error of the mean
Dispersion value	2.95

Notes:

[79] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [80]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.27
upper limit	-51.57
Variability estimate	Standard error of the mean
Dispersion value	2.96

Notes:

[80] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [81]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-66.95
upper limit	-52.21
Variability estimate	Standard error of the mean
Dispersion value	3.73

Notes:

[81] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [82]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-49.76

Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.26
upper limit	-41.27
Variability estimate	Standard error of the mean
Dispersion value	4.3

Notes:

[82] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [83]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-60.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-66.57
upper limit	-55.24
Variability estimate	Standard error of the mean
Dispersion value	2.87

Notes:

[83] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [84]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.63
upper limit	-48.62
Variability estimate	Standard error of the mean
Dispersion value	4.06

Notes:

[84] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in Apolipoprotein B at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in Apolipoprotein B at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	7.55 (± 1.89)	0.81 (± 2.19)	-17.29 (± 2)	-11.43 (± 2.2)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-50.95 (± 1.38)	-51.44 (± 1.52)	10.2 (± 3.02)	5.48 (± 2.83)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-14.22 (± 2.98)	-13.62 (± 2.87)	-49.14 (± 2.13)	-53.26 (± 2.02)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	5.07 (± 1.97)	2.54 (± 1.89)	-49.79 (± 1.46)	-53.59 (± 1.32)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	3.71 (± 2.46)	1.98 (± 2.57)	-47.07 (± 1.76)	-52.95 (± 1.76)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-0.31 (± 3.02)	2.49 (± 4.67)	-55.65 (± 2.63)	-54.37 (± 3.93)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [85]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-58.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.1
upper limit	-53.89
Variability estimate	Standard error of the mean
Dispersion value	2.34

Notes:

[85] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [86]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-52.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.49
upper limit	-47.01
Variability estimate	Standard error of the mean
Dispersion value	2.66

Notes:

[86] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [87]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-33.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.33
upper limit	-28.98
Variability estimate	Standard error of the mean
Dispersion value	2.37

Notes:

[87] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [88]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-40.01

Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.27
upper limit	-34.74
Variability estimate	Standard error of the mean
Dispersion value	2.67

Notes:

[88] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [89]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-66.61
upper limit	-52.07
Variability estimate	Standard error of the mean
Dispersion value	3.69

Notes:

[89] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [90]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-58.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.56
upper limit	-51.93
Variability estimate	Standard error of the mean
Dispersion value	3.46

Notes:

[90] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [91]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-34.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.09
upper limit	-27.75
Variability estimate	Standard error of the mean
Dispersion value	3.64

Notes:

[91] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [92]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-39.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.57
upper limit	-32.71
Variability estimate	Standard error of the mean
Dispersion value	3.52

Notes:

[92] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [93]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-54.86

Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.66
upper limit	-50.05
Variability estimate	Standard error of the mean
Dispersion value	2.43

Notes:

[93] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [94]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.66
upper limit	-51.61
Variability estimate	Standard error of the mean
Dispersion value	2.29

Notes:

[94] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [95]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-50.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-56.72
upper limit	-44.83
Variability estimate	Standard error of the mean
Dispersion value	3.01

Notes:

[95] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [96]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-54.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.11
upper limit	-48.76
Variability estimate	Standard error of the mean
Dispersion value	3.12

Notes:

[96] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [97]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-55.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.94
upper limit	-50.74
Variability estimate	Standard error of the mean
Dispersion value	2.33

Notes:

[97] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [98]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.87

Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.27
upper limit	-50.46
Variability estimate	Standard error of the mean
Dispersion value	3.24

Notes:

[98] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in Apolipoprotein B at Week 12

End point title	Percent Change From Baseline in Apolipoprotein B at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	7.89 (± 2.16)	0.21 (± 2.43)	-15.98 (± 2.26)	-10.95 (± 2.44)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-50.9 (± 1.56)	-47.15 (± 1.7)	11.64 (± 3.28)	6.54 (± 3.22)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-12.31 (± 3.2)	-12.16 (± 3.24)	-49.77 (± 2.28)	-46.47 (± 2.31)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	6.35 (± 2.1)	4.63 (± 2.11)	-50.15 (± 1.54)	-48.58 (± 1.49)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	4.91 (± 2.71)	3.24 (± 3.13)	-45.61 (± 1.93)	-43.71 (± 2.13)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	0.35 (± 3.17)	3.57 (± 4.74)	-55.95 (± 2.72)	-49.16 (± 3.97)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [99]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-58.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.03
upper limit	-53.55
Variability estimate	Standard error of the mean
Dispersion value	2.66

Notes:

[99] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [100]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-47.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.2
upper limit	-41.52
Variability estimate	Standard error of the mean
Dispersion value	2.96

Notes:

[100] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [101]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-34.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.23
upper limit	-29.6
Variability estimate	Standard error of the mean
Dispersion value	2.69

Notes:

[101] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [102]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-36.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.06
upper limit	-30.35
Variability estimate	Standard error of the mean
Dispersion value	2.97

Notes:

[102] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [103]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-61.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.27
upper limit	-53.54
Variability estimate	Standard error of the mean
Dispersion value	3.99

Notes:

[103] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [104]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-53.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.77
upper limit	-45.25
Variability estimate	Standard error of the mean
Dispersion value	3.93

Notes:

[104] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [105]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.17
upper limit	-29.74
Variability estimate	Standard error of the mean
Dispersion value	3.91

Notes:

[105] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [106]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-34.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.15
upper limit	-26.47
Variability estimate	Standard error of the mean
Dispersion value	3.98

Notes:

[106] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [107]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.6
upper limit	-51.4
Variability estimate	Standard error of the mean
Dispersion value	2.58

Notes:

[107] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [108]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-53.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.29
upper limit	-48.13
Variability estimate	Standard error of the mean
Dispersion value	2.57

Notes:

[108] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [109]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-50.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.06
upper limit	-43.99
Variability estimate	Standard error of the mean
Dispersion value	3.31

Notes:

[109] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [110]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-46.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.43
upper limit	-39.47
Variability estimate	Standard error of the mean
Dispersion value	3.78

Notes:

[110] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [111]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.47
upper limit	-51.14
Variability estimate	Standard error of the mean
Dispersion value	2.61

Notes:

[111] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [112]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-52.73

Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.4
upper limit	-46.06
Variability estimate	Standard error of the mean
Dispersion value	3.38

Notes:

[112] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in the Total Cholesterol/HDL-C Ratio at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in the Total Cholesterol/HDL-C Ratio at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	5.96 (± 1.76)	2.24 (± 2.11)	-14.39 (± 1.83)	-10.86 (± 2.08)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-40.44 (± 1.26)	-42.45 (± 1.48)	4.26 (± 2.59)	6.42 (± 2.34)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-11.92 (± 2.52)	-12.25 (± 2.35)	-40.22 (± 1.8)	-40.43 (± 1.66)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	5.41 (± 1.96)	5.02 (± 2.25)	-39.33 (± 1.43)	-42 (± 1.59)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	4.55 (± 1.98)	1.71 (± 2.36)	-36.04 (± 1.42)	-38.62 (± 1.64)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-0.14 (± 2.79)	5.45 (± 3.5)	-47.2 (± 2.37)	-43.17 (± 2.85)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [113]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-46.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.66
upper limit	-42.15
Variability estimate	Standard error of the mean
Dispersion value	2.16

Notes:

[113] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [114]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-49.75
upper limit	-39.63
Variability estimate	Standard error of the mean
Dispersion value	2.57

Notes:

[114] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [115]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-26.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.36
upper limit	-21.75
Variability estimate	Standard error of the mean
Dispersion value	2.19

Notes:

[115] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [116]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-31.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.61
upper limit	-26.57
Variability estimate	Standard error of the mean
Dispersion value	2.55

Notes:

[116] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [117]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.69
upper limit	-38.27
Variability estimate	Standard error of the mean
Dispersion value	3.15

Notes:

[117] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [118]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-46.85

Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.48
upper limit	-41.21
Variability estimate	Standard error of the mean
Dispersion value	2.86

Notes:

[118] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [119]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.39
upper limit	-22.21
Variability estimate	Standard error of the mean
Dispersion value	3.09

Notes:

[119] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [120]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.86
upper limit	-22.5
Variability estimate	Standard error of the mean
Dispersion value	2.88

Notes:

[120] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [121]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-49.5
upper limit	-39.97
Variability estimate	Standard error of the mean
Dispersion value	2.41

Notes:

[121] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001 [122]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-47.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.46
upper limit	-41.57
Variability estimate	Standard error of the mean
Dispersion value	2.75

Notes:

[122] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [123]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-40.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.38
upper limit	-35.79
Variability estimate	Standard error of the mean
Dispersion value	2.43

