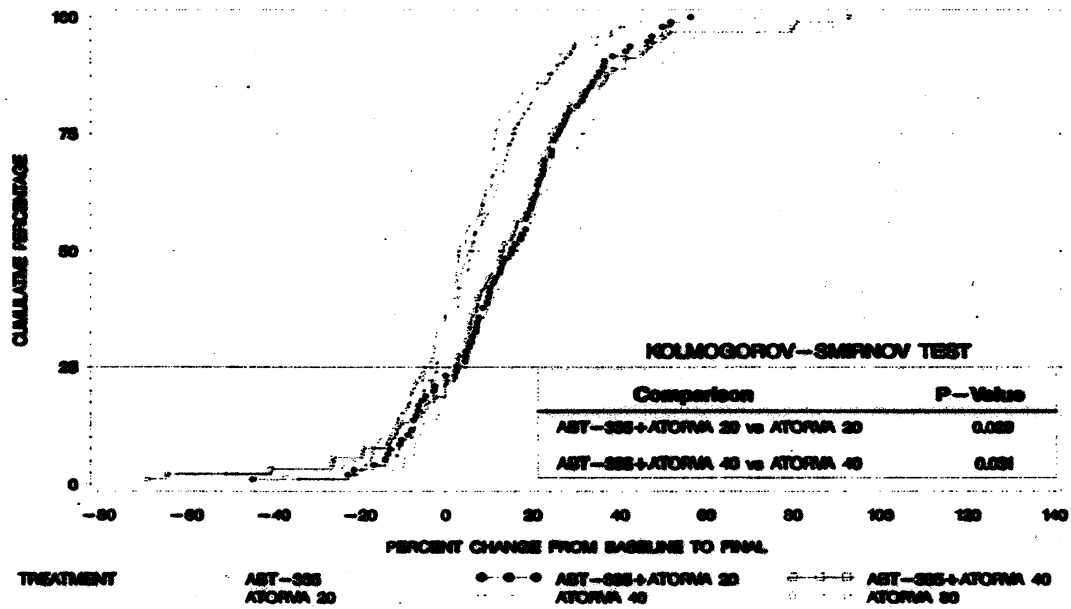


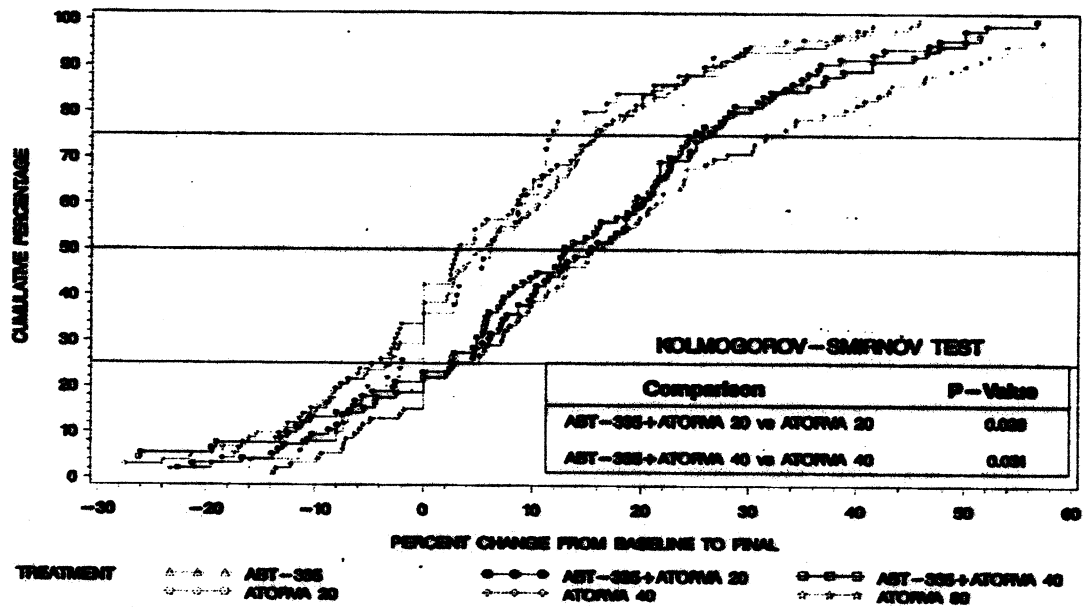
**CUMULATIVE DISTRIBUTION FUNCTION FOR % CHANGE IN HDL - C
STUDY M05-750**



The second figure for each of HDL-C, LDL-C, and Triglycerides is meant for better visualization with truncated X-axis.

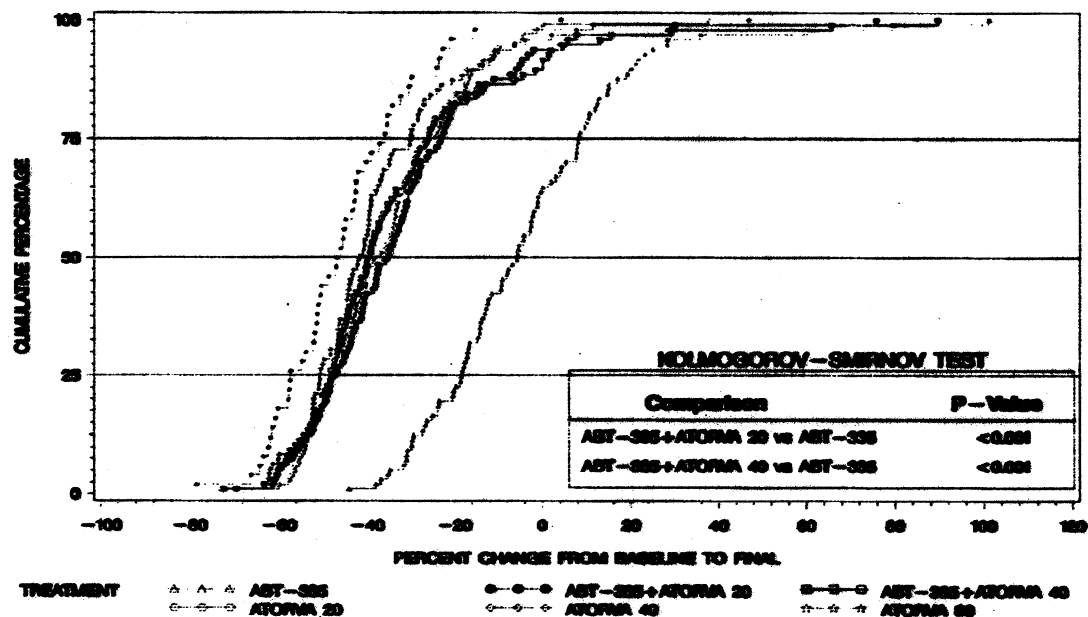
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**CUMULATIVE DISTRIBUTION FUNCTION FOR % CHANGE IN HDL - C
STUDY M05-750**



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CUMULATIVE DISTRIBUTION FUNCTION FOR % CHANGE IN LDL-C
STUDY M05-789

