Table 24 Primary Hypercholesterolemia
Randomized Controlled Trials
Monotherapy Pool
Baseline General Medical History/ Physical Findings

Number And (Percent) Of Patients

General Category	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Cardiovascular[a]	615 (77.4)	1303 (77.1)	1450 (73.1)
Dermatologic	249 (31.3)	534 (31.6)	630 (31.8)
Drug Allergies	231 (29.1)	501 (29.6)	569 (28.7)
Endocrinologic/Metabolic	259 (32.6)	532 (31.5)	592 (29.9)
Gastrointestinal	430 (54.1)	913 (54.0)	1043 (52.6)
Genitourinary	385 (48.4)	902 (53.3)	1050 (53.0)
Hematologic	61 (7.7)	77 (4.6)	92 (4.6)
Immunologic	187 (23.5)	364 (21.5)	416 (21.0)
Musculoskeletal	525 (66.0)	1097 (64.9)	1288 (65.0)
Neurologic	263 (33.1)	533 (31.5)	612 (30.9)
Ophthalmic	360 (45.3)	741 (43.8)	836 (42.2)
Otorhinolaryngologic	338 (42.5)	760 (44.9)	896 (45.2)
Psychiatric	148 (18.6)	316 (18.7)	358 (18.1)
Pulmonary	165 (20.8)	384 (22.7)	438 (22.1)

a: Includes subjects with cardiovascular history / risk factors or cardiovascular medical history / physical finding, and postmenopausal condition for women.

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Table 25 Primary Hypercholesterolemia
Randomized Controlled Trials
Factorial Coadministration Pool
Baseline Demographic Characteristics

Characteristics	Placebo (n=259)	Ezetimibe (n=262)	All Statins (n=936)	Ezetimibe + All Statins (n=925)
Age (y)				
Mean	56.9	55.9	56.3	57.5
SD	12	11.6	12.1	11.7
Median	57	57	57	58
Min	18	26	21	20
Max	84	84	87	86
Age (no. subjects, %)				
<65 y	183 (70.7)	198 (75.6)	676 (72.2)	656 (70.9)
≥65 y	76 (29.3)	64 (24.4)	260 (27.8)	269 (29.1)
Age (no. subjects, %)				
<75 y	241 (93.1)	248 (94.7)	879 (93.9)	859 (92.9)
≥75 y	18 (6.9)	14 (5.3)	57 (6.1)	66 (7.1)
Sex (no. subjects, %)				
Female	144 (55.6)	155 (59.2)	542 (57.9)	523 (56.5)
Male	115 (44.4)	107 (40.8)	394 (42.1)	402 (43.5)
Race (no. subjects, %)				
Caucasian	227 (87.6)	235 (89.7)	814 (87.0)	813 (87.9)
Black	15 (5.8)	11 (4.2)	56 (6.0)	44 (4.8)
American Indian	1 (0.4)	1 (0.4)	4 (0.4)	3 (0.3)
Asian	9 (3.5)	2 (0.8)	10 (1.1)	18 (1.9)
Hispanic	7 (2.7)	12 (4.6)	50 (5.3)	45 (4.9)
Pacific Islander	0	0	1 (0.1)	0
Other	0	1 (0.4)	1 (0.1)	2 (0.2)
Body Weight (kg)				
Mean	80.3	80.6	81.4	81.4
SD	16	17.5	16.7	17.1
Median	77.6	77.3	79.7	80.3
Min	46.3	44.5	46	43.7
Max	130	174.3	193.1	237.3
Body Mass Index (kg/m^2)	(n=258)	(n=261)	(n=935)	(n=924)
Mean	28.3	29	28.8	28.9
SD	4.8	5.9	5	5.2
Median	27.8	27.6	27.9	28
Min	19	17.5	18.3	17.4
Max	47.4	75.4	51.8	73.2
Smoker (no. subjects, %)				
No	224 (86.5)	220 (84.0)	796 (85.0)	810 (87.6)
Yes	35 (13.5)	42 (16.0)	140 (15.0)	115 (12.4)
Washout Info[a] (no. subjects, %)				
No	172 (66.4)	175 (66.8)	603 (64.4)	593 (64.1)
Yes	87 (33.6)	87 (33.2)	333 (35.6)	332 (35.9)
Statins	73 (28.2)	70 (26.7)	267 (28.5)	273 (29.5)
Fibric Acid Derivative	1 (0.4)	1 (0.4)	13 (1.4)	9 (1.0)
Bile Acid Sequestrant	0	0	3 (0.3)	6 (0.6)
Nicotinic Acid	3 (1.2)	8 (3.1)	21 (2.2)	21 (2.3)
Other	15 (5.8)	16 (6.1)	65 (6.9)	60 (6.5)

a: Prior therapy discontinued before investigational treatment.

Treatments: Ezetimibe = Ezetimibe 10 mg; All Statins = all doses of all statins.

SD = standard deviation.

Table 26 Primary Hypercholesterolemia
Randomized Controlled Trials
Factorial Coadministration Pool
Baseline Cardiovascular Risk Factors/Family History/Known CHD Or Cardiovascular Medical History/Physical Findings

Number And (Percent) Of Patients

Risk Factors/History/Finding	Placebo (n=259)	Ezetimibe (n=262)	All Statins (n=936)	Ezetimibe + All Statins (n=925)
CV Risk Factor/History or CV Medical History/Physical Findings	143 (55.2)	154 (58.8)	554 (59.2)	553 (59.8)
CV Risk Factor/History[a]	143 (55.2)	153 (58.4)	552 (59.0)	552 (59.7)
CV Medical History/Physical Finding	50 (19.3)	44 (16.8)	184 (19.7)	181 (19.6)

a: Any subject with "Yes" for any of the following: hypertension, diabetes mellitus, stroke, transient ischemia attack, peripheral vascular disease, myocardial infarction, congestive heart failure, angina, coronary angioplasty, history of arrhythmias, CABG, family history of CAD if premature, other significant CV History, known CHD. Does not include postmenopausal condition for women.

Treatments: Ezetimibe = Ezetimibe 10 mg. All Statins = all doses of all statins.

CABG = coronary artery bypass grafting; CAD = coronary artery disease; CHD = coronary heart disease; CV = cardiovascular.

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Table 27 Primary Hypercholesterolemia
Randomized Controlled Trials
Factorial Coadministration Pool
Baseline Cardiovascular Risk Factors/Family History/Known CHD

Risk Factors/History/ Known CHD	Number And (Percent) Of Patients			
	Placebo (n=259)	Ezetimibe (n=262)	All Statins (n=936)	Ezetimibe + All Statins (n=925)
Hypertension				
Yes	80 (30.9)	87 (33.2)	284 (30.3)	286 (30.9)
No	179 (69.1)	175 (66.8)	652 (69.7)	639 (69.1)
Diabetes Mellitus				
Yes	10 (3.9)	11 (4.2)	51 (5.4)	49 (5.3)
No	249 (96.1)	251 (95.8)	885 (94.6)	876 (94.7)
Stroke				
Yes	3 (1.2)	6 (2.3)	10 (1.1)	15 (1.6)
No	256 (98.8)	256 (97.7)	926 (98.9)	910 (98.4)
Transient Ischemic Attack				
Yes	4 (1.5)	2 (0.8)	15 (1.6)	16 (1.7)
No	255 (98.5)	260 (99.2)	921 (98.4)	909 (98.3)
Peripheral Vascular Disease				
Yes	3 (1.2)	5 (1.9)	19 (2.0)	27 (2.9)
No	256 (98.8)	257 (98.1)	917 (98.0)	898 (97.1)
Myocardial Infarction				
Yes	9 (3.5)	7 (2.7)	44 (4.7)	42 (4.5)
No	250 (96.5)	255 (97.3)	892 (95.3)	883 (95.5)
Congestive Heart Failure				
Yes	2 (0.8)	3 (1.1)	4 (0.4)	2 (0.2)
No	257 (99.2)	259 (98.9)	932 (99.6)	923 (99.8)
Angina				
Yes	16 (6.2)	11 (4.2)	54 (5.8)	57 (6.2)
No	242 (93.4)	251 (95.8)	882 (94.2)	868 (93.8)
Unknown	1 (0.4)	0	0	0
Coronary Angioplasty				
Yes	6 (2.3)	3 (1.1)	28 (3.0)	32 (3.5)
No	253 (97.7)	259 (98.9)	908 (97.0)	893 (96.5)
History of Arrhythmias				
Yes	20 (7.7)	16 (6.1)	49 (5.2)	66 (7.1)
No	239 (92.3)	246 (93.9)	886 (94.7)	859 (92.9)
Unknown	0	0	1 (0.1)	0
Coronary Artery Bypass Graft (CABG)				
Yes	4 (1.5)	2 (0.8)	22 (2.4)	31 (3.4)
No	255 (98.5)	260 (99.2)	914 (97.6)	894 (96.6)
Other Significant Cardiovascular History				
Yes	63 (24.3)	63 (24.0)	247 (26.4)	253 (27.4)
No	196 (75.7)	199 (76.0)	689 (73.6)	672 (72.6)
Post Menopausal[a]				
Yes	122 (84.7)	115 (74.2)	425 (78.4)	434 (83.0)
No	22 (15.3)	40 (25.8)	117 (21.6)	88 (16.8)
Missing	0	0	0	1 (0.2)
Family History of Coronary Artery Disease				
Yes	107 (41.3)	115 (43.9)	385 (41.1)	386 (41.7)
No	150 (57.9)	146 (55.7)	542 (57.9)	529 (57.2)
Unknown	2 (0.8)	1 (0.4)	9 (1.0)	10 (1.1)
(Other) Known (Indicator of) Coronary Heart Disease[b]				
Yes	5 (1.9)	4 (1.5)	32 (3.4)	24 (2.6)
No	254 (98.1)	258 (98.5)	904 (96.6)	900 (97.3)
Unknown	0	0	0	1 (0.1)

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Table 27 Completed.

Risk Factors/History/ Known CHD	Placebo (n=259)	Ezetimibe (n=262)	All Statins (n=936)	Ezetimibe + All Statins (n=925)
	Number And (Percent) Of Patients			
Known Coronary Heart Disease[c]				
Known CHD	14 (5.4)	13 (5.0)	76 (8.1)	76 (8.2)
No CHD				
NCEP ATP II Risk Factor.				
<1	7 (2.7)	7 (2.7)	27 (2.9)	24 (2.6)
0	62 (23.9)	50 (19.1)	214 (22.9)	174 (18.8)
1	100 (38.6)	104 (39.7)	350 (37.4)	364 (39.4)
2	53 (20.5)	63 (24.0)	189 (20.2)	209 (22.6)
>2	23 (8.9)	25 (9.5)	80 (8.5)	78 (8.4)

a: Female subjects only.

b: Represents data captured in a check box in the case report form to identify indicators of coronary heart disease other than those already specified.

c: Derived variable: comprises any one or combination of myocardial infarction, coronary angioplasty, CABG, and "known coronary heart disease" from the *Cardiovascular Risk Factors/History* module of the case report form.

Treatment: Ezetimibe = Ezetimibe 10 mg. All Statins = all doses of all statins.

NCEP ATP II = National Cholesterol Education Program Adult Treatment Panel II.