Notes:

[123] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [124]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-40.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46
upper limit	-34.66
Variability estimate	Standard error of the mean
Dispersion value	2.87

Notes:

[124] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [125]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-47.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.76
upper limit	-42.35
Variability estimate	Standard error of the mean
Dispersion value	2.38

Notes:

[125] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [126]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-48.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.27
upper limit	-42.98
Variability estimate	Standard error of the mean
Dispersion value	2.86

Notes:

[126] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in the Total Cholesterol/HDL-C Ratio at Week 12

End point title	Mean Percent Change From Baseline in the Total Cholesterol/HDL-C Ratio at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.09 (± 2.02)	2.8 (± 2.31)	-12.14 (± 2.1)	-9.85 (± 2.28)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-40.74 (± 1.45)	-40.07 (± 1.63)	4.31 (± 2.75)	6.18 (± 2.73)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-10.53 (± 2.66)	-11.06 (± 2.73)	-40.79 (± 1.89)	-36.25 (± 1.94)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	4.68 (± 2.28)	6.07 (± 2.36)	-38.57 (± 1.64)	-39.26 (± 1.68)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	5.96 (± 2.28)	2.69 (± 2.8)	-35.17 (± 1.63)	-32.3 (± 1.94)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-0.2 (± 2.81)	5.13 (± 3.62)	-47.24 (± 2.38)	-39.47 (± 2.92)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [127]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-46.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.73
upper limit	-41.94
Variability estimate	Standard error of the mean
Dispersion value	2.48

Notes:

[127] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [128]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-42.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.43
upper limit	-37.3
Variability estimate	Standard error of the mean
Dispersion value	2.82

Notes:

[128] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [129]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.56
upper limit	-23.65
Variability estimate	Standard error of the mean
Dispersion value	2.51

Notes:

[129] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [130]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-30.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.74
upper limit	-24.7
Variability estimate	Standard error of the mean
Dispersion value	2.8

Notes:

[130] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [131]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-45.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.66
upper limit	-38.54
Variability estimate	Standard error of the mean
Dispersion value	3.33

Notes:

[131] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [132]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-42.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-49.01
upper limit	-35.85
Variability estimate	Standard error of the mean
Dispersion value	3.34

Notes:

[132] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Ezetimibe (Q2W) v Evolocumab Q2W
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [133]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-30.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.68
upper limit	-23.84
Variability estimate	Standard error of the mean
Dispersion value	3.26

Notes:

[133] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [134]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-25.19

Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.79
upper limit	-18.59
Variability estimate	Standard error of the mean
Dispersion value	3.35

Notes:

[134] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [135]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-43.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.77
upper limit	-37.74
Variability estimate	Standard error of the mean
Dispersion value	2.79

Notes:

[135] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [136]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-45.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.04
upper limit	-39.61
Variability estimate	Standard error of the mean
Dispersion value	2.89

Notes:

[136] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [137]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-41.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.65
upper limit	-35.61
Variability estimate	Standard error of the mean
Dispersion value	2.79

Notes:

[137] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [138]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-34.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.72
upper limit	-28.25
Variability estimate	Standard error of the mean
Dispersion value	3.41

Notes:

[138] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [139]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-47.04

Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.83
upper limit	-42.25
Variability estimate	Standard error of the mean
Dispersion value	2.43

Notes:

[139] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001 [140]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-44.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.67
upper limit	-38.54
Variability estimate	Standard error of the mean
Dispersion value	3.07

Notes:

[140] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in Apolipoprotein B/Apolipoprotein A1 Ratio at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in Apolipoprotein B/Apolipoprotein A1 Ratio at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.41 (± 2.03)	0.78 (± 2.29)	-15.77 (± 2.14)	-11.47 (± 2.29)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-53.56 (± 1.48)	-53.33 (± 1.58)	4.48 (± 3.04)	5.79 (± 2.79)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-15.17 (± 2.99)	-12.91 (± 2.8)	-52.43 (± 2.14)	-56.2 (± 1.98)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	2.82 (± 2.26)	2.58 (± 2.05)	-52.46 (± 1.67)	-56.66 (± 1.43)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	2.17 (± 2.56)	2.6 (± 2.97)	-48.47 (± 1.83)	-54.17 (± 2.04)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-1 (± 3.12)	-1.42 (± 4.22)	-58.76 (± 2.73)	-57.47 (± 3.55)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [141]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.91
upper limit	-55.03
Variability estimate	Standard error of the mean
Dispersion value	2.51

Notes:

[141] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [142]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-54.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.57
upper limit	-48.64
Variability estimate	Standard error of the mean
Dispersion value	2.77

Notes:

[142] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [143]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.8
upper limit	-32.77
Variability estimate	Standard error of the mean
Dispersion value	2.54

Notes:

[143] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [144]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-41.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.34
upper limit	-36.67
Variability estimate	Standard error of the mean
Dispersion value	2.78

Notes:

[144] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [145]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.22
upper limit	-49.59
Variability estimate	Standard error of the mean
Dispersion value	3.71

Notes:

[145] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [146]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-61.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	-68.68
upper limit	-55.29
Variability estimate	Standard error of the mean
Dispersion value	3.39

Notes:

[146] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [147]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.48
upper limit	-30.04
Variability estimate	Standard error of the mean
Dispersion value	3.66

Notes:

[147] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [148]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-43.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.07
upper limit	-36.51
Variability estimate	Standard error of the mean
Dispersion value	3.44

Notes:

[148] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [149]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-55.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-60.79
upper limit	-49.79
Variability estimate	Standard error of the mean
Dispersion value	2.78

Notes:

[149] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [150]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-59.24

Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.16
upper limit	-54.32
Variability estimate	Standard error of the mean
Dispersion value	2.49

Notes:

[150] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [151]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-50.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-56.82
upper limit	-44.45
Variability estimate	Standard error of the mean
Dispersion value	3.13

Notes:

[151] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [152]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-63.91
upper limit	-49.64
Variability estimate	Standard error of the mean
Dispersion value	3.61

Notes:

[152] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [153]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-62.51
upper limit	-52.99
Variability estimate	Standard error of the mean
Dispersion value	2.41

Notes:

[153] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [154]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.85
upper limit	-50.27
Variability estimate	Standard error of the mean
Dispersion value	2.93

Notes:

[154] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in Apolipoprotein B/Apolipoprotein A1 Ratio at Week 12

End point title	Percent Change From Baseline in Apolipoprotein B/Apolipoprotein A1 Ratio at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.13 (± 2.2)	-1.21 (± 2.41)	-14.51 (± 2.31)	-12.33 (± 2.41)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-54.17 (± 1.59)	-49.65 (± 1.69)	4.19 (± 3.25)	6.5 (± 3.18)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-13.69 (± 3.17)	-12.19 (± 3.17)	-53.59 (± 2.26)	-50.76 (± 2.26)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	1.44 (± 2.3)	4 (± 2.27)	-52.97 (± 1.69)	-52.13 (± 1.6)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	1.64 (± 2.75)	3.16 (± 3.51)	-47.53 (± 1.96)	-45.65 (± 2.39)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-1.8 (± 3.21)	-0.52 (± 4.29)	-59.53 (± 2.77)	-52.56 (± 3.59)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [155]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-60.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.65
upper limit	-54.94
Variability estimate	Standard error of the mean
Dispersion value	2.71

Notes:

[155] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [156]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-48.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-54.23
upper limit	-42.65
Variability estimate	Standard error of the mean
Dispersion value	2.94

Notes:

[156] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [157]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-39.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.09
upper limit	-34.23
Variability estimate	Standard error of the mean
Dispersion value	2.75

Notes:

[157] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [158]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.12
upper limit	-31.52
Variability estimate	Standard error of the mean
Dispersion value	2.94

Notes:

[158] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W

Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [159]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-65.55
upper limit	-49.99
Variability estimate	Standard error of the mean
Dispersion value	3.95

Notes:

[159] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [160]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-64.91
upper limit	-49.6
Variability estimate	Standard error of the mean
Dispersion value	3.88

Notes:

[160] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [161]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-39.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.53
upper limit	-32.26
Variability estimate	Standard error of the mean
Dispersion value	3.87

Notes:

[161] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [162]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-38.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.26
upper limit	-30.88
Variability estimate	Standard error of the mean
Dispersion value	3.9

Notes:

[162] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [163]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-54.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-59.99
upper limit	-48.82
Variability estimate	Standard error of the mean
Dispersion value	2.83

Notes:

[163] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.001 [164]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-56.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-61.58
upper limit	-50.68
Variability estimate	Standard error of the mean
Dispersion value	2.76

Notes:

[164] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [165]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-49.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.8
upper limit	-42.53
Variability estimate	Standard error of the mean
Dispersion value	3.36

Notes:

[165] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [166]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-48.81

Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.21
upper limit	-40.4
Variability estimate	Standard error of the mean
Dispersion value	4.25

Notes:

[166] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [167]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-57.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-62.82
upper limit	-52.65
Variability estimate	Standard error of the mean
Dispersion value	2.57

Notes:

[167] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [168]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-52.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-58.1
upper limit	-45.98
Variability estimate	Standard error of the mean
Dispersion value	3.07

Notes:

[168] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percentage of Participants Who Achieved LDL-C < 70 mg/dL at Weeks 10 and 12

End point title	Mean Percentage of Participants Who Achieved LDL-C < 70 mg/dL at Weeks 10 and 12

End point description:

Calculated LDL-C was determined based on the Friedewald equation. The analysis was performed using the full analysis set.