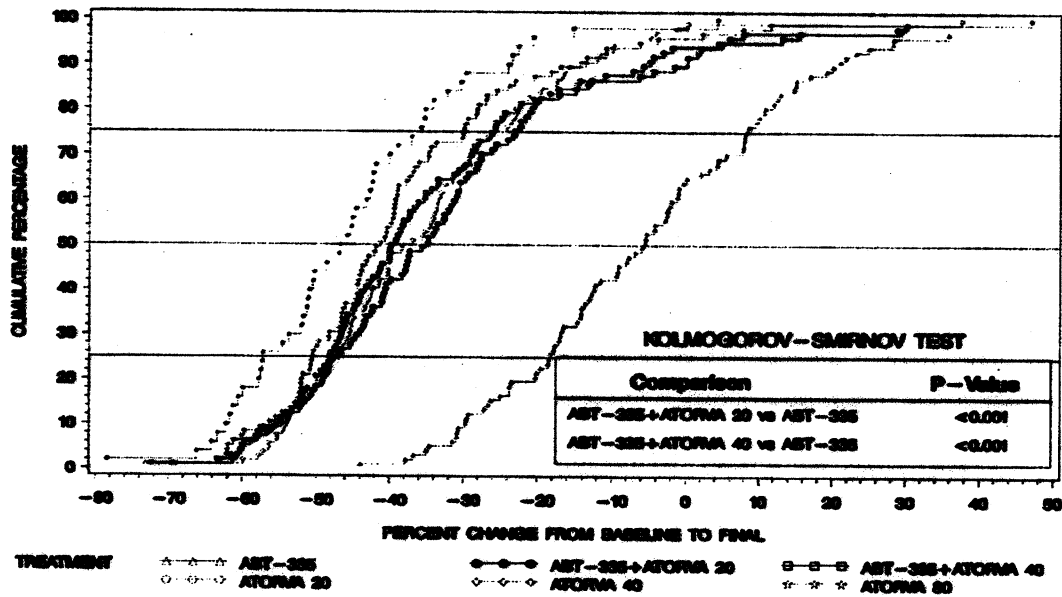


NOTE : ATORNA= ATORVASTATIN

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CUMULATIVE DISTRIBUTION FUNCTION FOR % CHANGE IN LDL-C

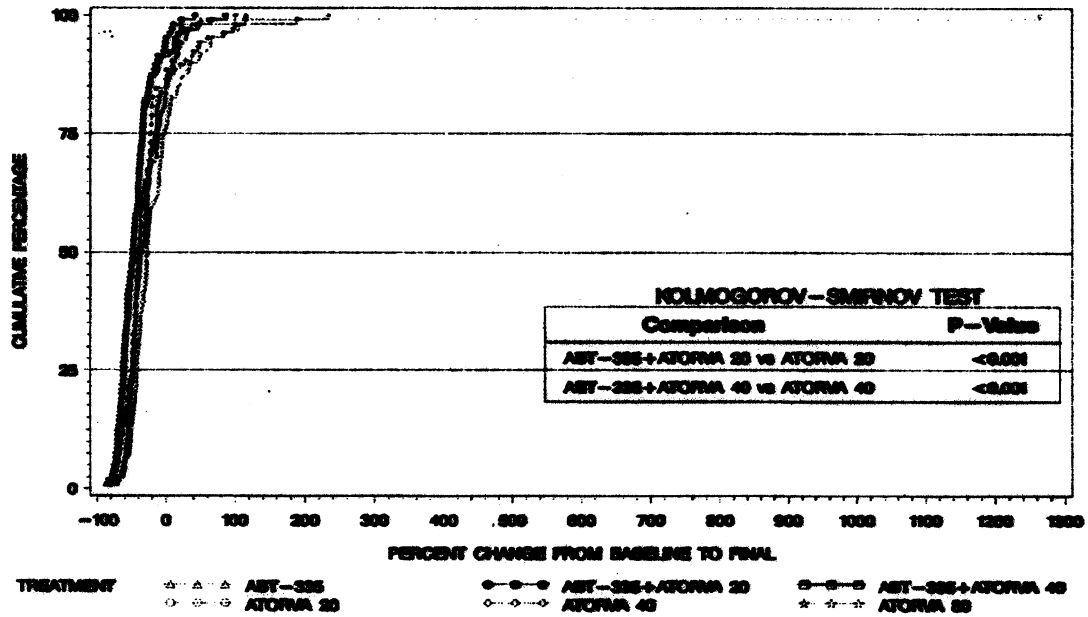
STUDY 1025-789
TRUNCATED X-Axis



NOTE : ATORNA= ATORVASTATIN

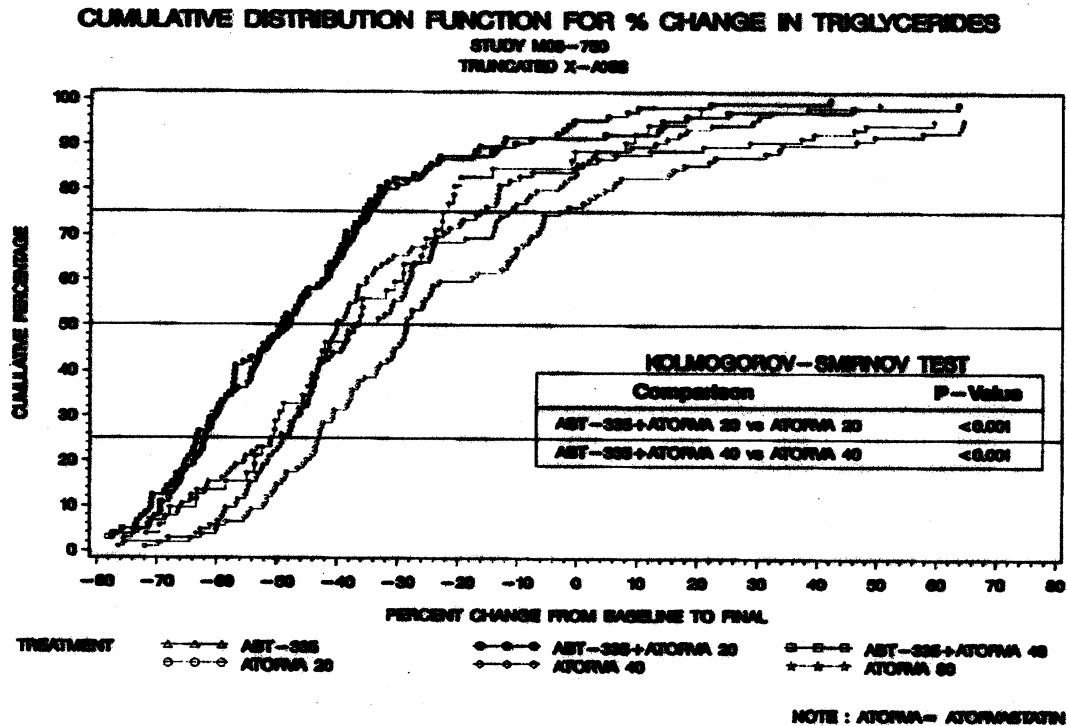
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CUMULATIVE DISTRIBUTION FUNCTION FOR % CHANGE IN TRIGLYCERIDES
STUDY M05-788



NOTE : ASTORMA= ATORVASTATIN

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Note: This reviewer's analyses and the many analyses of the sponsor have provided significant p-values for the pre-planned comparisons.

3.2 Evaluation of Safety

This reviewer did not perform any formal safety evaluation but was available to the clinical reviewer for statistical consultation.

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4. FINDINGS IN SPECIAL/SUBGROUP POPULATIONS

Note: Adjustments for so many subgroups cannot be properly done, without pre-specifying which subgroup results will be confirmatory.

Results of these demographic characteristics (at baseline) and other prognostic factors were presented before. There were no statistically significant baseline imbalances.

The sponsor provided many subgroup results which are presented in Appendix II, along with the discussions. Data from the three phase 3 trials were pooled for the analyses. There was a statistically highly significant quantitative gender by treatment interaction with respect to HDL-C ($p < .001$), and nominally significant gender by treatment interactions for non-HDL-C, and LDL-C.

In the sponsor's original submission, all six treatment arms were included individually in analyses of the treatment by gender interaction term with 5 degrees of freedom. To have a better understanding of the nature of this interaction, we requested of the sponsor new analyses, with a subset of treatment arms in each, which are presented below. The treatment group comparisons (pair-wise comparisons of combination vs. statin or ABT-335) in the tests for interaction were the same as those used in the primary analyses of HDL, TG, LDL, and non-HDL. There were at least nominally significant gender by treatment interactions ($p < .1$) in the analyses involving the combined combination arms for HDL, LDL, and non-HDL. There was another statistically significant gender by treatment interaction – in the case of HDL for the moderate dose combination vs moderate dose statin. There was no such significant interaction with respect to triglycerides either in the original or in the new analyses.

The significant gender-by-treatment interaction for HDL reflects that fact that, comparing combination therapy to statin monotherapy (measuring the additional benefit of ABT-335 on HDL), females had significantly greater HDL increases than did males. For LDL and non-HDL, in each treatment arm, females did better (that is, greater LDL and non-HDL lowering) than males. However, when we look at the superiority of the combination to ABT-335 monotherapy, this superiority (of the combination to monotherapy) is bigger for males than for females (in the cases of LDL and non-HDL).

4.1 Gender, Race, and Age

Please see Appendix II for subgroup results.

The tables and figures to show the nature of the gender by treatment interactions are presented below.

Summary

Significant treatment-by-gender interactions were observed for HDL-C in analyses of combination therapy vs. statin monotherapy (more details are presented below). These appeared to be driven by large gender effects (larger HDL-C increases in female subjects compared to the male subjects) in combination therapy regimens and inconsistent gender effect in statin monotherapy regimens (larger HDL-C increases in female subjects for low combo vs low monotherapy but smaller HDL-C increases in female subjects for comparisons involving the medium dose statin).

For both LDL-C and non-HDL-C, trends toward significant treatment-by-gender interactions were observed in analyses of combination therapy vs. ABT-335 monotherapy. The trends appeared to be driven by numerically larger gender effects in female vs. male subjects for ABT-335 monotherapy compared to combination therapy.

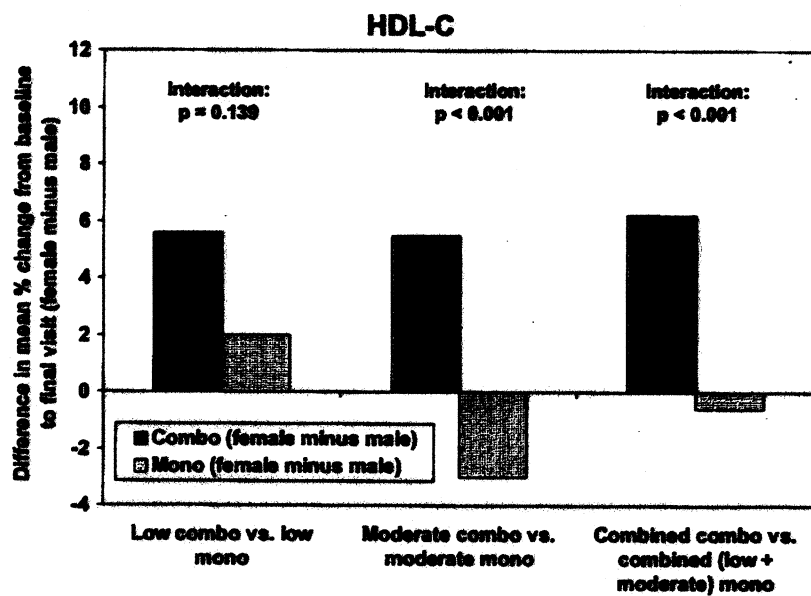
Table: Treatment-by-gender interaction p-values for HDL-C and TG and within-treatment-group differences between genders in mean percent changes from baseline to final visit.

Treatment groups included in analysis	HDL-C			TG		
	treatment-by-gender interaction p-value	Difference in mean % change (female minus male)		treatment-by-gender interaction p-value	Difference in mean % change (female minus male)	
		Combo	1 Mono		Combo	Mono
Low-dose combo vs. low-dose statin mono	0.139	5.6	2.0	0.675	-8.6	-11.8
Moderate-dose combo vs. moderate-dose statin mono	<0.001	5.5	-3.0	0.940	-1.9	-2.1
Low- and moderate-dose combo (combined) vs. low- and moderate-dose statin mono (combined)	<0.001	6.2	-0.6	0.671	-5.3	-6.7

mono, monotherapy; combo, ABT-335+statin combination therapy

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Figure: HDL-C: Illustration of large gender effect in combination therapy arms and inconsistent gender effect in statin monotherapy arms, resulting in treatment-by-gender interactions in the analysis of HDL-C changes.



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Figure: TG: Illustration of relatively consistent gender effects for combination therapy groups vs. statin monotherapy groups, resulting in no significant treatment-by-gender interactions in the analysis of TG changes.

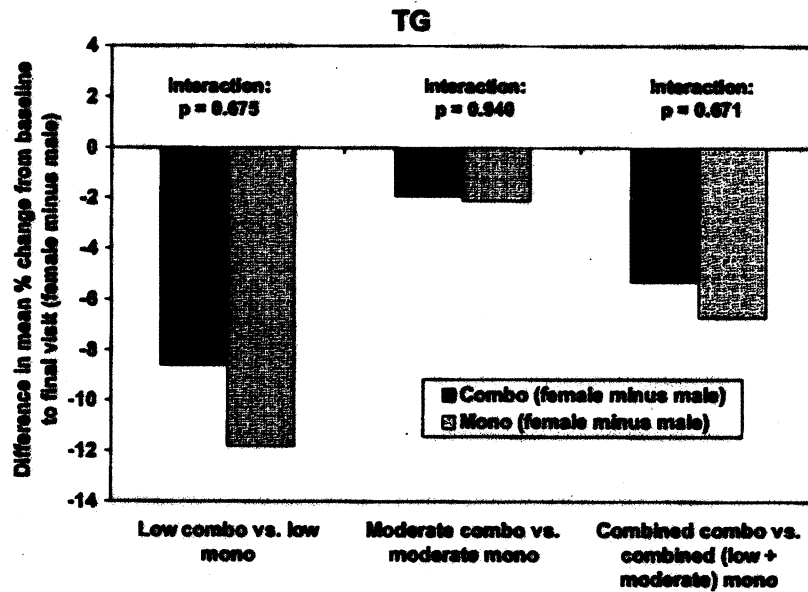
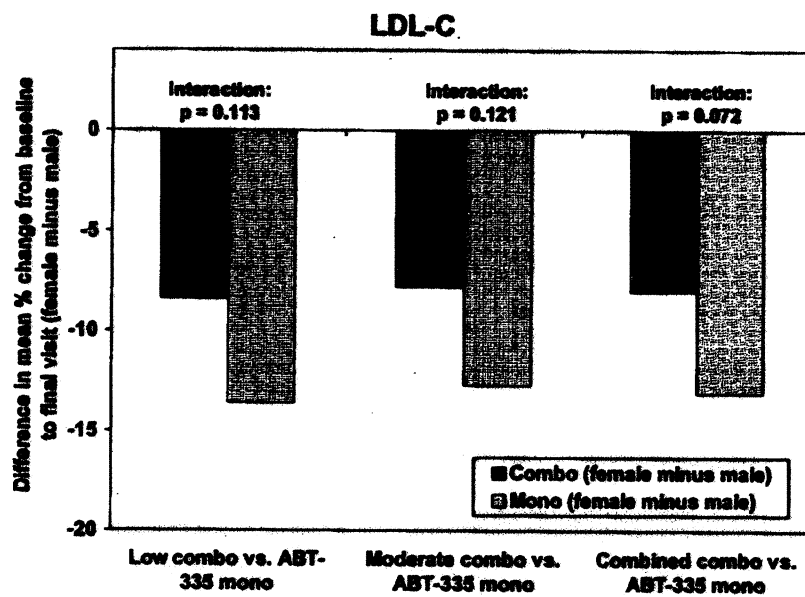


Table: Treatment-by-gender interaction p-values for LDL-C and non-HDL-C and within-treatment-group differences between genders in mean percent changes from baseline to final visit.