Table 28 Primary Hypercholesterolemia
Randomized Controlled Trials
Factorial Coadministration Pool
Baseline General Medical History/ Physical Findings

Number And (Percent) Of Patients

General Category	Placebo (n=259)	Ezetimibe (n=262)	All Statins (n=936)	Ezetimibe + All Statins (n=925)
Cardiovascular[a]	209 (80.7)	214 (81.7)	756 (80.8)	773 (83.6)
Dermatologic	88 (34.0)	87 (33.2)	296 (31.8)	289 (31.2)
Drug Allergies	79 (30.5)	66 (25.2)	270 (28.8)	259 (28.0)
Endocrinologic/Metabolic	91 (35.1)	84 (32.1)	303 (32.4)	304 (32.9)
Gastrointestinal	130 (50.2)	134 (51.1)	500 (53.4)	494 (53.4)
Genitourinary	120 (46.3)	128 (48.9)	456 (48.6)	430 (46.5)
Hematologic	26 (10.0)	9 (3.4)	68 (7.3)	63 (6.8)
Immunologic	63 (24.3)	56 (21.4)	206 (22.0)	193 (20.9)
Musculoskeletal	167 (64.5)	165 (63.0)	593 (63.4)	604 (65.3)
Neurologic	80 (30.9)	80 (30.5)	315 (33.7)	294 (31.8)
Ophthalmic	128 (49.4)	114 (43.5)	430 (45.9)	460 (49.7)
Otorhinolaryngologic	100 (38.6)	111 (42.4)	405 (43.3)	387 (41.8)
Psychiatric	52 (20.1)	54 (20.6)	178 (19.0)	166 (17.9)
Pulmonary	51 (19.7)	57 (21.8)	219 (23.4)	191 (20.6)

a. Includes subjects with cardiovascular history / risk factors or cardiovascular medical history / physical finding, and postmenopausal condition for women.

Treatment: Ezetimibe = Ezetimibe 10 mg, All Statins = all doses of all statins.

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Table 29 Primary Hypercholesterolemia/Patients With Documented CHD, Diabetes Mellitus, Or CVD Risk Factors Ezetimibe Added To An Established Statin Completed Randomized Clinical Trial Baseline Demographic Characteristics

Characteristics and Habits	Number And (Percent) Of Patients: Statin + Placebo (n=380)	Statin + Ezetimibe 10 mg (n=379)
Age (y)		
Mean	60.0	60.0
Median	61	61
Minimum	22	25
Maximum	83	85
Age (no. subjects, %)		
< 65	242 (62)	233 (61)
>= 65	148 (38)	146 (39)
< 75	352 (90)	337 (89)
>= 75	38 (10)	42 (11)
Sex (no. subjects, %)		
Female	169 (43)	157 (41)
Male	221 (57)	222 (59)
Race (no. subjects, %)		
Caucasian	356 (91)	337 (89)
Black	19 (5)	27 (7)
American Indian	2 (<1)	0
Asian	4 (1)	5 (1)
Hispanic	7 (2)	8 (2)
Caucasian/Black	1 (<1)	0
Pacific Islander	1 (<1)	1 (<1)
Caucasian/Pacific Islander	0	1 (<1)

Note: Mean values in this table are arithmetic means.

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Table 30 Homozygous Familial Hypercholesterolemia Ezetimibe Coadministered With A Statin Completed Randomized Clinical Trial Baseline Demographic Characteristics

Characteristics	Statin 80 mg (n=17)	EZ 10 mg + Statin 40/80 mg (n=33)	Ator 80 mg (n=12)	EZ 10 mg + Ator 40 mg (n=12)	EZ 10 mg + Ator 80 mg (n=12)	Sim 80 mg (n=5)	EZ 10 mg + Sim 40 mg (n=4)	EZ 10 mg + Sim 80 mg (n=5)
Age (y)								
Mean	32.7	32	30.2	32.8	31.6	38.8	36.3	28
Median	30	31	28	31.5	32.5	35	32.5	28
Minimum-Maximum	13-66	11-74	13-66	11-74	14-53	28-66	17-63	20-36
Age (no. subjects, %)								
<18 y	2 (12%)	5 (15%)	2 (17%)	2 (17%)	2 (17%)	0	1 (25%)	0
≥18 y	15 (88%)	28 (85%)	10 (83%)	10 (83%)	10 (83%)	5 (100%)	3 (75%)	5 (100%)
Sex (no. subjects, %)								
Female	12 (71%)	17 (52%)	8 (67%)	9 (75%)	5 (42%)	4 (80%)	2 (50%)	1 (20%)
Male	5 (29%)	16 (48%)	4 (33%)	3 (25%)	7 (58%)	1 (20%)	2 (50%)	4 (80%)
Race (no. subjects, %)								
Caucasian	16 (94%)	29 (88%)	11 (92%)	11 (92%)	11 (92%)	5 (100%)	4 (100%)	3 (60%)
Black	0	1 (3%)	0	0	1 (8%)	0	0	0
Hispanic	1 (6%)	3 (9%)	1 (8%)	1 (8%)	0	0	0	2 (40%)

Ator = atorvastatin; EZ = ezetimibe; Sim = simvastatin.

Note: Mean values in this table are arithmetic means.

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Table 31 Homozygous Sitosterolemia
Ezetimibe Coadministered With Established Therapy
Completed Randomized Clinical Trial
Baseline Demographic Characteristics

Characteristics	Placebo (n=7)	Ezetimibe 10 mg (n=30)
Age (y)		
Mean	37.6	37.0
Median	41	38
Minimum	13	9
Maximum	57	72
Age (no. subjects, %)		
<18 y	1 (14)	4 (13)
≥18 y	6 (86)	26 (87)
Sex (no. subjects, %)		
Female	6 (86)	18 (60)
Male	1 (14)	12 (40)
Race (no. subjects, %)		
Caucasian	6 (86)	27 (90)
Asian	0	1 (3)
Hispanic	1 (14)	2 (7)

Table 32 Primary Hypercholesterolemia Monotherapy Pool Summary Of Adverse Events

Number And (Percent) Of Patients

Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Death	0	1 (0.06)	1 (0.05)
Serious Adverse Event	19 (2.4)	35 (2.1)	37 (1.9)
Treatment-Related[a] Serious Adverse Event	0	6 (0.4)	7 (0.4)
Discontinuation Due to Adverse Event	30 (3.8)	68 (4.0)	71 (3.6)
Discontinuation Due to Treatment-Related[a] Adverse Event	17 (2.1)	39 (2.3)	40 (2.0)
Treatment-Emergent Adverse Event	511 (64.3)	1061 (62.7)	1241 (62.6)
Treatment-Related,[a] Treatment-Emergent Adverse Event	123 (15.5)	235 (13.9)	293 (14.8)
Severe/Life-Threatening, Treatment-Emergent Adverse Event	32 (4.0)	79 (4.7)	84 (4.2)

a: Judged to be at least possibly related to treatment by the investigator.

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Table 33 Primary Hypercholesterolemia
Monotherapy Pool
Serious Adverse Events (SAEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY SERIOUS ADVERSE EVENT	**19 (2.4)**	**35 (2.1)**	**37 (1.9)**
BENIGN & MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**3 (0.4)**	**8 (0.5)**	**8 (0.4)**
BASAL CELL CARCINOMA	2 (0.3)	0	0
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (0.1)	1 (0.1)
CARCINOMA	0	1 (0.1)	1 (0.1)
GASTRIC CARCINOMA	0	1 (0.1)	1 (0.1)
MENINGIOMA	0	1 (0.1)	1 (0.1)
NEOPLASM, BRAIN	0	1 (0.1)	1 (0.1)
PROSTATIC CANCER	0	2 (0.1)	2 (0.1)
PULMONARY CARCINOMA	1 (0.1)	1 (0.1)	1 (0.1)
RECTAL CARCINOMA	0	1 (0.1)	1 (0.1)
BODY AS A WHOLE - GENERAL DISORDERS	**1 (0.1)**	**5 (0.3)**	**5 (0.3)**
CHEST PAIN	1 (0.1)	3 (0.2)	3 (0.2)
DEATH	0	1 (0.1)	1 (0.1)
DIZZINESS	1 (0.1)	0	0
FATIGUE	0	1 (0.1)	1 (0.1)
CARDIOVASCULAR DISORDERS, GENERAL	**3 (0.4)**	**3 (0.2)**	**3 (0.2)**
ANGINA PECTORIS AGGRAVATED	0	1 (0.1)	1 (0.1)
CARDIAC FAILURE	1 (0.1)	0	0
CORONARY ARTERY DISORDER	2 (0.3)	2 (0.1)	2 (0.1)
HYPOTENSION POSTURAL	0	1 (0.1)	1 (0.1)
MITRAL INSUFFICIENCY	1 (0.1)	0	0
MYOCARDIAL ISCHEMIA	1 (0.1)	0	0
TRICUSPID VALVE INCOMPETENCE	1 (0.1)	0	0
CENTR AND PERIPH NERV SYST DISORDERS	**2 (0.3)**	**2 (0.1)**	**2 (0.1)**
CEREBROVASCULAR ACCIDENT NOS	1 (0.1)	0	0
HYPOESTHESIA	1 (0.1)	1 (0.1)	1 (0.1)
TRANSIENT ISCHEMIC ATTACK	0	2 (0.1)	2 (0.1)
DISORDERS OF THE REPRODUCTIVE SYSTEM AND BREAST	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
HYSTERECTOMY	1 (0.2)	0	0
MENSTRUAL DISORDER	1 (0.2)	0	0
OVARIAN MASS	0	1 (0.1)	1 (0.1)
UTERINE FIBROID	1 (0.2)	0	0

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Table 33 Completed.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
GASTRO-INTESTINAL SYSTEM DISORDERS	**1 (0.1)**	**3 (0.2)**	**3 (0.2)**
APPENDICITIS	0	1 (0.1)	1 (0.1)
DIVERTICULOSIS	0	1 (0.1)	1 (0.1)
GASTRO-INTESTINAL DISORDER NOS	0	1 (0.1)	1 (0.1)
GI HEMORRHAGE	1 (0.1)	0	0
ILEITIS	0	1 (0.1)	1 (0.1)
HEART RATE AND RHYTHM DISORDERS	**1 (0.1)**	**2 (0.1)**	**2 (0.1)**
BRADYCARDIA	1 (0.1)	0	0
FIBRILLATION ATRIAL	0	1 (0.1)	1 (0.1)
PALPITATION	0	1 (0.1)	1 (0.1)
INJURY AND POISONING	**0**	**3 (0.2)**	**3 (0.2)**
FRACTURE	0	1 (0.1)	1 (0.1)
INJURY ACCIDENTAL	0	2 (0.1)	2 (0.1)
LACERATION, SKIN	0	1 (0.1)	1 (0.1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	**2 (0.3)**	**5 (0.3)**	**5 (0.3)**
CHOLECYSTITIS	0	1 (0.1)	1 (0.1)
GAMMA-GT INCREASED	1 (0.1)	1 (0.1)	1 (0.1)
HEPATIC FUNCTION ABNORMAL	0	1 (0.1)	1 (0.1)
SGOT INCREASED	2 (0.3)	3 (0.2)	3 (0.2)
SGPT INCREASED	2 (0.3)	2 (0.1)	2 (0.1)
METABOLIC AND NUTRITIONAL DISORDERS	**2 (0.3)**	**1 (0.1)**	**1 (0.1)**
CREATINE PHOSPHOKINASE INCREASED[b]	1 (0.1)	1 (0.1)	1 (0.1)
PHOSPHATASE ALKALINE INCREASED	1 (0.1)	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS	**1 (0.1)**	**4 (0.2)**	**5 (0.3)**
BACK PAIN	0	0	1 (0.1)
JOINT DISLOCATION	0	1 (0.1)	1 (0.1)
MUSCULO-SKELETAL PAIN	0	1 (0.1)	1 (0.1)
SPINAL DISORDER	1 (0.1)	2 (0.1)	2 (0.1)
TENDON RUPTURE	0	1 (0.1)	1 (0.1)
PSYCHIATRIC DISORDERS	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
AMNESIA	1 (0.1)	0	0
MANIC DEPRESSION	0	1 (0.1)	1 (0.1)
RENAL & URINARY SYSTEM DISORDERS	**1 (0.1)**	**0**	**0**
RENAL CALCULUS	1 (0.1)	0	0
RESPIRATORY SYSTEM DISORDERS	**3 (0.4)**	**2 (0.1)**	**2 (0.1)**
CHRONIC OBSTRUCTIVE AIRWAY DISEASE	1 (0.1)	0	0
DYSPNEA	1 (0.1)	2 (0.1)	2 (0.1)
PLEURAL EFFUSION	1 (0.1)	1 (0.1)	1 (0.1)
PNEUMOTHORAX	0	1 (0.1)	1 (0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**1 (0.1)**	**1 (0.1)**	**2 (0.1)**
CELLULITIS	1 (0.1)	0	0
PANNICULITIS	0	1 (0.1)	1 (0.1)
URTICARIA	0	0	1 (0.1)
SURGICAL AND MEDICAL PROCEDURES	**3 (0.4)**	**4 (0.2)**	**4 (0.2)**
PROCEDURE	0	1 (0.1)	1 (0.1)
PROCEDURE (NO ADVERSE EVENT)	2 (0.3)	3 (0.2)	3 (0.2)
TUMOR EXCISION	1 (0.1)	0	0
VASCULAR (EXTRACARDIAC) DISORDERS	**1 (0.1)**	**0**	**0**
THROMBOSIS	1 (0.1)	0	0

a: SGOT = AST; SGPT = ALT. Several protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should be considered a serious adverse event.

b: Several protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should be considered a serious adverse event.