End point type	Secondary

End point timeframe:

Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percentage of participants				
number (confidence interval 95%)	5.7 (1.9 to 15.4)	5.6 (1.9 to 15.1)	20 (11.2 to 33)	16.7 (9 to 28.7)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percentage of participants				
number (confidence interval 95%)	88.1 (80.7 to 92.9)	85.8 (78 to 91.2)	13.7 (6.8 to 25.7)	9.3 (4 to 19.9)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percentage of participants				
number (confidence interval 95%)	50.9 (38.1 to 63.6)	62.3 (48.8 to 74.1)	94.4 (88.4 to 97.4)	92.5 (85.9 to 96.2)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percentage of participants				
number (confidence interval 95%)	7 (2.8 to 16.7)	5.3 (1.8 to 14.4)	88.7 (81.2 to 93.4)	89.9 (82.8 to 94.3)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percentage of participants				
number (confidence interval 95%)	38.9 (27 to 52.2)	28.8 (18.3 to 42.3)	93.5 (87.1 to 96.8)	94.5 (88.6 to 97.5)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percentage of participants				
number (confidence interval 95%)	1.9 (0.3 to 9.8)	3.9 (1.1 to 13.2)	93.6 (87.3 to 96.9)	88.5 (81.3 to 93.2)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [169]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	82.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.2
upper limit	88.5

Notes:

[169] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM

Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [170]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	80.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.9
upper limit	86.8

Notes:

[170] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [171]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	68.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.1
upper limit	78.1

Notes:

[171] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [172]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	69.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.8
upper limit	78.5

Notes:

[172] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [173]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	80.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.3
upper limit	88.3

Notes:

[173] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [174]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	83.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.7
upper limit	89.6

Notes:

[174] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [175]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	43.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	29.5
upper limit	56.7

Notes:

[175] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [176]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	30.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.7
upper limit	44.2

Notes:

[176] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [177]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	81.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.5
upper limit	88

Notes:

[177] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM

Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [178]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	84.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	73.1
upper limit	90.2

Notes:

[178] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [179]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	54.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.8
upper limit	66.9

Notes:

[179] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [180]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	65.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	51
upper limit	76.6

Notes:

[180] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [181]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	91.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	81.6
upper limit	95.3

Notes:

[181] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [182]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	84.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	72.8
upper limit	90

Notes:

[182] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percentage of Participants Who Achieved LDL-C < 70 mg/dL at Week 12

End point title	Percentage of Participants Who Achieved LDL-C < 70 mg/dL at Week 12

End point description:

Calculated LDL-C was determined based on the Friedewald equation. The analysis was performed using the full analysis set.

End point type	Secondary

End point timeframe:

Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percentage of participants				
number (confidence interval 95%)	2 (0.3 to 10.3)	5.9 (2 to 15.9)	22.4 (13 to 35.9)	19.2 (10.8 to 31.9)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percentage of participants				
number (confidence interval 95%)	85.4 (77.4 to 91)	84.2 (75.8 to 90)	13 (6.1 to 25.7)	9.8 (4.3 to 21)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percentage of participants				
number (confidence interval 95%)	52 (38.5 to 65.2)	55.8 (42.3 to 68.4)	93.1 (86.5 to 96.6)	91 (83.8 to 95.2)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percentage of participants				
number (confidence interval 95%)	7.7 (3 to 18.2)	5.5 (1.9 to 14.9)	85 (76.7 to 90.7)	86.5 (78.7 to 91.8)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percentage of participants				
number (confidence interval 95%)	39.6 (27.6 to 53.1)	28 (17.5 to 41.7)	92.3 (85.6 to 96.1)	92.3 (85.6 to 96.1)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percentage of participants				
number (confidence interval 95%)	1.9 (0.3 to 10.1)	6.4 (2.2 to 17.2)	94.4 (88.4 to 97.4)	84.8 (76.7 to 90.4)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [183]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	83.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	71.9
upper limit	89.2

Notes:

[183] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [184]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	78.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.2
upper limit	85.3

Notes:

[184] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [185]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	63
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.3
upper limit	73.9

Notes:

[185] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [186]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	64.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.8
upper limit	75.2

Notes:

[186] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [187]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	80.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.8
upper limit	87.9

Notes:

[187] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [188]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	81.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.9
upper limit	88.1

Notes:

[188] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [189]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	41.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.4
upper limit	55.1

Notes:

[189] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [190]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	35.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	20.7
upper limit	49.3

Notes:

[190] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [191]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	77.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.9
upper limit	84.7

Notes:

[191] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [192]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	81.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.8
upper limit	87.5

Notes:

[192] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W

Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [193]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	52.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.6
upper limit	65.3

Notes:

[193] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [194]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	64.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.1
upper limit	75.5

Notes:

[194] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [195]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	92.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	82.3
upper limit	95.9

Notes:

[195] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [196]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment Difference
Point estimate	78.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	64.9
upper limit	85.4

Notes:

[196] - Based on Cochran-Mantel Haenszel test stratified by the stratification factors (entry statin therapy and simvastatin contraindicated therapy usage). Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in Lipoprotein(a) at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in Lipoprotein(a) at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.07 (± 2.86)	-0.77 (± 3.28)	1.44 (± 3.02)	6.85 (± 3.29)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-26.01 (± 2.08)	-22.64 (± 2.27)	-3.45 (± 2.99)	1.51 (± 3.35)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	8.05 (± 2.94)	9.96 (± 3.4)	-23.97 (± 2.1)	-27.46 (± 2.39)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	11.41 (± 3)	3.65 (± 3.56)	-24.26 (± 2.21)	-23.16 (± 2.5)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	8.59 (± 2.98)	6.26 (± 3.59)	-24.96 (± 2.12)	-25.93 (± 2.46)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-10.57 (± 4.49)	-4.99 (± 5.37)	-38.64 (± 3.92)	-32.16 (± 4.5)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [197]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.06
upper limit	-25.11
Variability estimate	Standard error of the mean
Dispersion value	3.54

Notes:

[197] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [198]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-21.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.7
upper limit	-14.03
Variability estimate	Standard error of the mean
Dispersion value	3.98

Notes:

[198] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [199]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-27.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.53
upper limit	-20.38
Variability estimate	Standard error of the mean
Dispersion value	3.59

Notes:

[199] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [200]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-29.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.36
upper limit	-21.62
Variability estimate	Standard error of the mean
Dispersion value	3.99

Notes:

[200] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [201]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-20.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.71
upper limit	-13.33
Variability estimate	Standard error of the mean
Dispersion value	3.65

Notes:

[201] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [202]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.01
upper limit	-20.92
Variability estimate	Standard error of the mean
Dispersion value	4.08

Notes:

[202] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [203]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.11
upper limit	-24.93
Variability estimate	Standard error of the mean
Dispersion value	3.6

Notes:

[203] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [204]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-37.42

Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.61
upper limit	-29.23
Variability estimate	Standard error of the mean
Dispersion value	4.15

Notes:

[204] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [205]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-35.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.94
upper limit	-28.38
Variability estimate	Standard error of the mean
Dispersion value	3.69

Notes:

[205] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [206]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-26.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.36
upper limit	-18.27
Variability estimate	Standard error of the mean
Dispersion value	4.33

Notes:

[206] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [207]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-33.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.74
upper limit	-26.37
Variability estimate	Standard error of the mean
Dispersion value	3.64

Notes:

[207] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [208]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.8
upper limit	-23.58
Variability estimate	Standard error of the mean
Dispersion value	4.36

Notes:

[208] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [209]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.91
upper limit	-21.23
Variability estimate	Standard error of the mean
Dispersion value	3.46

Notes:

[209] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [210]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-27.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.59
upper limit	-19.73
Variability estimate	Standard error of the mean
Dispersion value	3.76

Notes:

[210] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in Lipoprotein(a) at Week 12

End point title	Percent Change From Baseline in Lipoprotein(a) at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	7.34 (± 3.13)	-0.43 (± 3.38)	3.29 (± 3.28)	7.18 (± 3.38)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-25.87 (± 2.26)	-20.25 (± 2.36)	-2.23 (± 3.35)	3.41 (± 3.54)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	8.01 (± 3.26)	10.2 (± 3.57)	-24.61 (± 2.31)	-24.68 (± 2.53)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	11.4 (± 3.37)	4.49 (± 3.68)	-25.09 (± 2.47)	-20.85 (± 2.59)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	10.38 (± 3.09)	10.21 (± 4.36)	-26.11 (± 2.21)	-21.97 (± 2.97)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	-6.81 (± 4.57)	-1.06 (± 5.67)	-38.06 (± 3.96)	-29.23 (± 4.68)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [211]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-33.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.81
upper limit	-25.6
Variability estimate	Standard error of the mean
Dispersion value	3.86

Notes:

[211] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [212]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-19.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.92
upper limit	-11.72
Variability estimate	Standard error of the mean
Dispersion value	4.11

Notes:

[212] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [213]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-29.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.87
upper limit	-21.44
Variability estimate	Standard error of the mean
Dispersion value	3.91

Notes:

[213] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [214]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-27.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.56
upper limit	-19.32
Variability estimate	Standard error of the mean
Dispersion value	4.12

Notes:

[214] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [215]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-22.38

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.39
upper limit	-14.36
Variability estimate	Standard error of the mean
Dispersion value	4.07

Notes:

[215] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [216]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.62
upper limit	-19.58
Variability estimate	Standard error of the mean
Dispersion value	4.32

Notes:

[216] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [217]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.46
upper limit	-24.78
Variability estimate	Standard error of the mean
Dispersion value	3.98

Notes:

[217] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [218]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-34.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.52
upper limit	-26.25
Variability estimate	Standard error of the mean
Dispersion value	4.38

Notes:

[218] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [219]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-36.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.69
upper limit	-28.3
Variability estimate	Standard error of the mean
Dispersion value	4.15

Notes:

[219] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [220]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-25.34

Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.19
upper limit	-16.49
Variability estimate	Standard error of the mean
Dispersion value	4.48

Notes:

[220] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [221]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-36.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.95
upper limit	-29.02
Variability estimate	Standard error of the mean
Dispersion value	3.78

Notes:

[221] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [222]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.61
upper limit	-21.74
Variability estimate	Standard error of the mean
Dispersion value	5.28

Notes:

[222] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [223]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-31.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.4
upper limit	-24.1
Variability estimate	Standard error of the mean
Dispersion value	3.62

Notes:

[223] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [224]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-28.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.79
upper limit	-19.55
Variability estimate	Standard error of the mean
Dispersion value	4.36

Notes:

[224] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in Triglycerides at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in Triglycerides at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.49 (± 3.94)	9.17 (± 4.41)	-3.16 (± 4.1)	1.57 (± 4.35)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-5.61 (± 2.81)	-13.38 (± 3.08)	6.16 (± 4.02)	8.05 (± 4.35)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-8.1 (± 3.92)	-4.86 (± 4.39)	-9.27 (± 2.8)	-6.36 (± 3.11)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	12.43 (± 4.19)	12.26 (± 4.67)	-10.28 (± 3.04)	-7.26 (± 3.29)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	8.44 (± 3.76)	10.75 (± 3.98)	-9.15 (± 2.7)	-15.43 (± 2.77)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	9.29 (± 6.97)	13.78 (± 7.44)	-11.67 (± 5.97)	-15.93 (± 6.15)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2 [225]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-12.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.63
upper limit	-2.58
Variability estimate	Standard error of the mean
Dispersion value	4.83

Notes:

[225] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [226]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-22.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.13
upper limit	-11.97
Variability estimate	Standard error of the mean
Dispersion value	5.36

Notes:

[226] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [227]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-2.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.09
upper limit	7.19
Variability estimate	Standard error of the mean
Dispersion value	4.89

Notes:

[227] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.053 [228]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-14.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.46
upper limit	-4.44
Variability estimate	Standard error of the mean
Dispersion value	5.33

Notes:

[228] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [229]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-15.43

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.06
upper limit	-5.79
Variability estimate	Standard error of the mean
Dispersion value	4.89

Notes:

[229] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027 [230]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-14.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.9
upper limit	-3.92
Variability estimate	Standard error of the mean
Dispersion value	5.32

Notes:

[230] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [231]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.63
upper limit	8.3
Variability estimate	Standard error of the mean
Dispersion value	4.8

Notes:

[231] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.63 [232]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.12
upper limit	9.11
Variability estimate	Standard error of the mean
Dispersion value	5.38

Notes:

[232] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [233]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-22.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.9
upper limit	-12.54
Variability estimate	Standard error of the mean
Dispersion value	5.15

Notes:

[233] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [234]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-19.52

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.76
upper limit	-8.28
Variability estimate	Standard error of the mean
Dispersion value	5.69

Notes:

[234] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [235]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-17.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.71
upper limit	-8.46
Variability estimate	Standard error of the mean
Dispersion value	4.62

Notes:

[235] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [236]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-26.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.76
upper limit	-16.59
Variability estimate	Standard error of the mean
Dispersion value	4.85

Notes:

[236] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [237]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-20.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.38
upper limit	-9.55
Variability estimate	Standard error of the mean
Dispersion value	5.78

Notes:

[237] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [238]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-29.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.84
upper limit	-18.57
Variability estimate	Standard error of the mean
Dispersion value	5.64

Notes:

[238] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in Triglycerides at Week 12

End point title	Percent Change From Baseline in Triglycerides at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	8.27 (± 5.23)	14.35 (± 5.92)	-0.43 (± 5.39)	4.88 (± 5.84)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-3.79 (± 3.72)	-13.26 (± 4.17)	6.65 (± 4.45)	8.22 (± 5.22)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-7.4 (± 4.32)	-3.11 (± 5.23)	-10.07 (± 3.05)	-1.1 (± 3.74)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	13.57 (± 5.76)	12.96 (± 5.32)	-4.46 (± 4.16)	-6.88 (± 3.8)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	10.97 (± 4.66)	10 (± 4.38)	-5.58 (± 3.34)	-10.51 (± 3.04)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	8.07 (± 6.88)	16.72 (± 7.88)	-13.71 (± 5.91)	-14.65 (± 6.39)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2 [239]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-12.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.69
upper limit	0.57
Variability estimate	Standard error of the mean
Dispersion value	6.41

Notes:

[239] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [240]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-27.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.86
upper limit	-13.35
Variability estimate	Standard error of the mean
Dispersion value	7.23

Notes:

[240] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [241]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-3.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.16
upper limit	9.43
Variability estimate	Standard error of the mean
Dispersion value	6.49

Notes:

[241] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.053 [242]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-18.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.28
upper limit	-3.99
Variability estimate	Standard error of the mean
Dispersion value	7.18

Notes:

[242] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [243]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-16.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.34
upper limit	-6.1
Variability estimate	Standard error of the mean
Dispersion value	5.39

Notes:

[243] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027 [244]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-9.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.92
upper limit	3.29
Variability estimate	Standard error of the mean
Dispersion value	6.39

Notes:

[244] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [245]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-2.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.05
upper limit	7.72
Variability estimate	Standard error of the mean
Dispersion value	5.27

Notes:

[245] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.63 [246]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	2.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.66
upper limit	14.69
Variability estimate	Standard error of the mean
Dispersion value	6.43

Notes:

[246] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [247]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-18.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.03
upper limit	-4.04
Variability estimate	Standard error of the mean
Dispersion value	7.08

Notes:

[247] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [248]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-19.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.71
upper limit	-6.96
Variability estimate	Standard error of the mean
Dispersion value	6.52

Notes:

[248] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [249]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-16.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.84
upper limit	-5.26
Variability estimate	Standard error of the mean
Dispersion value	5.71

Notes:

[249] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [250]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-20.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.04
upper limit	-9.98
Variability estimate	Standard error of the mean
Dispersion value	5.33

Notes:

[250] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [251]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-21.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.88
upper limit	-10.68
Variability estimate	Standard error of the mean
Dispersion value	5.62

Notes:

[251] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [252]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-31.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.1
upper limit	-18.62
Variability estimate	Standard error of the mean
Dispersion value	6.45

Notes:

[252] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean Percent Change From Baseline in Very Low-Density Cholesterol (VLDL-C) at Weeks 10 and 12