Treatment groups included in analysis	LDL-C			non-HDL-C		
	treatment-by-gender interaction p-value	Difference in mean % change (female minus male)		treatment-by-gender interaction p-value	Difference in mean % change (female minus male)	
		Combo	Mono		Combo	Mono
Low-dose combo vs. ABT-335 mono	0.113	-8.4	-13.6	0.116	-8.2	-11.9
Moderate-dose combo vs. ABT-335 mono	0.121	-7.8	-12.7	0.187	-7.5	-10.4
Low- and moderate-dose combo (combined) vs. ABT-335 mono	0.072	-8.0	-13.1	0.093	-7.6	-10.9

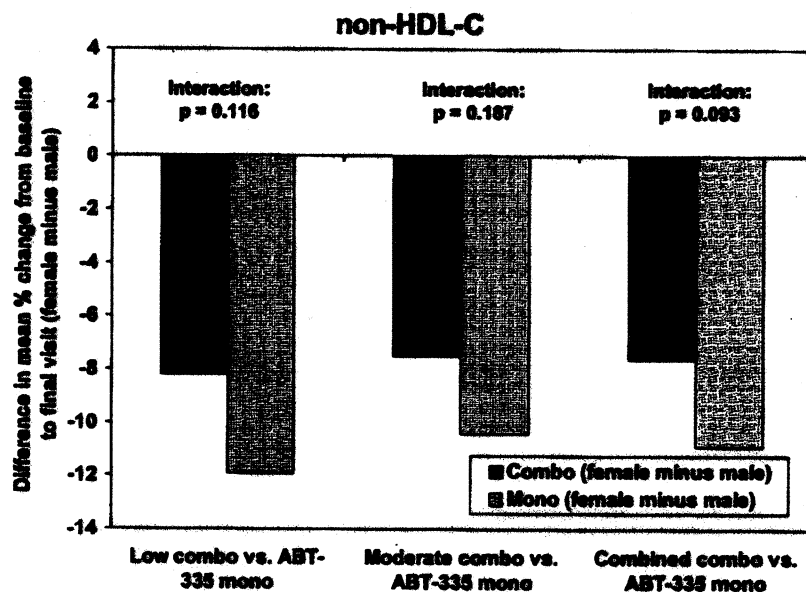
mono, monotherapy; combo, ABT-335+statin combination therapy

Figure: Illustration of modestly larger gender differences with ABT-335 monotherapy than with combination therapy in the analysis of LDL-C.



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Figure: Illustration of modestly larger gender differences with ABT-335 monotherapy than with combination therapy in the analysis of non-HDL-C.



4.2 Other Special/Subgroup Populations

See Appendix II.

5. SUMMARY AND CONCLUSIONS

5.1 Statistical Issues and Collective Evidence

This reviewer's analyses and the many analyses of the sponsor have provided significant p-values for the pre-planned primary comparisons:

- . TG: statin in combination with ABT-335 vs. statin monotherapy (low or medium dose of statin).
- . HDL-C: statin in combination with ABT-335 vs. statin monotherapy (low or medium dose of statin).
- . Direct LDL-C: rosuvastatin calcium in combination with ABT-335 vs. ABT-335 monotherapy.

There was a statistically significant quantitative treatment by gender interaction; there was no lack of benefit in any subgroups. The significant gender-by-treatment interaction for HDL ($p < .001$) reflects that fact that, comparing combination therapy to statin monotherapy (measuring the additional benefit of ABT-335 on HDL), females had significantly greater HDL increases than did males. For LDL and non-HDL, in each treatment arm, females did better (that is, greater LDL and non-HDL lowering) than males. However, when we look at the superiority of the combination to ABT-335 monotherapy, this superiority (of the combination to monotherapy) is bigger for males than for females (in the cases of LDL and non-HDL).

The beneficial treatment effect of combination therapy was generally greater in subjects ≥ 65 years of age than in subjects < 65 years of age. Combination therapy resulted in even greater mean percent decreases in TG among subjects with baseline TG > 200 mg/dL than among subjects with baseline TG ≤ 200 mg/dL and in even greater mean percent decreases in LDL-C among subjects with baseline LDL-C > 160 mg/dL than among subjects with baseline LDL-C ≤ 160 mg/dL.

Some non-crucial observations:

This reviewer's nonparametric analyses for Study 749, produced non-significant p-values for HDL-C at Week 4 for medium dose comparison.

There was a similar lack of robustness for the low dose comparison at earlier weeks for HDL-C in Study 750.

5.2 Conclusions and Recommendations

The three studies have provided significant p-values for the pre-planned primary comparisons:

- . TG: statin in combination with ABT-335 vs. statin monotherapy (low or medium dose of statin).
- . HDL-C: statin in combination with ABT-335 vs. statin monotherapy (low or medium dose of statin).
- . Direct LDL-C: rosuvastatin calcium in combination with ABT-335 vs. ABT-335 monotherapy.

There was a statistically significant quantitative treatment by gender interaction; there was no lack of benefit in any subgroups. The significant gender-by-treatment interaction for HDL ($p < .001$) reflects that fact that, comparing combination therapy to statin monotherapy (measuring the additional benefit of ABT-335 on HDL), females had significantly greater HDL increases than did males. For LDL and non-HDL, in each treatment arm, females did better (that is, greater LDL and non-HDL lowering) than males. However, when we look at the superiority of the combination to ABT-335 monotherapy, this superiority (of the combination to monotherapy) is bigger for males than for females (in the cases of LDL and non-HDL).

Labeling

Because of the fixed-sequence rule of multiple comparisons pre-specified by the sponsor, the medium dose combination is superior to ABT-335 monotherapy only with respect to Non HDL-C. Nothing else can be claimed for the medium dose combination with respect to pre-specified secondary efficacy variables.

The pre-specified comparisons for the low dose combination produced significant p-values with respect to all pre-specified secondary efficacy variables.

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APPENDICES

Appendix I: List of Abbreviations and Definitions of Terms

List of Abbreviations

ABT-335	choline fenofibrate capsules
AERS	Adverse Event Reporting System
AHA	American Heart Association
ANCOVA	analysis of covariance
ANOVA	analysis of variance
ApoAI	apolipoprotein AI (mg/dL)
ApoAII	apolipoprotein AII (mg/dL)
ApoB	apolipoprotein B (mg/dL)
ApoCIII	apolipoprotein CIII (mg/dL)
atorva	atorvastatin
ATP III	Adult Treatment Panel III
BL	baseline
CHD	coronary heart disease
CMH	Cochran-Mantel-Haenszel
d/c	discontinued
Δ	change
ECG	electrocardiogram
eGFR	estimated glomerular filtration rate
GERD	gastroesophageal reflux disease
HDL-C	high-density lipoprotein cholesterol (mg/dL)
HMG-CoA	3-hydroxy-3-methylglutaryl coenzyme A
hsCRP	high sensitivity C-reactive protein (mg/dL)
ISE	Integrated Summary of Efficacy
IVRS	interactive voice response system
LDL-C	low-density lipoprotein cholesterol (mg/dL)
LDL-P	low-density lipoprotein particle number
LOCF	last observation carried forward
LpPLA2	lipoprotein-associated phospholipase A2 (ng/mL)
Max	maximum
Min	minimum
NCEP	National Cholesterol Education Program
NMR	nuclear magnetic resonance
non-HDL-C	non-high-density lipoprotein cholesterol

PAD	peripheral arterial disease
PGP	Pfizer Global Pharmaceuticals
PROBE	Prospective Randomized Open-label Blinded Endpoint
PVD	peripheral vascular disease
RBC	red blood cell
rosuva	rosuvastatin
SAE	serious adverse event
SAP	statistical analysis plan
SC	Steering Committee
SE	standard error
simva	simvastatin
TC	total cholesterol
TCI	transitory cerebral ischemia
TESS	treatment emergent signs and symptoms
TG	triglycerides
TG total-C	triglycerides total cholesterol
TIA	transient ischemic attack
TNT	Treating to New Targets
TSH	thyroid-stimulating hormone
ULN	upper limit of normal
VLDL-C	very-low-density lipoprotein-C (mg/dL)
VLDL-P	very-low-density lipoprotein particle number
WBC	white blood cell
4S	Scandinavian Simvastatin Survival Study

Appendix II: Subgroup Results

Efficacy results among subgroups of subjects stratified by diabetic status, metabolic syndrome status, gender, age, baseline LDL-C level, and baseline TG level were generally consistent with the overall results. Overall treatment effects of combination therapy were generally similar in diabetics and non-diabetics and in subjects meeting or not meeting criteria for metabolic syndrome. There was a statistically significant quantitative treatment by gender interaction. The beneficial treatment effect of combination therapy was generally greater in females than in males, and greater in subjects ≥ 65 years of age than in subjects < 65 years of age. Combination therapy resulted in even greater mean percent decreases in TG among subjects with baseline TG > 200 mg/dL than among subjects with baseline TG ≤ 200 mg/dL and in even greater mean percent decreases in LDL-C among subjects with baseline LDL-C > 160 mg/dL than among subjects with baseline LDL-C ≤ 160 mg/dL. Of special note, in the higher risk subgroup of subjects with baseline LDL-C > 160 mg/dL, the mean percent decreases in LDL-C were similar with ABT-335 in combination with moderate-dose statins and moderate-dose statin

monotherapy. In both risk subgroups of subjects, the mean percent decreases in LDL-C were similar with ABT-335 in combination with low-dose statins and low-dose statin monotherapy.

Gender, Race, and Age

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY AGE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT		WITHIN GROUP						BETWEEN GROUP COMPARISON		
PARAMETER				-- % CHANGE FROM BASELINE----			-COMBINATION THERAPY VS MONOTHERAPY-			
SUBGROUP					SE	MIN	MAX		SE	P-VALUE:
TREATMENT	N	BASELINE MEAN	VISIT MEAN	MEAN				MEAN		
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
AGE < 65 (YEARS)										
ABT-335	344	38.0	43.7	15.9	1.09	-68.8	115.8			
ABT-335 + STATIN LOW (#)	342	37.6	43.8	17.3	1.10	-68.1	86.9	1.3	1.46	0.359
ABT-335 + STATIN MOD (#)	338	37.7	43.6	16.8	1.10	-68.8	113.0	0.9	1.46	0.556
STATIN LOW (\$)	389	38.4	40.7	7.4	1.03	-56.4	80.8	9.7	1.42	<0.001***
STATIN MOD (\$)	354	38.3	40.8	8.8	1.07	-34.1	146.7	8.0	1.45	<0.001***
STATIN HIGH	171	37.6	40.3	7.9	1.51	-30.8	72.4			
AGE >= 65 (YEARS)										
ABT-335	76	40.0	46.5	17.5	2.17	-41.9	79.6			
ABT-335 + STATIN LOW (#)	81	40.6	48.7	21.3	2.08	-58.7	80.0	3.8	2.96	0.205
ABT-335 + STATIN MOD (#)	84	39.7	47.1	19.8	2.05	-64.3	92.9	2.3	2.93	0.429
STATIN LOW (\$)	66	38.2	40.9	6.6	2.31	-27.5	43.5	14.7	3.08	<0.001***
STATIN MOD (\$)	76	39.2	42.3	8.1	2.17	-18.5	57.8	11.7	2.93	<0.001***
STATIN HIGH	46	39.3	41.7	7.2	2.77	-28.8	71.4			

TREATMENT BY AGE INTERACTION P-value (@@)= 0.591

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 \$ P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 % P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 ^ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 & P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY AGE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE*
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
AGE < 65 (YEARS)										
ABT-335	350	159.2	148.3	-3.9	1.07	-53.8	179.2			
ABT-335 + STATIN LOW (#)	354	153.8	104.1	-31.3	1.07	-69.5	89.6	-27.4	1.43	<0.001***
ABT-335 + STATIN MOD (#)	350	154.9	100.8	-33.1	1.08	-79.5	90.1	-29.1	1.43	<0.001***
STATIN LOW (%)	390	153.6	102.3	-32.6	1.02	-73.1	77.9	1.2	1.39	0.374
STATIN MOD (%)	342	157.1	93.0	-39.6	1.05	-73.4	56.5	6.5	1.42	<0.001***
STATIN HIGH	177	155.2	83.7	-45.7	1.47	-78.4	9.2			
AGE >= 65 (YEARS)										
ABT-335	77	154.5	137.4	-9.7	2.01	-47.3	83.5			
ABT-335 + STATIN LOW (#)	82	163.2	93.7	-39.9	1.94	-70.6	33.3	-30.2	2.76	<0.001***
ABT-335 + STATIN MOD (#)	84	161.7	93.3	-40.0	1.92	-72.8	75.6	-30.3	2.74	<0.001***
STATIN LOW (%)	73	153.4	93.1	-39.8	2.07	-59.7	29.8	-0.1	2.80	0.971
STATIN MOD (%)	77	161.9	86.7	-44.2	2.03	-74.7	7.6	4.2	2.74	0.127
STATIN HIGH	48	159.3	75.8	-51.4	2.53	-75.5	4.3			

TREATMENT BY AGE INTERACTION P-value (@@)= 0.913

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
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 * P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 % P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY AGE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -COMBINATION THERAPY VS MONOTHERAPY-		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE ¹
WEEK 12 (FINAL VISIT)										
TRIGLYCERIDES (MG/DL)										
AGE < 65 (YEARS)										
ABT-335	377	281.3	182.7	-28.8	2.32	-91.8	123.2			
ABT-335 + STATIN LOW (#)	378	285.6	152.7	-41.6	2.23	-88.1	64.2	-12.7	2.97	<0.001***
ABT-335 + STATIN MOD (#)	367	287.5	151.8	-39.7	2.26	-95.0	96.6	-10.8	2.99	<0.001***
STATIN LOW (\$)	403	281.5	219.5	-19.1	2.16	-85.4	1264.3	-26.4	2.92	<0.001***
STATIN MOD (%)	392	287.3	206.4	-22.3	2.18	-89.1	232.5	-17.4	2.96	<0.001***
STATIN HIGH	186	285.6	191.6	-26.7	3.08	-82.9	111.3			
AGE >= 65 (YEARS)										
ABT-335	82	277.0	157.1	-39.7	2.57	-78.6	38.2			
ABT-335 + STATIN LOW (#)	92	266.1	127.0	-51.0	2.43	-80.2	32.8	-12.3	3.48	<0.001***
ABT-335 + STATIN MOD (#)	95	279.8	134.5	-48.9	2.38	-83.4	22.1	-10.1	3.46	0.004**
STATIN LOW (\$)	74	308.8	219.1	-22.5	2.72	-72.0	83.5	-28.5	3.60	<0.001***
STATIN MOD (%)	80	289.1	188.4	-27.9	2.63	-63.3	64.4	-21.0	3.49	<0.001***
STATIN HIGH	49	269.7	169.3	-30.7	3.32	-71.8	99.6			

TREATMENT BY AGE INTERACTION P-value (@@)= 0.968

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
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 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY AGE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -COMBINATION THERAPY VS MONOTHERAPY-		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE ¹
WEEK 12 (FINAL VISIT)										
NON HDL CHOLESTEROL (MG/DL)										
AGE < 65 (YEARS)										
ABT-335	344	222.6	184.6	-15.9	0.90	-82.7	67.3			
ABT-335 + STATIN LOW (#)	341	218.0	133.0	-38.5	0.91	-71.6	25.1	-22.7	1.21	<0.001***
ABT-335 + STATIN MOD (#)	337	216.7	128.7	-40.3	0.92	-76.4	33.9	-24.5	1.22	<0.001***
STATIN LOW (\$)	388	217.1	142.5	-33.9	0.86	-65.3	122.4	-4.6	1.18	<0.001***
STATIN MOD (%)	355	221.1	128.7	-41.4	0.99	-64.9	13.1	1.1	1.21	0.360
STATIN HIGH	171	219.4	118.3	-46.1	1.25	-77.1	13.5			
AGE ≥ 65 (YEARS)										
ABT-335	76	220.9	169.3	-22.7	1.59	-49.3	28.1			
ABT-335 + STATIN LOW (#)	81	226.5	117.7	-47.1	1.53	-66.7	0.2	-24.3	2.17	<0.001***
ABT-335 + STATIN MOD (#)	83	226.6	115.4	-47.9	1.51	-75.8	2.0	-25.2	2.16	<0.001***
STATIN LOW (\$)	66	218.3	134.1	-39.3	1.69	-57.6	-6.0	-7.7	2.25	0.001***
STATIN MOD (%)	75	227.6	120.8	-46.1	1.55	-68.3	-5.7	-1.9	2.16	0.389
STATIN HIGH	46	222.5	106.8	-51.1	2.03	-77.1	7.4			

TREATMENT BY AGE INTERACTION P-value (@@)= 0.679

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY GENDER (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE**
WEEK 12 (FINAL VISIT)										
MDL CHOLESTEROL (MG/DL)										
MALE										
ABT-335	187	34.8	38.9	12.9	1.36	-56.1	115.8			
ABT-335 + STATIN LOW (‡)	197	34.5	39.7	15.3	1.35	-58.7	87.7	2.4	1.82	0.188
ABT-335 + STATIN MOD (§)	208	34.5	38.8	13.3	1.31	-64.3	113.0	0.4	1.80	0.822
STATIN LOW (¶)	240	35.3	37.4	7.3	1.23	-56.4	80.8	8.0	1.72	<0.001***
STATIN MOD (¶)	221	35.0	37.7	9.8	1.27	-34.1	146.7	3.5	1.72	0.040*
STATIN HIGH	108	34.5	36.8	6.8	1.79	-30.8	57.7			
FEMALE										
ABT-335	233	41.1	48.3	18.3	1.28	-68.8	100.0			
ABT-335 + STATIN LOW (‡)	226	41.2	49.0	19.9	1.29	-34.8	88.9	1.6	1.75	0.366
ABT-335 + STATIN MOD (§)	214	41.4	49.4	21.1	1.33	-68.8	92.9	2.8	1.78	0.117
STATIN LOW (¶)	215	41.6	44.2	8.1	1.33	-37.7	55.6	11.8	1.79	<0.001***
STATIN MOD (¶)	209	41.8	44.5	7.9	1.35	-25.0	75.8	13.2	1.82	<0.001***
STATIN HIGH	109	41.0	44.1	8.7	1.83	-28.8	72.4			

TREATMENT BY GENDER INTERACTION P-value (@@)= 0.004**

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY GENDER (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--			
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE ⁶
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
MALE										
ART-335	193	154.4	151.6	2.3	1.45	-35.3	179.2			
ART-335 + STATIN LOW (#)	207	149.6	105.5	-28.6	1.43	-62.0	63.6	-30.9	1.94	<0.001***
ART-335 + STATIN MOD (#)	216	151.0	102.8	-30.1	1.40	-72.4	90.1	-32.5	1.92	<0.001***
STATIN LOW (\$)	244	148.2	100.0	-31.8	1.33	-73.1	77.5	3.3	1.83	0.072
STATIN MOD (\$)	223	152.7	91.6	-38.4	1.37	-67.0	56.5	8.3	1.85	<0.001***
STATIN HIGH	111	146.3	79.5	-47.2	1.92	-78.4	9.2			
FEMALE										
ART-335	234	161.3	141.8	-11.1	1.20	-53.8	79.4			
ART-335 + STATIN LOW (#)	229	161.0	98.8	-37.2	1.20	-70.6	89.6	-26.1	1.63	<0.001***
ART-335 + STATIN MOD (#)	218	161.4	95.3	-39.0	1.24	-73.5	75.6	-27.9	1.66	<0.001***
STATIN LOW (\$)	219	159.9	101.2	-35.8	1.23	-65.9	39.3	-1.4	1.66	0.408
STATIN MOD (\$)	216	163.3	92.0	-42.5	1.25	-74.7	16.0	3.5	1.69	0.037 ⁷
STATIN HIGH	114	165.8	84.8	-47.2	1.67	-75.5	4.3			

TREATMENT BY GENDER INTERACTION P-value (@@)= <0.001***

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 \$ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 * P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 † P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ‡ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY GENDER (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--			
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE
WEEK 12 (FINAL VISIT) TRIGLYCERIDES (MG/DL)										
MALE										
ART-335	203	295.7	198.1	-25.2	3.47	-91.8	123.2			
ART-335 + STATIN LOW (#)	218	283.6	156.0	-42.0	3.41	-86.2	66.2	-14.8	4.63	<0.001***
ART-335 + STATIN MOD (#)	229	290.8	157.6	-39.8	3.31	-80.7	90.4	-14.3	4.57	0.002**
STATIN LOW (\$)	251	296.2	230.0	-13.5	3.19	-85.6	1254.3	-28.5	4.39	<0.001***
STATIN MOD (\$)	238	297.0	212.9	-21.9	3.25	-89.1	232.5	-17.8	4.39	<0.001***
STATIN HIGH	117	304.1	186.7	-31.4	4.56	-82.9	111.3			
FEMALE										
ART-335	256	269.2	160.2	-35.7	1.74	-88.1	114.6			
ART-335 + STATIN LOW (#)	252	281.6	138.3	-45.6	1.74	-88.1	50.8	-9.9	2.35	<0.001***
ART-335 + STATIN MOD (#)	233	242.2	137.9	-44.2	1.81	-95.0	96.6	-8.5	2.40	<0.001***
STATIN LOW (\$)	225	275.5	204.8	-20.2	1.82	-72.2	118.9	-25.4	2.43	<0.001***
STATIN MOD (\$)	234	279.2	190.4	-26.0	1.81	-82.3	98.6	-16.2	2.45	<0.001***
STATIN HIGH	118	262.2	155.3	-24.5	2.48	-74.9	99.6			