Table 34 Primary Hypercholesterolemia Monotherapy Pool Serious Adverse Events (SAEs) Considered As Treatment-Related By Investigators

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY TREATMENT-RELATED SERIOUS ADVERSE EVENT	0	6 (0.4)	7 (0.4)
GASTRO-INTESTINAL SYSTEM DISORDERS	0	1 (0.1)	1 (0.1)
GASTRO-INTESTINAL DISORDER NOS	0	1 (0.1)	1 (0.1)
HEART RATE AND RHYTHM DISORDERS	0	1 (0.1)	1 (0.1)
PALPITATION	0	1 (0.1)	1 (0.1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	0	4 (0.2)	4 (0.2)
GAMMA-GT INCREASED	0	1 (0.1)	1 (0.1)
HEPATIC FUNCTION ABNORMAL	0	1 (0.1)	1 (0.1)
SGOT INCREASED	0	3 (0.2)	3 (0.2)
SGPT INCREASED	0	2 (0.1)	2 (0.1)
METABOLIC AND NUTRITIONAL DISORDERS	0	1 (0.1)	1 (0.1)
CREATINE PHOSPHOKINASE INCREASED[b]	0	1 (0.1)	1 (0.1)
MUSCULO-SKELETAL SYSTEM DISORDERS	0	1 (0.1)	1 (0.1)
MUSCULO-SKELETAL PAIN	0	1 (0.1)	1 (0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	1 (0.1)	2 (0.1)
PANNICULITIS	0	1 (0.1)	1 (0.1)
URTICARIA	0	0	1 (0.1)

a: SGOT = AST; SGPT = ALT. Several protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should be considered a serious adverse event.

b: Several protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should be considered a serious adverse event.

Note: "Treatment-Related" means judged to be at least possibly related to treatment by the investigator.

Table 35 Primary Hypercholesterolemia Monotherapy Pool Discontinuations Due To Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY ADVERSE EVENT	**30 (3.8)**	**68 (4.0)**	**71 (3.6)**
AUTONOMIC NERVOUS SYSTEM DISORDERS	**1 (0.1)**	**0**	**0**
HOT FLUSHES	1 (0.1)	0	0
BENIGN & MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**1 (0.1)**	**7 (0.4)**	**7 (0.4)**
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (0.1)	1 (0.1)
CARCINOMA	0	1 (0.1)	1 (0.1)
GASTRIC CARCINOMA	0	1 (0.1)	1 (0.1)
MENINGIOMA	0	1 (0.1)	1 (0.1)
PROSTATIC CANCER	0	2 (0.1)	2 (0.1)
PULMONARY CARCINOMA	1 (0.1)	0	0
RECTAL CARCINOMA	0	1 (0.1)	1 (0.1)
BODY AS A WHOLE - GENERAL DISORDERS	**7 (0.9)**	**13 (0.8)**	**13 (0.7)**
CHEST PAIN	0	3 (0.2)	3 (0.2)
DEATH	0	1 (0.1)	1 (0.1)
DIZZINESS	1 (0.1)	3 (0.2)	3 (0.2)
EDEMA GENERALIZED	1 (0.1)	0	0
EDEMA LEGS	1 (0.1)	0	0
EDEMA PERIPHERAL	1 (0.1)	0	0
FATIGUE	2 (0.3)	2 (0.1)	2 (0.1)
HEADACHE	2 (0.3)	5 (0.3)	5 (0.3)
CARDIOVASCULAR DISORDERS, GENERAL	**2 (0.3)**	**4 (0.2)**	**5 (0.3)**
ANGINA PECTORIS AGGRAVATED	0	1 (0.1)	1 (0.1)
CORONARY ARTERY DISORDER	1 (0.1)	2 (0.1)	2 (0.1)
EDEMA DEPENDENT	0	0	1 (0.1)
HYPERTENSION	1 (0.1)	2 (0.1)	2 (0.1)
CENTR AND PERIPH NERV SYST DISORDERS	**2 (0.3)**	**3 (0.2)**	**3 (0.2)**
CEREBROVASCULAR ACCIDENT NOS	1 (0.1)	0	0
DYSPHONIA	1 (0.1)	0	0
PARESTHESIA	0	3 (0.2)	3 (0.2)
DISORDERS OF BLOOD AND LYMPHATIC SYSTEM	**0**	**1 (0.1)**	**1 (0.1)**
LEUKOPENIA	0	1 (0.1)	1 (0.1)
DISORDERS OF THE EYE	**2 (0.3)**	**2 (0.1)**	**2 (0.1)**
VISION BLURRED	1 (0.1)	2 (0.1)	2 (0.1)
XEROPHTHALMIA	1 (0.1)	0	0
DISORDERS OF THE IMMUNE SYSTEM	**1 (0.1)**	**0**	**0**
INFLAMMATION, NON- SPECIFIC	1 (0.1)	0	0
DISORDERS OF THE REPRODUCTIVE SYSTEM AND BREAST	**0**	**2 (0.1)**	**2 (0.1)**
BREAST PAIN	0	1 (0.1)	1 (0.1)
OVARIAN MASS	0	1 (0.1)	1 (0.1)
ENDOCRINE DISORDERS	**0**	**2 (0.1)**	**2 (0.1)**
DIABETES MELLITUS AGGRAVATED	0	1 (0.1)	1 (0.1)
TSH INCREASED	0	1 (0.1)	1 (0.1)

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Table 35 Continued.

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
	Number And (Percent) Of Patients		
GASTRO-INTESTINAL SYSTEM DISORDERS	**9 (1.1)**	**16 (0.9)**	**16 (0.8)**
ABDOMINAL DISTENSION	2 (0.3)	1 (0.1)	1 (0.1)
ABDOMINAL PAIN	0	6 (0.4)	6 (0.3)
CONSTIPATION	3 (0.4)	1 (0.1)	1 (0.1)
DIARRHEA	5 (0.6)	5 (0.3)	5 (0.3)
DIVERTICULOSIS	0	1 (0.1)	1 (0.1)
DYSPEPSIA	0	2 (0.1)	2 (0.1)
FLATULENCE	0	1 (0.1)	1 (0.1)
ILEITIS	0	1 (0.1)	1 (0.1)
LOOSE STOOLS	0	4 (0.2)	4 (0.2)
MOUTH DRY	0	1 (0.1)	1 (0.1)
MOUTH ULCERATION	1 (0.1)	0	0
NAUSEA	1 (0.1)	1 (0.1)	1 (0.1)
VOMITING	1 (0.1)	0	0
HEART RATE AND RHYTHM DISORDERS	**0**	**2 (0.1)**	**2 (0.1)**
BRADYCARDIA	0	1 (0.1)	1 (0.1)
PALPITATION	0	1 (0.1)	1 (0.1)
INFECTION AND INFESTATIONS	**4 (0.5)**	**1 (0.1)**	**1 (0.1)**
PHARYNGITIS	1 (0.1)	0	0
PNEUMONIA	1 (0.1)	0	0
TOOTH ABSCESS	1 (0.1)	0	0
UPPER RESP TRACT INFECTION	1 (0.1)	1 (0.1)	1 (0.1)
INJURY AND POISONING	**0**	**1 (0.1)**	**1 (0.1)**
FRACTURE	0	1 (0.1)	1 (0.1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	**2 (0.3)**	**10 (0.6)**	**10 (0.5)**
GAMMA-GT INCREASED	0	5 (0.3)	5 (0.3)
HEPATIC ENZYMES INCREASED	1 (0.1)	1 (0.1)	1 (0.1)
HEPATIC FUNCTION ABNORMAL	0	2 (0.1)	2 (0.1)
SGOT INCREASED	1 (0.1)	4 (0.2)	4 (0.2)
SGPT INCREASED	1 (0.1)	4 (0.2)	4 (0.2)
METABOLIC AND NUTRITIONAL DISORDERS	**2 (0.3)**	**8 (0.5)**	**8 (0.4)**
CREATINE PHOSPHOKINASE INCREASED[b]	2 (0.3)	5 (0.3)	5 (0.3)
PHOSPHATASE ALKALINE INCREASED	0	2 (0.1)	2 (0.1)
WEIGHT INCREASE	0	1 (0.1)	1 (0.1)

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Table 35 Completed.

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients: Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
MUSCULO-SKELETAL SYSTEM DISORDERS	**6 (0.8)**	**12 (0.7)**	**13 (0.7)**
ARTHRALGIA	2 (0.3)	4 (0.2)	5 (0.3)
ARTHRALGIA AGGRAVATED	0	2 (0.1)	2 (0.1)
ARTHROPATHY	1 (0.1)	0	0
BACK PAIN	0	2 (0.1)	2 (0.1)
CRAMPS LEGS	1 (0.1)	2 (0.1)	2 (0.1)
JOINT DISLOCATION	0	1 (0.1)	1 (0.1)
MUSCLE SPRAIN	0	1 (0.1)	1 (0.1)
MUSCLE WEAKNESS	1 (0.1)	1 (0.1)	1 (0.1)
MUSCULO-SKELETAL PAIN	2 (0.3)	2 (0.1)	2 (0.1)
MYALGIA	1 (0.1)	0	0
TENDON RUPTURE	0	1 (0.1)	1 (0.1)
PLATELET, BLEEDING AND CLOTTING DISORD	**0**	**0**	**1 (0.1)**
THROMBOCYTOPENIA	0	0	1 (0.1)
PSYCHIATRIC DISORDERS	**1 (0.1)**	**3 (0.2)**	**4 (0.2)**
ANXIETY	0	2 (0.1)	2 (0.1)
INSOMNIA	1 (0.1)	1 (0.1)	1 (0.1)
PARONIRIA	0	0	1 (0.1)
RENAL & URINARY SYSTEM DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
RENAL PAIN	0	1 (0.1)	1 (0.1)
RESPIRATORY SYSTEM DISORDERS	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
DYSPNEA	1 (0.1)	1 (0.1)	1 (0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**5 (0.6)**	**5 (0.3)**	**7 (0.4)**
ALOPECIA	1 (0.1)	0	0
CELLULITIS	1 (0.1)	0	0
PRURITUS	0	2 (0.1)	2 (0.1)
RASH	1 (0.1)	1 (0.1)	1 (0.1)
RASH MACULOPAPULAR	1 (0.1)	0	0
SKIN DISORDER	0	0	1 (0.1)
SWEATING INCREASED	1 (0.1)	0	0
URTICARIA	1 (0.1)	2 (0.1)	3 (0.2)
SPECIAL SENSES OTHER, DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
TASTE PERVERSION	0	1 (0.1)	1 (0.1)

a: SGOT = AST; SGPT = ALT. Several protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should result in discontinuation.

b: Several protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should result in discontinuation.