End point title	Mean Percent Change From Baseline in Very Low-Density Cholesterol (VLDL-C) at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	6.51 (± 3.56)	9.53 (± 4.45)	-5.35 (± 3.74)	1.77 (± 4.41)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-6.85 (± 2.56)	-11.77 (± 3.11)	6.24 (± 4.03)	8.31 (± 4.26)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-8.52 (± 3.93)	-6.13 (± 4.31)	-8.96 (± 2.82)	-6.38 (± 3.05)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	12.86 (± 3.95)	12.54 (± 4.58)	-12.22 (± 2.86)	-7.25 (± 3.23)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	7.06 (± 3.76)	8.13 (± 3.72)	-9.09 (± 2.71)	-15.05 (± 2.58)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	8.64 (± 6.01)	16.37 (± 7.15)	-14.57 (± 5.17)	-16.5 (± 5.87)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088 [253]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-13.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.99
upper limit	-4.74
Variability estimate	Standard error of the mean
Dispersion value	4.38

Notes:

[253] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [254]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-21.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.98
upper limit	-10.64
Variability estimate	Standard error of the mean
Dispersion value	5.41

Notes:

[254] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [255]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.27
upper limit	7.27
Variability estimate	Standard error of the mean
Dispersion value	4.45

Notes:

[255] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056 [256]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-13.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.17
upper limit	-2.91
Variability estimate	Standard error of the mean
Dispersion value	5.39

Notes:

[256] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [257]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-15.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.88
upper limit	-5.54
Variability estimate	Standard error of the mean
Dispersion value	4.91

Notes:

[257] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027 [258]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-14.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.97
upper limit	-4.42
Variability estimate	Standard error of the mean
Dispersion value	5.21

Notes:

[258] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [259]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.94
upper limit	9.05
Variability estimate	Standard error of the mean
Dispersion value	4.82

Notes:

[259] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62 [260]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.66
upper limit	10.16
Variability estimate	Standard error of the mean
Dispersion value	5.28

Notes:

[260] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [261]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-25.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.64
upper limit	-15.5
Variability estimate	Standard error of the mean
Dispersion value	4.85

Notes:

[261] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [262]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-19.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.81
upper limit	-8.77
Variability estimate	Standard error of the mean
Dispersion value	5.58

Notes:

[262] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [263]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-16.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.27
upper limit	-7.03
Variability estimate	Standard error of the mean
Dispersion value	4.61

Notes:

[263] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [264]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-23.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.11
upper limit	-14.25
Variability estimate	Standard error of the mean
Dispersion value	4.52

Notes:

[264] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [265]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-23.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33
upper limit	-13.43
Variability estimate	Standard error of the mean
Dispersion value	4.95

Notes:

[265] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [266]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-32.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.6
upper limit	-22.14
Variability estimate	Standard error of the mean
Dispersion value	5.43

Notes:

[266] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in VLDL-C at Week 12

End point title	Percent Change From Baseline in VLDL-C at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	8.32 (± 4)	14.74 (± 5.91)	-4.61 (± 4.19)	3.45 (± 5.89)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	-6.16 (± 2.88)	-11.73 (± 4.16)	6.73 (± 4.45)	8.54 (± 5)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	-7.92 (± 4.32)	-6 (± 5.04)	-9.69 (± 3.05)	-1.06 (± 3.58)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	13.79 (± 5.05)	12.47 (± 5.31)	-8.2 (± 3.64)	-6.28 (± 3.78)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	10.09 (± 4.65)	8.59 (± 4.37)	-6.1 (± 3.33)	-9.95 (± 3.03)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab	S40 EvoMab

			Q2W	QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	7.63 (± 6.26)	20.97 (± 7.53)	-14.83 (± 5.3)	-15.86 (± 6.09)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.088 [267]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-14.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.16
upper limit	-4.78
Variability estimate	Standard error of the mean
Dispersion value	4.92

Notes:

[267] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [268]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-26.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.71
upper limit	-12.24
Variability estimate	Standard error of the mean
Dispersion value	7.22

Notes:

[268] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [269]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.41
upper limit	8.32
Variability estimate	Standard error of the mean
Dispersion value	5

Notes:

[269] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.056 [270]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-15.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.4
upper limit	-0.97
Variability estimate	Standard error of the mean
Dispersion value	7.21

Notes:

[270] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.073 [271]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-16.42

Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.05
upper limit	-5.8
Variability estimate	Standard error of the mean
Dispersion value	5.39

Notes:

[271] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.027 [272]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-9.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.68
upper limit	2.48
Variability estimate	Standard error of the mean
Dispersion value	6.13

Notes:

[272] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [273]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-1.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.16
upper limit	8.61
Variability estimate	Standard error of the mean
Dispersion value	5.27

Notes:

[273] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62 [274]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	4.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.25
upper limit	17.14
Variability estimate	Standard error of the mean
Dispersion value	6.18

Notes:

[274] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [275]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-21.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.24
upper limit	-9.73
Variability estimate	Standard error of the mean
Dispersion value	6.2

Notes:

[275] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007 [276]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-18.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.6
upper limit	-5.9
Variability estimate	Standard error of the mean
Dispersion value	6.5

Notes:

[276] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005 [277]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-16.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.46
upper limit	-4.92
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[277] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [278]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-18.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.04
upper limit	-8.05
Variability estimate	Standard error of the mean
Dispersion value	5.31

Notes:

[278] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [279]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-22.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.09
upper limit	-11.81
Variability estimate	Standard error of the mean
Dispersion value	5.39

Notes:

[279] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [280]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	-36.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.96
upper limit	-24.7
Variability estimate	Standard error of the mean
Dispersion value	6.14

Notes:

[280] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Mean percent Change From Baseline in HDL-C at Weeks 10 and 12

End point title	Mean percent Change From Baseline in HDL-C at Weeks 10 and 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Weeks 10 and 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	-0.99 (± 1.5)	-0.45 (± 1.94)	-1.13 (± 1.56)	-0.92 (± 1.92)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	5.54 (± 1.07)	7.66 (± 1.37)	4.48 (± 1.73)	-1.37 (± 1.85)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	0.86 (± 1.68)	-0.59 (± 1.86)	8.44 (± 1.2)	7.76 (± 1.31)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	0.87 (± 1.52)	-0.94 (± 2.55)	6.23 (± 1.1)	7.72 (± 1.8)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	-0.6 (± 1.56)	-0.4 (± 1.81)	4.86 (± 1.12)	6.35 (± 1.26)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	0.13 (± 2.75)	-2.14 (± 2.72)	10.35 (± 2.26)	6.71 (± 2.25)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034 [281]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	6.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.91
upper limit	10.15
Variability estimate	Standard error of the mean
Dispersion value	1.84

Notes:

[281] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017 [282]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.43
upper limit	12.79
Variability estimate	Standard error of the mean
Dispersion value	2.37

Notes:

[282] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [283]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	6.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	10.34
Variability estimate	Standard error of the mean
Dispersion value	1.86

Notes:

[283] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [284]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.93
upper limit	13.22
Variability estimate	Standard error of the mean
Dispersion value	2.36

Notes:

[284] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [285]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.95

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	8.09
Variability estimate	Standard error of the mean
Dispersion value	2.1

Notes:

[285] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [286]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	9.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.68
upper limit	13.58
Variability estimate	Standard error of the mean
Dispersion value	2.26

Notes:

[286] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [287]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	7.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.51
upper limit	11.64
Variability estimate	Standard error of the mean
Dispersion value	2.06

Notes:

[287] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [288]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.86
upper limit	12.84
Variability estimate	Standard error of the mean
Dispersion value	2.28

Notes:

[288] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [289]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	5.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.68
upper limit	9.04
Variability estimate	Standard error of the mean
Dispersion value	1.87

Notes:

[289] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01 [290]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.66

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.51
upper limit	14.8
Variability estimate	Standard error of the mean
Dispersion value	3.11

Notes:

[290] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013 [291]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	5.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.69
upper limit	9.23
Variability estimate	Standard error of the mean
Dispersion value	1.91

Notes:

[291] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [292]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	6.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	11.1
Variability estimate	Standard error of the mean
Dispersion value	2.2

Notes:

[292] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [293]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	10.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.13
upper limit	15.32
Variability estimate	Standard error of the mean
Dispersion value	2.58

Notes:

[293] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [294]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.73
upper limit	12.97
Variability estimate	Standard error of the mean
Dispersion value	2.09

Notes:

[294] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Secondary: Percent Change From Baseline in HDL-C at Week 12

End point title	Percent Change From Baseline in HDL-C at Week 12

End point description:

Efficacy analyses were performed on the full analysis set. Least squares (LS) means are from a repeated measures linear effects model; missing values were not imputed.