TREATMENT BY GENDER INTERACTION P-value (@@)= 0.162

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 * P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY GENDER (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE [§]
WEEK 12 (FINAL VISIT)										
NON HDL CHOLESTEROL (MG/DL)										
MALE										
ART-335	197	216.5	190.5	-11.1	1.19	-40.6	67.3			
ART-335 + STATIN LOW (#)	196	212.7	134.9	-36.3	1.18	-68.5	25.1	-25.2	1.59	<0.001***
ART-335 + STATIN MOD (†)	208	214.7	131.7	-38.0	1.15	-75.6	15.6	-26.9	1.37	<0.001***
STATIN LOW (§)	239	214.1	143.1	-32.4	1.08	-57.6	122.4	-3.9	1.50	0.010**
STATIN MOD (*)	221	220.2	127.5	-41.3	1.11	-66.9	13.1	3.3	1.51	0.031*
STATIN HIGH	108	213.7	110.7	-48.4	1.56	-77.1	3.2			
FEMALE										
ART-335	233	226.8	174.4	-22.1	1.04	-82.7	22.4			
ART-335 + STATIN LOW (#)	226	225.9	125.4	-43.7	1.04	-71.6	8.3	-21.6	1.41	<0.001***
ART-335 + STATIN MOD (†)	212	223.0	119.8	-45.9	1.08	-76.4	33.9	-23.8	1.44	<0.001***
STATIN LOW (§)	215	221.4	138.8	-37.3	1.07	-65.3	49.7	-6.4	1.44	<0.001***
STATIN MOD (*)	210	224.6	126.4	-43.6	1.09	-68.3	-3.0	-2.2	1.47	0.127
STATIN HIGH	109	226.9	120.1	-46.2	1.47	-77.1	13.5			

TREATMENT BY GENDER INTERACTION P-value (@@)= <0.001***

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 * P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
WHITE										
ABT-335	394	38.4	44.4	16.6	1.01	-68.8	115.8			
ABT-335 + STATIN LOW (8)	390	38.2	44.7	17.8	1.02	-59.7	88.9	1.3	1.36	0.359
ABT-335 + STATIN MOD (8)	388	38.1	44.4	17.8	1.02	-68.8	113.0	1.2	1.37	0.377
STATIN LOW (8)	425	38.3	40.7	7.5	0.98	-56.4	80.8	10.4	1.34	<0.001***
STATIN MOD (8)	403	38.4	41.0	8.5	1.01	-34.1	166.7	9.3	1.36	<0.001***
STATIN HIGH	205	37.9	40.6	8.0	1.17	-32.8	72.4			
BLACK										
ABT-335	16	37.0	39.3	3.1	4.59	-23.3	27.3			
ABT-335 + STATIN LOW (8)	20	40.1	44.6	11.9	4.23	-14.0	52.0	10.8	4.04	0.077
ABT-335 + STATIN MOD (8)	22	37.7	43.8	15.2	4.02	-23.8	71.4	12.2	5.85	0.340*
STATIN LOW (8)	18	40.0	42.1	7.4	4.34	-21.6	61.5	6.2	5.81	0.284
STATIN MOD (8)	17	41.1	43.9	9.8	4.43	-17.9	34.0	5.5	5.76	0.345
STATIN HIGH	5	41.9	41.2	2.3	8.08	-20.8	17.6			
OTHER										
ABT-335	10	39.4	48.2	25.2	6.01	-7.1	54.1			
ABT-335 + STATIN LOW (8)	13	35.9	48.6	33.8	5.03	20.0	59.5	8.7	7.70	0.264
ABT-335 + STATIN MOD (8)	12	40.6	43.7	11.1	5.40	-17.0	34.4	-14.0	7.62	0.071
STATIN LOW (8)	12	37.3	40.1	7.7	5.46	-15.4	27.6	26.1	7.35	0.001***
STATIN MOD (8)	10	36.1	42.2	16.8	5.60	-8.5	75.8	-5.7	7.81	0.465
STATIN HIGH	7	39.0	39.8	12.1	6.88	-7.3	40.0			

TREATMENT BY RACE INTERACTION P-value (@@)= 0.411

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION. 'BLACK' AND 'OTHER' RACE CATEGORIES WERE COMBINED INTO ONE SUBGROUP FOR THIS ANALYSIS.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT		WITHIN GROUP						BETWEEN GROUP COMPARISON		
PARAMETER				-- % CHANGE FROM BASELINE----				-- COMBINATION THERAPY VS MONOTHERAPY--		
SUBGROUP		BASELINE	VISIT		SE	MIN	MAX	MEAN	SE	P-VALUE
TREATMENT	N	MEAN	MEAN							
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
WHITE										
ABT-335	400	158.4	145.7	-8.2	0.99	-93.8	179.2			
ABT-335 + STATIN LOW (8)	403	155.7	151.2	-3.5	0.99	-70.6	89.6	-26.3	1.33	<0.001***
ABT-335 + STATIN MOD (8)	399	156.5	98.5	-34.8	1.20	-79.5	20.1	23.6	1.34	<0.001***
STATIN LOW (8)	412	154.2	100.1	-34.3	0.94	-73.1	77.5	0.8	1.31	0.530
STATIN MOD (8)	411	157.3	91.0	-40.8	0.93	-74.7	56.5	6.0	1.33	<0.001***
STATIN HIGH	212	155.6	80.8	-47.5	1.13	-79.1	9.2			
BLACK										
ABT-335	17	164.6	151.6	-8.3	4.75	-29.7	24.4			
ABT-335 + STATIN LOW (8)	20	155.5	104.5	-32.2	4.49	-64.4	2.8	-24.0	6.35	<0.001***
ABT-335 + STATIN MOD (8)	22	159.0	117.1	-31.7	4.30	-55.9	24.5	-23.4	6.20	<0.001***
STATIN LOW (8)	18	149.7	124.4	-16.9	4.73	-61.2	2.8	-1.3	4.32	0.641
STATIN MOD (8)	17	167.0	99.1	-40.1	4.73	-69.2	7.5	-8.4	6.19	0.178
STATIN HIGH	5	172.5	110.7	-34.2	8.33	-60.6	-6.9			

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET) Continued

VISIT		N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON --COMBINATION THERAPY VS MONOTHERAPY--		
PARAMETER SUBGROUP TREATMENT	MEAN				SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL) CONT.										
OTHER										
ART-335	10	139.1	139.7	-3.2	9.09	-17.4	25.5			
ART-335 + STATIN LOW (†)	13	152.4	159.3	-26.8	4.21	-53.4	0.0	-23.5	6.42	0.001***
ART-335 + STATIN MOD (‡)	13	130.0	90.1	-37.9	4.32	-49.4	-24.4	-34.6	6.28	<0.001***
STATIN LOW (§)	13	137.9	101.9	-27.3	4.37	-59.9	33.8	0.5	6.01	0.929
STATIN MOD (†)	11	165.6	91.5	-38.1	4.87	-69.2	-4.6	0.2	6.33	0.975
STATIN HIGH	7	155.8	73.2	-50.5	5.75	-57.8	-46.3			

TREATMENT BY RACE INTERACTION P-value (@@)= 0.923

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION. 'BLACK' AND 'OTHER' RACE CATEGORIES WERE COMBINED INTO ONE SUBGROUP FOR THIS ANALYSIS.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON --COMBINATION THERAPY VS MONOTHERAPY--			
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE [§]
WEEK 12 (FINAL VISIT)										
TRIGLYCERIDES (MG/DL)										
WHITE										
ART-335	431	280.9	177.1	-32.2	1.94	-91.8	123.2			
ART-335 + STATIN LOW (†)	432	283.8	147.7	-44.0	1.94	-88.1	66.2	-11.9	2.61	<0.001***
ART-335 + STATIN MOD (‡)	423	288.6	148.7	-42.0	1.97	-95.0	90.4	-9.8	2.63	<0.001***
STATIN LOW (§)	446	286.5	217.6	-16.8	1.92	-85.6	1264.3	-27.2	2.59	<0.001***
STATIN MOD (†)	441	290.8	203.0	-24.3	1.93	-89.1	232.5	-17.6	2.61	<0.001***
STATIN HIGH	219	284.0	187.0	-28.3	2.66	-82.9	111.3			
BLACK										
ART-335	17	214.2	165.2	-8.3	8.65	-70.1	114.0			
ART-335 + STATIN LOW (†)	24	243.7	141.8	-33.7	7.45	-86.2	80.0	-25.4	11.18	0.028*
ART-335 + STATIN MOD (‡)	24	248.2	138.0	-35.5	7.56	-78.2	96.6	-27.2	11.16	0.016*
STATIN LOW (§)	18	275.7	179.4	-21.6	8.74	-68.3	42.7	-10.1	11.09	0.365
STATIN MOD (†)	20	256.5	207.9	-13.8	8.15	-53.8	63.2	-21.7	10.54	0.342*
STATIN HIGH	9	265.1	176.4	-17.8	12.16	-67.7	46.5			

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET) continued

VISIT		WITHIN GROUP						BETWEEN GROUP COMPARISON		
PARAMETER				-- % CHANGE FROM BASELINE----				--COMBINATION THERAPY VS MONOTHERAPY--		
SUBGROUP		BASELINE	VISIT		SE	MIN	MAX		SE	P-VALUE:
TREATMENT	N	MEAN	MEAN	MEAN				MEAN		
WEEK 12 (FINAL VISIT)										
TRIGLYCERIDES (MG/DL) CONT.										
OTHER										
ABT-335	11	402.9	222.8	-21.2	13.47	-78.6	34.2			
ABT-335 + STATIN LOW (#)	14	290.5	130.3	-52.8	10.97	-79.1	-23.2	-31.6	16.69	0.063
ABT-335 + STATIN MOD (#)	15	286.6	133.6	-50.2	10.71	-75.7	20.0	-29.8	16.30	0.080
STATIN LOW (§)	13	303.1	279.6	-2.3	11.55	-54.7	187.8	-50.5	15.64	0.002**
STATIN MOD (§)	11	237.5	183.1	-12.7	12.14	-76.4	82.1	-37.5	16.02	0.022*
STATIN HIGH	7	274.5	175.1	-30.1	15.43	-63.3	16.2			

TREATMENT BY RACE INTERACTION P-value (@@)= 0.451

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION. 'BLACK' AND 'OTHER' RACE CATEGORIES WERE COMBINED INTO ONE SUBGROUP FOR THIS ANALYSIS.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT				WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON --COMBINATION THERAPY VS MONOTHERAPY--		
PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT) NON HDL CHOLESTEROL (MG/DL)										
WHITE										
ABT-335	394	222.1	180.9	-17.5	0.82	-82.7	67.3			
ABT-335 + STATIN LOW (#)	389	219.5	129.0	-40.7	0.93	-71.6	25.1	-23.1	1.12	<0.001***
ABT-335 + STATIN MOD (#)	386	219.2	125.2	-42.3	0.84	-76.4	33.3	-24.7	1.12	<0.001***
STATIN LOW (§)	424	217.6	140.6	-35.1	0.80	-65.3	122.4	-5.6	1.10	<0.001***
STATIN MOD (§)	404	222.3	126.7	-42.6	0.82	-66.3	13.1	0.3	1.11	0.775
STATIN HIGH	205	219.5	115.0	-47.5	1.12	-77.1	13.5			
BLACK										
ABT-335	15	215.6	186.8	-12.6	4.59	-27.6	-4.0			
ABT-335 + STATIN LOW (#)	20	229.4	136.4	-38.6	4.28	-68.5	10.2	-26.0	6.08	<0.001***
ABT-335 + STATIN MOD (#)	22	214.0	133.0	-37.9	4.32	-61.6	8.9	-24.7	5.91	<0.001***
STATIN LOW (§)	18	216.8	142.2	-35.1	4.38	-61.4	-2.3	-3.5	5.96	0.938
STATIN MOD (§)	17	223.4	127.7	-42.6	4.47	-66.2	-5.7	5.3	5.77	0.358
STATIN HIGH	5	248.0	117.5	-42.4	8.28	-43.0	-24.5			

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SINVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SINVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SINVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
 \$ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 † P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY RACE CATEGORY (CONTROLLED STUDIES ANALYSIS SET) continued

VISIT				WITHIN GROUP				BETWEEN GROUP COMPARISON		
PARAMETER				-- % CHANGE FROM BASELINE----				-- COMBINATION THERAPY VS MONOTHERAPY--		
SUBGROUP										
TREATMENT	N	BASELINE MEAN	VISIT MEAN	MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT)										
NON HDL CHOLESTEROL (MG/DL) CGWT.										
OTHER										
AST-335	10	240.8	185.9	-12.8	4.96	-49.2	20.3			
AST-335 + STATIN LOW (#)	13	214.0	132.9	-36.1	4.02	-58.2	-1.9	-23.4	6.22	<0.001***
AST-335 + STATIN MOD (\$)	12	204.8	113.9	-45.4	4.26	-65.6	-31.6	-32.6	6.34	<0.001***
STATIN LOW (‡)	12	206.5	143.5	-30.6	4.41	-52.3	7.7	-5.5	5.91	0.357
STATIN MOD (†)	10	211.1	124.2	-39.7	4.49	-61.3	-3.0	-5.8	6.14	0.352
STATIN HIGH	7	217.2	104.8	-50.3	5.49	-58.5	-33.3			

TREATMENT BY RACE INTERACTION P-value (@@)= 0.984

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SINVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SINVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SINVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
 \$ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 † P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ‡ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION. 'BLACK' AND 'OTHER' RACE CATEGORIES WERE COMBINED INTO ONE SUBGROUP FOR THIS ANALYSIS.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

Appears This Way
 On Original

Other Special/Subgroup Populations

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY BODY WEIGHT CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON -COMBINATION THERAPY VS MONOTHERAPY-		
				SE	MIN	MAX	MEAN	SE	P-VALUE*
WEEK 12 (FINAL VISIT) LDL CHOLESTEROL (MG/DL)									
WEIGHT < 70 KG									
ABT-335	57	40.6	48.0	18.4	2.80	-82.9	84.5		
ABT-335 + STATIN LOW (8)	60	41.7	50.0	21.3	2.45	-17.4	67.7	2.8	3.52 0.432
ABT-335 + STATIN MOD (8)	45	42.2	50.6	23.2	3.25	-26.0	93.7	4.6	3.81 0.229
STATIN LOW (8)	50	42.0	44.4	7.4	3.93	-27.5	43.6	14.0	3.64 <0.001***
STATIN MOD (8)	51	42.6	46.4	11.2	3.00	-17.4	78.8	12.0	3.88 0.002**
STATIN HIGH	26	45.0	46.8	8.1	4.32	-23.4	40.0		
WEIGHT >= 70 KG									
ABT-335	363	38.2	43.8	15.9	1.03	-68.8	113.8		
ABT-335 + STATIN LOW (8)	363	37.7	44.1	17.6	1.03	-56.7	88.9	1.7	1.40 0.230
ABT-335 + STATIN MOD (8)	377	37.8	43.7	17.0	1.01	-68.8	113.0	1.8	1.39 0.459
STATIN LOW (8)	405	38.0	40.4	7.6	0.98	-56.4	80.8	10.0	1.37 <0.001***
STATIN MOD (8)	379	38.0	40.6	8.5	1.01	-34.1	166.7	8.5	1.37 <0.001***
STATIN HIGH	191	37.2	40.0	8.1	1.40	-30.8	72.4		

TREATMENT BY WEIGHT INTERACTION P-value (@@)= 0.624

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 || P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY BODY WEIGHT CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -COMBINATION THERAPY VS MONOTHERAPY-		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE*
WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
WEIGHT < 70 KG										
ABT-335	57	158.9	135.8	-13.7	2.42	-47.0	44.0			
ABT-335 + STATIN LOW (8)	61	166.9	98.3	-39.7	2.38	-66.3	30.0	-26.1	3.28	<0.001***
ABT-335 + STATIN MOD (8)	48	165.8	94.7	-41.0	3.34	-78.3	24.5	-27.3	3.56	<0.001***
STATIN LOW (8)	52	161.6	102.7	-35.1	2.70	-59.9	33.8	-4.6	3.36	0.172
STATIN MOD (8)	51	170.8	91.1	-44.5	2.81	-74.7	11.4	3.5	3.64	0.338
STATIN HIGH	27	162.5	77.0	-52.5	3.76	-75.5	-14.3			
WEIGHT >= 70 KG										
ABT-335	376	158.6	147.5	-3.9	1.02	-53.8	179.2			
ABT-335 + STATIN LOW (8)	375	154.1	102.4	-32.3	1.12	-70.6	89.6	-28.7	1.39	<0.001***
ABT-335 + STATIN MOD (8)	389	155.5	99.4	-34.0	1.10	-72.4	90.1	-30.1	1.37	<0.001***
STATIN LOW (8)	411	153.0	100.2	-33.8	0.97	-73.1	77.5	1.6	1.35	0.246
STATIN MOD (8)	388	150.5	91.6	-39.0	1.00	-73.4	56.5	6.2	1.35	<0.001***
STATIN HIGH	199	155.6	82.2	-46.5	1.37	-78.4	9.2			

TREATMENT BY WEIGHT INTERACTION P-value (@@)= 0.323

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (≤ 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY BODY WEIGHT CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

WEEK 12 (FINAL VISIT)										
TRIGLYCERIDES (MG/DL)										
WEIGHT < 70 KG										
WEIGHT ≥ 70 KG										
WEIGHT < 70 KG										
WEIGHT ≥ 70 KG										

TREATMENT BY WEIGHT INTERACTION P-value (@@)= 0.946

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (≤ 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY BODY WEIGHT CATEGORY (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON --COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT)										
NON HDL CHOLESTEROL (MG/DL)										
WEIGHT < 70 KG										
ABT-335	57	229.1	173.0	-22.3	2.28	-49.4	22.5			
ABT-335 + STATIN LOW (8)	59	229.1	120.7	-46.1	2.10	-71.6	8.3	-23.7	2.88	<0.001***
ABT-335 + STATIN MOD (8)	45	229.8	118.7	-46.5	2.65	-76.4	5.7	-24.1	3.10	<0.001***
STATIN LOW (8)	50	222.4	139.5	-37.0	2.39	-64.2	-0.7	-9.1	2.99	0.003**
STATIN MOD (8)	51	230.5	127.0	-44.0	2.45	-67.2	8.5	-2.5	3.17	0.437
STATIN HIGH	26	231.5	115.2	-50.2	3.34	-66.1	-9.0			
WEIGHT >= 70 KG										
ABT-335	363	221.8	182.6	-16.6	0.85	-82.7	47.3			
ABT-335 + STATIN LOW (8)	363	218.6	131.1	-39.5	0.86	-69.6	25.1	-22.9	1.16	<0.001***
ABT-335 + STATIN MOD (8)	175	218.0	126.4	-41.6	0.86	-75.8	33.9	-25.0	1.15	<0.001***
STATIN LOW (8)	404	217.2	141.0	-34.7	0.82	-65.3	122.4	-4.8	1.13	<0.001***
STATIN MOD (8)	380	221.7	126.9	-42.3	0.84	-69.3	13.1	0.7	1.14	0.521
STATIN HIGH	191	219.1	115.4	-47.1	1.16	-77.1	13.5			

TREATMENT BY WEIGHT INTERACTION P-value (@@)= 0.556

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 § P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY METABOLIC SYNDROME STATUS (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON --COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT)										
HDL CHOLESTEROL (MG/DL)										
METABOLIC SYNDROME PRESENT										
ABT-335	289	37.8	44.0	17.5	1.18	-68.8	115.8			
ABT-335 + STATIN LOW (8)	283	37.5	44.1	18.4	1.19	-58.7	88.9	0.9	1.64	0.574
ABT-335 + STATIN MOD (8)	271	37.6	44.3	19.2	1.21	-68.8	92.9	1.6	1.65	0.322
STATIN LOW (8)	283	37.2	40.0	8.3	1.19	-56.4	61.5	10.1	1.64	<0.001***
STATIN MOD (8)	292	37.9	40.9	9.7	1.17	-30.6	166.7	9.4	1.55	<0.001***
STATIN HIGH	193	37.4	40.1	8.1	1.61	-30.8	71.4			
METABOLIC SYNDROME ABSENT										
ABT-335	131	41.1	45.8	11.7	1.92	-28.9	86.5			
ABT-335 + STATIN LOW (8)	140	41.1	47.3	17.4	1.91	-44.7	80.0	3.7	2.19	0.090
ABT-335 + STATIN MOD (8)	151	40.5	45.5	14.2	1.89	-40.5	113.0	0.6	2.15	0.795
STATIN LOW (8)	172	41.8	43.1	5.6	1.82	-36.6	80.8	11.8	2.05	<0.001***
STATIN MOD (8)	139	41.1	42.8	6.5	1.94	-34.1	75.8	7.8	2.12	<0.001***
STATIN HIGH	64	40.9	43.2	7.9	2.52	-20.0	72.4			

TREATMENT BY SUBGROUP PARAMETER (METABOLIC SYNDROME STATUS) INTERACTION P-value (@@)= 0.706

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY METABOLIC SYNDROME STATUS (CONTROLLED STUDIES ANALYSIS SET)