Table 36 Primary Hypercholesterolemia Monotherapy Pool Discontinuations Due To Adverse Events (AEs) Considered As Treatment-related By Investigators

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY TREATMENT-RELATED ADVERSE EVENT	**17 (2.1)**	**39 (2.3)**	**40 (2.0)**
BODY AS A WHOLE - GENERAL DISORDERS	**4 (0.5)**	**5 (0.3)**	**5 (0.3)**
CHEST PAIN	0	1 (0.1)	1 (0.1)
EDEMA GENERALIZED	1 (0.1)	0	0
EDEMA LEGS	1 (0.1)	0	0
EDEMA PERIPHERAL	1 (0.1)	0	0
FATIGUE	1 (0.1)	1 (0.1)	1 (0.1)
HEADACHE	1 (0.1)	3 (0.2)	3 (0.2)
CARDIOVASCULAR DISORDERS, GENERAL	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
HYPERTENSION	1 (0.1)	1 (0.1)	1 (0.1)
CENTR AND PERIPH NERV SYST DISORDERS	**0**	**2 (0.1)**	**2 (0.1)**
PARESTHESIA	0	2 (0.1)	2 (0.1)
DISORDERS OF BLOOD AND LYMPHATIC SYSTEM	**0**	**1 (0.1)**	**1 (0.1)**
LEUKOPENIA	0	1 (0.1)	1 (0.1)
DISORDERS OF THE EYE	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
VISION BLURRED	1 (0.1)	1 (0.1)	1 (0.1)
DISORDERS OF THE IMMUNE SYSTEM	**1 (0.1)**	**0**	**0**
INFLAMMATION, NON- SPECIFIC	1 (0.1)	0	0
ENDOCRINE DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
TSH INCREASED	0	1 (0.1)	1 (0.1)
GASTRO-INTESTINAL SYSTEM DISORDERS	**6 (0.8)**	**10 (0.6)**	**10 (0.5)**
ABDOMINAL DISTENSION	2 (0.3)	0	0
ABDOMINAL PAIN	0	4 (0.2)	4 (0.2)
CONSTIPATION	2 (0.3)	1 (0.1)	1 (0.1)
DIARRHEA	4 (0.5)	4 (0.2)	4 (0.2)
LOOSE STOOLS	0	3 (0.2)	3 (0.2)
MOUTH DRY	0	1 (0.1)	1 (0.1)
NAUSEA	0	1 (0.1)	1 (0.1)
VOMITING	1 (0.1)	0	0
HEART RATE AND RHYTHM DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
BRADYCARDIA	0	1 (0.1)	1 (0.1)
INFECTION AND INFESTATIONS	**1 (0.1)**	**0**	**0**
PHARYNGITIS	1 (0.1)	0	0
LIVER AND BILIARY SYSTEM DISORDERS*	**1 (0.1)**	**9 (0.5)**	**9 (0.5)**
GAMMA-GT INCREASED	0	3 (0.2)	3 (0.2)
HEPATIC ENZYMES INCREASED	1 (0.1)	1 (0.1)	1 (0.1)
HEPATIC FUNCTION ABNORMAL	0	2 (0.1)	2 (0.1)
SGOT INCREASED	0	4 (0.2)	4 (0.2)
SGPT INCREASED	0	3 (0.2)	3 (0.2)

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Table 36 Completed.

	Number And (Percent) Of Patients		
METABOLIC AND NUTRITIONAL DISORDERS	**1 (0.1)**	**5 (0.3)**	**5 (0.3)**
CREATINE PHOSPHOKINASE INCREASED[b]	1 (0.1)	5 (0.3)	5 (0.3)
MUSCULO-SKELETAL SYSTEM DISORDERS	**5 (0.6)**	**5 (0.3)**	**5 (0.3)**
ARTHRALGIA	2 (0.3)	3 (0.2)	3 (0.2)
ARTHROPATHY	1 (0.1)	0	0
CRAMPS LEGS	1 (0.1)	1 (0.1)	1 (0.1)
MUSCLE WEAKNESS	1 (0.1)	0	0
MUSCULO-SKELETAL PAIN	2 (0.3)	1 (0.1)	1 (0.1)
PSYCHIATRIC DISORDERS	**0**	**2 (0.1)**	**2 (0.1)**
ANXIETY	0	1 (0.1)	1 (0.1)
INSOMNIA	0	1 (0.1)	1 (0.1)
RENAL & URINARY SYSTEM DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
RENAL PAIN	0	1 (0.1)	1 (0.1)
RESPIRATORY SYSTEM DISORDERS	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
DYSPNEA	1 (0.1)	1 (0.1)	1 (0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**3 (0.4)**	**4 (0.2)**	**5 (0.3)**
PRURITUS	0	1 (0.1)	1 (0.1)
RASH	1 (0.1)	1 (0.1)	1 (0.1)
RASH MACULOPAPULAR	1 (0.1)	0	0
SWEATING INCREASED	1 (0.1)	0	0
URTICARIA	1 (0.1)	2 (0.1)	3 (0.2)
SPECIAL SENSES OTHER, DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
TASTE PERVERSION	0	1 (0.1)	1 (0.1)

a: SGOT = AST; SGPT = ALT. Several protocols specified that elevated ALT or AST at least three times the upper limit of the reference range (≥3xULN) on two consecutive occasions at least 1 week apart should result in discontinuation.

b: Several protocols specified that elevated CPK ≥10xULN, or ≥5xULN with symptoms of myopathy in the absence of muscle trauma, on two consecutive occasions at least 48 hours apart should result in discontinuation.

Note: "Treatment-Related" means judged to be at least possibly related to treatment by the investigator.

Table 37 Primary Hypercholesterolemia Monotherapy Pool Adverse Events (AEs) Of Any Severity Reported For ≥2% Of Patients In Any Pooled Treatment Group

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1953)
ANY ADVERSE EVENT	**511 (64.3)**	**1061 (62.7)**	**1241 (63.6)**
BODY AS A WHOLE – GENERAL DISORDERS			
DIZZINESS	18 (2.3)	34 (2.0)	40 (2.0)
FATIGUE	14 (1.8)	38 (2.2)	44 (2.2)
HEADACHE	61 (7.7)	112 (6.6)	133 (6.7)
GASTRO-INTESTINAL SYSTEM DISORDERS			
ABDOMINAL PAIN	22 (2.8)	50 (3.0)	59 (3.0)
CONSTIPATION	22 (2.8)	33 (2.0)	42 (2.1)
DIARRHEA	24 (3.0)	62 (3.7)	67 (3.4)
DYSPEPSIA	25 (3.1)	40 (2.4)	47 (2.4)
NAUSEA	28 (3.5)	37 (2.2)	43 (2.2)
INFECTION AND INFESTATIONS			
INFECTION VIRAL	14 (1.8)	38 (2.2)	57 (2.9)
PHARYNGITIS	17 (2.1)	39 (2.3)	51 (2.6)
SINUSITIS	22 (2.8)	61 (3.6)	69 (3.5)
UPPER RESP TRACT INFECTION	70 (8.8)	148 (8.8)	171 (8.6)
URINARY TRACT INFECTION	16 (2.0)	23 (1.4)	31 (1.6)
MUSCULO-SKELETAL SYSTEM DISORDERS			
ARTHRALGIA	27 (3.4)	64 (3.8)	81 (4.1)
BACK PAIN	31 (3.9)	70 (4.1)	81 (4.1)
MUSCULO-SKELETAL PAIN	32 (4.0)	66 (3.9)	72 (3.6)
MYALGIA	25 (3.1)	42 (2.5)	54 (2.7)
RESPIRATORY SYSTEM DISORDERS			
COUGHING	17 (2.1)	39 (2.3)	46 (2.3)

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Table 38 Primary Hypercholesterolemia Monotherapy Pool Adverse Events (AEs) Of Any Severity, Considered As Treatment-Related By Investigators Reported For ≥2% Of Patients In Any Pooled Treatment Group

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
SUBJECTS REPORTING ANY ADVERSE EVENT	**123 (15.5)**	**235 (13.9)**	**293 (14.8)**
BODY AS A WHOLE – GENERAL DISORDERS			
HEADACHE	17 (2.1)	20 (1.2)	28 (1.4)
GASTRO-INTESTINAL SYSTEM DISORDERS			
CONSTIPATION	16 (2.0)	14 (0.8)	21 (1.1)

Note: "Treatment-related" means judged to be at least possibly related to treatment by the investigator.

Table 39 Primary Hypercholesterolemia Monotherapy Pool Severe Or Life-Threatening Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1963)
ANY SEVERE/LIFE THREATENING ADVERSE EVENT	**32 (4.0)**	**79 (4.7)**	**84 (4.2)**
AUTONOMIC NERVOUS SYSTEM DISORDERS	**1 (0.1)**	**0**	**0**
HOT FLUSHES	1 (0.1)	0	0
BENIGN & MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**1 (0.1)**	**8 (0.5)**	**8 (0.4)**
BASAL CELL CARCINOMA	0	2 (0.1)	2 (0.1)
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (0.1)	1 (0.1)
CARCINOMA	0	1 (0.1)	1 (0.1)
GASTRIC CARCINOMA	0	1 (0.1)	1 (0.1)
MENINGIOMA	0	1 (0.1)	1 (0.1)
NEOPLASM, BRAIN	0	1 (0.1)	1 (0.1)
PROSTATIC CANCER	0	1 (0.1)	1 (0.1)
PULMONARY CARCINOMA	1 (0.1)	1 (0.1)	1 (0.1)
BODY AS A WHOLE - GENERAL DISORDERS	**8 (1.0)**	**14 (0.8)**	**16 (0.8)**
APPETITE INCREASED	0	1 (0.1)	1 (0.1)
BACK PAIN, AGGRAVATED	0	1 (0.1)	1 (0.1)
CHEST PAIN	1 (0.1)	3 (0.2)	3 (0.2)
DEATH	0	1 (0.1)	1 (0.1)
DIZZINESS	4 (0.5)	1 (0.1)	1 (0.1)
EDEMA PERIPHERAL	1 (0.1)	0	0
FALL	0	1 (0.1)	1 (0.1)
FATIGUE	1 (0.1)	1 (0.1)	1 (0.1)
HEADACHE	2 (0.3)	4 (0.2)	6 (0.3)
HYPOXIA	0	1 (0.1)	1 (0.1)
SYNCOPE	0	2 (0.1)	2 (0.1)
CARDIOVASCULAR DISORDERS, GENERAL	**3 (0.4)**	**3 (0.2)**	**3 (0.2)**
ANGINA PECTORIS	0	1 (0.1)	1 (0.1)
ANGINA PECTORIS AGGRAVATED	0	1 (0.1)	1 (0.1)
CARDIAC FAILURE	1 (0.1)	0	0
CORONARY ARTERY DISORDER	2 (0.3)	1 (0.1)	1 (0.1)
HYPOTENSION POSTURAL	0	1 (0.1)	1 (0.1)
MITRAL INSUFFICIENCY	1 (0.1)	0	0
TRICUSPID VALVE INCOMPETENCE	1 (0.1)	0	0

