MK0653C in High Cardiovascular Risk Patients With High Cholesterol (Switch Study)(MK-0653C-162)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT01154036

First received: June 29, 2010
Last updated: October 30, 2015
Last verified: October 2015
History of Changes

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Purpose

This study will compare the lipid-altering efficacy and safety of switching to co-administration of ezetimibe and atorvastatin versus treatment with atorvastatin or rosuvastatin in high cardiovascular risk patients with hypercholesterolemia who have not achieved specified low-density lipoprotein cholesterol (LDL-C) levels. The primary hypothesis is that the co-administration of ezetimibe 10 mg and atorvastatin 10 mg will be superior to both atorvastatin 20 mg and rosuvastatin 10 mg with respect to the percentage reduction in low-density lipoprotein-cholesterol (LDL-C) after 6 weeks of treatment.

Condition	Intervention	Phase
Hypercholesterolemia	Drug: ezetimibe 10 mg Drug: atorvastatin Drug: Comparator: rosuvastatin	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, Double-Blind, Active-Controlled, Multicenter Study of Patients With Primary Hypercholesterolemia and High Cardiovascular Risk Who Are Not Adequately Controlled With Atorvastatin 10 mg: A Comparison of the Efficacy and Safety of Switching to Coadministration Ezetimibe and Atorvastatin Versus Doubling the Dose of Atorvastatin or Switching to Rosuvastatin

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol

Drug Information available for: Atorvastatin Atorvastatin calcium Rosuvastatin calcium Ezetimibe Rosuvastatin

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)] [Designated as safety issue: No]

  LDL-C levels measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4. LDL-C was calculated using the Friedewald method when triglyceride (TG)<350 mg/dL (3.95 mmol/L) and beta quantification ultracentrifugation when TG≥350 mg/dL (3.95 mmol/L).

Secondary Outcome Measures:

- Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase II). [Time Frame: Baseline (Week 6) and Week 12] [Designated as safety issue: No]

  LDL-C levels measured at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12). Baseline was defined as the average of the values at Visits 5 and 6. LDL-C was calculated using the Friedewald method when triglyceride (TG)<350 mg/dL (3.95 mmol/L) and beta quantification ultracentrifugation when TG ≥350 mg/dL (3.95 mmol/L).

- Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase I) [Time Frame: Week 6 (End of Phase I)] [Designated as safety issue: No]
- Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase II) [Time Frame: Week 12 (End of Phase II)] [Designated as safety issue: No]
- Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase I) [Time Frame: Week 6 (End of Phase I)] [Designated as safety issue: No]
- Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase II) [Time Frame: Week 12 (end of Phase II)] [Designated as safety issue: No]
- Percent Change From Baseline in Total Cholesterol (TC) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)] [Designated as safety issue: No]

  TC measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in Total Cholesterol (TC) (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  TC levels measured at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in Triglycerides (TG) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)] [Designated as safety issue: No]

  TG measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.

- Percent Change From Baseline in Triglycerides (TG) (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  TG levels measured at Baseline (Week 6: end of Phase I) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.

- Percent Change From Baseline in High-density Lipoprotein-Cholesterol (HDL-C) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)] [Designated as safety issue: No]

  HDL-C measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in HDL-C (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  HDL-C levels measured at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in Apolipoprotein B (Apo B) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]
  [Designated as safety issue: No]

  Apo-B measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in Apo B (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]
  [Designated as safety issue: No]

  Apo-B levels measured at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in Apolipoprotein A-I (Apo A-I) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]
  [Designated as safety issue: No]

  Apo-A-I measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in Apo A-I (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)]
  [Designated as safety issue: No]

  Apo-A-I levels measured at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in Non-HDL-C (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]
  [Designated as safety issue: No]

  Non-HDL-C measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in Non-HDL-C (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)]
  [Designated as safety issue: No]

  Non-HDL-C levels calculated at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in TC/HDL-C Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]
  [Designated as safety issue: No]

  TC/HDL-C ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in TC/HDL-C Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  TC/HDL-C Ratio calculated at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]
  [Designated as safety issue: No]

  LDL-C/HDL-C ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  LDL-C/HDL-C Ratio calculated at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]
  [Designated as safety issue: No]

  Apo B/Apo A-I ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  Apo B/Apo A-I Ratio calculated at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)] [Designated as safety issue: No]

  Non HDL-C/HDL-C ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

- Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  Non HDL-C/HDL-C Ratio calculated at baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.

- Percent Change From Baseline in High-sensitivity C-reactive Protein (Hs-CRP) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)] [Designated as safety issue: No]

  hs-CRP measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.

- Percent Change From Baseline in Hs-CRP (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)] [Designated as safety issue: No]

  hs-CRP measured at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.