End point type	Secondary

End point timeframe:

Baseline and Week 12

End point values	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)	A10 EZE (QM)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	56	55
Units: percent change				
least squares mean (standard error)	0.22 (± 1.72)	0.01 (± 2.02)	-1.76 (± 1.78)	-0.4 (± 1.99)

End point values	A10 EvoMab Q2W	A10 EvoMab QM	A80 PBO Q2W	A80 PBO QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	110	110	55	55
Units: percent change				
least squares mean (standard error)	7.04 (± 1.23)	7.88 (± 1.42)	5.02 (± 1.88)	0.3 (± 2.01)

End point values	A80 EZE (Q2W)	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	54	109	110
Units: percent change				
least squares mean (standard error)	0.62 (± 1.83)	0.21 (± 2.01)	9.09 (± 1.29)	7.36 (± 1.43)

End point values	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W	R5 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	57	113	115
Units: percent change				
least squares mean (standard error)	2.87 (± 1.87)	-0.16 (± 2.64)	6.07 (± 1.35)	7.18 (± 1.87)

End point values	R40 PBO Q2W	R40 PBO QM	R40 EvoMab Q2W	R40 EvoMab QM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	111	112
Units: percent change				
least squares mean (standard error)	-0.39 (± 1.86)	0.73 (± 1.98)	4.65 (± 1.34)	5.57 (± 1.37)

End point values	S40 PBO Q2W	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	112	115
Units: percent change				
least squares mean (standard error)	1.14 (± 2.96)	-2.65 (± 2.87)	10.92 (± 2.38)	6.41 (± 2.34)

Statistical analyses

Statistical analysis title	A10: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A10 PBO Q2W v A10 EvoMab Q2W
Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.034 [295]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	6.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.66
upper limit	10.99
Variability estimate	Standard error of the mean
Dispersion value	2.11

Notes:

[295] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Placebo QM
Comparison groups	A10 PBO QM v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.017 [296]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	7.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.01
upper limit	12.73
Variability estimate	Standard error of the mean
Dispersion value	2.46

Notes:

[296] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A10 EZE (Q2W) v A10 EvoMab Q2W

Number of subjects included in analysis	166
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001 [297]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.58
upper limit	13.03
Variability estimate	Standard error of the mean
Dispersion value	2.14

Notes:

[297] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A10: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A10 EZE (QM) v A10 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006 [298]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.46
upper limit	13.11
Variability estimate	Standard error of the mean
Dispersion value	2.45

Notes:

[298] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Placebo Q2W
Comparison groups	A80 PBO Q2W v A80 EvoMab Q2W
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85 [299]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	4.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	8.57
Variability estimate	Standard error of the mean
Dispersion value	2.28

Notes:

[299] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Placebo QM
Comparison groups	A80 PBO QM v A80 EvoMab QM
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [300]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	7.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.22
upper limit	11.89
Variability estimate	Standard error of the mean
Dispersion value	2.45

Notes:

[300] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab Q2W vs Ezetimibe (Q2W)
Comparison groups	A80 EZE (Q2W) v A80 EvoMab Q2W
Number of subjects included in analysis	165
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [301]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	8.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.07
upper limit	12.87
Variability estimate	Standard error of the mean
Dispersion value	2.23

Notes:

[301] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	A80: Evolocumab QM vs Ezetimibe (QM)
Comparison groups	A80 EZE (QM) v A80 EvoMab QM
Number of subjects included in analysis	164
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 [302]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	7.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.29
upper limit	11.99
Variability estimate	Standard error of the mean
Dispersion value	2.46

Notes:

[302] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R5 PBO Q2W v R5 EvoMab Q2W
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [303]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.33
upper limit	7.73
Variability estimate	Standard error of the mean
Dispersion value	2.3

Notes:

[303] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R5: Evolocumab QM vs Placebo QM
Comparison groups	R5 PBO QM v R5 EvoMab QM
Number of subjects included in analysis	172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01 [304]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	7.35

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	13.72
Variability estimate	Standard error of the mean
Dispersion value	3.23

Notes:

[304] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	R40 PBO Q2W v R40 EvoMab Q2W
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013 [305]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	5.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	9.56
Variability estimate	Standard error of the mean
Dispersion value	2.29

Notes:

[305] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	R40: Evolocumab QM vs Placebo QM
Comparison groups	R40 PBO QM v R40 EvoMab QM
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 [306]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	4.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.07
upper limit	9.6
Variability estimate	Standard error of the mean
Dispersion value	2.41

Notes:

[306] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab Q2W vs Placebo Q2W
Comparison groups	S40 PBO Q2W v S40 EvoMab Q2W
Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [307]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	9.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.05
upper limit	15.51
Variability estimate	Standard error of the mean
Dispersion value	2.9

Notes:

[307] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Statistical analysis title	S40: Evolocumab QM vs Placebo QM
Comparison groups	S40 PBO QM v S40 EvoMab QM
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [308]
Method	Repeated measures linear effects model
Parameter estimate	LS Mean Treatment Difference
Point estimate	9.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.4
upper limit	13.72
Variability estimate	Standard error of the mean
Dispersion value	2.36

Notes:

[308] - The model included treatment group, stratification factors, scheduled visit and the interaction of treatment with scheduled visit. Multiplicity adjusted p-value is significant if less than the familywise error rate of 0.05.

Adverse events information

Timeframe for reporting adverse events:

From the first dose of blinded investigational product until the end of the study (up to 14 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	A10 PBO Q2W

Reporting group description:

Participants received atorvastatin 10 mg once daily during the 4 week lipid stabilization period and then in combination with placebo (PBO) subcutaneous injection once every 2 weeks (Q2W) and placebo tablets once daily for up to 12 weeks.

Reporting group title	A10 PBO QM

Reporting group description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month (QM) and placebo tablets once a day for up to 12 weeks.

Reporting group title	A10 EZE (Q2W)

Reporting group description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe (EZE) orally once a day for up to 12 weeks.

Reporting group title	A10 EZE (QM)

Reporting group description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.

Reporting group title	A10 EvoMab Q2W

Reporting group description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab (EvoMab) by subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.

Reporting group title	A10 EvoMab QM

Reporting group description:

Participants received atorvastatin 10 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.

Reporting group title	A80 PBO Q2W

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.

Reporting group title	A80 PBO QM

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month and placebo tablets once a day for up to 12 weeks.

Reporting group title	A80 EZE (Q2W)

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks and 10 mg ezetimibe orally once a day for up to 12 weeks.

Reporting group title	A80 EZE (QM)

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once a month and 10 mg ezetimibe orally once a day for up to 12 weeks.

Reporting group title	A80 EvoMab Q2W

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks and placebo tablets once a day for up to 12 weeks.

Reporting group title	A80 EvoMab QM

Reporting group description:

Participants received atorvastatin 80 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month and placebo tablets once a day for up to 12 weeks.

Reporting group title	R5 PBO Q2W

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R5 PBO QM

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	R5 EvoMab Q2W

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R5 EvoMab QM

Reporting group description:

Participants received rosuvastatin 5 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group title	R40 PBO Q2W

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R40 PBO QM

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	R40 EvoMab Q2W

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	R40 EvoMab QM

Reporting group description:

Participants received rosuvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Reporting group title	S40 PBO Q2W

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	S40 PBO QM

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with placebo subcutaneous injection once every month for up to 12 weeks.

Reporting group title	S40 EvoMab Q2W

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 140 mg evolocumab by subcutaneous injection once every 2 weeks for up to 12 weeks.

Reporting group title	S40 EvoMab QM

Reporting group description:

Participants received simvastatin 40 mg a day during the 4-week lipid stabilization period and then in combination with 420 mg evolocumab by subcutaneous injection once a month for up to 12 weeks.