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Table 39 Continued.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1681)	Ezetimibe All Doses (n=1983)
CENTR AND PERIPH NERV SYST DISORDERS	**1 (0.1)**	**5 (0.3)**	**5 (0.3)**
HYPERKINESIA	0	1 (0.1)	1 (0.1)
HYPERTONIA	0	1 (0.1)	1 (0.1)
HYPOESTHESIA	1 (0.1)	0	0
LOSS OF CONSCIOUSNESS	0	1 (0.1)	1 (0.1)
PARESTHESIA	0	1 (0.1)	1 (0.1)
SOMNOLENCE	0	1 (0.1)	1 (0.1)
DISORDERS OF THE EAR & LABYRINTH	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
HEARING IMPAIRMENT	1 (0.1)	0	0
VERTIGO	0	1 (0.1)	1 (0.1)
DISORDERS OF THE EYE	**1 (0.1)**	**1 (0.1)**	**1 (0.1)**
CONJUNCTIVITIS	0	1 (0.1)	1 (0.1)
XEROPHTHALMIA	1 (0.1)	0	0
DISORDERS OF THE IMMUNE SYSTEM	**0**	**1 (0.1)**	**1 (0.1)**
ALLERGY AGGRAVATED	0	1 (0.1)	1 (0.1)
DISORDERS OF THE REPRODUCTIVE SYSTEM AND BREAST	**1 (0.1)**	**1 (0.1)**	**2 (0.1)**
HYSTERECTOMY	1 (0.2)	0	0
OVARIAN MASS	0	1 (0.1)	1 (0.1)
UTERINE HEMORRHAGE	0	0	1 (0.1)
GASTRO-INTESTINAL SYSTEM DISORDERS	**6 (0.8)**	**18 (1.1)**	**18 (0.9)**
ABDOMINAL DISTENSION	0	2 (0.1)	2 (0.1)
ABDOMINAL PAIN	1 (0.1)	2 (0.1)	2 (0.1)
APPENDICITIS	0	1 (0.1)	1 (0.1)
CONSTIPATION	1 (0.1)	0	0
DIARRHEA	2 (0.3)	5 (0.3)	5 (0.3)
DIVERTICULOSIS	0	1 (0.1)	1 (0.1)
DYSPEPSIA	0	1 (0.1)	1 (0.1)
GASTRO-INTESTINAL DISORDER NOS	0	1 (0.1)	1 (0.1)
GASTROENTERITIS	1 (0.1)	2 (0.1)	2 (0.1)
GASTROESOPHAGEAL REFLUX	0	1 (0.1)	1 (0.1)
ILEITIS	0	1 (0.1)	1 (0.1)
MOUTH DRY	0	1 (0.1)	1 (0.1)
NAUSEA	0	2 (0.1)	2 (0.1)
RUQ (right upper quadrant) PAIN	0	1 (0.1)	1 (0.1)
TOOTHACHE	1 (0.1)	0	0
VOMITING	0	3 (0.2)	3 (0.2)
HEART RATE AND RHYTHM DISORDERS	**0**	**3 (0.2)**	**3 (0.2)**
FIBRILLATION ATRIAL	0	2 (0.1)	2 (0.1)
PALPITATION	0	1 (0.1)	1 (0.1)

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Table 39 Continued.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1681)	Ezetimibe All Doses (n=1983)
INFECTION AND INFESTATIONS	**3 (0.4)**	**7 (0.4)**	**7 (0.4)**
INFECTION VIRAL	0	1 (0.1)	1 (0.1)
MASTOIDITIS	0	1 (0.1)	1 (0.1)
PHARYNGITIS	0	1 (0.1)	1 (0.1)
SINUSITIS	1 (0.1)	2 (0.1)	2 (0.1)
TOOTH ABSCESS	1 (0.1)	0	0
UPPER RESP TRACT INFECTION	0	2 (0.1)	2 (0.1)
URINARY TRACT INFECTION	1 (0.1)	0	0
INJURY AND POISONING	**1 (0.1)**	**2 (0.1)**	**2 (0.1)**
FRACTURE	0	1 (0.1)	1 (0.1)
FRACTURE, BONE	1 (0.1)	1 (0.1)	1 (0.1)
LIVER AND BILIARY SYSTEM DISORDERS[a]	**2 (0.3)**	**5 (0.3)**	**5 (0.3)**
GALLBLADDER DISEASE	1 (0.1)	0	0
GAMMA-GT INCREASED	0	2 (0.1)	2 (0.1)
HEPATIC ENZYMES INCREASED	0	1 (0.1)	1 (0.1)
HEPATIC FUNCTION ABNORMAL	0	1 (0.1)	1 (0.1)
SGOT INCREASED	1 (0.1)	2 (0.1)	2 (0.1)
SGPT INCREASED	1 (0.1)	1 (0.1)	1 (0.1)
METABOLIC AND NUTRITIONAL DISORDERS	**1 (0.1)**	**4 (0.2)**	**4 (0.2)**
CREATINE PHOSPHOKINASE INCREASED	1 (0.1)	4 (0.2)	4 (0.2)
MUSCULO-SKELETAL SYSTEM DISORDERS	**5 (0.6)**	**19 (1.1)**	**21 (1.1)**
ARTHRALGIA	1 (0.1)	3 (0.2)	3 (0.2)
ARTHRALGIA AGGRAVATED	0	2 (0.1)	2 (0.1)
ARTHRITIS	0	1 (0.1)	1 (0.1)
BACK PAIN	2 (0.3)	7 (0.4)	8 (0.4)
JOINT DISLOCATION	0	2 (0.1)	2 (0.1)
MUSCLE SPRAIN	0	1 (0.1)	1 (0.1)
MUSCULO-SKELETAL PAIN	2 (0.3)	6 (0.4)	7 (0.4)
OSTEOARTHRITIS NOS	0	1 (0.1)	1 (0.1)
SPINAL DISORDER	0	2 (0.1)	2 (0.1)
TENDON RUPTURE	0	1 (0.1)	1 (0.1)
PSYCHIATRIC DISORDERS	**2 (0.3)**	**0**	**0**
AMNESIA	1 (0.1)	0	0
IMPOTENCE	1 (0.3)	0	0
RENAL & URINARY SYSTEM DISORDERS	**1 (0.1)**	**4 (0.2)**	**4 (0.2)**
CYSTITIS	0	1 (0.1)	1 (0.1)
DYSURIA	0	1 (0.1)	1 (0.1)
RENAL CALCULUS	1 (0.1)	2 (0.1)	2 (0.1)

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Table 39 Completed.

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
RESPIRATORY SYSTEM DISORDERS	**4 (0.5)**	**3 (0.2)**	**3 (0.2)**
BRONCHITIS	0	1 (0.1)	1 (0.1)
CHRONIC OBSTRUCTIVE AIRWAY DISEASE	1 (0.1)	0	0
COUGHING AGGRAVATED	1 (0.1)	0	0
DYSPNEA	1 (0.1)	2 (0.1)	2 (0.1)
PLEURAL EFFUSION	1 (0.1)	1 (0.1)	1 (0.1)
PNEUMOTHORAX	0	1 (0.1)	1 (0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	**1 (0.1)**	**3 (0.2)**	**4 (0.2)**
CELLULITIS	1 (0.1)	0	0
PANNICULITIS	0	1 (0.1)	1 (0.1)
RASH	0	0	1 (0.1)
SWEATING INCREASED	0	2 (0.1)	2 (0.1)
SPECIAL SENSES OTHER, DISORDERS	**0**	**1 (0.1)**	**1 (0.1)**
TASTE PERVERSION	0	1 (0.1)	1 (0.1)
SURGICAL AND MEDICAL PROCEDURES	**4 (0.5)**	**2 (0.1)**	**2 (0.1)**
DENTAL PROCEDURE	1 (0.1)	0	0
PROCEDURE (NO ADVERSE EVENT)	3 (0.4)	2 (0.1)	2 (0.1)
VASCULAR (EXTRAÇARDIAC) DISORDERS	**1 (0.1)**	**0**	**0**
THROMBOSIS	1 (0.1)	0	0

a. SGOT = AST, SGPT = ALT.

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Table 40 Primary Hypercholesterolemia Monotherapy Pool Blood Urea Nitrogen (BUN) And Creatinine Postbaseline Values Outside Prespecified Limits

	Number And (Percent) Of Patients		
Prespecified Limits	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Blood Urea Nitrogen (BUN); Reference Range: 5–20 mg/dL			
<5 mg/dL	0/785	0/1663	0/1995
>20 mg/dL	150/785 (19.1)	320/1663 (19.2)	361/1955 (18.5)
Creatinine; Reference Range: 0.7–1.4 mg/dL			
>1.4 mg/dL	28/786 (3.6)	71/1674 (4.2)	84/1966 (4.3)

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 40 A Primary Hypercholesterolemia Monotherapy Pool Blood Urea Nitrogen (BUN) And Creatinine Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

Prespecified Limits	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Blood Urea Nitrogen (BUN); Reference Range: 5–20 mg/dL			
US: <5 mg/dL SI: 1.785 mmol/L	0/785	0/1663	0/1995
US: >30 mg/dL SI: >10.7 mmol/L	9/785 (1.1)	16/1663 (1.0)	18/1955 (0.9)
Creatinine; Reference Range: 0.7–1.4 mg/dL			
US: >2 mg/dL SI: >176.8 µmol/L	2/786 (0.3)	2/1674 (0.1)	2/1966 (0.1)

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside preespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 41 Primary Hypercholesterolemia Monotherapy Pool Blood Urea Nitrogen (BUN) And Creatinine Mean And Median Changes From Baseline To Endpoint

Values	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Blood Urea Nitrogen (BUN); Reference Range: 5–20 mg/dL			
Baseline Value (mg/dL)			
Mean	15.3	15.4	15.3
SD, n	4.33, 795	4.28, 1691	4.29, 1983
Median	15	15	15
Change from Baseline to Endpoint (mg/dL)			
Mean	-0.092	0.024	-0.001
SD, n	3.41, 771	3.65, 1637	3.57, 1926
Median	0	0	0
Creatinine; Reference Range: 0.7–1.4 mg/dL			
Baseline Value (mg/dL)			
Mean	1.07	1.08	1.08
SD, n	0.173, 795	0.174, 1691	0.174, 1983
Median	1.1	1.1	1.1
Change from Baseline to Endpoint (mg/dL)			
Mean	-0.003	-0.011	-0.009
SD, n	0.089, 779	0.094, 1657	0.092, 1948
Median	0	0	0

SD, n = standard deviation, number of subjects included in calculation of change.