Enrollment:	1547
Study Start Date:	July 2010
Study Completion Date:	October 2012
Primary Completion Date:	September 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Phase I: ezetimibe (EZ) 10 mg + atorvastatin (Atorva) 10 mg Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks	Drug: ezetimibe 10 mg Drug: atorvastatin
Active Comparator: Phase I: Atorvastatin 20 mg Atorvastatin 20 mg tablet once daily for 6 weeks	Drug: atorvastatin
Active Comparator: Phase I: Rosuvastatin 10 mg Rosuvastatin 10 mg tablet once daily for 6 weeks	Drug: Comparator: rosuvastatin
Experimental: Phase II: EZ 10mg+Atorva 10mg Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I	Drug: ezetimibe 10 mg Drug: atorvastatin
Experimental: Phase II: EZ 10mg + Atorva 20mg [A] Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II	Drug: ezetimibe 10 mg Drug: atorvastatin
Active Comparator: Phase II: Atorva 40mg Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II	Drug: atorvastatin
Experimental: Phase II: EZ 10mg + Atorva 20mg [R] Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ	Drug: ezetimibe 10 mg Drug:

10 mg + Atorva 20 mg once daily for 6 weeks in Phase II	atorvastatin
Active Comparator: Phase II: Rosuvastatin 20mg Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase	Drug: Comparator: rosuvastatin

Detailed Description:

This is a 18 week randomized, double-blind, active-controlled, multicenter study composed of a 6 week screening/run-in and 12 week double-blind treatment period (composed of 2 phases; each 6 weeks in duration). Only those participants who do not meet low density lipoprotein-cholesterol (LDL-C) goals at the end of Phase I (Week 6), were eligible to continue into Phase II (Week 12).

Eligibility

Ages Eligible for Study: 18 Years to 79 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patient is at high cardiovascular risk and meets one of the following conditions: has never taken lipid-lowering therapy or has been off such therapy for at least 6 weeks; or, is currently taking a stable dose of certain lipid-lowering agents
- Patient is willing to maintain a cholesterol lowering diet during the study
- Female patients receiving non-cyclical hormone therapy have maintained a stable dose and regimen for at least 8 weeks and are willing to continue the same regimen during the study

Exclusion Criteria:

- Patient is Asian
- Patient routinely has more than 2 alcoholic drinks per day
- Female patient is pregnant or breastfeeding
- Patient has congestive heart failure
- Patient has had a myocardial infarction, coronary bypass surgery, angioplasty, or acute coronary syndrome within 3 months of screening
- Patient has uncontrolled cardiac arrhythmias
- Patient has had a partial ileal or gastric bypass or other significant intestinal malabsorption
- Patient has uncontrolled high blood pressure
- Patient has kidney disease
- Patient has any disease known to influence blood lipid levels
- Patient has any disorders of the blood, digestive system, or nervous system including stroke and degenerative disease that would limit study participation
- Patient has poorly controlled or newly diagnosed diabetes
- Patient is known to be HIV positive
- Patient has a history of cancer in the last 5 years, except certain skin and cervical cancers

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01154036

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

No publications provided by Merck Sharp & Dohme Corp.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Krempf M, Simpson RJ Jr, Ramey DR, Brudi P, Giezek H, Tomassini JE, Lee R, Farnier M. Patient and physician factors influence decision-making in hypercholesterolemia: a questionnaire-based survey. Lipids Health Dis. 2015 May 19;14:45. doi: 10.1186/s12944-015-0037-y.

Bays HE, Averna M, Majul C, Muller-Wieland D, De Pellegrin A, Giezek H, Lee R, Lowe RS, Brudi P, Triscari J, Farnier M. Efficacy and safety of ezetimibe added to atorvastatin versus atorvastatin uptitration or switching to rosuvastatin in patients with primary hypercholesterolemia. Am J Cardiol. 2013 Dec 15;112(12):1885-95. doi: 10.1016/j.amjcard.2013.08.031. Epub 2013 Sep 21.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01154036 History of Changes
Other Study ID Numbers:	**0653C-162** 2010_517
Study First Received:	June 29, 2010
Results First Received:	September 5, 2013
Last Updated:	October 30, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Hypercholesterolemia	Antimetabolites
Dyslipidemias	Enzyme Inhibitors
Hyperlipidemias	Hydroxymethylglutaryl-CoA Reductase Inhibitors
Lipid Metabolism Disorders	Hypolipidemic Agents
Metabolic Diseases	Lipid Regulating Agents
Atorvastatin	Molecular Mechanisms of Pharmacological Action
Ezetimibe	Pharmacologic Actions
Rosuvastatin	Therapeutic Uses
Anticholesteremic Agents	

ClinicalTrials.gov processed this record on March 30, 2016

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Sponsor:
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ClinicalTrials.gov Identifier:
NCT01154036

First received: June 29, 2010
Last updated: October 30, 2015
Last verified: October 2015
History of Changes

Results First Received: September 5, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hypercholesterolemia
Interventions:	Drug: ezetimibe 10 mg Drug: atorvastatin Drug: Comparator: rosuvastatin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants in the Atorvastatin 20mg and Rosuvastatin 10mg arms who did not meet low density lipoprotein-cholesterol goals during Phase I were eligible for Phase II. Approximately 25% of participants in the ezetimibe 10mg+atorvastatin10mg arm continued to Phase II regardless of LDL-C control but were not included in any of the statistical analyses

Reporting Groups

	Description

Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase I: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II

Participant Flow for 2 periods

Period 1: Phase I

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Phase I: Rosuvastatin 10 mg	Phase II: EZ 10mg+Atorva 10mg	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg
STARTED	120	483	944	0	0	0	0	0
COMPLETED	117 [1]	455 [1]	888 [1]	0	0	0	0	0
NOT COMPLETED	3	28	56	0	0	0	0	0
Physician Decision	0	1	0	0	0	0	0	0
Lost to Follow-up	0	3	6	0	0	0	0	0
Protocol Violation	0	3	9	0	0	0	0	0
Withdrawal by Subject	2	10	29	0	0	0	0	0
Adverse Event	1	11	12	0	0	0	0	0

