Table 1.

Adverse events leading to permanent discontinuation occurring in ≥0.2% of subjects in either treatment group

Body System/AE	Atorvastatin (N=5158)	Placebo (N=5124)
	number (%) of subjects	
Permanently Discontinued	138 (2.7)	132 (2.6)
Cardiac disorders	4 (0.1)	9 (0.2)
Gastrointestinal disorders	38 (0.7)	38 (0.7)
Diarrhea NOS	9 (0.2)	7 (0.1)
Dyspepsia	7 (0.1)	8 (0.2)
Nausea	8 (0.2)	10 (0.2)
General disorders and administration site conditions	22 (0.4)	21 (0.4)
Fatigue	9 (0.2)	8 (0.2)
Musculoskeletal and connective tissue disorders	37 (0.7)	23 (0.4)
Myalgia	17 (0.3)	9 (0.2)
Nervous system disorders	21 (0.4)	19 (0.4)
Headache	11 (0.2)	10 (0.2)
Psychiatric disorders	9 (0.2)	10 (0.2)
Reproductive system and breast disorders	8 (0.2)	7 (0.1)
Respiratory, thoracic and mediastinal disorders	10 (0.2)	9 (0.2)
Skin and subcutaneous tissue disorders	11 (0.2)	14 (0.3)

NOS = no other symptoms

The proportion of subjects discontinuing treatment because of AEs was similar in the atorvastatin and placebo treatment groups (2.7% and 2.6%, respectively), with a similar incidence of individual AEs causing discontinuation between treatment groups with the exception of myalgia (17 [0.3%] and 9 [0.2%], respectively).

Table 2.

Serious adverse events occurring in >0.2% of subjects in either treatment group

Body System/AE	Atorvastatin (N=5158)	Placebo (N=5124)
	number (%) of subjects	
Number (%) with SAEs	1099 (21.3)	1190 (23.2)
Blood and lymphatic system disorders	14 (0.3)	22 (0.4)
Anemia NOS	9 (0.2)	16 (0.3)
Cardiac disorders	95 (1.8)	95 (1.9)
Atrial fibrillation	35 (0.7)	44 (0.9)
Ear and labyrinth disorders	24 (0.5)	27 (0.5)
Vertigo	18 (0.3)	17 (0.3)
Eye disorders	22 (0.4)	21 (0.4)
Gastrointestinal disorders	181 (3.5)	170 (3.3)
Abdominal pain NOS	26 (0.5)	17 (0.3)
Diarrhea NOS	13 (0.3)	14 (0.3)
Inguinal hernia NOS	19 (0.4)	19 (0.4)
General disorders and administration site conditions	109 (2.1)	123 (2.4)
Chest pain	41 (0.8)	59 (1.2)
Fatigue	15 (0.3)	11 (0.2)
Hepatobiliary disorders	25 (0.5)	28 (0.5)
Infections and infestations	113 (2.2)	127 (2.5)
Pneumonia NOS	24 (0.5)	29 (0.6)
Urinary tract infection NOS	18 (0.3)	9 (0.2)
Injury, poisoning and procedural complications	75 (1.5)	107 (2.1)
Investigations	31 (0.6)	29 (0.6)

NOS = not otherwise specified

Table 3.

Serious adverse events occurring in >0.2% of subjects in either treatment group (continued)

Body System/AE	Atorvastatin (N=5158)	Placebo (N=5124)
	number (%) of subjects	
Metabolism and nutrition disorders	15 (0.3)	23 (0.4)
Musculoskeletal and connective tissue disorders	145 (2.8)	166 (3.2)
Arthralgia	27 (0.5)	35 (0.7)
Back pain	20 (0.4)	18 (0.4)
Joint swelling	7 (0.1)	13 (0.3)
Localized osteoarthritis	19 (0.4)	22 (0.4)
Osteoarthritis NOS	7 (0.1)	18 (0.4)
Pain in limb	12 (0.2)	15 (0.3)
Neoplasms benign, malignant and unspecified	141 (2.7)	146 (2.8)
Prostate cancer NOS	29 (0.6)	31 (0.6)
Nervous system disorders	119 (2.3)	127 (2.5)
Dizziness	15 (0.3)	15 (0.3)
Syncope	19 (0.4)	20 (0.4)
Psychiatric disorders	11 (0.2)	32 (0.6)
Renal and urinary disorders	61 (1.2)	72 (1.4)
Hematuria	10 (0.2)	21 (0.4)
Reproductive system and breast disorders	38 (0.7)	37 (0.7)
Respiratory, thoracic and mediastinal disorders	78 (1.5)	96 (1.9)
Dyspnea NOS	19 (0.4)	31 (0.6)
Skin and subcutaneous tissue disorders	26 (0.5)	26 (0.5)
Surgical and medical procedures	79 (1.5)	83 (1.6)
Uncoded	3 (0.1)	14 (0.3)
Vascular disorders	56 (1.1)	70 (1.4)
Circulatory collapse	16 (0.3)	11 (0.2)

NOS=not otherwise specified

The proportion of subjects experiencing SAEs was similar in the atorvastatin and placebo treatment groups (21.3% and 23.2%, respectively), and there were no specific SAEs that had an increased incidence in one treatment group compared with the other.

Table 4

Serious adverse events by frequency occurring in >0.2% of subjects in either treatment group

Adverse Event	Atorvastatin (N=5158)		Placebo (N=5124)	
	number (%) of subjects			
Chest pain	41	(0.8)	59	(1.2)
Atrial fibrillation	35	(0.7)	44	(0.9)
Prostate cancer NOS	29	(0.6)	31	(0.6)
Arthralgia	27	(0.5)	35	(0.7)
Abdominal pain NOS	26	(0.5)	17	(0.3)
Pneumonia NOS	24	(0.5)	29	(0.6)
Back pain	20	(0.4)	18	(0.4)
Dyspnea NOS	19	(0.4)	31	(0.6)
Syncope	19	(0.4)	20	(0.4)
Localized osteoarthritis	19	(0.4)	22	(0.4)
Inguinal hernia NOS	19	(0.4)	19	(0.4)
Urinary tract infection NOS	18	(0.3)	9	(0.2)
Vertigo	18	(0.3)	17	(0.3)
Circulatory collapse	16	(0.3)	11	(0.2)
Dizziness	15	(0.3)	15	(0.3)
Fatigue	15	(0.3)	11	(0.2)
Diarrhea NOS	13	(0.3)	14	(0.3)
Pain in limb	12	(0.2)	15	(0.3)
Hematuria	10	(0.2)	21	(0.4)
Anemia NOS	9	(0.2)	16	(0.3)
Joint swelling	7	(0.1)	13	(0.3)
Osteoarthritis NOS	7	(0.1)	18	(0.4)
Deep vein thrombosis	6	(0.1)	15	(0.3)

NOS=not otherwise specified

Table 5.

Selected serious adverse events

	Atorvastatin (N=5158)		Placebo (N=5124)	
	N	(%)	N	(%)
Liver-related events	11	(0.21)	10	(0.20)
Rhabdomyolysis	2	(0.04)	0	(0.00)
Other muscle-related events	3	(0.06)	11	(0.21)
Neuropathy	10	(0.19)	4	(0.08)
Dyspnea	8	(0.14)	16	(0.31)

Table 6.

Incidence of laboratory test abnormalities (without regard to baseline abnormality)

		Atorvastatin (N=4734)	Placebo (N=4678)
Parameter	Criteria	n/N (%)	
Total bilirubin	>1.5 x ULN	121/2173 (5.6)	78/2141 (3.6)
ALT	>3.0 x ULN	39/4669 (0.8)	64/4607 (1.4)
CPK	>2.0 x ULN	1/39 (2.6)	1/31 (3.2)
Blood sugar	<0.6 x LLN	69/4700 (1.5)	60/4644 (1.3)
	>1.5.0 x ULN	822/4700 (17.5)	787/4644 (16.9)

Bilirubin was only tested in the UK. CPK analysis was not routine, but only done if subjects had symptoms of myopathy.
N = number of subjects with a laboratory abnormality meeting the specified criteria while on study treatment or during the lag period.
N = total number of subjects with at least one observation of the given laboratory test while on study treatment or during the lag period.
ULN = upper limit of normal; LLN = lower limit of normal