Serious adverse events	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 56 (1.79%)	2 / 55 (3.64%)	0 / 56 (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)			
Bladder neoplasm			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 metastatic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Ovarian cancer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			

Aortic aneurysm			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Hypertensive crisis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Affective disorder			

subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Troponin increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Radius fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 fibrillation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Coma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Grand mal convulsion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Ischaemic stroke			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Abdominal pain upper			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Hiatus hernia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 55 (0.00%)	0 / 56 (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
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glomerulonephritis acute			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Spinal pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Campylobacter infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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

Gastroenteritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Herpes simplex meningoencephalitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Infected bites			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 56 (0.00%)	1 / 55 (1.82%)	0 / 56 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (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

Serious adverse events	A10 EZE (QM)	A10 EvoMab Q2W	A10 EvoMab QM
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 55 (0.00%)	4 / 110 (3.64%)	2 / 110 (1.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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 metastatic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Ovarian cancer			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Aortic aneurysm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Hypertensive crisis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	1 / 110 (0.91%)
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			
Pulmonary oedema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Affective disorder			
subjects affected / exposed	0 / 55 (0.00%)	1 / 110 (0.91%)	0 / 110 (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
Investigations			
Troponin increased			

subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Radius fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 55 (0.00%)	1 / 110 (0.91%)	0 / 110 (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 myocardial infarction			
subjects affected / exposed	0 / 55 (0.00%)	1 / 110 (0.91%)	0 / 110 (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
Myocardial infarction			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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 fibrillation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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

Coma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Grand mal convulsion			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Ischaemic stroke			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Abdominal pain upper			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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 haemorrhage			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Hiatus hernia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 55 (0.00%)	1 / 110 (0.91%)	0 / 110 (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
Spinal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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			
Campylobacter infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Gastroenteritis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Herpes simplex meningoencephalitis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Infected bites			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Pneumonia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 55 (0.00%)	1 / 110 (0.91%)	0 / 110 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (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

Serious adverse events	A80 PBO Q2W	A80 PBO QM	A80 EZE (Q2W)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 55 (3.64%)	1 / 55 (1.82%)	1 / 56 (1.79%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	1 / 56 (1.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 metastatic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Ovarian cancer			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Aortic aneurysm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Hypertensive crisis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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

Peripheral artery stenosis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Affective disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Troponin increased			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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

Radius fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 fibrillation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Coma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Grand mal convulsion			
subjects affected / exposed	1 / 55 (1.82%)	0 / 55 (0.00%)	0 / 56 (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

Ischaemic stroke			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Abdominal pain upper			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 haemorrhage			
subjects affected / exposed	1 / 55 (1.82%)	0 / 55 (0.00%)	0 / 56 (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
Hiatus hernia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	1 / 55 (1.82%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Spinal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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			
Campylobacter infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Gastroenteritis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 55 (0.00%)	0 / 56 (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
Herpes simplex meningoencephalitis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 55 (0.00%)	0 / 56 (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
Infected bites			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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

Pneumonia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 55 (0.00%)	0 / 55 (0.00%)	0 / 56 (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

Serious adverse events	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 54 (1.85%)	3 / 109 (2.75%)	1 / 110 (0.91%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Colon cancer metastatic			

subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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 metastatic			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Ovarian cancer			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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			
Aortic aneurysm			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	0 / 110 (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
Hypertensive crisis			
subjects affected / exposed	1 / 54 (1.85%)	0 / 109 (0.00%)	0 / 110 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Surgical and medical procedures			

Hip arthroplasty			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	1 / 110 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	0 / 110 (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
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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			
Troponin increased			
subjects affected / exposed	1 / 54 (1.85%)	0 / 109 (0.00%)	0 / 110 (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
Injury, poisoning and procedural complications			
Injury			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Radius fracture			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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			

Acute coronary syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	0 / 110 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	0 / 110 (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
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Coma			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	0 / 110 (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
Grand mal convulsion			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Ischaemic stroke			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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			

Abdominal pain upper			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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 haemorrhage			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Hiatus hernia			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Musculoskeletal and connective tissue disorders			
Myalgia			

subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Spinal pain			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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			
Campylobacter infection			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Gastroenteritis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Herpes simplex meningoencephalitis			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Infected bites			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	0 / 110 (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	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Pneumonia mycoplasmal			

subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (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

Serious adverse events	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 58 (1.72%)	2 / 57 (3.51%)	3 / 113 (2.65%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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 metastatic			

subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	0 / 58 (0.00%)	1 / 57 (1.75%)	0 / 113 (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
Pleomorphic adenoma			
subjects affected / exposed	1 / 58 (1.72%)	0 / 57 (0.00%)	0 / 113 (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
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Hypertensive crisis			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Reproductive system and breast			

disorders			
Breast pain			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Affective disorder			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Troponin increased			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Injury			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Radius fracture			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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 fibrillation			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Coma			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Grand mal convulsion			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Ischaemic stroke			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Abdominal pain upper			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Hiatus hernia			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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

Spinal pain			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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			
Campylobacter infection			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Herpes simplex meningoencephalitis			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Infected bites			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Pneumonia			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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
Urinary tract infection bacterial			

subjects affected / exposed	0 / 58 (0.00%)	1 / 57 (1.75%)	0 / 113 (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			
Dehydration			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	0 / 113 (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

Serious adverse events	R5 EvoMab QM	R40 PBO Q2W	R40 PBO QM
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 115 (2.61%)	2 / 56 (3.57%)	1 / 55 (1.82%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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 metastatic			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Ovarian cancer			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Pleomorphic adenoma			

subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Aortic aneurysm			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Hypertensive crisis			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Peripheral artery stenosis			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			

subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Affective disorder			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Troponin increased			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Injury			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Radius fracture			
subjects affected / exposed	1 / 115 (0.87%)	0 / 56 (0.00%)	0 / 55 (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 disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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	1 / 115 (0.87%)	1 / 56 (1.79%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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 fibrillation			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 115 (0.00%)	1 / 56 (1.79%)	0 / 55 (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
Coma			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Grand mal convulsion			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Ischaemic stroke			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Abdominal pain upper			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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 haemorrhage			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			

subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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	1 / 115 (0.87%)	0 / 56 (0.00%)	0 / 55 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Spinal pain			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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			
Campylobacter infection			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Gastroenteritis			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Herpes simplex meningoencephalitis			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Infected bites			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Pneumonia			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (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

Serious adverse events	R40 EvoMab Q2W	R40 EvoMab QM	S40 PBO Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 111 (0.90%)	3 / 112 (2.68%)	0 / 56 (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)			
Bladder neoplasm			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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 metastatic			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Ovarian cancer			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Aortic aneurysm			

subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Hypertensive crisis			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Orthostatic hypotension			
subjects affected / exposed	1 / 111 (0.90%)	0 / 112 (0.00%)	0 / 56 (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 artery stenosis			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Affective disorder			

subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Troponin increased			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Injury			
subjects affected / exposed	0 / 111 (0.00%)	1 / 112 (0.89%)	0 / 56 (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
Radius fracture			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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 fibrillation			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Coma			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Grand mal convulsion			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Ischaemic stroke			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Abdominal pain upper			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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 haemorrhage			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Hiatus hernia			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 111 (0.00%)	1 / 112 (0.89%)	0 / 56 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 111 (0.00%)	1 / 112 (0.89%)	0 / 56 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Spinal pain			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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			
Campylobacter infection			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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

Gastroenteritis			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Herpes simplex meningoencephalitis			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Infected bites			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Pneumonia			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 111 (0.90%)	0 / 112 (0.00%)	0 / 56 (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	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 55 (1.82%)	2 / 112 (1.79%)	1 / 115 (0.87%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder neoplasm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Colon cancer metastatic			
subjects affected / exposed	0 / 55 (0.00%)	1 / 112 (0.89%)	0 / 115 (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
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Ovarian cancer			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Pleomorphic adenoma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Aortic aneurysm			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Hypertensive crisis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Peripheral artery stenosis			
subjects affected / exposed	1 / 55 (1.82%)	0 / 112 (0.00%)	0 / 115 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Affective disorder			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Troponin increased			

subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Radius fracture			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Acute coronary syndrome			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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 fibrillation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Cerebrovascular accident			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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

Coma			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Grand mal convulsion			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Ischaemic stroke			
subjects affected / exposed	0 / 55 (0.00%)	1 / 112 (0.89%)	0 / 115 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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 haemorrhage			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Hiatus hernia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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			
Glomerulonephritis acute			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Spinal pain			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	1 / 115 (0.87%)
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			
Campylobacter infection			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Gastroenteritis			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Herpes simplex meningoencephalitis			

subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Infected bites			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Pneumonia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 55 (0.00%)	0 / 112 (0.00%)	0 / 115 (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	A10 PBO Q2W	A10 PBO QM	A10 EZE (Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 56 (8.93%)	3 / 55 (5.45%)	9 / 56 (16.07%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	2 / 56 (3.57%)
occurrences (all)	0	0	2
Headache			
subjects affected / exposed	1 / 56 (1.79%)	1 / 55 (1.82%)	1 / 56 (1.79%)
occurrences (all)	1	1	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	3 / 56 (5.36%)	0 / 55 (0.00%)	0 / 56 (0.00%)
occurrences (all)	3	0	0
Diarrhoea			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	3 / 56 (5.36%)
occurrences (all)	0	0	3
Muscle spasms			
subjects affected / exposed	0 / 56 (0.00%)	0 / 55 (0.00%)	1 / 56 (1.79%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	2 / 56 (3.57%)	2 / 55 (3.64%)	2 / 56 (3.57%)
occurrences (all)	2	2	2