[1] Not all completers were eligible for Phase II

Period 2: Phase II

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Phase I: Rosuvastatin 10 mg	Phase II: EZ 10mg+Atorva 10mg	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg

STARTED	0	0	0	28 [1]	124 [1]	126 [1]	234 [1]	206 [1]
COMPLETED	0	0	0	27	116	121	225	200
NOT COMPLETED	0	0	0	1	8	5	9	6
Adverse Event	0	0	0	0	1	1	1	1
Physician Decision	0	0	0	0	0	0	1	0
Lost to Follow-up	0	0	0	1	2	0	2	1
Protocol Violation	0	0	0	0	1	2	0	0
Withdrawal by Subject	0	0	0	0	4	2	5	4

[1] Only participants who did not meet LDL-C goals at the end of Phase I, were eligible for Phase II

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase I: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks
Total	Total of all reporting groups

Baseline Measures

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Phase I: Rosuvastatin 10 mg**	**Total**
Number of Participants [units: participants]	**120**	**483**	**944**	**1547**
Age, Customized [units: Participants]				
<20 years	**0**	**0**	**1**	**1**
20 to 29 years	**0**	**4**	**2**	**6**
30 to 39 years	**1**	**13**	**25**	**39**

40 to 49 years	16	50	99	165
50 to 59 years	37	170	324	531
60 to 64 years	27	87	183	297
≥65 years	39	159	310	508
Gender [units: Participants]				
Female	71	253	489	813
Male	49	230	455	734

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Primary
Measure Title	Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase I)
Measure Description	LDL-C levels measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4. LDL-C was calculated using the Friedewald method when triglyceride (TG)<350 mg/dL (3.95 mmol/L) and beta quantification ultracentrifugation when TG≥350 mg/dL (3.95 mmol/L).
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participant who received at least one dose of study drug during Phase I and had a baseline or at least one measurement available during Phase I

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase I: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Phase I: Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	120	480	939

Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-24.8 (23.6)**	**-10.1 (20.8)**	**-13.8 (22.8)**

Statistical Analysis 1 for Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-12.7
95% Confidence Interval	-16.6 to -8.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The primary hypotheses were tested at 0.045, applying Hochberg's procedure.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimate [4]	-9.1
95% Confidence Interval	-12.9 to -5.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The primary hypotheses were tested at 0.045, applying Hochberg's procedure.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase II). [Time Frame: Baseline (Week 6) and

Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase II).
Measure Description	LDL-C levels measured at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12). Baseline was defined as the average of the values at Visits 5 and 6. LDL-C was calculated using the Friedewald method when triglyceride (TG)<350 mg/dL (3.95 mmol/L) and beta quantification ultracentrifugation when TG ≥350 mg/dL (3.95 mmol/L).
Time Frame	Baseline (Week 6) and Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**28**
Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase II). [units: Percentage Change] Median (Standard Deviation)	**-16.4 (31.1)**	**-8.1 (23.3)**	**-19.3 (32.1)**	**-8.4 (20.8)**	**2.4 (27.4)**

Statistical Analysis 1 for Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase II).

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-10.5

95% Confidence Interval	-15.9 to -5.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The secondary hypotheses were tested at an adaptive alpha level depending on the hypotheses testing result of the primary hypotheses.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) (Phase II).

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-9.5
95% Confidence Interval	-13.6 to -5.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The secondary hypotheses were tested at an adaptive alpha level depending on the hypotheses testing result of the primary hypotheses.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase I) [Time Frame: Week 6 (End of Phase I)]

Measure Type	Secondary
Measure Title	Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase I)
Measure Description	No text entered.
Time Frame	Week 6 (End of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I and had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Rosuvastatin 10 mg
Number of Participants Analyzed [units: participants]	**119**	**471**	**915**
Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase I) [units: Percentage of Participants]	**56.3**	**37.4**	**43.6**

Statistical Analysis 1 for Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Logistic Regression Model
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.51
95% Confidence Interval	1.62 to 3.89

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Logistic Regression Model
P Value [3]	0.007
Odds Ratio (OR) [4]	1.77
95% Confidence Interval	1.17 to 2.67

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

4. Secondary: Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase II) [Time Frame: Week 12 (End of Phase II)]

Measure Type	Secondary
Measure Title	Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase II)
Measure Description	No text entered.
Time Frame	Week 12 (End of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II and had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**120**	**123**	**228**	**201**	**28**

Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase II) [units: Percentage of Participants]	**55.8**	**34.1**	**53.5**	**35.8**	**NA [1]**

[1] Study plan did not include the collection of data for this arm for this Phase II endpoint; data not obtained or recorded

Statistical Analysis 1 for Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Logistic regression Model
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.71
95% Confidence Interval	1.55 to 4.73

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants That Reach Target LDL-C Level of < 100 mg/dL (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Logistic Regression Model
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.38
95% Confidence Interval	1.56 to 3.63

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Secondary: Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase I) [Time Frame: Week 6 (End of Phase I)]

Measure Type	Secondary
Measure Title	Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase I)
Measure Description	No text entered.
Time Frame	Week 6 (End of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I and had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**119**	**471**	**915**
Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase I) [units: Percentage of Participants]	**19.3**	**3.0**	**6.6**