Table 42 Primary Hypercholesterolemia
Monotherapy Pool
Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time
Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

Prespecified Limits	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Platelet Count; Reference Range: 150–450 x 10^9/L			
<150x10^9/L	24/785 (3.1)	62/1662 (3.7)	70/1954 (3.6)
>450x10^9/L	6/785 (0.8)	8/1662 (0.5)	8/1954 (0.4)
White Blood Cell (WBC) Count; Reference Range: 4.8–10.8 x 10^9/L			
<4.8x10^9/L	291/785 (37.1)	617/1662 (37.1)	725/1954 (37.1)
>10.8x10^9/L	12/785 (1.5)	38/1662 (2.3)	41/1954 (2.1)
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL			
F:<12; M:<14 g/dL	92/785 (11.7)	245/1662 (14.7)	299/1954 (15.3)
F:>16; M:>18 g/dL	2/785 (0.3)	12/1662 (0.7)	13/1954 (0.7)
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%			
F:<36%; M:<42%	162/785 (20.6)	389/1662 (23.4)	477/1954 (24.4)
F:>46%; M:>54%	14/785 (1.8)	35/1662 (2.1)	36/1954 (1.8)
Prothrombin (PT) Time; Reference Range: 10.5–13.5 seconds			
>13.5 seconds	15/713 (2.1)	28/1534 (1.8)	29/1816 (1.6)

ULN = upper limit of the reference range.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 42 A Primary Hypercholesterolemia
Monotherapy Pool
Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time
Postbaseline Values Outside Prespecified Limits

Number And (Percent) Of Patients

Prespecified Limits	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Platelet Count; Reference Range: 150–450 x 10^9/L			
US/SI: <100x10^9/L	1/785 (0.1)	10/1662 (0.6)	13/1954 (0.7)
US:SI: >450x10^9/L	6/785 (0.8)	8/1662 (0.5)	8/1954 (0.4)
White Blood Cell (WBC) Count; Reference Range: 4.8–10.8 x 10^9/L			
US/SI: <3.0x10^9/L	5/785 (0.6)	18/1662 (1.1)	21/1954 (1.1)
US/SI: >10.8x10^9/L	12/785 (1.5)	38/1662 (2.3)	41/1954 (2.1)
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL			
F:<11; M:<13 g/dL F:<110; M:<130 g/L	18/785 (2.3)	42/1662 (2.5)	54/1954 (2.8)
F:>16; M:>18 g/dL F:>160; M:>180 g/L	2/785 (0.3)	12/1662 (0.7)	13/1954 (0.7)
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%			
F:<33%; M:<39%	29/785 (3.7)	69/1662 (4.2)	85/1954 (4.4)
F:>46%; M:>54%	14/785 (1.8)	35/1662 (2.1)	36/1954 (1.8)
Prothrombin (PT) Time; Reference Range: 10.5–13.5 seconds			
>1.5xULN	0/713	4/1534 (0.3)	5/1816 (0.3)

ULN = upper limit of the reference range.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a value outside prespecified limits as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 43 Primary Hypercholesterolemia
Monotherapy Pool
Hematology: Platelet Count, White Blood Cell (WBC) Count, Hemoglobin, Hematocrit, And Prothrombin Time
Mean And Median Changes From Baseline To Endpoint

Number And (Percent) Of Patients

Values	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Platelet Count; Reference Range: 150–450 x 10^9/L			
Baseline Value (x 10^9/L)			
Mean	251	249	246
SD, n	59.5, 795	56.1, 1690	55.4, 1982
Median	244	245	242
Change from Baseline to Endpoint (x 10^9/L)			
Mean	2.33	1.78	1.55
SD, n	31.2, 770	31.8, 1634	31.4, 1923
Median	3	3.5	3
White Blood Cell (WBC) Count; Reference Range: 4.8–10.8 x 10^9/L			
Baseline Value (x 10^9/L)			
Mean	5.67	5.64	5.65
SD, n	1.49, 795	1.53, 1690	1.52, 1982
Median	5.4	5.4	5.4
Change from Baseline to Endpoint (x 10^9/L)			
Mean	0.078	0.149	0.111
SD, n	1.04, 770	1.1, 1634	1.11, 1923
Median	0.1	0.1	0.1

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Table 43 Completed

Number And (Percent) Of Patients

Values	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Hemoglobin; Reference Range: Female 12–16 g/dL; Male 14–18 g/dL			
Baseline Value (x g/dL)			
Mean	14.2	14.3	14.3
SD, n	1.26, 795	1.21, 1690	1.21, 1982
Median	14.2	14.3	14.3
Change from Baseline to Endpoint (x g/dL)			
Mean	-0.021	-0.016	-0.033
SD, n	0.621, 770	0.592, 1634	0.589, 1923
Median	0	0	0
Hematocrit; Reference Range: Female 36%–46%; Male 42%–54%			
Baseline Value			
Mean	41.9	42	42
SD, n	3.58, 795	3.47, 1690	3.47, 1982
Median	41.9	42	42
Change from Baseline to Endpoint			
Mean	0.075	0.129	0.076
SD, n	1.93, 770	1.88, 1634	1.89, 1923
Median	0.1	0.1	0.1
Prothrombin Time (PT); Reference Range: 10.5–13.5 seconds			
Baseline Value (sec)			
Mean	11.6	11.6	11.6
SD, n	0.67, 773	0.97, 1657	0.935, 1944
Median	11.5	11.6	11.5
Change from Baseline to Endpoint (sec)			
Mean	0.021	-0.026	-0.0006
SD, n	0.76, 670	0.798, 1430	0.878, 1697
Median	0	-0.1	0

SD, n = standard deviation, number of subjects included in calculation of change.

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Table 44 Primary Hypercholesterolemia
Monotherapy Pool
Allergic Reaction/Rash Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY ALLERGIC REACTION / RASH ADVERSE EVENT	**28 (3.5)**	**79 (4.7)**	**91 (4.6)**
ALLERGIC REACTION	1 (0.1)	1 (0.1)	2 (0.1)
ALLERGY	6 (0.8)	29 (1.7)	32 (1.6)
ALLERGY AGGRAVATED	1 (0.1)	10 (0.6)	10 (0.5)
DERMATITIS	1 (0.1)	5 (0.3)	6 (0.3)
EOSINOPHILIA	0	1 (0.1)	1 (0.1)
FACE EDEMA	0	1 (0.1)	1 (0.1)
PRURITUS	3 (0.4)	5 (0.3)	5 (0.3)
RASH	11 (1.4)	19 (1.1)	24 (1.2)
RASH ERYTHEMATOUS	0	2 (0.1)	3 (0.2)
RASH MACULOPAPULAR	1 (0.1)	1 (0.1)	1 (0.1)
RASH VESICULAR	1 (0.1)	0	0
SKIN DISORDER	0	3 (0.2)	4 (0.2)
URTICARIA	3 (0.4)	3 (0.2)	4 (0.2)

Table 45 Primary Hypercholesterolemia
Monotherapy Pool
Central and Peripheral Nervous System Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY CNS/PNS ADVERSE EVENT	**26 (3.3)**	**58 (3.4)**	**67 (3.4)**
ATAXIA	1 (0.1)	2 (0.1)	2 (0.1)
CEREBROVASCULAR ACCIDENT NOS	1 (0.1)	0	0
CNS DYSFUNCTION	0	1 (0.1)	1 (0.1)
CONCENTRATION IMPAIRED	0	2 (0.1)	2 (0.1)
COORDINATION ABNORMAL	1 (0.1)	0	0
DYSPHONIA	2 (0.3)	0	0
HYPERESTHESIA	1 (0.1)	1 (0.1)	1 (0.1)
HYPERKINESIA	0	1 (0.1)	1 (0.1)
HYPERREFLEXIA	0	1 (0.1)	1 (0.1)
HYPERTONIA	0	8 (0.5)	9 (0.5)
HYPOESTHESIA	7 (0.9)	10 (0.6)	10 (0.5)
HYPOREFLEXIA	0	3 (0.2)	3 (0.2)
LOSS OF CONSCIOUSNESS	0	1 (0.1)	1 (0.1)
MIGRAINE	3 (0.4)	6 (0.4)	8 (0.4)
MIGRAINE AGGRAVATED	0	1 (0.1)	1 (0.1)
MIGRAINE, OPHTHALMIC	0	1 (0.1)	1 (0.1)
NEURALGIA	0	5 (0.3)	5 (0.3)
NEUROPATHY	1 (0.1)	0	0
PARESTHESIA	3 (0.4)	8 (0.5)	13 (0.7)
PTOSIS	1 (0.1)	0	0
SOMNOLENCE	3 (0.4)	6 (0.4)	7 (0.4)
TORTICOLLIS	1 (0.1)	2 (0.1)	2 (0.1)
TRANSIENT ISCHEMIC ATTACK	0	2 (0.1)	2 (0.1)
TREMOR	1 (0.1)	0	0
TWITCHING	1 (0.1)	2 (0.1)	2 (0.1)
VASOVAGAL ATTACK	0	1 (0.1)	1 (0.1)

Table 46 Primary Hypercholesterolemia Monotherapy Pool Psychiatric Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY PSYCHIATRIC ADVERSE EVENT	**25 (3.1)**	**59 (3.5)**	**66 (3.3)**
AGITATION	0	1 (0.1)	1 (0.1)
AMNESIA	1 (0.1)	1 (0.1)	2 (0.1)
ANXIETY	3 (0.4)	13 (0.8)	13 (0.7)
ANXIETY AGGRAVATED	0	1 (0.1)	2 (0.1)
DEPRESSION	3 (0.4)	9 (0.5)	11 (0.6)
DEPRESSION WORSENED	1 (0.1)	4 (0.2)	4 (0.2)
EMOTIONAL LABILITY	0	1 (0.1)	1 (0.1)
IMPOTENCE	1 (0.3)	5 (0.6)	5 (0.5)
INSOMNIA	15 (1.9)	23 (1.4)	26 (1.3)
INSOMNIA AGGRAVATED	0	2 (0.1)	2 (0.1)
IRRITABILITY	1 (0.1)	0	0
NERVOUSNESS	0	1 (0.1)	1 (0.1)
PANIC ATTACK	0	1 (0.1)	1 (0.1)
PARONIRIA	1 (0.1)	0	1 (0.1)
PSYCHOSIS	0	1 (0.1)	1 (0.1)

Table 47 Primary Hypercholesterolemia Monotherapy Pool Gastrointestinal Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY GASTROINTESTINAL ADVERSE EVENT	**155 (19.5)**	**303 (17.9)**	**348 (17.5)**
ABDOMINAL DISTENSION	7 (0.9)	18 (1.1)	19 (1.0)
ABDOMINAL PAIN	22 (2.8)	50 (3.0)	59 (3.0)
ABDOMINAL TENDERNESS	2 (0.3)	6 (0.4)	6 (0.3)
APPENDICITIS	0	1 (0.1)	1 (0.1)
BLOOD IN STOOL	1 (0.1)	3 (0.2)	5 (0.3)
BOWEL SOUNDS ABNORMAL	0	1 (0.1)	1 (0.1)
CHANGE IN BOWEL HABIT (NOS)	1 (0.1)	1 (0.1)	1 (0.1)
COLITIS	1 (0.1)	0	0
COLONIC POLYP	2 (0.3)	5 (0.3)	5 (0.3)
CONSTIPATION	22 (2.8)	33 (2.0)	42 (2.1)
CONSTIPATION AGGRAVATED	0	2 (0.1)	2 (0.1)
DIARRHEA	24 (3.0)	62 (3.7)	67 (3.4)
DIVERTICULITIS	0	2 (0.1)	2 (0.1)
DIVERTICULOSIS	1 (0.1)	4 (0.2)	4 (0.2)
DYSPEPSIA	25 (3.1)	40 (2.4)	47 (2.4)
DYSPHAGIA	1 (0.1)	0	0
ERUCTATION	0	0	1 (0.1)
ESOPHAGITIS	1 (0.1)	0	0
FECAL OCCULT BLOOD POSITIVE	2 (0.3)	2 (0.1)	2 (0.1)
FECES DISCOLORED	1 (0.1)	0	0
FECES MALODOROUS	1 (0.1)	0	0
FLATULENCE	7 (0.9)	17 (1.0)	21 (1.1)
FREQUENT BOWEL MOVEMENTS	0	1 (0.1)	1 (0.1)
GASTRIC POLYPS	0	1 (0.1)	1 (0.1)
GASTRITIS	1 (0.1)	3 (0.2)	3 (0.2)
GASTRO-INTESTINAL DISORDER NOS	0	1 (0.1)	1 (0.1)
GASTROENTERITIS	8 (1.0)	21 (1.2)	23 (1.2)
GASTROESOPHAGEAL REFLUX	1 (0.1)	8 (0.5)	9 (0.5)
GASTROESOPHAGEAL REFLUX AGGRAVATED	0	6 (0.4)	6 (0.3)
GI HEMORRHAGE	1 (0.1)	0	0
GINGIVAL BLEEDING	1 (0.1)	0	0
GINGIVAL PAIN	1 (0.1)	1 (0.1)	1 (0.1)
GINGIVAL RECESSION	0	1 (0.1)	1 (0.1)
GINGIVITIS	1 (0.1)	2 (0.1)	3 (0.2)
HALITOSIS	0	1 (0.1)	1 (0.1)
HEMORRHOIDAL BLEEDING	0	1 (0.1)	1 (0.1)
HEMORRHOIDS	4 (0.5)	8 (0.5)	8 (0.4)

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Table 47 Completed.

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients: Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
HIATAL HERNIA AGGRAVATED	1 (0.1)	0	0
HIATUS HERNIA	0	3 (0.2)	3 (0.2)
ILEITIS	0	1 (0.1)	1 (0.1)
INTESTINAL DISORDER	2 (0.3)	0	0
IRRITABLE BOWEL SYNDROME AGGRAVATED	0	1 (0.1)	1 (0.1)
LOOSE STOOLS	9 (1.1)	12 (0.7)	12 (0.6)
MELENA	0	3 (0.2)	3 (0.2)
MOUTH DRY	6 (0.8)	7 (0.4)	7 (0.4)
MOUTH ULCERATION	4 (0.5)	0	0
NAUSEA	28 (3.5)	37 (2.2)	43 (2.2)
PROCTALGIA	1 (0.1)	1 (0.1)	1 (0.1)
RECTAL BLEEDING	0	1 (0.1)	1 (0.1)
RETCHING	0	1 (0.1)	1 (0.1)
RUQ PAIN	1 (0.1)	4 (0.2)	4 (0.2)
SALIVA INCREASED	1 (0.1)	0	0
STOMATITIS	1 (0.1)	1 (0.1)	1 (0.1)
STOMATITIS APHTHOUS	1 (0.1)	0	0
STOMATITIS ULCERATIVE	0	1 (0.1)	1 (0.1)
STOOL ABNORMAL	0	1 (0.1)	3 (0.2)
TONGUE DISORDER	0	1 (0.1)	1 (0.1)
TOOTH CARIES	2 (0.3)	0	0
TOOTH DISORDER	6 (0.8)	8 (0.5)	11 (0.6)
TOOTHACHE	8 (1.0)	17 (1.0)	18 (0.9)
VOMITING	6 (0.8)	13 (0.8)	15 (0.8)

Table 48 Primary Hypercholesterolemia Monotherapy Pool Gallbladder-related Adverse Events (AEs)

	Number And (Percent) Of Patients		
Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
ANY GALLBLADDER-RELATED ADVERSE EVENT	2 (0.3)	1 (0.1)	1 (0.1)
CHOLECYSTITIS	1 (0.1)	1[a] (0.1)	1[a] (0.1)
GALLBLADDER DISEASE	1 (0.1)	0	0

a: This subject subsequently had a cholecystectomy that was captured in the case report form as a concomitant therapy rather than as an adverse event.

Table 49 Primary Hypercholesterolemia Monotherapy Pool Liver And Biliary System Adverse Events (AEs)

Number And (Percent) Of Patients

Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
TREATMENT-EMERGENT LIVER AND BILIARY SYSTEM DISORDERS	**11 (1.4)**	**32 (1.9)**	**33 (1.7)**
BILIRUBINEMIA	0	1 (0.1)	1 (0.1)
CHOLECYSTITIS	1 (0.1)	1 (0.1)	1 (0.1)
GALLBLADDER DISEASE	1 (0.1)	0	0
GAMMA-GT INCREASED	4 (0.5)	11 (0.7)	11 (0.6)
HEPATIC ENZYMES INCREASED	2 (0.3)	2 (0.1)	2 (0.1)
HEPATIC FUNCTION ABNORMAL	0	7 (0.4)	7 (0.4)
SGOT INCREASED	2 (0.3)	11 (0.7)	12 (0.6)
SGPT INCREASED	5 (0.6)	12 (0.7)	13 (0.7)
POOL[a]: TREATMENT-EMERGENT HEPATIC ENZYMES INCREASED, HEPATIC FUNCTION ABNORMAL, SGOT INCREASED, SGPT INCREASED	**7 (0.9)**	**26 (1.5)**	**27 (1.4)**
POOL[a]: TREATMENT RELATED, TREATMENT EMERGENT	**2 (0.3)**	**18 (1.1)**	**18 (0.9)**
POOL[a]: SERIOUS[b]	**2 (0.3)**	**4 (0.2)**	**4 (0.2)**
POOL[a]: DISCONTINUATION[b]	**2 (0.3)**	**9 (0.5)**	**9 (0.5)**

a: The "pool" comprises the four terms within the boxed outline above.

b: Phase III protocols stipulated that ALT/AST at least three time the upper limit of the reference range on two consecutive occasions at least 1 week apart should be considered a serious adverse event and result in discontinuation.

Note: SGOT = AST; SGPT = ALT.

Table 50 Primary Hypercholesterolemia
Monotherapy Pool
Liver Function: Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST)
Postbaseline Values Above Upper Limits Of Normal (ULN)

Number And (Percent) Of Patients

High Ranges[a]	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Alanine Aminotransferase (ALT); Reference Range: 5–25 mU/mL			
2xULN to <3xULN	11/786 (1.4)	31/1674 (1.9)	35/1966 (1.8)
≥3xULN	3/786 (0.4)	10/1674 (0.6)	11/1966 (0.6)
≥3xULN, consecutive[b,c]	2/786 (0.3)	5/1674 (0.3)	5/1966 (0.3)
≥5xULN[b]	0/786	2/1674 (0.1)	2/1966 (0.1)
≥10xULN[b]	0/786	0/1674	0/1966
Aspartate Aminotransferase (AST); Reference Range: 8–22 mU/mL			
2xULN to <3xULN	6/786 (0.8)	13/1674 (0.8)	15/1966 (0.8)
≥3xULN	3/786 (0.4)	8/1674 (0.5)	10/1966 (0.5)
≥3xULN, consecutive[b,c]	2/786 (0.3)	5/1674 (0.3)	6/1966 (0.3)
≥5xULN[b]	0/786	0/1674	1/1966 (0.1)
≥10xULN[b]	0/786	0/1674	0/1966
ALT and/or AST			
≥3xULN	4/786 (0.5)	14/1674 (0.8)	16/1966 (0.8)
≥3xULN, consecutive[b,c]	3/786 (0.4)	9/1674 (0.5)	10/1966 (0.5)
≥5xULN[b]	0/786	2/1674 (0.1)	3/1966 (0.2)
≥10xULN[b]	0/786	0/1674	0/1966

a: Subjects appear in category of maximum value.

b: This is a subset of ≥3xULN.

c: "Consecutive" is defined as follows: (1) two or more consecutive values ≥3xULN in the subject's record; (2) last value in subject's record is ≥3xULN (presumed consecutive); or (3) a value ≥3xULN during treatment or ≤2 days after the end of treatment is followed by a value <3xULN, but the sample for the second value was collected more than 2 days after the subject's last day of dosing (presumed consecutive).

ULN=upper limit of the reference range.

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a high value as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question

Table 51 Primary Hypercholesterolemia
Monotherapy Pool
Liver Function: Alanine Aminotransferase (ALT) And Aspartate Aminotransferase (AST)
Baseline To Endpoint and Maximum Postbaseline Changes In Values

Number Of Patients

	Baseline		Postbaseline Grade[a,b]			
	Grade[a]	Number	0	1	2	3
Alanine Aminotransferase (ALT); Reference Range: 5–25 mU/ml						
			Endpoint Grade			
Placebo	0	702	670	30	1	1
(no. subjects with a baseline value	1	71	33	36	2	0
and an endpoint value = 779)	2	5	2	0	3	0
	3	1	1	0	0	0
Ezetimibe 10 mg	0	1486	1356	123	6	1
(no. subjects with a baseline value	1	164	60	94	9	1
and an endpoint value = 1657)	2	6	1	1	3	1
	3	1	0	1	0	0
			Maximum Postbaseline Grade			
Placebo	0	709	639	65	2	3
(no. subjects with a baseline value	1	71	17	48	6	0
and at least one other value any	2	5	1	1	3	0
time after baseline = 786)	3	1	1	0	0	0
Ezetimibe 10 mg	0	1500	1221	262	13	4
(no. subjects with a baseline value	1	167	21	126	16	4
and at least one other value any	2	6	1	1	2	2
time after baseline = 1674)	3	1	0	1	0	0
Aspartate Aminotransferase (AST); Reference Range: 8–22 mU/ml						
			Endpoint Grade			
Placebo	0	698	658	38	2	0
(no. subjects with a baseline value	1	79	43	34	1	1
and an endpoint value = 779)	2	1	0	1	0	0
	3	1	1	0	0	0
Ezetimibe 10 mg	0	1493	1363	127	0	3
(no. subjects with a baseline value	1	160	65	88	5	2
and an endpoint value = 1657)	2	3	0	2	1	0
	3	1	1	0	0	0
			Maximum Postbaseline Grade			
Placebo	0	705	609	91	3	2
(no. subjects with a baseline value	1	79	14	61	3	1
and at least one other value any	2	1	0	1	0	0
time after baseline = 786)	3	1	1	0	0	0
Ezetimibe 10 mg	0	1507	1179	318	5	5
(no. subjects with a baseline value	1	163	32	121	7	3
and at least one other value any	2	3	0	2	1	0
time after baseline = 1674)	3	1	1	0	0	0

a: Grade 0 = <1xULN; Grade 1 = 1 to <2xULN; Grade 2 = 2 to <3xULN; Grade 3 = ≥3xULN.
b: Boxed cells indicate an increase from baseline in grade.
ULN = upper limit of the reference range.

Table 52 Primary Hypercholesterolemia Monotherapy Pool Liver Function: Gamma-Glutamyl Transpeptidase (GGT), Alkaline Phosphatase, and Total Bilirubin Postbaseline Values Above Upper Limits Of Normal (ULN)

Number And (Percent) Of Patients

High Ranges[a]	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Gamma-Glutamyl Transpeptidase (GGT); Reference Range: 5–29 mU/mL			
2xULN to <3xULN	25/786 (3.2)	56/1674 (3.3)	63/1966 (3.2)
≥3xULN	13/786 (1.7)	40/1674 (2.4)	42/1966 (2.1)
Alkaline Phosphatase; Reference Range: 32–72 mU/mL			
2xULN to <3xULN	2/786 (0.3)	1/1674 (0.1)	1/1966 (0.1)
≥3xULN	0/786	0/1674	0/1966
Total Bilirubin; Reference Range: 0.1–1.1 mg/dL			
2xULN to <3xULN	0/786	4/1674 (0.2)	4/1966 (0.2)
≥3xULN	0/786	0/1674	0/1966

a: Subjects appear in category of maximum value.

ULN=upper limit of the reference range

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a high value as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 53 Primary Hypercholesterolemia Monotherapy Pool Increased Creatine Phosphokinase (CPK) Reported As Adverse Events (AEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
TREATMENT-EMERGENT ADVERSE EVENT	12 (1.5)	24 (1.4)	27 (1.4)
TREATMENT-RELATED, TREATMENT-EMERGENT ADVERSE EVENT	5 (0.6)	16 (0.9)	18 (0.9)
SERIOUS ADVERSE EVENT	1 (0.1)	1 (0.1)	1 (0.1)
ADVERSE EVENT CAUSING DISCONTINUATION	2 (0.3)	5 (0.3)	5 (0.3)

Table 54 Primary Hypercholesterolemia
Monotherapy Pool
Creatine Phosphokinase (CPK)
Postbaseline Values Above Upper Limit Of Normal (ULN)

Number And (Percent) Of Patients

High Ranges[a]	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
3xULN[b] to <5xULN	9/786 (1.1)	26/1674 (1.6)	28/1966 (1.4)
5xULN to <10xULN	1/786 (0.1)	12/1674 (0.7)	13/1966 (0.7)
≥10xULN	1/786 (0.1)	4/1674 (0.2)	6/1966 (0.3)

a: Subjects appear only in the category of maximum value.

b: ULN = upper limit of the reference range (0-120 mU/mL).

Note: These data are presented in the form X/Y, where X represents the number of subjects who met the criterion for a high value as indicated, and Y represents the number of subjects who had at least one postbaseline observation for the test in question.

Table 55 Primary Hypercholesterolemia Monotherapy Pool Creatine Phosphokinase (CPK) Postbaseline Values Above Upper Limit Of Normal (ULN), With Associated Muscle Symptoms

	Number And (Percent) Of Patients		
Event of Interest[a]	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
≥10xULN[b] With Muscle Symptoms[c]	0/786	0/1674	0/1966
≥10xULN	1/786 (0.1)	4/1674 (0.2)	6/1966 (0.3)
5xULN to <10xULN With Muscle Symptoms	0/786	4[d]/1674 (0.2)	5[d]/1966 (0.3)

a: The third row is mutually exclusive of the first and second rows; a subject appears only in the category of greatest CPK value during treatment. The first row is a subset of the second row.

b: ULN = upper limit of the reference range (0-120 mU/mL).

c: "Muscle symptoms" comprise a predefined list of symptoms that could potentially indicate drug-induced muscle damage and that were recorded as present within 7 days before or after the observed high CPK value.

d: One additional subject had CPK 5 to <10xULN with muscle symptoms that was not discovered until after subject had entered the extension protocol as Subject P00476-061/0095.

NOTE: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high value (X) / the number of subjects who had at least one postbaseline observation for the test in question (Y).

Table 56 Primary Hypercholesterolemia Monotherapy Pool Postbaseline Values And Changes From Baseline In Pulse, Systolic Blood Pressure, Diastolic Blood Pressure, And Body Weight

Number And (Percent) Of Patients

Value/Change	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Pulse (bpm)			
Value <60	67/779 (8.6)	150/1638 (9.2)	192/1930 (9.9)
Value >100	1/779 (0.1)	2/1638 (0.1)	2/1930 (0.1)
Decrease >20	9/776 (1.2)	21/1630 (1.3)	27/1922 (1.4)
Increase >20	18/776 (2.3)	20/1630 (1.2)	28/1922 (1.5)
Systolic Blood Pressure (mm Hg)			
Value >150	53/778 (6.8)	87/1637 (5.3)	107/1929 (5.5)
Decrease >20	87/774 (11.2)	170/1637 (10.4)	206/1923 (10.7)
Increase >20	35/774 (4.5)	64/1631 (3.9)	92/1923 (4.8)
Diastolic Blood Pressure (mm Hg)			
Value >100	3/778 (0.4)	8/1637 (0.5)	9/1929 (0.5)
Decrease >20	12/774 (1.6)	37/1631 (2.3)	41/1923 (2.1)
Increase >20	9/774 (1.2)	13/1631 (0.8)	16/1923 (0.8)
Body Weight (kg)			
Decrease ≥3	88/788 (11.2)	158/1672 (9.4)	185/1964 (9.4)
Increase ≥3	62/788 (7.9)	95/1672 (5.7)	109/1964 (5.5)

NOTE: The entries in the form X/Y correspond to the number of subjects who met the criterion for a high value (X) / the number of subjects who had at least one postbaseline observation for the test in question (Y).

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Table 57 Primary Hypercholesterolemia Monotherapy Pool Changes From Baseline In Electrocardiograms

Number And (Percent) Of Patients

At Last Observation	Placebo (n=795)	Ezetimibe 10 mg (n=1691)	Ezetimibe All Doses (n=1983)
Normal at Baseline	(n=371)	(n=769)	(n=942)
Clinically Significant Change	0	4 (0.5)	5 (0.5)
Change, but Not Clinically Significant	88 (23.7)	178 (23.1)	209 (22.2)
No Change	274 (73.9)	548 (71.3)	689 (73.1)
Missing	9 (2.4)	39 (5.1)	39 (4.1)
Abnormal at Baseline	(n=424)	(n=915)	(n=1034)
Clinically Significant Change	7 (1.7)	5 (0.5)	5 (0.5)
Change, but Not Clinically Significant	203 (47.9)	413 (45.1)	463 (44.8)
No Change	199 (46.9)	469 (51.3)	537 (51.9)
Missing	15 (3.5)	28 (3.1)	29 (2.8)
Change From Baseline Not Evaluable[a]	(n=0)	(n=7)	(n=7)

a: Subject was missing results at Baseline.

Table 58 Primary Hypercholesterolemia Factorial Coadministration Pool Summary Of Adverse Events

Number And (Percent) Of Patients

Event	Placebo[a] (n=259)	Ezetimibe 10 mg[a] (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
Death	0	0	0	1 (0.11)
Serious Adverse Event (SAE)	11 (4.2)	7 (2.7)	20 (2.1)	22 (2.4)
Treatment-Related[b] SAE	0	1 (0.4)	1 (0.1)	10 (1.1)
Discontinuation Because of Adverse Event	16 (6.2)	13 (5.0)	40 (4.3)	53 (5.7)
Discontinuation Because of Treatment-Related[b] Adverse Event	10 (3.9)	7 (2.7)	23 (2.5)	34 (3.7)
Treatment-Emergent Adverse Event	166 (64.1)	177 (67.6)	606 (64.7)	593 (64.1)
Treatment-Related[b] TEAE	47 (18.1)	41 (15.6)	158 (16.9)	180 (19.5)
Severe/LT TEAE	13 (5.0)	14 (5.3)	52 (5.6)	56 (6.1)

a: These were all reported previously as part of the Monotherapy Pool.

b: Judged to be at least possibly related to treatment by the investigator.

EZ=ezetimibe 10 mg; All Statins=all doses of all statins; SAE=serious adverse event; TEAE=treatment-emergent adverse event; LT=life-threatening.

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Table 59 Primary Hypercholesterolemia
Factorial Coadministration Pool
Serious Adverse Events (SAEs)

Number And (Percent) Of Patients

Body System/Organ Class and Adverse Event	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
SUBJECTS REPORTING ANY SAE	**11 (4.2)**	**7 (2.7)**	**20 (2.1)**	**22 (2.4)**
BENIGN & MALIGNANT NEOPLASMS (INCLUDING CYSTS AND POLYPS)	**2 (0.8)**	**4 (1.5)**	**2 (0.2)**	**6 (0.6)**
BASAL CELL CARCINOMA	2 (0.8)	0	1 (0.1)	1 (0.1)
BREAST NEOPLASM MALIGNANT FEMALE	0	1 (0.6)	1 (0.2)	0
GASTRIC CARCINOMA	0	1 (0.4)	0	0
MENINGIOMA	0	1 (0.4)	0	0
NEOPLASM, BRAIN	0	1 (0.4)	0	0
PROSTATIC CANCER	0	0	0	1 (0.1)
PULMONARY CARCINOMA	0	1 (0.4)	0	1 (0.1)
RECTAL CARCINOMA	0	0	0	1 (0.1)
SKIN CARCINOMA	0	0	0	1 (0.1)
SQUAMOUS CELL CARCINOMA	0	0	0	1 (0.1)
BODY AS A WHOLE - GENERAL DISORDERS	**0**	**1 (0.4)**	**7 (0.7)**	**2 (0.2)**
CHEST PAIN	0	1 (0.4)	4 (0.4)	1 (0.1)
DIZZINESS	0	0	1 (0.1)	0
FEVER	0	0	1 (0.1)	0
HEADACHE	0	0	1 (0.1)	0
POST-PROCEDURE PAIN	0	0	1 (0.1)	0
RIGORS	0	0	1 (0.1)	0
WEAKNESS	0	0	1 (0.1)	1 (0.1)
CARDIOVASCULAR DISORDERS, GENERAL	**2 (0.8)**	**0**	**4 (0.4)**	**2 (0.2)**
ANGINA PECTORIS	0	0	0	1 (0.1)
CARDIAC FAILURE	1 (0.4)	0	0	0
CORONARY ARTERY DISORDER	1 (0.4)	0	1 (0.1)	0
EJECTION FRACTION DECREASED	0	0	0	1 (0.1)
HYPERTENSION	0	0	1 (0.1)	0
MITRAL INSUFFICIENCY	1 (0.4)	0	0	0
MYOCARDIAL INFARCTION	0	0	2 (0.2)	1 (0.1)
MYOCARDIAL ISCHEMIA	1 (0.4)	0	0	0
TRICUSPID VALVE INCOMPETENCE	1 (0.4)	0	0	0
CENTR AND PERIPH NERV SYST DISORDERS	**1 (0.4)**	**0**	**2 (0.2)**	**1 (0.1)**
CEREBROVASCULAR ACCIDENT NOS	1 (0.4)	0	0	0
CEREBROVASCULAR DISORDER	0	0	0	1 (0.1)
HYPOESTHESIA	0	0	1 (0.1)	0
SPEECH DISORDER	0	0	1 (0.1)	0
TRANSIENT ISCHEMIC ATTACK	0	0	1 (0.1)	0
TREMOR	0	0	1 (0.1)	0

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Table 59 Continued.

Body System/Organ Class and Adverse Event	Number And (Percent) Of Patients			
	Placebo (n=259)	Ezetimibe 10 mg (n=262)	All Statins (n=936)	EZ + All Statins (n=925)
DISORDERS OF THE REPRODUCTIVE SYSTEM AND BREAST	**0**	**1 (0.4)**	**2 (0.2)**	**0**
BREAST MASS	0	0	1 (0.2)	0
OVARIAN MASS	0	1 (0.6)	0	0
PROSTATIC DISORDER	0	0	1 (0.3)	0
GASTRO-INTESTINAL SYSTEM DISORDERS	**1 (0.4)**	**1 (0.4)**	**4 (0.4)**	**1 (0.1)**
ABDOMINAL PAIN	0	0	3 (0.3)	0
DIVERTICULITIS	0	0	1 (0.1)	1 (0.1)
DIVERTICULOSIS	0	1 (0.4)	0	0
GASTROESOPHAGEAL REFLUX	0	0	1 (0.1)	0
GI HEMORRHAGE	1 (0.4)	0	0	0
ILEITIS	0	1 (0.4)	0	0
ILEUS	0	0	1 (0.1)	0
NAUSEA	0	0	2 (0.2)	0
HEART RATE AND RHYTHM DISORDERS	**1 (0.4)**	**0**	**0**	**0**
BRADYCARDIA	1 (0.4)	0	0	0
INFECTION AND INFESTATIONS	**0**	**0**	**2 (0.2)**	**0**
PNEUMONIA	0	0	2 (0.2)	0
LIVER AND BILIARY SYSTEM DISORDERS[a]	**1 (0.4)**	**1 (0.4)**	**4 (0.4)**	**8 (0.9)**
CHOLECYSTITIS	0	0	1 (0.1)	0
CHOLELITHIASIS	0	0	2 (0.2)	0
HEPATIC ENZYMES INCREASED	0	0	0	4 (0.4)
HEPATOMEGALY	0	0	1 (0.1)	0
SGOT INCREASED	1 (0.4)	1 (0.4)	1 (0.1)	0
SGPT INCREASED	1 (0.4)	1 (0.4)	1 (0.1)	4 (0.4)
METABOLIC AND NUTRITIONAL DISORDERS	**1 (0.4)**	**0**	**0**	**1 (0.1)**
CREATINE PHOSPHOKINASE INCREASED[b]	1 (0.4)	0	0	1 (0.1)
MUSCULO-SKELETAL SYSTEM DISORDERS	**1 (0.4)**	**0**	**0**	**1 (0.1)**
MYALGIA	0	0	0	1 (0.1)
SPINAL DISORDER	1 (0.4)	0	0	0
PLATELET, BLEEDING AND CLOTTING DISORD	**0**	**0**	**1 (0.1)**	**0**
THROMBOCYTOPENIA	0	0	1 (0.1)	0
PSYCHIATRIC DISORDERS	**1 (0.4)**	**1 (0.4)**	**1 (0.1)**	**0**
AMNESIA	1 (0.4)	0	0	0
ANXIETY	0	0	1 (0.1)	0
MANIC DEPRESSION	0	1 (0.4)	0	0

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