WEEK 12 (FINAL VISIT)										
LDL CHOLESTEROL (MG/DL)										
METABOLIC SYNDROME PRESENT										
ART-335	293	159.7	148.1	-3.6	1.14	-53.8	179.2			
ART-335 + STATIN LOW (‡)	292	154.4	102.7	-31.8	1.14	-70.6	89.6	-28.2	1.57	<0.001***
ART-335 + STATIN MOD (‡)	277	154.6	98.1	-34.4	1.16	-72.4	90.1	-30.8	1.59	<0.001***
STATIN LOW (§)	288	153.7	100.1	-33.9	1.14	-73.1	37.5	2.1	1.58	0.181
STATIN MOD (§)	294	155.7	91.6	-40.1	1.13	-73.0	52.3	5.7	1.59	<0.001***
STATIN HIGH	159	156.3	81.7	-46.8	1.53	-78.4	4.3			
METABOLIC SYNDROME ABSENT										
ART-335	134	156.2	139.7	-9.7	1.93	-49.4	96.8			
ART-335 + STATIN LOW (‡)	144	158.9	97.8	-37.7	1.94	-66.7	34.3	-27.9	2.21	<0.001***
ART-335 + STATIN MOD (‡)	157	159.9	98.4	-36.8	1.89	-79.5	96.0	-27.1	2.17	<0.001***
STATIN LOW (§)	175	154.3	98.8	-35.7	1.84	-61.2	77.5	-1.9	2.07	0.351
STATIN MOD (§)	145	163.2	89.3	-43.4	1.94	-74.7	56.5	6.6	2.12	0.002**
STATIN HIGH	66	156.8	79.8	-49.1	2.54	-67.1	9.2			

TREATMENT BY SUBGROUP PARAMETER (METABOLIC SYNDROME STATUS) INTERACTION P-value (@@)= 0.500

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 † P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 § P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ¶ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY METABOLIC SYNDROME STATUS (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT)										
TRIGLYCERIDES (MG/DL)										
METABOLIC SYNDROME PRESENT										
ABT-335	311	292.4	183.7	-33.0	2.37	-51.8	96.7			
ABT-335 + STATIN LOW (#)	313	295.1	193.0	-44.7	2.36	-88.1	64.2	-11.7	3.26	<0.001***
ABT-335 + STATIN MOD (#)	293	298.5	148.5	-46.2	2.43	-89.1	41.9	-13.1	3.32	<0.001***
STATIN LOW (\$)	295	298.6	231.6	-18.3	2.42	-72.2	1264.3	-26.5	3.31	<0.001***
STATIN MOD (\$)	318	297.7	201.4	-27.8	2.34	-89.1	114.0	-18.3	3.30	<0.001***
STATIN HIGH	164	290.6	190.1	-30.3	3.24	-82.9	131.3			
METABOLIC SYNDROME ABSENT										
ABT-335	148	232.3	150.3	-27.8	3.23	-86.4	123.2			
ABT-335 + STATIN LOW (#)	157	231.2	119.6	-43.1	3.27	-86.2	50.0	-15.4	3.71	<0.001***
ABT-335 + STATIN MOD (#)	169	240.1	131.6	-35.0	3.18	-95.0	96.6	-7.2	3.65	0.047*
STATIN LOW (\$)	182	240.9	180.3	-14.6	3.14	-85.6	118.9	-28.6	3.53	<0.001***
STATIN MOD (\$)	154	242.5	190.4	-15.8	3.28	-82.2	332.5	-19.2	3.61	<0.001***
STATIN HIGH	71	236.5	161.5	-24.6	4.30	-75.1	74.9			

TREATMENT BY SUBGROUP PARAMETER (METABOLIC SYNDROME STATUS) INTERACTION P-value (@@)= 0.342

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 \$ P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 % P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 * P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (≤ 250 MG/DL, > 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
 ** P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY METABOLIC SYNDROME STATUS (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----				BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY--		
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUE:
WEEK 12 (FINAL VISIT)										
NON HDL CHOLESTEROL (MG/DL)										
METABOLIC SYNDROME PRESENT										
ABT-335	289	225.9	184.6	-17.3	0.94	-56.2	33.5			
ABT-335 + STATIN LOW (#)	282	220.2	131.6	-39.7	0.95	-69.6	25.1	-22.4	1.30	<0.001***
ABT-335 + STATIN MOD (#)	270	219.8	125.3	-42.7	0.97	-75.0	13.9	-25.4	1.32	<0.001***
STATIN LOW (\$)	282	218.7	141.9	-34.9	0.95	-65.3	122.4	-4.9	1.31	<0.001***
STATIN MOD (\$)	292	221.4	127.4	-42.4	0.93	-68.3	13.1	-0.3	1.31	0.923
STATIN HIGH	153	223.2	115.6	-47.8	1.28	-77.1	13.5			
METABOLIC SYNDROME ABSENT										
ABT-335	131	211.0	169.5	-19.8	1.68	-82.7	67.1			
ABT-335 + STATIN LOW (#)	140	214.8	120.5	-43.1	1.58	-71.6	10.2	-24.4	1.92	<0.001***
ABT-335 + STATIN MOD (#)	150	213.0	130.7	-42.4	1.66	-76.4	33.9	-23.6	1.89	<0.001***
STATIN LOW (\$)	172	211.4	133.7	-36.4	1.59	-61.4	48.7	-6.7	1.80	<0.001***
STATIN MOD (\$)	125	220.2	120.4	-44.9	1.69	-67.2	10.1	1.6	1.96	0.381
STATIN HIGH	64	209.0	116.3	-47.9	2.01	-65.6	3.2			

TREATMENT BY SUBGROUP PARAMETER (METABOLIC SYNDROME STATUS) INTERACTION P-value (@@)= 0.755

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
* P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
§ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
¶ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
|| P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, DIABETIC STATUS (DIABETIC, NON-DIABETIC), SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL) AND INTERACTION OF DIABETIC STATUS BY SCREENING TRIGLYCERIDE LEVEL.
||| P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY DIABETIC STATUS^ (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON -- COMBINATION THERAPY VS MONOTHERAPY --			
				MEAN	SE	MIN	MAX	MEAN	SE	P-VALUES
WEEK 12 (FINAL VISIT)										
HDL CHOLESTEROL (MG/DL)										
DIABETIC										
AST-335	93	38.0	43.9	15.6	2.14	-68.8	89.2			
AST-335 + STATIN LOW (¶)	96	38.4	44.6	16.8	2.11	-58.7	80.0	1.2	3.00	0.699
AST-335 + STATIN MOD (¶)	93	38.6	44.2	16.3	2.14	-68.8	92.9	0.7	3.02	0.821
STATIN LOW (§)	96	38.0	39.2	4.1	2.10	-56.4	44.8	12.7	2.98	<0.001***
STATIN MOD (§)	95	38.5	40.9	8.8	2.12	-25.0	166.7	7.6	3.01	0.012*
STATIN HIGH	45	38.3	40.4	7.7	3.08	-28.8	71.4			
NON-DIABETIC										
AST-335	327	38.5	44.6	17.2	1.03	-33.3	115.8			
AST-335 + STATIN LOW (¶)	327	38.1	45.1	19.3	1.03	-48.1	88.9	2.1	1.45	0.150
AST-335 + STATIN MOD (¶)	329	38.0	44.6	18.5	1.02	-40.5	113.0	1.4	1.45	0.344
STATIN LOW (§)	359	38.4	41.4	9.0	0.98	-45.9	80.8	10.2	1.42	<0.001***
STATIN MOD (§)	335	38.4	41.5	9.4	1.01	-34.1	86.4	9.2	1.44	<0.001***
STATIN HIGH	172	37.8	41.0	8.8	1.41	-30.8	72.4			

TREATMENT BY SUBGROUP PARAMETER (DIABETIC STATUS) INTERACTION P- value (@@)= 0.825

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
* DIABETIC STATUS AS REPORTED IN SUBJECT'S MEDICAL HISTORY.
* P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND AST-335 MONOTHERAPY ARM.
§ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
¶ P-VALUE FOR DIFFERENCE BETWEEN AST-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
|| P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP AND SCREENING TRIGLYCERIDE LEVEL (\leq 250 MG/DL, $>$ 250 MG/DL).
||| P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY DIABETIC STATUS (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON -COMBINATION THERAPY VS MONOTHERAPY-		
				MEAN	SE	MIN	MAX	MEAN	SE
WEEK 12 (FINAL VISIT)									
LDL CHOLESTEROL (MG/DL)									
DIABETIC									
ABT-335	97	159.8	145.5	-5.3	1.87	-39.3	32.4		
ABT-335 + STATIN LOW (#)	97	149.5	97.4	-34.9	1.87	-62.9	89.6	-28.7	2.64 <0.001***
ABT-335 + STATIN MOD (#)	96	156.2	131.0	-16.6	1.88	-72.4	75.6	27.3	2.64 <0.001***
STATIN LOW (\$)	102	153.2	95.2	-37.5	1.83	-73.1	29.8	3.5	2.61 0.184
STATIN MOD (%)	99	154.2	88.9	-41.5	1.85	-69.1	7.5	8.8	2.63 0.001***
STATIN HIGH	48	158.4	76.1	-50.2	2.45	-78.4	-22.7		
NON-DIABETIC									
ABT-335	330	159.3	148.6	-6.7	1.04	-53.8	179.2		
ABT-335 + STATIN LOW (#)	339	158.8	135.6	-14.5	1.03	-79.6	65.6	-27.8	1.46 <0.001***
ABT-335 + STATIN MOD (#)	338	157.6	131.0	-16.7	1.03	-79.5	30.1	-30.0	1.45 <0.001***
STATIN LOW (\$)	363	155.2	104.5	-32.5	0.99	-65.9	77.5	0.0	1.43 0.999
STATIN MOD (%)	340	160.4	94.9	-38.9	1.03	-74.7	56.5	5.2	1.45 <0.001***
STATIN HIGH	177	156.8	85.7	-44.7	1.42	-75.5	9.3		

TREATMENT BY SUBGROUP PARAMETER (DIABETIC STATUS) INTERACTION P-value (@@)= 0.276

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 30 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 60 MG AND ATORVASTATIN CALCIUM 80 MG.
 * DIABETIC STATUS AS REPORTED IN SUBJECT'S MEDICAL HISTORY.
 # P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ABT-335 MONOTHERAPY ARM.
 \$ P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 % P-VALUE FOR DIFFERENCE BETWEEN ABT-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 % P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP AND SCREENING TRIGLYCERIDE LEVEL (<= 250 MG/DL, > 250 MG/DL).
 % P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY DIABETIC STATUS (CONTROLLED STUDIES ANALYSIS SET)

VISIT PARAMETER SUBGROUP TREATMENT	N	BASELINE MEAN	VISIT MEAN	WITHIN GROUP -- % CHANGE FROM BASELINE----			BETWEEN GROUP COMPARISON -COMBINATION THERAPY VS MONOTHERAPY-		
				MEAN	SE	MIN	MEAN	SE	P-VALUE*
WEEK 12 (FINAL VISIT)									
TRIGLYCERIDES (MG/DL)									
DIABETIC									
ABT-335	102	293.0	179.3	-32.1	6.05	-91.8	96.7		
ABT-335 + STATIN LOW (#)	103	299.9	137.5	-54.2	4.93	-80.2	61.6	-12.1	8.52 0.156
ABT-335 + STATIN MOD (#)	103	283.6	149.1	-47.9	6.02	-78.3	41.9	-11.7	8.52 0.171
STATIN LOW (\$)	102	292.6	265.3	-9.3	6.05	-67.8	1264.3	-38.4	8.52 <0.001***
STATIN MOD (%)	106	294.4	205.9	-30.5	5.93	-89.1	114.0	-19.3	8.54 0.022*
STATIN HIGH	50	250.0	198.3	-20.7	8.68	-82.9	46.5		
NON-DIABETIC									
ABT-335	357	272.8	170.7	-37.5	1.92	-88.1	123.2		
ABT-335 + STATIN LOW (#)	367	272.4	137.2	-49.2	1.90	-88.1	46.2	-13.2	2.14 <0.001***
ABT-335 + STATIN MOD (#)	359	282.2	140.8	-50.6	1.92	-95.0	96.6	-10.7	2.15 <0.001***
STATIN LOW (\$)	375	279.7	198.5	-29.0	1.48	-85.6	150.8	-24.3	2.11 <0.001***
STATIN MOD (%)	366	281.4	195.3	-30.5	1.50	-87.1	232.5	-17.9	2.13 <0.001***
STATIN HIGH	195	296.4	186.2	-37.5	2.11	-81.5	111.3		

TREATMENT BY SUBGROUP PARAMETER (DIABETIC STATUS) INTERACTION P-value (@@)= 0.031*

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * DIABETIC STATUS AS REPORTED IN SUBJECT'S MEDICAL HISTORY.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ¶ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 † P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP AND SCREENING TRIGLYCERIDE LEVEL (≤ 250 MG/DL, > 250 MG/DL).
 ‡ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

PERCENT CHANGES FROM BASELINE TO THE FINAL VISIT IN THE PRIMARY AND SECONDARY EFFICACY PARAMETERS BY DIABETIC STATUS (CONTROLLED STUDIES ANALYSIS SET)

WEEK 12 (FINAL VISIT)										
NON HDL CHOLESTEROL (MG/DL)										
DIABETIC										
ART-335	93	223.0	180.1	-17.9	1.75	-49.4	44.4			
ART-335 + STATIN LOW (‡)	96	217.2	125.5	-41.8	1.73	-66.9	25.1	-24.0	2.46	<0.001***
ART-335 + STATIN MOD (‡)	93	218.6	127.7	-40.9	1.75	-75.8	15.8	-23.0	2.47	<0.001***
STATIN LOW (§)	96	217.6	139.4	-35.9	1.72	-63.5	122.4	-5.9	2.44	0.015*
STATIN MOD (†)	95	221.2	126.3	-42.5	1.73	-68.3	13.1	1.4	2.46	0.504
STATIN HIGH	45	212.6	103.2	-53.0	2.52	-77.1	-15.5			
NON-DIABETIC										
ART-335	327	223.4	183.9	-16.3	0.85	-82.7	67.3			
ART-335 + STATIN LOW (‡)	326	221.6	133.1	-39.1	0.89	-71.6	10.2	-22.8	1.20	<0.001***
ART-335 + STATIN MOD (‡)	327	220.0	127.2	-41.5	0.84	-76.4	33.9	-25.2	1.20	<0.001***
STATIN LOW (§)	358	218.6	143.5	-33.8	0.81	-65.3	49.7	-9.3	1.17	<0.001***
STATIN MOD (†)	336	223.8	129.3	-41.6	0.83	-67.2	10.3	0.1	1.19	0.962
STATIN HIGH	172	223.1	120.8	-45.3	1.17	-77.1	13.5			

TREATMENT BY SUBGROUP PARAMETER (DIABETIC STATUS) INTERACTION P-value (@@)= 0.382

NOTE: STATIN LOW: ROSUVASTATIN CALCIUM 10 MG, SIMVASTATIN 20 MG AND ATORVASTATIN CALCIUM 20 MG.
 STATIN MOD: ROSUVASTATIN CALCIUM 20 MG, SIMVASTATIN 40 MG AND ATORVASTATIN CALCIUM 40 MG.
 STATIN HIGH: ROSUVASTATIN CALCIUM 40 MG, SIMVASTATIN 80 MG AND ATORVASTATIN CALCIUM 80 MG.
 * DIABETIC STATUS AS REPORTED IN SUBJECT'S MEDICAL HISTORY.
 ‡ P-VALUE FOR DIFFERENCE BETWEEN COMBINATION THERAPY ARM AND ART-335 MONOTHERAPY ARM.
 § P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN LOW ARM AND STATIN LOW MONOTHERAPY ARM.
 ¶ P-VALUE FOR DIFFERENCE BETWEEN ART-335 + STATIN MOD ARM AND STATIN MOD MONOTHERAPY ARM.
 † P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP AND SCREENING TRIGLYCERIDE LEVEL (≤ 250 MG/DL, > 250 MG/DL).
 ‡ P-VALUE FROM AN ANCOVA WITH CORRESPONDING BASELINE LIPID VALUE AS THE COVARIATE AND WITH EFFECTS FOR TREATMENT GROUP, SUBGROUP PARAMETER AND THE TREATMENT GROUP BY SUBGROUP PARAMETER INTERACTION.
 ***, **, * STATISTICALLY SIGNIFICANT AT THE P=0.001, 0.01, AND 0.05 LEVELS, RESPECTIVELY.

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Mean Percent Change from Baseline to the Final Value in HDL-C, TG, and LDL-C by Baseline LDL-C (Controlled Studies Analysis Set)

		ABT-335	Low-dose statin	ABT-335 + low statin	p-value	Moderate- dose statin	ABT-335 + moderate statin	p-value	High- dose statin
Baseline LDL-C ≤ 160 mg/dL									
HDL-C	BL mean	(N=229) 37.6	(N=292) 37.2	(N=262) 36.8	< 0.001 ^a	(N=248) 37.2	(N=239) 37.2	< 0.001 ^a	(N=128) 36.8
	Mean % Δ	17.7%	7.7%	17.8%		8.5%	17.7%		7.4%
TG	BL mean	(N=248) 301.1	(N=303) 306.5	(N=287) 302.9	< 0.001 ^a	(N=270) 310.0	(N=262) 312.4	< 0.001 ^a	(N=139) 291.4
	Mean % Δ	-32.5%	-16.7%	-45.3%		-27.2%	-42.5%		-30.8%
LDL-C	BL mean	(N=232) 134.9	(N=296) 134.4	(N=270) 134.1	< 0.001 ^b	(N=251) 135.6	(N=244) 134.1	< 0.001 ^b	(N=132) 135.5
	Mean % Δ	1.2%	-29.2%	-28.2%		-37.7%	-27.7%		-43.9%
Baseline LDL-C > 160 mg/dL									
HDL-C	BL mean	(N=191) 39.5	(N=162) 40.5	(N=161) 40.6	< 0.001 ^a	(N=179) 40.4	(N=181) 39.5	< 0.001 ^a	(N=89) 39.8
	Mean % Δ	14.4%	7.3%	18.9%		9.1%	17.3%		8.7%
TG	BL mean	(N=211) 254.1	(N=173) 249.9	(N=182) 246.2	< 0.001 ^a	(N=199) 256.0	(N=198) 248.3	< 0.001 ^a	(N=96) 265.2
	Mean % Δ	-28.7%	-17.2%	-42.6%		-18.2%	-41.0%		-24.1%
LDL-C	BL mean	(N=195) 187.9	(N=167) 189.6	(N=166) 192.6	< 0.001 ^b	(N=188) 189.5	(N=190) 186.6	< 0.001 ^b	(N=93) 187.2
	Mean % Δ	-13.5%	-40.1%	-40.7%		-44.4%	-43.9%		-50.9%

Note: P-value from an ANCOVA with corresponding baseline lipid value as the covariate and effects for treatment group, diabetic status, screening TG level, and interaction of diabetic status by screening TG level.

a. ABT-335 in combination with statin vs. corresponding statin monotherapy

b. ABT-335 in combination with statin vs. ABT-335 monotherapy

Cross Reference: Table 1.1_2.7.10

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Mean Percent Change from Baseline to the Final Value in HDL-C, TG, and LDL-C by Baseline TG (Controlled Studies Analysis Set)

		ABT-335	Low-dose statin	ABT-335 + low statin	p-value	Moderate- dose statin	ABT-335 + moderate statin	p-value	High-dose statin
Baseline TG ≤ 200 mg/dL									
HDL-C	BL mean	(N=147) 39.8	(N=147) 40.8	(N=139) 38.8	< 0.001 ^a	(N=133) 40.2	(N=136) 40.1	< 0.001 ^a	(N=70) 41.3
	Mean % Δ	12.4%	5.2%	14.3%		5.3%	14.3%		6.3%
TG	BL mean	(N=156) 162.9	(N=149) 160.9	(N=156) 168.2	< 0.001 ^a	(N=145) 163.0	(N=150) 158.7	< 0.001 ^a	(N=75) 162.1
	Mean % Δ	-18.4%	-2.9%	-28.5%		-4.2%	-28.7%		-7.5%
LDL-C	BL mean	(N=148) 169.0	(N=147) 162.4	(N=141) 162.6	< 0.001 ^b	(N=132) 167.7	(N=137) 164.6	< 0.001 ^b	(N=73) 168.0
	Mean % Δ	-12.1%	-37.8%	-39.4%		-43.0%	-40.9%		-47.7%
Baseline TG > 200 mg/dL									
HDL-C	BL mean	(N=273) 37.9	(N=308) 37.4	(N=284) 38.1	< 0.001 ^a	(N=297) 37.8	(N=286) 37.4	< 0.001 ^a	(N=147) 36.6
	Mean % Δ	18.1%	8.3%	19.9%		10.1%	19.0%		8.5%
TG	BL mean	(N=303) 323.4	(N=328) 325.9	(N=314) 322.4	< 0.001 ^a	(N=327) 327.9	(N=312) 333.5	< 0.001 ^a	(N=160) 320.6
	Mean % Δ	-38.2%	-24.2%	-51.3%		-33.3%	-49.9%		-38.8%
LDL-C	BL mean	(N=279) 153.9	(N=316) 150.9	(N=295) 153.4	< 0.001 ^b	(N=307) 154.7	(N=297) 153.5	< 0.001 ^b	(N=152) 151.6
	Mean % Δ	-1.9%	-32.2%	-30.2%		-39.7%	-31.9%		-47.1%

Note: P-value from an ANCOVA with corresponding baseline lipid value as the covariate and effects for treatment group, diabetic status, screening TG level, and interaction of diabetic status by screening TG level.

a. ABT-335 in combination with statin vs. corresponding statin monotherapy

b. ABT-335 in combination with statin vs. ABT-335 monotherapy

Cross Reference: Table 1.1_2.7.11

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