Statistical Analysis 1 for Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Logistic Regression Model
P Value [3]	<0.001
Odds Ratio (OR) [4]	9.46
95% Confidence Interval	4.56 to 19.62

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Logistic Regression Model
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.90
95% Confidence Interval	2.23 to 6.82

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

6. Secondary: Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase II) [Time Frame: Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase II)
Measure Description	No text entered.
Time Frame	Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II and had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal

	and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg	Phase II: EZ 10mg+Atorva 10mg
Number of Participants Analyzed [units: participants]	**120**	**123**	**228**	**201**	**28**
Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase II) [units: Percentage of Participants]	**18.3**	**0.8**	**15.4**	**3.0**	**NA [1]**

[1] Study plan did not include the collection of data for this arm for this Phase II endpoint; data not obtained or recorded

Statistical Analysis 1 for Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Logistic Regression Model
P Value [3]	0.001
Odds Ratio (OR) [4]	27.77
95% Confidence Interval	3.64 to 211.83

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percentage of Participants That Reach Target LDL-C Level of < 70 mg/dL (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Logistic Regression Model
P Value [3]	<0.001
Odds Ratio (OR) [4]	7.08
95% Confidence Interval	2.85 to 17.56

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Logistic regression model included terms for treatment and baseline LDL-C (where baseline LDL-C was fitted as 3 categories based on tertiles)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

7. Secondary: Percent Change From Baseline in Total Cholesterol (TC) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Total Cholesterol (TC) (Phase I)
Measure Description	TC measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**480**	**939**
Percent Change From Baseline in Total Cholesterol (TC) (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-13.6 (17.0)**	**-6.3 (14.1)**	**-8.2 (14.7)**

Statistical Analysis 1 for Percent Change From Baseline in Total Cholesterol (TC) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression

P Value [3]	<0.001
Difference in M-estimates [4]	-7.1
95% Confidence Interval	-9.7 to -4.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Total Cholesterol (TC) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-5.8
95% Confidence Interval	-8.3 to -3.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

8. Secondary: Percent Change From Baseline in Total Cholesterol (TC) (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Total Cholesterol (TC) (Phase II)
Measure Description	TC levels measured at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**28**
Percent Change From Baseline in Total Cholesterol (TC) (Phase II) [units: Percentage Change] Median (Standard Deviation)	**-10.2 (19.9)**	**-2.9 (15.7)**	**-13.1 (22.8)**	**-5.0 (14.0)**	**2.2 (15.4)**

Statistical Analysis 1 for Percent Change From Baseline in Total Cholesterol (TC) (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-6.8
95% Confidence Interval	-10.7 to -3.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Total Cholesterol (TC) (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-7.4
95% Confidence Interval	-10.2 to -4.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

9. Secondary: Percent Change From Baseline in Triglycerides (TG) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Triglycerides (TG) (Phase I)
Measure Description	TG measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I and had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Rosuvastatin 10 mg
Number of Participants Analyzed [units: participants]	119	471	915
Percent Change From Baseline in Triglycerides (TG) (Phase I) [units: Percentage Change] Least Squares Mean (95% Confidence Interval)	-6.0 (-10.9 to -0.8)	-3.9 (-6.5 to -1.2)	-1.1 (-3.1 to 0.9)

Statistical Analysis 1 for Percent Change From Baseline in Triglycerides (TG) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.466
Difference in least-squares means [4]	-2.1
95% Confidence Interval	-7.8 to 3.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Triglycerides (TG) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Constrained Longitudinal Analysis
P Value [3]	0.081
Difference in Least-squares means [4]	-4.9
95% Confidence Interval	-10.3 to 0.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:

No text entered.

10. Secondary: Percent Change From Baseline in Triglycerides (TG) (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Triglycerides (TG) (Phase II)
Measure Description	TG levels measured at Baseline (Week 6: end of Phase I) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.
Time Frame	Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II and had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**120**	**123**	**228**	**201**	**28**
Percent Change From Baseline in Triglycerides (TG) (Phase II) [units: Percentage Change] Least Squares Mean (95% Confidence Interval)	**-5.9 (-11.0 to -0.4)**	**-3.1 (-8.4 to 2.4)**	**-10.2 (-13.9 to -6.4)**	**-3.2 (-7.3 to 1.2)**	**NA** [1]

[1] Study plan did not include the calculation of these values

Statistical Analysis 1 for Percent Change From Baseline in Triglycerides (TG) (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.466
Difference in Least-squares Means [4]	-2.8
95% Confidence Interval	-10.2 to 4.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Triglycerides (TG) (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.011
Difference in Least-squarres Means [4]	-7.1
95% Confidence Interval	-12.6 to -1.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

11. Secondary: Percent Change From Baseline in High-density Lipoprotein-Cholesterol (HDL-C) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in High-density Lipoprotein-Cholesterol (HDL-C) (Phase I)
Measure Description	HDL-C measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4

Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**480**	**939**
Percent Change From Baseline in High-density Lipoprotein-Cholesterol (HDL-C) (Phase I) [units: Percentage Change] Median (Standard Deviation)	**0.9 (11.9)**	**-1.3 (11.6)**	**1.0 (13.1)**

Statistical Analysis 1 for Percent Change From Baseline in High-density Lipoprotein-Cholesterol (HDL-C) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.133
Difference in M--estimates [4]	1.7
95% Confidence Interval	-0.5 to 4.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in High-density Lipoprotein-Cholesterol (HDL-C) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.610
Difference in M-estimates [4]	-0.6
95% Confidence Interval	-2.7 to 1.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

12. Secondary: Percent Change From Baseline in HDL-C (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in HDL-C (Phase II)
Measure Description	HDL-C levels measured at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10

	mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg	Phase II: EZ 10mg+Atorva 10mg
Number of Participants Analyzed [units: participants]	124	124	231	205	28
Percent Change From Baseline in HDL-C (Phase II) [units: Percentage Change] Median (Standard Deviation)	0.9 (14.1)	1.0 (16.0)	-0.8 (13.7)	0.0 (15.2)	0.0 (11.7)

Statistical Analysis 1 for Percent Change From Baseline in HDL-C (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.520
Difference in M-estimates [4]	-1.0
95% Confidence Interval	-4.2 to 2.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in HDL-C (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.567
Difference in M-estimates [4]	-0.7
95% Confidence Interval	-3.1 to 1.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

13. Secondary: Percent Change From Baseline in Apolipoprotein B (Apo B) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apolipoprotein B (Apo B) (Phase I)
Measure Description	Apo-B measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**479**	**938**
Percent Change From Baseline in Apolipoprotein B (Apo B) (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-12.1 (20.7)**	**-6.1 (20.7)**	**-7.6 (20.1)**

Statistical Analysis 1 for Percent Change From Baseline in Apolipoprotein B (Apo B) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.003
Difference in M-estimates [4]	-5.3
95% Confidence Interval	-8.8 to -1.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Apolipoprotein B (Apo B) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.011
Difference in M-estimates [4]	-4.3
95% Confidence Interval	-7.7 to -1.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

14. Secondary: Percent Change From Baseline in Apo B (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo B (Phase II)
Measure Description	Apo-B levels measured at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately

controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg	Phase II: EZ 10mg+Atorva 10mg
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**27**
Percent Change From Baseline in Apo B (Phase II) [units: Percentage Change] Median (Standard Deviation)	**-12.0 (26.5)**	**-6.3 (19.6)**	**-14.0 (25.1)**	**-4.9 (21.8)**	**-4.0 (16.8)**

Statistical Analysis 1 for Percent Change From Baseline in Apo B (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.079
Difference in M-estimates [4]	-4.3
95% Confidence Interval	-9.2 to 0.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Apo B (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-7.7
95% Confidence Interval	-11.4 to -4.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

15. Secondary: Percent Change From Baseline in Apolipoprotein A-I (Apo A-I) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apolipoprotein A-I (Apo A-I) (Phase I)
Measure Description	Apo-A-I measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**479**	**938**

Percent Change From Baseline in Apolipoprotein A-I (Apo A-I) (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-0.6 (13.1)**	**-1.9 (12.5)**	**1.4 (13.0)**

Statistical Analysis 1 for Percent Change From Baseline in Apolipoprotein A-I (Apo A-I) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.156
Difference in M-estimates [4]	1.6
95% Confidence Interval	-0.6 to 3.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Apolipoprotein A-I (Apo A-I) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.425
Difference in M-estimates [4]	-0.9
95% Confidence Interval	-2.9 to 1.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

16. Secondary: Percent Change From Baseline in Apo A-I (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of

Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo A-I (Phase II)
Measure Description	Apo-A-I levels measured at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**27**
Percent Change From Baseline in Apo A-I (Phase II) [units: Percentage Change] Median (Standard Deviation)	**1.6 (11.9)**	**1.4 (14.1)**	**-0.6 (14.4)**	**0.0 (16.0)**	**-0.7 (14.3)**

Statistical Analysis 1 for Percent Change From Baseline in Apo A-I (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.739
Difference in M-estimates [4]	0.5
95% Confidence Interval	-2.5 to 3.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Apo A-I (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.410
Difference in M-estimates [4]	-1.0
95% Confidence Interval	-3.3 to 1.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

17. Secondary: Percent Change From Baseline in Non-HDL-C (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-HDL-C (Phase I)
Measure Description	Non-HDL-C measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of

study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Rosuvastatin 10 mg
Number of Participants Analyzed [units: participants]	**120**	**480**	**939**
Percent Change From Baseline in Non-HDL-C (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-18.0 (22.3)**	**-7.9 (17.6)**	**-11.1 (19.8)**

Statistical Analysis 1 for Percent Change From Baseline in Non-HDL-C (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-10.1
95% Confidence Interval	-13.6 to -6.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Non-HDL-C (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-7.6
95% Confidence Interval	-10.9 to -4.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

18. Secondary: Percent Change From Baseline in Non-HDL-C (Phase II) [Time Frame: Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-HDL-C (Phase II)
Measure Description	Non-HDL-C levels calculated at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase I) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed	**124**	**124**	**231**	**205**	**28**

[units: participants]					
Percent Change From Baseline in Non-HDL-C (Phase II) [units: Percentage Change] Median (Standard Deviation)	**-17.5 (26.1)**	**-5.5 (16.6)**	**-18.1 (29.4)**	**-6.3 (18.5)**	**-0.5 (17.7)**

Statistical Analysis 1 for Percent Change From Baseline in Non-HDL-C (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-9.3
95% Confidence Interval	-14.0 to -4.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Non-HDL-C (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.001
Difference in M-estimates [4]	-9.8
95% Confidence Interval	-13.5 to -6.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

19. Secondary: Percent Change From Baseline in TC/HDL-C Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in TC/HDL-C Ratio (Phase I)
Measure Description	TC/HDL-C ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**480**	**939**
Percent Change From Baseline in TC/HDL-C Ratio (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-14.3 (17.9)**	**-4.5 (16.8)**	**-9.0 (19.1)**

Statistical Analysis 1 for Percent Change From Baseline in TC/HDL-C Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-8.1
95% Confidence Interval	-11.2 to -4.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in TC/HDL-C Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.001
Difference in M-estimates [4]	-4.8
95% Confidence Interval	-7.8 to -1.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

20. Secondary: Percent Change From Baseline in TC/HDL-C Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in TC/HDL-C Ratio (Phase II)
Measure Description	TC/HDL-C Ratio calculated at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and

	were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg	Phase II: EZ 10mg+Atorva 10mg
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**28**
Percent Change From Baseline in TC/HDL-C Ratio (Phase II) [units: Percentage Change] Median (Standard Deviation)	**-13.5 (21.7)**	**-6.5 (13.9)**	**-11.7 (23.3)**	**-4.0 (17.8)**	**-1.0 (9.6)**

Statistical Analysis 1 for Percent Change From Baseline in TC/HDL-C Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-6.9
95% Confidence Interval	-11.0 to -2.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in TC/HDL-C Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-6.4
95% Confidence Interval	-9.4 to -3.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

21. Secondary: Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase I)
Measure Description	LDL-C/HDL-C ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase 1: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Phase 1: Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**480**	**939**
Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-23.9 (23.6)**	**-7.1 (23.2)**	**-14.7 (26.9)**

Statistical Analysis 1 for Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg

Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-13.7
95% Confidence Interval	-18.1 to -9.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase 1: Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-7.8
95% Confidence Interval	-11.9 to -3.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

22. Secondary: Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase II)
Measure Description	LDL-C/HDL-C Ratio calculated at Baseline (end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**28**
Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase II) [units: Percentage Change] Median (Standard Deviation)	**-20.6 (31.4)**	**-8.2 (20.6)**	**-18.2 (31.6)**	**-7.5 (21.5)**	**-4.5 (22.9)**

Statistical Analysis 1 for Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-10.4
95% Confidence Interval	-15.8 to -4.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in LDL-C/HDL-C Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-8.3
95% Confidence Interval	-12.5 to -4.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

23. Secondary: Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase I)
Measure Description	Apo B/Apo A-I ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase 1: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Phase 1: Rosuvastatin 10 mg
Number of Participants Analyzed [units: participants]	120	479	938
Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase I) [units: Percentage Change] Median (Standard Deviation)	-13.0 (22.3)	-4.8 (18.9)	-8.8 (23.0)

Statistical Analysis 1 for Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-6.3
95% Confidence Interval	-10.0 to -2.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase 1: Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.052
Difference in M-estimates [4]	-3.5
95% Confidence Interval	-7.1 to 0.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	No text entered.

24. Secondary: Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase II)
Measure Description	Apo B/Apo A-I Ratio calculated at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	**Phase II: Atorva 40mg**	**Phase II: EZ 10mg + Atorva 20mg [R]**	**Phase II: Rosuvastatin 20mg**	**Phase II: EZ 10mg+Atorva 10mg**
Number of Participants Analyzed [units: participants]	**124**	**124**	**231**	**205**	**27**
Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase II) [units: Percentage Change] Median (Standard Deviation)	**-11.2 (26.2)**	**-6.4 (19.4)**	**-11.2 (27.5)**	**-5.4 (21.5)**	**-6.7 (11.3)**

Statistical Analysis 1 for Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression

P Value [3]	0.024
Difference in M-estimates [4]	-5.8
95% Confidence Interval	-10.8 to -0.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Apo B/Apo A-I Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	0.002
Difference in M-estimates [4]	-6.1
95% Confidence Interval	-9.9 to -2.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

25. Secondary: Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase I)
Measure Description	Non HDL-C/HDL-C ratio calculated at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I or had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase 1: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Phase 1: Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**120**	**480**	**939**
Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase I) [units: Percentage Change] Median (Standard Deviation)	**-18.9 (23.9)**	**-6.3 (22.8)**	**-12.2 (25.9)**

Statistical Analysis 1 for Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-10.6
95% Confidence Interval	-14.9 to -6.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase 1: Rosuvastatin 10 mg
Method [2]	Multiple Imputation Robust Regression

P Value [3]	0.002
Difference in M-estimates [4]	-6.2
95% Confidence Interval	-10.2 to -2.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

26. Secondary: Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase II)
Measure Description	Non HDL-C/HDL-C Ratio calculated at baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6.
Time Frame	Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II or had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg	Phase II: EZ 10mg+Atorva 10mg
Number of Participants Analyzed [units: participants]	124	124	231	205	28
Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase II) [units: Percentage Change] Median (Standard Deviation)	-18.2 (29.5)	-8.8 (18.8)	-16.3 (32.3)	-5.9 (23.4)	-1.9 (12.9)

Statistical Analysis 1 for Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-9.3
95% Confidence Interval	-14.8 to -3.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Non-HDL-C/HDL-C Ratio (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Multiple Imputation Robust Regression
P Value [3]	<0.001
Difference in M-estimates [4]	-8.4
95% Confidence Interval	-12.6 to -4.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	M-Estimates, 95% CI, and p-value obtained from a robust regression model with terms for treatment and baseline values, after imputing missing values
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:

	No text entered.

27. Secondary: Percent Change From Baseline in High-sensitivity C-reactive Protein (Hs-CRP) (Phase I) [Time Frame: Baseline and Week 6 (end of Phase I)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in High-sensitivity C-reactive Protein (Hs-CRP) (Phase I)
Measure Description	hs-CRP measured at Baseline and after 6 weeks of treatment (Week 6; end of Phase I). Baseline was defined as the average value of the measurements taken at Visits 3 and 4. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.
Time Frame	Baseline and Week 6 (end of Phase I)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Efficacy analyses were performed using the Full Analysis Set (FAS). For Phase I this population consisted of all randomized participants who received at least 1 dose of study drug during Phase I, had a baseline measurement for Phase I and had at least 1 measurement after the start of study drug provided during Phase I.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase I: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks;

Measured Values

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	**Phase I: Atorvastatin 20 mg**	**Phase I: Rosuvastatin 10 mg**
Number of Participants Analyzed [units: participants]	**117**	**458**	**899**
Percent Change From Baseline in High-sensitivity C-reactive Protein (Hs-CRP) (Phase I) [units: Percentage Change] Least Squares Mean (95% Confidence Interval)	**-10.5 (-23.0 to 4.0)**	**-6.6 (-13.6 to 1.0)**	**-9.0 (-14.0 to -3.6)**

Statistical Analysis 1 for Percent Change From Baseline in High-sensitivity C-reactive Protein (Hs-CRP) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Atorvastatin 20 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.613
Difference in Least-squares Means [4]	-3.9
95% Confidence Interval	-18.9 to 11.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in High-sensitivity C-reactive Protein (Hs-CRP) (Phase I)

Groups [1]	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg vs. Phase I: Rosuvastatin 10 mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.831
Difference in Least-squares Means [4]	-1.5
95% Confidence Interval	-15.7 to 12.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

28. Secondary: Percent Change From Baseline in Hs-CRP (Phase II) [Time Frame: Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Hs-CRP (Phase II)
Measure Description	hs-CRP measured at Baseline (Week 6; end of Phase 1) and after 6 weeks of study drug administration (Week 12; end of Phase II). Baseline was defined as the average of the values at Visits 5 and 6. Baseline and post-baseline measurements were log-transformed in the response vector, with fixed effects for treatment, time and the interaction of time by treatment.
Time Frame	Baseline (Week 6; end of Phase 1) and Week 12 (end of Phase II)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS). For Phase II this population consisted of all randomized participants who completed Phase I and were not adequately

controlled at the end of Phase I, received at least 1 dose of study treatment during Phase II, had a baseline measurement for Phase II and had at least 1 measurement after the start of Phase II

Reporting Groups

	Description
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.

Measured Values

	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg	Phase II: EZ 10mg+Atorva 10mg
Number of Participants Analyzed [units: participants]	**119**	**121**	**226**	**200**	**27**
Percent Change From Baseline in Hs-CRP (Phase II) [units: Percentage Change] Least Squares Mean (95% Confidence Interval)	**-19.5 (-31.5 to -5.3)**	**-6.4 (-20.2 to 9.8)**	**-10.9 (-20.9 to 0.3)**	**0.7 (-11.2 to 14.2)**	**NA** [1]

[1] Study plan did not include the calculation of these values

Statistical Analysis 1 for Percent Change From Baseline in Hs-CRP (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [A] vs. Phase II: Atorva 40mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.187
Difference in Least-squares Means [4]	-13.1
95% Confidence Interval	-32.6 to 6.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Hs-CRP (Phase II)

Groups [1]	Phase II: EZ 10mg + Atorva 20mg [R] vs. Phase II: Rosuvastatin 20mg
Method [2]	Constrained Longitudinal Data Analysis
P Value [3]	0.153
Difference in Least-squares Means [4]	-11.6
95% Confidence Interval	-27.7 to 4.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Geometric mean percent changes from baseline were calculated based on back-transformation via exponentiation of the model-based least square means
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	up to 12 weeks
Additional Description	Adverse events were reported using the All Patients as Treated (APaT) Population, which was defined as all randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase I: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II

Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II

Serious Adverse Events

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Phase I: Rosuvastatin 10 mg	Phase II: EZ 10mg+Atorva 10mg	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg
Total, serious adverse events								
# participants affected / at risk	0/120 (0.00%)	3/480 (0.63%)	10/939 (1.06%)	0/28 (0.00%)	2/124 (1.61%)	2/124 (1.61%)	5/231 (2.16%)	1/205 (0.49%)
Blood and lymphatic system disorders								
Anaemia † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Cardiac disorders								
Acute myocardial infarction † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Coronary artery disease † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	1/231 (0.43%)	0/205 (0.00%)
# events	0	1	0	0	0	0	1	0
Myocardial infarction † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	1/124 (0.81%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	1	0	0
Ventricular extrasystoles † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Angina pectoris † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	1/231 (0.43%)	0/205 (0.00%)
# events	0	0	0	0	0	0	1	0
Angina unstable † 1								

# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	1/124 (0.81%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	0	0	0	1	0	0
Eye disorders								
Vitreous haemorrhage † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	1/124 (0.81%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	0	0	1	0	0	0
Gastrointestinal disorders								
Gastrooesophageal reflux disease † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Haemorrhoids † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
General disorders								
Chest pain † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	1/124 (0.81%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	0	0	1	0	0	0
Infections and infestations								
Urinary tract infection † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0
Injury, poisoning and procedural complications								
Pelvic fracture † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0
Road traffic accident † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0
Alcohol poisoning † 1								
# participants								

affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	1/231 (0.43%)	0/205 (0.00%)
# events	0	0	0	0	0	0	1	0
Metabolism and nutrition disorders								
Hyperglycaemia † [1]								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	1/231 (0.43%)	0/205 (0.00%)
# events	0	0	0	0	0	0	1	0
Musculoskeletal and connective tissue disorders								
Back pain † [1]								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
Basal cell carcinoma † [1]								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Bile duct cancer † [1]								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Lung neoplasm malignant † [1]								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0
Uterine leiomyoma † [1]								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Nervous system disorders								
Transient ischaemic attack † [1]								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)

# events	0	0	1	0	0	0	0	0
Cerebral infarction † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	1/205 (0.49%)
# events	0	0	0	0	0	0	0	1
Psychiatric disorders								
Mental status changes † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0
Renal and urinary disorders								
Renal failure acute † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0
Calculus urinary † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	1/231 (0.43%)	0/205 (0.00%)
# events	0	0	0	0	0	0	1	0
Respiratory, thoracic and mediastinal disorders								
Asthma † 1								
# participants affected / at risk	0/120 (0.00%)	0/480 (0.00%)	1/939 (0.11%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	0	1	0	0	0	0	0
Vascular disorders								
Deep vein thrombosis † 1								
# participants affected / at risk	0/120 (0.00%)	1/480 (0.21%)	0/939 (0.00%)	0/28 (0.00%)	0/124 (0.00%)	0/124 (0.00%)	0/231 (0.00%)	0/205 (0.00%)
# events	0	1	0	0	0	0	0	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	up to 12 weeks
Additional Description	Adverse events were reported using the All Patients as Treated (APaT) Population, which was defined as all

	randomized participants who received at least 1 dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Co-administration of EZ 10 mg tablet + Atorva 10 mg tablet; once daily for 6 weeks
Phase I: Atorvastatin 20 mg	Atorvastatin 20 mg tablet once daily for 6 weeks
Phase I: Rosuvastatin 10 mg	Rosuvastatin 10 mg tablet once daily for 6 weeks
Phase II: EZ 10mg+Atorva 10mg	Participants who had previously received EZ 10 mg + Atorva 10 mg in Phase I and continued on EZ 10 mg + Atorva 10 mg once daily for 6 weeks during Phase II regardless of whether or not LDL-C goals were achieved in Phase I.
Phase II: EZ 10mg + Atorva 20mg [A]	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched to EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Atorva 40mg	Participants who had previously received Atorva 20 mg in Phase I and did not reach LDL-C goal and were switched Atorva 40 mg once daily for 6 weeks in Phase II
Phase II: EZ 10mg + Atorva 20mg [R]	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and received EZ 10 mg + Atorva 20 mg once daily for 6 weeks in Phase II
Phase II: Rosuvastatin 20mg	Participants who had previously received Rosuvastatin 10 mg in Phase I and did not reach LDL-C goal and were switched to Rosuvastatin 20 mg once daily for 6 weeks in Phase II

Other Adverse Events

	Phase I: Ezetimibe (EZ) 10 mg + Atorvastatin (Atorva) 10 mg	Phase I: Atorvastatin 20 mg	Phase I: Rosuvastatin 10 mg	Phase II: EZ 10mg+Atorva 10mg	Phase II: EZ 10mg + Atorva 20mg [A]	Phase II: Atorva 40mg	Phase II: EZ 10mg + Atorva 20mg [R]	Phase II: Rosuvastatin 20mg
Total, other (not including serious) adverse events								
# participants affected / at risk	**0/120 (0.00%)**	**0/480 (0.00%)**	**0/939 (0.00%)**	**0/28 (0.00%)**	**0/124 (0.00%)**	**0/124 (0.00%)**	**0/231 (0.00%)**	**0/205 (0.00%)**

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** The sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

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No publications provided by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Krempf M, Simpson RJ Jr, Ramey DR, Brudi P, Giezek H, Tomassini JE, Lee R, Farnier M. Patient and physician factors influence decision-making in hypercholesterolemia: a questionnaire-based survey. Lipids Health Dis. 2015 May 19;14:45. doi: 10.1186/s12944-015-0037-y.

Bays HE, Averna M, Majul C, Muller-Wieland D, De Pellegrin A, Giezek H, Lee R, Lowe RS, Brudi P, Triscari J, Farnier M. Efficacy and safety of ezetimibe added to atorvastatin versus atorvastatin uptitration or switching to rosuvastatin in patients with primary hypercholesterolemia. Am J Cardiol. 2013 Dec 15;112(12):1885-95. doi: 10.1016/j.amjcard.2013.08.031. Epub 2013 Sep 21.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01154036 History of Changes
Other Study ID Numbers:	**0653C-162** 2010_517 (Other Identifier: Merck Study Number)
Study First Received:	June 29, 2010
Results First Received:	September 5, 2013
Last Updated:	October 30, 2015
Health Authority:	United States: Food and Drug Administration

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