Non-serious adverse events	A10 EZE (QM)	A10 EvoMab Q2W	A10 EvoMab QM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 55 (10.91%)	9 / 110 (8.18%)	7 / 110 (6.36%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 55 (1.82%)	1 / 110 (0.91%)	1 / 110 (0.91%)
occurrences (all)	1	1	1
Headache			

subjects affected / exposed	4 / 55 (7.27%)	1 / 110 (0.91%)	0 / 110 (0.00%)
occurrences (all)	4	1	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 55 (1.82%)	2 / 110 (1.82%)	0 / 110 (0.00%)
occurrences (all)	1	2	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 55 (1.82%)	2 / 110 (1.82%)	1 / 110 (0.91%)
occurrences (all)	1	2	1
Muscle spasms			
subjects affected / exposed	2 / 55 (3.64%)	3 / 110 (2.73%)	4 / 110 (3.64%)
occurrences (all)	2	3	4
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	0 / 110 (0.00%)	1 / 110 (0.91%)
occurrences (all)	0	0	1

Non-serious adverse events	A80 PBO Q2W	A80 PBO QM	A80 EZE (Q2W)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 55 (12.73%)	13 / 55 (23.64%)	8 / 56 (14.29%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 55 (1.82%)	1 / 55 (1.82%)	1 / 56 (1.79%)
occurrences (all)	1	1	1
Headache			
subjects affected / exposed	2 / 55 (3.64%)	2 / 55 (3.64%)	0 / 56 (0.00%)
occurrences (all)	3	2	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 55 (1.82%)	0 / 55 (0.00%)	1 / 56 (1.79%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	1 / 55 (1.82%)	4 / 55 (7.27%)	1 / 56 (1.79%)
occurrences (all)	2	4	1

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 55 (3.64%)	2 / 55 (3.64%)	2 / 56 (3.57%)
occurrences (all)	2	2	2
Muscle spasms			
subjects affected / exposed	1 / 55 (1.82%)	2 / 55 (3.64%)	3 / 56 (5.36%)
occurrences (all)	1	2	3
Myalgia			
subjects affected / exposed	0 / 55 (0.00%)	3 / 55 (5.45%)	1 / 56 (1.79%)
occurrences (all)	0	3	1

Non-serious adverse events	A80 EZE (QM)	A80 EvoMab Q2W	A80 EvoMab QM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 54 (3.70%)	11 / 109 (10.09%)	9 / 110 (8.18%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 54 (1.85%)	0 / 109 (0.00%)	1 / 110 (0.91%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	0 / 54 (0.00%)	1 / 109 (0.92%)	3 / 110 (2.73%)
occurrences (all)	0	1	3
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 54 (0.00%)	0 / 109 (0.00%)	0 / 110 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 54 (0.00%)	4 / 109 (3.67%)	2 / 110 (1.82%)
occurrences (all)	0	5	2
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 54 (1.85%)	3 / 109 (2.75%)	0 / 110 (0.00%)
occurrences (all)	1	3	0
Muscle spasms			
subjects affected / exposed	0 / 54 (0.00%)	2 / 109 (1.83%)	1 / 110 (0.91%)
occurrences (all)	0	2	1
Myalgia			

subjects affected / exposed	1 / 54 (1.85%)	1 / 109 (0.92%)	2 / 110 (1.82%)
occurrences (all)	1	2	2

Non-serious adverse events	R5 PBO Q2W	R5 PBO QM	R5 EvoMab Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 58 (18.97%)	1 / 57 (1.75%)	6 / 113 (5.31%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 58 (5.17%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences (all)	3	0	1
Headache			
subjects affected / exposed	3 / 58 (5.17%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences (all)	3	0	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 58 (0.00%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 58 (0.00%)	1 / 57 (1.75%)	0 / 113 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	4 / 58 (6.90%)	0 / 57 (0.00%)	1 / 113 (0.88%)
occurrences (all)	4	0	1
Muscle spasms			
subjects affected / exposed	1 / 58 (1.72%)	0 / 57 (0.00%)	2 / 113 (1.77%)
occurrences (all)	1	0	2
Myalgia			
subjects affected / exposed	1 / 58 (1.72%)	0 / 57 (0.00%)	0 / 113 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	R5 EvoMab QM	R40 PBO Q2W	R40 PBO QM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 115 (7.83%)	3 / 56 (5.36%)	8 / 55 (14.55%)
Nervous system disorders			
Dizziness			

subjects affected / exposed	2 / 115 (1.74%)	0 / 56 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	1 / 115 (0.87%)	2 / 56 (3.57%)	1 / 55 (1.82%)
occurrences (all)	2	2	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 115 (1.74%)	1 / 56 (1.79%)	1 / 55 (1.82%)
occurrences (all)	2	1	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 115 (1.74%)	0 / 56 (0.00%)	5 / 55 (9.09%)
occurrences (all)	2	0	6
Muscle spasms			
subjects affected / exposed	0 / 115 (0.00%)	0 / 56 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	2 / 115 (1.74%)	0 / 56 (0.00%)	1 / 55 (1.82%)
occurrences (all)	2	0	1

Non-serious adverse events	R40 EvoMab Q2W	R40 EvoMab QM	S40 PBO Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 111 (4.50%)	8 / 112 (7.14%)	3 / 56 (5.36%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 111 (0.00%)	1 / 112 (0.89%)	1 / 56 (1.79%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	2 / 111 (1.80%)	3 / 112 (2.68%)	2 / 56 (3.57%)
occurrences (all)	3	3	2
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 111 (0.00%)	0 / 112 (0.00%)	0 / 56 (0.00%)
occurrences (all)	0	0	0

Diarrhoea			
subjects affected / exposed	0 / 111 (0.00%)	1 / 112 (0.89%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 111 (1.80%)	1 / 112 (0.89%)	0 / 56 (0.00%)
occurrences (all)	2	1	0
Muscle spasms			
subjects affected / exposed	0 / 111 (0.00%)	1 / 112 (0.89%)	0 / 56 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	1 / 111 (0.90%)	1 / 112 (0.89%)	0 / 56 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	S40 PBO QM	S40 EvoMab Q2W	S40 EvoMab QM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 55 (9.09%)	18 / 112 (16.07%)	11 / 115 (9.57%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 55 (0.00%)	3 / 112 (2.68%)	1 / 115 (0.87%)
occurrences (all)	0	3	1
Headache			
subjects affected / exposed	1 / 55 (1.82%)	2 / 112 (1.79%)	5 / 115 (4.35%)
occurrences (all)	1	2	6
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 55 (0.00%)	2 / 112 (1.79%)	0 / 115 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	1 / 55 (1.82%)	1 / 112 (0.89%)	0 / 115 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 55 (1.82%)	6 / 112 (5.36%)	2 / 115 (1.74%)
occurrences (all)	1	6	2
Muscle spasms			

subjects affected / exposed	1 / 55 (1.82%)	3 / 112 (2.68%)	1 / 115 (0.87%)
occurrences (all)	1	3	1
Myalgia			
subjects affected / exposed	1 / 55 (1.82%)	1 / 112 (0.89%)	3 / 115 (2.61%)
occurrences (all)	2	1	3

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 August 2012	- added testing for prior or existing HCV infection in high risk individuals and evaluation of viral load in those who showed evidence thereof - clarified that subjects with known sensitivity to the 'active substances or their excipients' were excluded - added urine pregnancy testing at day 1, week 4, and week 8 for women of childbearing potential
10 October 2012	- added the LAPLACE-2 study acronym and short title - included a lipid stabilization period for background statin therapy - added new evolocumab formulation and autoinjectors to allow administration of investigational product in a home-use setting, revised schedule of assessment and description of procedures to replace week 4 and 6 visits with home-use IP administration, added reporting requirements for product/device complaints - updated program status in evolocumab background section - provide instruction regarding missed ezetimibe doses - added subjects with a history of HCV infection to the HCV antibody testing and viral load monitoring, if positive - updated sections on collection and reporting of adverse events and serious adverse events, including adding device-related AEs, and the serious adverse event contingency form - move change from baseline in VLDL-C at week 12 from tertiary to secondary endpoints - added transient ischemic attacks and non-coronary revascularization as exploratory endpoints - implemented minor clarifications and error corrections
10 December 2012	- added the LDL-C endpoint of mean percent change from baseline at weeks 10 and 12 as a co-primary endpoint - added the means of weeks 10 and 12 as co-secondary endpoints to all secondary endpoints - added an alert threshold for elevated triglycerides - added publication references for primary result publications of phase 2 studies MENDEL and LAPLACE - introduce the simplified terminology of once-monthly (QM) dosing - implemented minor clarifications and error corrections

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported