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Table 14.1.1: Demographic data and other baseline characteristics, descriptive statistics

 14FEB2013

Safety Population

Parameter	Treatment	N	Mean	SD	CV	Minimum	Median	Maximum
AGE [years]	ACI-91	32	70.3	6.10	8.7	55	70.5	82
	Placebo	31	71.1	7.13	10.0	54	73.0	82
	Total	63	70.7	6.58	9.3	54	72.0	82
BODY HEIGHT [cm]	ACI-91	32	166.3	7.68	4.6	149	165.0	180
	Placebo	31	167.7	8.13	4.8	155	165.0	183
	Total	63	167.0	7.88	4.7	149	165.0	183
BODY WEIGHT [kg]	ACI-91	32	71.2	12.52	17.6	51	70.0	97
	Placebo	31	73.8	11.01	14.9	58	70.0	104
	Total	63	72.5	11.78	16.2	51	70.0	104
MMSE	ACI-91	32	22.6	2.92	12.9	18	23.0	28
	Placebo	31	22.4	2.83	12.7	18	22.0	27
	Total	63	22.5	2.86	12.7	18	23.0	28

Values for Weight, Height, MMSE, Race were assessed at Visit 1 (Baseline, Week 0)

Table 14.1.1: Demographic data and other baseline characteristics, descriptive statistics

 14FEB2013

Safety Population

Parameter	Treatment		N	%
SEX	ACI-91	MALE	13	40.6
		FEMALE	19	59.4
	Placebo	MALE	12	38.7
		FEMALE	19	61.3
	Total	MALE	25	39.7
		FEMALE	38	60.3
RACE	ACI-91	CAUCASIAN	32	100.0
	Placebo	CAUCASIAN	31	100.0
	Total	CAUCASIAN	63	100.0

Values for Weight, Height, MMSE, Race were assessed at Visit 1 (Baseline, Week 0)

Table 14.1.2: Patient disposition

 14FEB2013

Number of patients	ACI-91	Placebo	Total
SCREENED			83
RANDOMIZED	32	32	64
TREATED	32	31	63
COMPLETED THE STUDY	22	28	50
DISCONTINUED THE STUDY	10	4	14
DISCONTINUED DUE TO			
ADVERSE EVENT(S)	5	2	7
PATIENT NON-COMPLIANCE	1		1
CONSENT WITHDRAWN	4	2	6
INCLUDED IN			
SAFETY POPULATION	32	31	63
INTENTION-TO-TREAT POPULATION	32	31	63
PER PROTOCOL POPULATION	17	24	41
PK POPULATION	30	27	57

Table 14.1.3: Frequency of previous and concomitant medications

 14FEB2013

Safety Population

ATC Level 2 Term	ATC Level 4 Term	ACI-91 (n=32) F	ACI-91 (n=32) N	ACI-91 (n=32) %	Placebo (n=31) F	Placebo (n=31) N	Placebo (n=31) %	Total (n=63) F	Total (n=63) N	Total (n=63) %
PSYCHOANALEPTICS	ANTICHOLINESTERASES	45	32	100.0	47	31	100.0	92	63	100.0
	OTHER ANTIDEPRESSANTS	9	7	21.9	13	9	29.0	22	16	25.4
	SELECTIVE SEROTONIN REUPTAKE INHIBITORS	10	7	21.9	7	6	19.4	17	13	20.6
PSYCHOLEPTICS	BUTYROPHENONE DERIVATIVES	7	4	12.5	5	2	6.5	12	6	9.5
	OTHER ANTIPSYCHOTICS	3	3	9.4	7	4	12.9	10	7	11.1
	DIAZEPINES, OXAZEPINES AND THIAZEPINES	4	3	9.4	5	2	6.5	9	5	7.9
	BENZODIAZEPINE DERIVATIVES	4	4	12.5	1	1	3.2	5	5	7.9
	BENZODIAZEPINE RELATED DRUGS	3	2	6.3	1	1	3.2	4	3	4.8
AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM	ACE INHIBITORS, PLAIN	10	8	25.0	13	11	35.5	23	19	30.2
	ANGIOTENSIN II ANTAGONISTS, PLAIN	6	5	15.6	3	3	9.7	9	8	12.7
	ACE INHIBITORS AND DIURETICS				2	2	6.5	2	2	3.2
	ANGIOTENSIN II ANTAGONISTS AND DIURETICS	1	1	3.1				1	1	1.6
	RENIN-INHIBITORS				1	1	3.2	1	1	1.6
ANALGESICS	ANILIDES	4	2	6.3	5	1	3.2	9	3	4.8
	PYRAZOLONES	4	2	6.3	4	3	9.7	8	5	7.9
	SALICYLIC ACID AND DERIVATIVES	2	2	6.3	5	4	12.9	7	6	9.5
	OTHER ANALGESICS AND ANTIPYRETICS				2	1	3.2	2	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

 14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
ANALGESICS	OTHER OPIOIDS				2	1	3.2	2	1	1.6
LIPID MODIFYING AGENTS	HMG COA REDUCTASE INHIBITORS	9	9	28.1	15	15	48.4	24	24	38.1
ANTITHROMBOTIC AGENTS	PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	8	8	25.0	10	9	29.0	18	17	27.0
	HEPARIN GROUP	1	1	3.1	2	2	6.5	3	3	4.8
	VITAMIN K ANTAGONISTS	1	1	3.1				1	1	1.6
BETA BLOCKING AGENTS	BETA BLOCKING AGENTS, SELECTIVE	7	4	12.5	11	9	29.0	18	13	20.6
	ALPHA AND BETA BLOCKING AGENTS				3	2	6.5	3	2	3.2
THYROID THERAPY	THYROID HORMONES	5	5	15.6	13	10	32.3	18	15	23.8
	IODINE THERAPY				1	1	3.2	1	1	1.6
	NOT AVAILABLE				1	1	3.2	1	1	1.6
	SULFUR-CONTAINING IMIDAZOLE DERIVATIVES				1	1	3.2	1	1	1.6
ANTIBACTERIALS FOR SYSTEMIC USE	FLUOROQUINOLONES	2	2	6.3	8	4	12.9	10	6	9.5
	COMB.SULFONAMIDES & TRIMETHOPRIM INCL. DERIVATIVES	2	1	3.1	1	1	3.2	3	2	3.2

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
ANTIBACTERIALS FOR SYSTEMIC USE	MACROLIDES	1	1	3.1	1	1	3.2	2	2	3.2
	COMB OF PENICILLINS, INCL. BETA-LACTAMASE INHIB.	1	1	3.1				1	1	1.6
	FIRST-GENERATION CEPHALOSPORINS	1	1	3.1				1	1	1.6
	LINCOSAMIDES				1	1	3.2	1	1	1.6
	NITROFURAN DERIVATIVES				1	1	3.2	1	1	1.6
	SECOND-GENERATION CEPHALOSPORINS	1	1	3.1				1	1	1.6
DRUGS FOR ACID RELATED DISORDERS	PROTON PUMP INHIBITORS	6	6	18.8	7	5	16.1	13	11	17.5
	COMB AND COMPL. OF ALUMIN., CALC. AND MAGNES. COMP				2	1	3.2	2	1	1.6
	ALUMINIUM COMPOUNDS	1	1	3.1				1	1	1.6
	MAGNESIUM COMPOUNDS				1	1	3.2	1	1	1.6
DIURETICS	THIAZIDES, PLAIN	5	4	12.5	5	3	9.7	10	7	11.1
	ALDOSTERONE ANTAGONISTS	1	1	3.1	1	1	3.2	2	2	3.2
	SULFONAMIDES, PLAIN				2	2	6.5	2	2	3.2
	OTHER POTASSIUM-SPARING AGENTS	1	1	3.1				1	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

 14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
DRUGS USED IN DIABETES	BIGUANIDES	4	3	9.4	2	1	3.2	6	4	6.3
	INSULIN/ANAL.FOR INJ,INTEM.-ACT.,COMB.W/FAST ACT.				2	1	3.2	2	1	1.6
	INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	2	1	3.1				2	1	1.6
	SULFONAMIDES, UREA DERIVATIVES	1	1	3.1	1	1	3.2	2	2	3.2
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	ANTIINFL. PREP., NON-STEROIDS FOR TOPICAL USE	6	4	12.5	6	4	12.9	12	8	12.7
CALCIUM CHANNEL BLOCKERS	DIHYDROPYRIDINE DERIVATIVES	6	6	18.8	4	3	9.7	10	9	14.3
UROLOGICALS	URINARY ANTISPASMODICS	1	1	3.1	5	1	3.2	6	2	3.2
	ALPHA-ADRENORECEPTOR ANTAGONISTS	1	1	3.1	2	2	6.5	3	3	4.8
	TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	1	1	3.1				1	1	1.6
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	3	3	9.4	1	1	3.2	4	4	6.3
	PROPIONIC ACID DERIVATIVES				2	2	6.5	2	2	3.2
	COXIBS	1	1	3.1				1	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

14FEB2013

Safety Population

ATC Level 2 Term	ATC Level 4 Term	ACI-91 (n=32) F	ACI-91 (n=32) N	ACI-91 (n=32) %	Placebo (n=31) F	Placebo (n=31) N	Placebo (n=31) %	Total (n=63) F	Total (n=63) N	Total (n=63) %
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	FENAMATES	1	1	3.1				1	1	1.6
ANTIFUNGALS FOR DERMATOLOGICAL USE	IMIDAZOLE AND TRIAZOLE DERIVATIVES	4	3	9.4				4	3	4.8
	OTHER ANTIFUNGALS FOR TOPICAL USE	2	2	6.3				2	2	3.2
	ANTIFUNGALS FOR SYSTEMIC USE	1	1	3.1				1	1	1.6
OTHER NERVOUS SYSTEM DRUGS	ANTIVERTIGO PREPARATIONS	2	1	3.1	3	2	6.5	5	3	4.8
	DRUGS USED IN OPIOID DEPENDENCE				2	1	3.2	2	1	1.6
UNSPECIFIED HERBAL	NOT AVAILABLE	3	2	6.3	4	4	12.9	7	6	9.5
VITAMINS	VIT B1 IN COMB WITH VITAMIN B6 AND/OR VITAMIN B12	1	1	3.1	2	2	6.5	3	3	4.8
	VITAMIN D AND ANALOGUES	1	1	3.1	2	2	6.5	3	3	4.8
	OTHER PLAIN VITAMIN PREPARATIONS	1	1	3.1				1	1	1.6
ANTIANEMIC PREPARATIONS	VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	2	2	6.3	3	3	9.7	5	5	7.9
	FOLIC ACID AND DERIVATIVES	1	1	3.1				1	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

 14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
ANTIGOUT PREPARATIONS	PREPARATIONS INHIBITING URIC ACID PRODUCTION	3	3	9.4	1	1	3.2	4	4	6.3
	PREPARATIONS INCREASING URIC ACID EXCRETION				1	1	3.2	1	1	1.6
CARDIAC THERAPY	ORGANIC NITRATES	1	1	3.1	1	1	3.2	2	2	3.2
	OTHER CARDIAC COMBINATION PRODUCTS				1	1	3.2	1	1	1.6
	OTHER CARDIAC GLYCOSIDES	1	1	3.1				1	1	1.6
	OTHER VASODILATORS USED IN CARDIAC DISEASES	1	1	3.1				1	1	1.6
OPHTHALMOLOGICALS	CORTICOSTEROIDS, PLAIN	2	1	3.1				2	1	1.6
	OTHER OPHTHALMOLOGICALS				2	2	6.5	2	2	3.2
	PROSTAGLANDIN ANALOGUES				1	1	3.2	1	1	1.6
CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS	CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	2	2	6.3				2	2	3.2
	CORTICOSTEROIDS, POTENT (GROUP III)	2	2	6.3				2	2	3.2
COUGH AND COLD PREPARATIONS	MUCOLYTICS	2	2	6.3	1	1	3.2	3	3	4.8
	NOT AVAILABLE	1	1	3.1				1	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

 14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
LAXATIVES	OSMOTICALLY ACTING LAXATIVES	2	2	6.3	2	2	6.5	4	4	6.3
MINERAL SUPPLEMENTS	MAGNESIUM				3	3	9.7	3	3	4.8
	CALCIUM				1	1	3.2	1	1	1.6
VACCINES	INFLUENZA VACCINES	3	3	9.4	1	1	3.2	4	4	6.3
ANTIHISTAMINES FOR SYSTEMIC USE	PHENOTHIAZINE DERIVATIVES	2	1	3.1				2	1	1.6
	OTHER ANTIHISTAMINES FOR SYSTEMIC USE	1	1	3.1				1	1	1.6
DRUGS FOR TREATMENT OF BONE DISEASES	BISPHOSPHONATES	1	1	3.1	2	2	6.5	3	3	4.8
ALL OTHER THERAPEUTIC PRODUCTS	OTHER THERAPEUTIC PRODUCTS	1	1	3.1	1	1	3.2	2	2	3.2
ANESTHETICS	AMIDES				1	1	3.2	1	1	1.6
	NOT AVAILABLE	1	1	3.1				1	1	1.6
ANTIBIOTICS AND CHEMOTHER. FOR DERMATOLOGICAL USE	ANTIVIRALS				2	1	3.2	2	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
ANTIEPILEPTICS	OTHER ANTIEPILEPTICS				2	1	3.2	2	1	1.6
CORTICOSTEROIDS FOR SYSTEMIC USE	GLUCOCORTICOIDS	1	1	3.1	1	1	3.2	2	2	3.2
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	PROPULSIVES	2	1	3.1				2	1	1.6
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	ANTICHOLINERGICS	1	1	3.1				1	1	1.6
	SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	1	1	3.1				1	1	1.6
EMOLLIENTS AND PROTECTIVES	SALICYLIC ACID PREPARATIONS	1	1	3.1				1	1	1.6
	SOFT PARAFFIN AND FAT PRODUCTS				1	1	3.2	1	1	1.6
ANTIDIARR.,INTEST. ANTIINFL./ANTIINFECT. AGENTS	ANTIDIARRHEAL MICROORGANISMS				1	1	3.2	1	1	1.6
ANTISEPTICS AND DISINFECTANTS	OTHER ANTISEPTICS AND DISINFECTANTS				1	1	3.2	1	1	1.6

F = number of medications, N/% = number/percent of patients taken medications

Table 14.1.3: Frequency of previous and concomitant medications

 14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
ATC Level 2 Term	ATC Level 4 Term	F	N	%	F	N	%	F	N	%
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	OTHER IRRIGATING SOLUTIONS	1	1	3.1				1	1	1.6
DIGESTIVES, INCL. ENZYMES	ENZYME PREPARATIONS				1	1	3.2	1	1	1.6
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	ORGANIC ACIDS				1	1	3.2	1	1	1.6
NOT CODEABLE	NOT CODEABLE				1	1	3.2	1	1	1.6
OTHER GYNECOLOGICALS	INTRAUTERINE CONTRACEPTIVES	1	1	3.1				1	1	1.6
PERIPHERAL VASODILATORS	PURINE DERIVATIVES	1	1	3.1				1	1	1.6
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	1	1	3.1				1	1	1.6
VASOPROTECTIVES	LOCAL ANESTHETICS				1	1	3.2	1	1	1.6
TOTAL		246	32	100.0	282	31	100.0	528	63	100.0

F = number of medications, N/% = number/percent of patients taken medications

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Aß1-42 [pg/mL]	ACI-91	V1 (WEEK 0)	32	831.429	346.04	61.17	41.62	0.00	797.020	2067.90
		V3 (WEEK 12)	6	635.340	145.11	59.24	22.84	409.81	616.285	840.37
		V6 (WEEK 52)	17	757.115	252.14	61.15	33.30	284.54	773.180	1406.70
		V3 (WEEK 12) - V1 (WEEK 0)	6	-19.577	180.40	73.65		-291.87	6.430	229.83
		V6 (WEEK 52) - V1 (WEEK 0)	17	19.151	219.56	53.25		-417.14	8.300	484.98
	Placebo	V1 (WEEK 0)	28	811.712	307.77	58.16	37.92	405.89	767.975	1613.80
		V3 (WEEK 12)	8	775.616	347.35	122.81	44.78	473.25	675.145	1599.50
		V6 (WEEK 52)	21	735.099	250.62	54.69	34.09	299.64	730.410	1266.70
		V3 (WEEK 12) - V1 (WEEK 0)	7	13.587	66.73	25.22		-48.84	-1.030	156.83
		V6 (WEEK 52) - V1 (WEEK 0)	19	-53.676	239.11	54.86		-794.96	-12.840	210.03

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Aß1-40 [pg/mL]	ACI-91	V1 (WEEK 0)	32	6880.867	2021.17	357.30	29.37	1588.10	6402.500	11646.00
		V3 (WEEK 12)	6	6370.600	1563.83	638.43	24.55	3946.10	6070.400	8433.10
		V6 (WEEK 52)	17	7363.847	2425.58	588.29	32.94	2546.60	6647.800	13104.00
		V3 (WEEK 12) - V1 (WEEK 0)	6	-524.067	1132.86	462.49		-2251.20	-533.050	862.50
		V6 (WEEK 52) - V1 (WEEK 0)	17	220.574	1794.69	435.28		-3650.70	186.400	3479.40
	Placebo	V1 (WEEK 0)	28	7074.114	2203.99	416.51	31.16	2643.70	7354.850	11162.00
		V3 (WEEK 12)	8	7172.369	1943.24	687.04	27.09	4550.00	6592.625	9833.40
		V6 (WEEK 52)	21	6683.543	2501.42	545.86	37.43	2831.30	6702.500	12002.00
		V3 (WEEK 12) - V1 (WEEK 0)	7	-13.429	887.36	335.39		-1487.55	-220.200	1343.35
		V6 (WEEK 52) - V1 (WEEK 0)	19	-501.445	1553.12	356.31		-3810.20	15.500	1610.80

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level F2-Isoprostane [pg/mL]	ACI-91	V1 (WEEK 0)	16	24.376	32.99	8.25	135.33	0.00	0.000	76.44
		V3 (WEEK 12)	5	35.706	33.02	14.76	92.46	0.00	54.770	68.07
		V6 (WEEK 52)	1						56.860	
		V3 (WEEK 12) - V1 (WEEK 0)	5	9.688	26.15	11.70		-12.79	0.000	54.77
		V6 (WEEK 52) - V1 (WEEK 0)	1						-4.750	
	Placebo	V1 (WEEK 0)	14	20.801	29.30	7.83	140.86	0.00	0.000	70.86
		V3 (WEEK 12)	7	18.131	31.58	11.94	174.17	0.00	0.000	74.20
		V6 (WEEK 52)	2	54.055	2.31	1.63	4.28	52.42	54.055	55.69
		V3 (WEEK 12) - V1 (WEEK 0)	7	-5.954	37.98	14.35		-57.61	0.000	52.72
		V6 (WEEK 52) - V1 (WEEK 0)	2	-0.250	2.36	1.67		-1.92	-0.250	1.42

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Tau protein [ng/L]	ACI-91	V1 (WEEK 0)	32	713.648	448.06	79.21	62.79	89.82	551.465	1941.20
		V3 (WEEK 12)	6	880.340	402.20	164.20	45.69	432.57	827.045	1483.90
		V6 (WEEK 52)	17	667.065	324.53	78.71	48.65	317.60	516.400	1536.30
		V3 (WEEK 12) - V1 (WEEK 0)	6	-177.187	616.43	251.66		-1429.72	47.875	148.80
		V6 (WEEK 52) - V1 (WEEK 0)	17	-93.506	373.09	90.49		-1424.80	-1.000	378.54
	Placebo	V1 (WEEK 0)	28	614.693	379.60	71.74	61.75	103.39	526.570	1767.00
		V3 (WEEK 12)	8	769.646	329.66	116.55	42.83	329.79	806.895	1200.00
		V6 (WEEK 52)	21	584.950	323.37	70.56	55.28	91.86	522.420	1200.00
		V3 (WEEK 12) - V1 (WEEK 0)	7	-26.883	84.97	32.11		-197.23	0.000	52.80
		V6 (WEEK 52) - V1 (WEEK 0)	19	-10.466	121.95	27.98		-433.96	10.510	103.56

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Phospho Tau [pg/mL]	ACI-91	V1 (WEEK 0)	32	80.603	39.31	6.95	48.77	0.00	75.070	180.24
		V3 (WEEK 12)	6	102.890	36.20	14.78	35.18	67.68	91.295	148.92
		V6 (WEEK 52)	17	84.990	32.32	7.84	38.03	46.68	77.980	168.93
		V3 (WEEK 12) - V1 (WEEK 0)	6	-1.263	6.51	2.66		-10.91	-0.260	6.69
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.349	19.09	4.63		-19.32	-2.340	69.95
	Placebo	V1 (WEEK 0)	28	77.974	43.04	8.13	55.20	0.00	70.495	194.82
		V3 (WEEK 12)	8	107.536	52.26	18.48	48.59	51.94	92.140	216.27
		V6 (WEEK 52)	21	71.526	45.18	9.86	63.17	0.00	75.630	181.44
		V3 (WEEK 12) - V1 (WEEK 0)	7	1.491	10.26	3.88		-12.41	1.040	21.45
		V6 (WEEK 52) - V1 (WEEK 0)	19	-6.806	18.65	4.28		-73.26	-1.240	9.33

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level BACE-1 [ng/mL]	ACI-91	V1 (WEEK 0)	7	0.869	0.88	0.33	100.96	0.00	1.040	1.92
		V3 (WEEK 12)	1						1.200	
		V6 (WEEK 52)	7	0.829	0.67	0.25	80.52	0.00	0.770	1.75
		V3 (WEEK 12) - V1 (WEEK 0)	1						0.160	
		V6 (WEEK 52) - V1 (WEEK 0)	7	-0.040	0.69	0.26		-1.20	0.000	0.77
	Placebo	V1 (WEEK 0)	9	0.668	1.05	0.35	156.59	0.00	0.000	2.35
		V6 (WEEK 52)	9	0.426	0.98	0.33	229.71	0.00	0.000	2.90
		V6 (WEEK 52) - V1 (WEEK 0)	9	-0.242	0.82	0.27		-2.35	0.000	0.55

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-42 [pg/mL]	ACI-91	V1 (WEEK 0)	31	29.843	109.27	19.63	366.15	0.00	0.000	572.36
		V3 (WEEK 12)	22	13.663	53.70	11.45	393.07	0.00	0.000	249.03
		V4 (WEEK 24)	22	55.738	139.92	29.83	251.03	0.00	0.000	550.04
		V5 (WEEK 36)	21	64.392	169.40	36.97	263.07	0.00	0.000	625.18
		V6 (WEEK 52)	21	42.805	119.04	25.98	278.09	0.00	0.000	448.26
		V7 (WEEK 56)	22	38.116	98.66	21.03	258.83	0.00	0.000	370.34
		V3 (WEEK 12) - V1 (WEEK 0)	22	-0.165	9.12	1.95		-31.33	0.000	27.70
		V4 (WEEK 24) - V1 (WEEK 0)	22	13.687	41.02	8.75		-22.32	0.000	172.78
		V5 (WEEK 36) - V1 (WEEK 0)	20	21.355	65.99	14.76		-16.22	0.000	278.67
		V6 (WEEK 52) - V1 (WEEK 0)	20	-1.311	39.84	8.91		-124.10	0.000	102.47
		V7 (WEEK 56) - V1 (WEEK 0)	21	-4.123	52.97	11.56		-202.02	0.000	94.09
	Placebo	V1 (WEEK 0)	31	5.970	19.74	3.55	330.64	0.00	0.000	78.67
		V3 (WEEK 12)	24	8.074	27.41	5.60	339.48	0.00	0.000	102.77
		V4 (WEEK 24)	31	13.116	33.07	5.94	252.12	0.00	0.000	149.35
		V5 (WEEK 36)	29	12.126	37.11	6.89	306.05	0.00	0.000	149.75
		V6 (WEEK 52)	26	11.779	43.68	8.57	370.80	0.00	0.000	200.04
		V7 (WEEK 56)	28	13.823	46.57	8.80	336.93	0.00	0.000	209.10
		V3 (WEEK 12) - V1 (WEEK 0)	24	0.363	8.91	1.82		-31.47	0.000	24.10
		V4 (WEEK 24) - V1 (WEEK 0)	31	7.146	17.53	3.15		0.00	0.000	70.68
		V5 (WEEK 36) - V1 (WEEK 0)	29	5.745	19.88	3.69		-31.47	0.000	74.83

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-42 [pg/mL]	Placebo	V6 (WEEK 52) - V1 (WEEK 0)	26	4.661	25.95	5.09		-31.47	0.000	125.12
		V7 (WEEK 56) - V1 (WEEK 0)	28	7.213	27.16	5.13		0.00	0.000	134.18

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

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Intention-To-Treat Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-40 [pg/mL]	ACI-91	V1 (WEEK 0)	31	122.662	46.35	8.32	37.78	0.00	119.270	263.33
		V3 (WEEK 12)	22	121.461	29.65	6.32	24.41	84.21	118.795	189.70
		V4 (WEEK 24)	22	151.585	60.23	12.84	39.74	86.71	137.755	335.92
		V5 (WEEK 36)	21	150.659	58.11	12.68	38.57	78.61	135.930	274.64
		V6 (WEEK 52)	21	128.995	45.45	9.92	35.24	79.46	122.520	301.80
		V7 (WEEK 56)	22	129.141	33.01	7.04	25.56	75.77	125.685	219.18
		V3 (WEEK 12) - V1 (WEEK 0)	22	5.282	32.72	6.98		-79.60	5.595	93.18
		V4 (WEEK 24) - V1 (WEEK 0)	22	26.992	43.43	9.26		-68.44	25.640	113.26
		V5 (WEEK 36) - V1 (WEEK 0)	20	28.718	50.08	11.20		-56.04	23.220	162.20
		V6 (WEEK 52) - V1 (WEEK 0)	20	-2.757	44.43	9.94		-97.40	-0.905	103.73
		V7 (WEEK 56) - V1 (WEEK 0)	21	3.158	41.73	9.11		-85.34	5.650	96.75
	Placebo	V1 (WEEK 0)	31	123.133	29.66	5.33	24.09	73.41	123.790	195.76
		V3 (WEEK 12)	24	122.238	33.26	6.79	27.21	27.35	122.955	195.18
		V4 (WEEK 24)	31	146.320	44.16	7.93	30.18	90.89	140.290	283.89
		V5 (WEEK 36)	29	146.269	45.13	8.38	30.85	78.20	137.690	258.03
		V6 (WEEK 52)	26	124.184	27.63	5.42	22.25	73.55	126.940	177.15
		V7 (WEEK 56)	28	135.360	29.45	5.57	21.76	92.88	129.945	222.20
		V3 (WEEK 12) - V1 (WEEK 0)	24	4.220	26.52	5.41		-78.64	6.080	46.44
		V4 (WEEK 24) - V1 (WEEK 0)	31	23.186	32.30	5.80		-26.01	15.680	96.24
		V5 (WEEK 36) - V1 (WEEK 0)	29	20.979	40.47	7.52		-77.97	21.210	108.65

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Intention-To-Treat Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-40 [pg/mL]	Placebo	V6 (WEEK 52) - V1 (WEEK 0)	26	-1.470	26.80	5.26		-90.94	0.070	47.58
		V7 (WEEK 56) - V1 (WEEK 0)	28	10.493	35.59	6.73		-72.48	3.560	84.70

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

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Per Protocol Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Aß1-42 [pg/mL]	ACI-91	V1 (WEEK 0)	17	761.712	281.16	68.19	36.91	0.00	807.250	1309.20
		V3 (WEEK 12)	4	593.748	135.20	67.60	22.77	409.81	616.285	732.61
		V6 (WEEK 52)	12	747.146	301.60	87.07	40.37	284.54	729.460	1406.70
		V3 (WEEK 12) - V1 (WEEK 0)	4	-74.805	170.78	85.39		-291.87	-34.885	62.42
		V6 (WEEK 52) - V1 (WEEK 0)	12	-4.728	240.80	69.51		-417.14	31.680	484.98
	Placebo	V1 (WEEK 0)	22	800.930	312.15	66.55	38.97	405.89	719.320	1613.80
		V3 (WEEK 12)	7	787.029	373.56	141.19	47.46	473.25	663.940	1599.50
		V6 (WEEK 52)	20	734.407	257.11	57.49	35.01	299.64	722.365	1266.70
		V3 (WEEK 12) - V1 (WEEK 0)	6	-10.287	23.57	9.62		-48.84	-3.275	18.42
		V6 (WEEK 52) - V1 (WEEK 0)	18	-68.327	237.10	55.89		-794.96	-13.160	142.56

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

 14FEB2013

Per Protocol Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Aß1-40 [pg/mL]	ACI-91	V1 (WEEK 0)	17	6844.991	2064.50	500.72	30.16	1588.10	6412.000	10419.00
		V3 (WEEK 12)	4	5947.488	1540.65	770.33	25.90	3946.10	6070.400	7703.05
		V6 (WEEK 52)	12	7130.550	2295.38	662.62	32.19	2546.60	6806.200	10981.00
		V3 (WEEK 12) - V1 (WEEK 0)	4	-742.525	1160.53	580.27		-2251.20	-533.050	347.20
		V6 (WEEK 52) - V1 (WEEK 0)	12	-14.037	1694.46	489.15		-3650.70	86.750	3175.00
	Placebo	V1 (WEEK 0)	22	6948.711	2239.54	477.47	32.23	2643.70	7335.750	11162.00
		V3 (WEEK 12)	7	7366.621	2013.30	760.96	27.33	4550.00	6935.250	9833.40
		V6 (WEEK 52)	20	6682.595	2566.40	573.87	38.40	2831.30	6536.900	12002.00
		V3 (WEEK 12) - V1 (WEEK 0)	6	51.133	953.88	389.42		-1487.55	68.600	1343.35
		V6 (WEEK 52) - V1 (WEEK 0)	18	-556.475	1578.97	372.17		-3810.20	2.025	1610.80

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Per Protocol Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level F2-Isoprostane [pg/mL]	ACI-91	V1 (WEEK 0)	8	7.701	21.78	7.70	282.84	0.00	0.000	61.61
		V3 (WEEK 12)	4	30.710	35.87	17.94	116.82	0.00	27.385	68.07
		V6 (WEEK 52)	1						56.860	
		V3 (WEEK 12) - V1 (WEEK 0)	4	15.308	26.48	13.24		0.00	3.230	54.77
		V6 (WEEK 52) - V1 (WEEK 0)	1						-4.750	
	Placebo	V1 (WEEK 0)	12	19.955	29.79	8.60	149.28	0.00	0.000	70.86
		V3 (WEEK 12)	7	18.131	31.58	11.94	174.17	0.00	0.000	74.20
		V6 (WEEK 52)	2	54.055	2.31	1.63	4.28	52.42	54.055	55.69
		V3 (WEEK 12) - V1 (WEEK 0)	7	-5.954	37.98	14.35		-57.61	0.000	52.72
		V6 (WEEK 52) - V1 (WEEK 0)	2	-0.250	2.36	1.67		-1.92	-0.250	1.42

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

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Per Protocol Population

Biomarker	Treatment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Tau protein [ng/L]	ACI-91	V1 (WEEK 0)	17	672.290	464.16	112.58	69.04	89.82	464.800	1941.20
		V3 (WEEK 12)	4	740.963	348.66	174.33	47.06	432.57	665.640	1200.00
		V6 (WEEK 52)	12	565.923	248.04	71.60	43.83	317.60	478.100	1200.00
		V3 (WEEK 12) - V1 (WEEK 0)	4	-333.493	731.76	365.88		-1429.72	5.935	83.88
		V6 (WEEK 52) - V1 (WEEK 0)	12	-90.141	436.37	125.97		-1424.80	-0.500	378.54
	Placebo	V1 (WEEK 0)	22	618.006	399.36	85.14	64.62	103.39	516.205	1767.00
		V3 (WEEK 12)	7	812.114	331.59	125.33	40.83	329.79	914.720	1200.00
		V6 (WEEK 52)	20	590.047	330.90	73.99	56.08	91.86	553.740	1200.00
		V3 (WEEK 12) - V1 (WEEK 0)	6	-20.075	90.96	37.13		-197.23	5.605	52.80
		V6 (WEEK 52) - V1 (WEEK 0)	18	-7.876	124.95	29.45		-433.96	17.560	103.56

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Per Protocol Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level Phospho Tau [pg/mL]	ACI-91	V1 (WEEK 0)	17	74.710	33.10	8.03	44.30	0.00	67.550	149.57
		V3 (WEEK 12)	4	95.565	37.45	18.73	39.19	67.68	82.830	148.92
		V6 (WEEK 52)	12	75.583	27.17	7.84	35.94	46.68	64.560	139.62
		V3 (WEEK 12) - V1 (WEEK 0)	4	-1.922	6.29	3.14		-10.91	-0.260	3.74
		V6 (WEEK 52) - V1 (WEEK 0)	12	2.421	22.43	6.47		-19.32	-1.350	69.95
	Placebo	V1 (WEEK 0)	22	80.074	47.98	10.23	59.92	0.00	70.495	194.82
		V3 (WEEK 12)	7	111.586	55.07	20.81	49.35	51.94	92.420	216.27
		V6 (WEEK 52)	20	71.497	46.36	10.37	64.84	0.00	76.285	181.44
		V3 (WEEK 12) - V1 (WEEK 0)	6	1.567	11.24	4.59		-12.41	0.885	21.45
		V6 (WEEK 52) - V1 (WEEK 0)	18	-6.849	19.19	4.52		-73.26	-1.155	9.33

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

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Per Protocol Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
CSF level BACE-1 [ng/mL]	ACI-91	V1 (WEEK 0)	5	0.624	0.89	0.40	142.88	0.00	0.000	1.92
		V6 (WEEK 52)	5	0.646	0.72	0.32	111.44	0.00	0.710	1.75
		V6 (WEEK 52) - V1 (WEEK 0)	5	0.022	0.80	0.36		-1.20	0.000	0.77
	Placebo	V1 (WEEK 0)	9	0.668	1.05	0.35	156.59	0.00	0.000	2.35
		V6 (WEEK 52)	9	0.426	0.98	0.33	229.71	0.00	0.000	2.90
		V6 (WEEK 52) - V1 (WEEK 0)	9	-0.242	0.82	0.27		-2.35	0.000	0.55

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

 14FEB2013

Per Protocol Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-42 [pg/mL]	ACI-91	V1 (WEEK 0)	16	49.606	149.94	37.48	302.26	0.00	0.000	572.36
		V3 (WEEK 12)	10	24.903	78.75	24.90	316.23	0.00	0.000	249.03
		V4 (WEEK 24)	15	71.253	167.00	43.12	234.38	0.00	0.000	550.04
		V5 (WEEK 36)	16	76.911	192.75	48.19	250.62	0.00	0.000	625.18
		V6 (WEEK 52)	15	51.471	137.85	35.59	267.83	0.00	0.000	448.26
		V7 (WEEK 56)	17	44.259	110.58	26.82	249.84	0.00	0.000	370.34
		V3 (WEEK 12) - V1 (WEEK 0)	10	2.770	8.76	2.77		0.00	0.000	27.70
		V4 (WEEK 24) - V1 (WEEK 0)	15	18.340	49.33	12.74		-22.32	0.000	172.78
		V5 (WEEK 36) - V1 (WEEK 0)	15	29.125	75.04	19.37		0.00	0.000	278.67
		V6 (WEEK 52) - V1 (WEEK 0)	14	-1.545	44.61	11.92		-124.10	0.000	102.47
		V7 (WEEK 56) - V1 (WEEK 0)	16	-2.581	60.00	15.00		-202.02	0.000	94.09
	Placebo	V1 (WEEK 0)	24	7.711	22.23	4.54	288.29	0.00	0.000	78.67
		V3 (WEEK 12)	18	10.766	31.40	7.40	291.65	0.00	0.000	102.77
		V4 (WEEK 24)	24	16.942	36.86	7.52	217.57	0.00	0.000	149.35
		V5 (WEEK 36)	24	14.653	40.47	8.26	276.23	0.00	0.000	149.75
		V6 (WEEK 52)	23	13.315	46.33	9.66	347.93	0.00	0.000	200.04
		V7 (WEEK 56)	24	16.126	50.07	10.22	310.51	0.00	0.000	209.10
		V3 (WEEK 12) - V1 (WEEK 0)	18	0.484	10.36	2.44		-31.47	0.000	24.10
		V4 (WEEK 24) - V1 (WEEK 0)	24	9.231	19.51	3.98		0.00	0.000	70.68
		V5 (WEEK 36) - V1 (WEEK 0)	24	6.942	21.73	4.44		-31.47	0.000	74.83

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Per Protocol Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-42 [pg/mL]	Placebo	V6 (WEEK 52) - V1 (WEEK 0)	23	5.269	27.61	5.76		-31.47	0.000	125.12
		V7 (WEEK 56) - V1 (WEEK 0)	24	8.415	29.24	5.97		0.00	0.000	134.18

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

Per Protocol Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-40 [pg/mL]	ACI-91	V1 (WEEK 0)	16	124.332	34.10	8.52	27.42	49.37	123.575	193.34
		V3 (WEEK 12)	10	129.390	36.37	11.50	28.11	84.62	126.185	189.70
		V4 (WEEK 24)	15	146.561	45.92	11.86	31.33	86.71	155.580	225.70
		V5 (WEEK 36)	16	147.896	55.24	13.81	37.35	80.98	134.155	274.64
		V6 (WEEK 52)	15	120.613	20.22	5.22	16.76	89.46	116.780	150.94
		V7 (WEEK 56)	17	124.985	22.21	5.39	17.77	94.19	124.860	180.28
		V3 (WEEK 12) - V1 (WEEK 0)	10	-0.162	21.99	6.95		-52.40	1.760	35.44
		V4 (WEEK 24) - V1 (WEEK 0)	15	21.533	45.99	11.88		-68.44	26.710	113.26
		V5 (WEEK 36) - V1 (WEEK 0)	15	28.599	50.56	13.05		-56.04	22.480	162.20
		V6 (WEEK 52) - V1 (WEEK 0)	14	-10.468	19.62	5.24		-53.87	-6.420	15.61
		V7 (WEEK 56) - V1 (WEEK 0)	16	0.130	33.91	8.48		-50.54	2.390	77.14
	Placebo	V1 (WEEK 0)	24	126.692	29.69	6.06	23.44	73.57	125.065	195.76
		V3 (WEEK 12)	18	128.371	29.15	6.87	22.71	85.36	124.880	195.18
		V4 (WEEK 24)	24	150.570	47.18	9.63	31.33	90.89	143.840	283.89
		V5 (WEEK 36)	24	142.593	44.20	9.02	30.99	78.20	136.370	258.03
		V6 (WEEK 52)	23	123.548	25.57	5.33	20.69	73.83	126.170	177.15
		V7 (WEEK 56)	24	134.423	29.90	6.10	22.24	92.88	124.920	222.20
		V3 (WEEK 12) - V1 (WEEK 0)	18	6.534	20.57	4.85		-29.24	6.080	45.77
		V4 (WEEK 24) - V1 (WEEK 0)	24	23.878	34.27	7.00		-26.01	17.905	96.24
		V5 (WEEK 36) - V1 (WEEK 0)	24	15.901	40.13	8.19		-77.97	13.620	106.86

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.1: Biochemical efficacy - biomarkers, descriptive statistics

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Per Protocol Population

Biomarker	Treat-ment	Visit / Difference to baseline	N	Mean	SD	SEM	CV	Minimum	Median	Maximum
Plasma level Aß1-40 [pg/mL]	Placebo	V6 (WEEK 52) - V1 (WEEK 0)	23	-3.270	27.86	5.81		-90.94	-3.190	47.58
		V7 (WEEK 56) - V1 (WEEK 0)	24	7.731	36.43	7.44		-72.48	1.855	84.70

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.1.2: Biochemical efficacy - biomarkers, ANCOVA estimates for change from baseline

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Intention-To-Treat Population

Biomarker	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
CSF level Aß1-42 [pg/mL]	13.60	-47.98	61.58	-76.34	199.50	0.932
CSF level Aß1-40 [pg/mL]	276.09	-546.54	822.63	-259.73	1904.98	0.554
CSF level F2-Isoprostane [pg/mL]	-	-1.48	-	-	-	-
CSF level Tau protein [ng/L]	-38.19	-14.91	-23.29	-157.15	110.58	0.016
CSF level Phospho Tau [pg/mL]	1.65	-6.94	8.59	-3.46	20.65	0.035
CSF level BACE-1 [ng/mL]	0.02	-0.28	0.29	-0.48	1.07	0.411
Plasma level Aß1-42 [pg/mL]	1.65	19.03	-17.38	-36.48	1.72	0.483
Plasma level Aß1-40 [pg/mL]	-1.10	-2.77	1.67	-16.53	19.86	0.992

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.2: Biochemical efficacy - biomarkers, ANCOVA estimates for change from baseline

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Per Protocol Population

Biomarker	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
CSF level Aß1-42 [pg/mL]	-9.77	-64.07	54.29	-112.40	220.98	0.947
CSF level Aß1-40 [pg/mL]	40.50	-590.82	631.32	-573.33	1835.97	0.708
CSF level F2-Isoprostane [pg/mL]	-	-1.48	-	-	-	-
CSF level Tau protein [ng/L]	-53.84	-9.50	-44.34	-179.02	90.35	0.003
CSF level Phospho Tau [pg/mL]	1.75	-6.81	8.56	-6.07	23.20	0.029
CSF level BACE-1 [ng/mL]	0.01	-0.24	0.24	-0.70	1.18	0.493
Plasma level Aß1-42 [pg/mL]	2.75	20.86	-18.11	-40.81	4.59	0.448
Plasma level Aß1-40 [pg/mL]	-9.32	-4.11	-5.21	-19.02	8.60	0.574

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.3: Biochemical efficacy - biomarkers, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Biomarker	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
CSF level Aß1-42 [pg/mL]	8.30	-12.84	23.53	-75.94	139.49	0.612
CSF level Aß1-40 [pg/mL]	186.40	15.50	543.00	-348.50	1773.60	0.281
CSF level F2-Isoprostane [pg/mL]	-4.75	-0.25	-4.50	-6.17	-2.83	0.540
CSF level Tau protein [ng/L]	-1.00	10.51	-32.30	-93.30	30.66	0.334
CSF level Phospho Tau [pg/mL]	-2.34	-1.24	-0.46	-5.83	5.80	0.849
CSF level BACE-1 [ng/mL]	0.00	0.00	0.16	-0.55	0.77	0.740
Plasma level Aß1-42 [pg/mL]	0.00	0.00	0.00	0.00	0.00	0.736
Plasma level Aß1-40 [pg/mL]	-0.91	0.07	-5.59	-20.02	6.76	0.471

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.1.3: Biochemical efficacy - biomarkers, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Biomarker	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
CSF level Aß1-42 [pg/mL]	31.68	-13.16	26.42	-93.06	155.04	0.568
CSF level Aß1-40 [pg/mL]	86.75	2.03	260.62	-574.10	1773.60	0.485
CSF level F2-Isoprostane [pg/mL]	-4.75	-0.25	-4.50	-6.17	-2.83	0.540
CSF level Tau protein [ng/L]	-0.50	17.56	-24.86	-72.34	33.17	0.397
CSF level Phospho Tau [pg/mL]	-1.35	-1.16	-0.17	-6.66	9.23	0.983
CSF level BACE-1 [ng/mL]	0.00	0.00	0.16	-0.82	0.77	0.669
Plasma level Aß1-42 [pg/mL]	0.00	0.00	0.00	0.00	0.00	0.732
Plasma level Aß1-40 [pg/mL]	-6.42	-3.19	-6.85	-21.32	5.91	0.389

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.1.4: Biochemical efficacy - biomarkers, ANCOVA estimates for repeated measure effects

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Intention-To-Treat Population

Biomarker	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
CSF level Aß1-42 [pg/mL]	OVERALL	30.49	-50.05	80.54	-47.42	208.49	0.210
	V3 (WEEK 12)	34.38	-63.79	98.18	-61.27	257.63	0.197
	V6 (WEEK 52)	26.59	-36.30	62.90	-78.14	203.93	0.339
CSF level Aß1-40 [pg/mL]	OVERALL	257.62	-444.39	702.01	-296.21	1700.24	0.162
	V3 (WEEK 12)	256.49	-346.62	603.10	-778.55	1984.76	0.349
	V6 (WEEK 52)	258.76	-542.16	800.93	-287.89	1889.75	0.130
CSF level F2-Isoprostane [pg/mL]	OVERALL	1.23	17.09	-15.86	-55.92	24.20	0.394
	V3 (WEEK 12)	6.81	-9.89	16.70	-207.93	241.34	0.518
	V6 (WEEK 52)	-4.35	44.07	-48.42	-275.27	178.43	0.225
CSF level Tau protein [ng/L]	OVERALL	-37.50	-72.71	35.21	-2638.81	2709.23	0.979
	V3 (WEEK 12)	-23.68	-76.93	53.25	-2926.53	3033.03	0.969
	V6 (WEEK 52)	-51.32	-68.49	17.17	-2962.49	2996.83	0.990

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.4: Biochemical efficacy - biomarkers, ANCOVA estimates for repeated measure effects

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Intention-To-Treat Population

Biomarker	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
CSF level Phospho Tau [pg/mL]	OVERALL	2.21	-3.53	5.74	-6.51	17.99	0.348
	V3 (WEEK 12)	4.43	0.99	3.44	-13.83	20.70	0.663
	V6 (WEEK 52)	-0.01	-8.06	8.05	-5.29	21.38	0.205
Plasma level Aß1-42 [pg/mL]	OVERALL	6.68	4.73	1.95	-11.04	14.94	0.765
	V3 (WEEK 12)	-4.54	0.51	-5.04	-22.59	12.51	0.571
	V6 (WEEK 52)	-2.87	4.60	-7.47	-25.35	10.40	0.410
	V4 (WEEK 24)	13.29	7.69	5.61	-11.42	22.63	0.516
	V5 (WEEK 36)	20.83	6.13	14.71	-2.89	32.30	0.101
Plasma level Aß1-40 [pg/mL]	OVERALL	14.05	11.52	2.53	-9.60	14.66	0.678
	V3 (WEEK 12)	1.54	3.61	-2.07	-22.42	18.29	0.841
	V6 (WEEK 52)	-0.75	-1.45	0.71	-19.84	21.25	0.946
	V4 (WEEK 24)	27.20	23.11	4.08	-15.22	23.39	0.676
	V5 (WEEK 36)	28.21	20.81	7.40	-12.70	27.49	0.468

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.4: Biochemical efficacy - biomarkers, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Biomarker	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
CSF level Aß1-42 [pg/mL]	OVERALL	3.93	-66.53	70.46	-90.34	231.26	0.377
	V3 (WEEK 12)	8.35	-78.64	86.99	-111.79	285.77	0.342
	V6 (WEEK 52)	-0.50	-54.43	53.93	-124.18	232.03	0.505
CSF level Aß1-40 [pg/mL]	OVERALL	91.35	-405.99	497.34	-661.45	1656.13	0.386
	V3 (WEEK 12)	136.46	-228.61	365.07	-1198.24	1928.39	0.605
	V6 (WEEK 52)	46.24	-583.37	629.61	-635.41	1894.62	0.284
CSF level F2-Isoprostane [pg/mL]	OVERALL	2.41	18.53	-16.12	-62.96	30.72	0.450
	V3 (WEEK 12)	7.99	-8.46	16.45	-241.37	274.27	0.566
	V6 (WEEK 52)	-3.18	45.51	-48.69	-308.33	210.95	0.253
CSF level Tau protein [ng/L]	OVERALL	-93.24	-66.17	-27.07	-3400.06	3345.92	0.987
	V3 (WEEK 12)	-79.42	-70.20	-9.22	-3800.17	3781.73	0.996
	V6 (WEEK 52)	-107.06	-62.13	-44.93	-3835.73	3745.88	0.979

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.4: Biochemical efficacy - biomarkers, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Biomarker	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
CSF level Phospho Tau [pg/mL]	OVERALL	3.71	-2.96	6.67	-9.28	22.61	0.399
	V3 (WEEK 12)	5.99	1.64	4.34	-17.58	26.27	0.660
	V6 (WEEK 52)	1.43	-7.56	8.99	-8.34	26.32	0.266
CSF level BACE-1 [ng/mL]	OVERALL	0.01	-0.24	0.25	-0.65	1.14	0.557
	V6 (WEEK 52)	0.01	-0.24	0.25	-0.65	1.14	0.557
Plasma level Aß1-42 [pg/mL]	OVERALL	8.13	5.82	2.31	-17.15	21.77	0.811
	V3 (WEEK 12)	-7.48	0.36	-7.84	-34.48	18.80	0.561
	V6 (WEEK 52)	-4.81	5.60	-10.41	-34.62	13.79	0.395
	V4 (WEEK 24)	16.79	9.80	6.98	-16.74	30.70	0.560
	V5 (WEEK 36)	28.02	7.51	20.50	-3.20	44.20	0.089
Plasma level Aß1-40 [pg/mL]	OVERALL	9.12	10.85	-1.73	-16.61	13.16	0.815
	V3 (WEEK 12)	-1.62	6.46	-8.08	-34.25	18.09	0.541
	V6 (WEEK 52)	-9.84	-3.31	-6.53	-29.27	16.21	0.570

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.4: Biochemical efficacy - biomarkers, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Biomarker	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Plasma level Aß1-40 [pg/mL]	V4 (WEEK 24)	20.80	24.11	-3.31	-25.44	18.81	0.767
	V5 (WEEK 36)	27.15	16.14	11.02	-11.13	33.16	0.326

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Intention-To-Treat Population

Biomarker	Visit	Treatment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Albumin (CSF)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.171	0.746
			Biomarker	6	0.01	0.04	-0.03	0.07		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.129	0.760
			Biomarker	8	-0.01	0.04	-0.10	0.05		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.375	0.138
			Biomarker	17	-0.00	0.08	-0.25	0.15		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	0.632	0.003
			Biomarker	20	-0.02	0.13	-0.53	0.11		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Aß1-40	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.176	0.738
			Biomarker	6	-524.07	1132.86	-2251.2	862.50		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.077	0.870
			Biomarker	7	-13.43	887.36	-1487.6	1343.35		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.439	0.078
			Biomarker	17	220.57	1794.69	-3650.7	3479.40		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	0.222	0.360
			Biomarker	19	-501.44	1553.12	-3810.2	1610.80		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Aß1-42	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.381	0.457
			Biomarker	6	-19.58	180.40	-291.87	229.83		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.370	0.414
			Biomarker	7	13.59	66.73	-48.84	156.83		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.242	0.349
			Biomarker	17	19.15	219.56	-417.14	484.98		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	0.468	0.044
			Biomarker	19	-53.68	239.11	-794.96	210.03		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level BACE-1	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	1	8.30		8.30	8.30		
			Biomarker	1	0.16		0.16	0.16		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	6	4.26	2.04	2.33	7.44	-0.056	0.916
			Biomarker	7	-0.04	0.69	-1.20	0.77		
		Placebo	Albumin CSF/Serum Ratio	9	4.58	2.04	0.79	7.61	-0.059	0.880
			Biomarker	9	-0.24	0.82	-2.35	0.55		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level F2-Isoprostane	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	6.69	0.78	5.95	7.66	-0.673	0.213
			Biomarker	5	9.69	26.15	-12.79	54.77		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.371	0.412
			Biomarker	7	-5.95	37.98	-57.61	52.72		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	1	5.65		5.65	5.65		
			Biomarker	1	-4.75		-4.75	-4.75		
		Placebo	Albumin CSF/Serum Ratio	2	6.32	0.66	5.85	6.79	-1.000	
			Biomarker	2	-0.25	2.36	-1.92	1.42		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Phospho Tau	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.061	0.909
			Biomarker	6	-1.26	6.51	-10.91	6.69		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.161	0.731
			Biomarker	7	1.49	10.26	-12.41	21.45		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.222	0.393
			Biomarker	17	0.35	19.09	-19.32	69.95		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	0.197	0.420
			Biomarker	19	-6.81	18.65	-73.26	9.33		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

14FEB2013

Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Tau protein	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.297	0.568
			Biomarker	6	-177.19	616.43	-1429.7	148.80		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.044	0.925
			Biomarker	7	-26.88	84.97	-197.23	52.80		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.111	0.673
			Biomarker	17	-93.51	373.09	-1424.8	378.54		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.080	0.745
			Biomarker	19	-10.47	121.95	-433.96	103.56		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

14FEB2013

Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Plasma level Aß1-40	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.488	0.327
			Biomarker	22	5.28	32.72	-79.60	93.18		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.733	0.039
			Biomarker	24	4.22	26.52	-78.64	46.44		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.023	0.932
			Biomarker	20	-2.76	44.43	-97.40	103.73		
		Placebo	Albumin CSF/Serum Ratio	20	5.33	1.82	0.79	9.15	-0.113	0.636
			Biomarker	26	-1.47	26.80	-90.94	47.58		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

 14FEB2013

Intention-To-Treat Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Plasma level Aß1-42	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30		
			Biomarker	22	-0.17	9.12	-31.33	27.70		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.468	0.243
			Biomarker	24	0.36	8.91	-31.47	24.10		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.186	0.490
			Biomarker	20	-1.31	39.84	-124.10	102.47		
		Placebo	Albumin CSF/Serum Ratio	20	5.33	1.82	0.79	9.15	0.032	0.895
			Biomarker	26	4.66	25.95	-31.47	125.12		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

14FEB2013

Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Albumin (CSF)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.570	0.430
			Biomarker	4	0.02	0.04	-0.03	0.07		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.259	0.575
			Biomarker	7	-0.01	0.05	-0.10	0.05		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.142	0.661
			Biomarker	12	0.00	0.03	-0.05	0.05		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	0.638	0.003
			Biomarker	19	-0.03	0.13	-0.53	0.11		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

 14FEB2013

Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Aß1-40	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.101	0.899
			Biomarker	4	-742.53	1160.53	-2251.2	347.20		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.003	0.996
			Biomarker	6	51.13	953.88	-1487.6	1343.35		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.360	0.251
			Biomarker	12	-14.04	1694.46	-3650.7	3175.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	0.228	0.363
			Biomarker	18	-556.48	1578.97	-3810.2	1610.80		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Aß1-42	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.241	0.759
			Biomarker	4	-74.80	170.78	-291.87	62.42		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.017	0.975
			Biomarker	6	-10.29	23.57	-48.84	18.42		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.396	0.202
			Biomarker	12	-4.73	240.80	-417.14	484.98		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	0.490	0.039
			Biomarker	18	-68.33	237.10	-794.96	142.56		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level BACE-1	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	5	3.89	2.05	2.33	7.44	0.096	0.877
			Biomarker	5	0.02	0.80	-1.20	0.77		
		Placebo	Albumin CSF/Serum Ratio	9	4.58	2.04	0.79	7.61	-0.059	0.880
			Biomarker	9	-0.24	0.82	-2.35	0.55		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level F2-Isoprostane	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.538	0.462
			Biomarker	4	15.31	26.48	0.00	54.77		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.371	0.412
			Biomarker	7	-5.95	37.98	-57.61	52.72		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	1	5.65		5.65	5.65		
			Biomarker	1	-4.75		-4.75	-4.75		
		Placebo	Albumin CSF/Serum Ratio	2	6.32	0.66	5.85	6.79	-1.000	
			Biomarker	2	-0.25	2.36	-1.92	1.42		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Phospho Tau	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.137	0.863
			Biomarker	4	-1.92	6.29	-10.91	3.74		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.166	0.753
			Biomarker	6	1.57	11.24	-12.41	21.45		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.438	0.155
			Biomarker	12	2.42	22.43	-19.32	69.95		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	0.197	0.434
			Biomarker	18	-6.85	19.19	-73.26	9.33		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
CSF level Tau protein	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.059	0.941
			Biomarker	4	-333.49	731.76	-1429.7	83.88		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.041	0.938
			Biomarker	6	-20.08	90.96	-197.23	52.80		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.291	0.359
			Biomarker	12	-90.14	436.37	-1424.8	378.54		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	-0.082	0.747
			Biomarker	18	-7.88	124.95	-433.96	103.56		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

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Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Plasma level Aß1-40	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.000	1.000
			Biomarker	10	-0.16	21.99	-52.40	35.44		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.689	0.087
			Biomarker	18	6.53	20.57	-29.24	45.77		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.322	0.335
			Biomarker	14	-10.47	19.62	-53.87	15.61		
		Placebo	Albumin CSF/Serum Ratio	19	5.34	1.87	0.79	9.15	-0.112	0.647
			Biomarker	23	-3.27	27.86	-90.94	47.58		

Table 14.2.1.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Biomarkers

 14FEB2013

Per Protocol Population

Biomarker	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Plasma level Aß1-42	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37		
			Biomarker	10	2.77	8.76	0.00	27.70		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.567	0.185
			Biomarker	18	0.48	10.36	-31.47	24.10		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	0.316	0.344
			Biomarker	14	-1.55	44.61	-124.10	102.47		
		Placebo	Albumin CSF/Serum Ratio	19	5.34	1.87	0.79	9.15	0.032	0.897
			Biomarker	23	5.27	27.61	-31.47	125.12		

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Controlled Oral Word Association Test (COWAT) - FAS	Treatment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	ACI-91	SCREENING	32	26.3	15.0	56.9	7	22.5	70
		V1 (WEEK 0)	31	27.3	13.9	51.0	2	26.0	75
		V3 (WEEK 12)	27	23.8	13.9	58.3	1	25.0	61
		V4 (WEEK 24)	23	24.1	13.8	57.1	3	25.0	68
		V5 (WEEK 36)	22	25.0	14.1	56.4	3	23.5	59
		V6 (WEEK 52)	28	20.8	12.4	59.5	0	21.5	43
		V7 (WEEK 56)	22	23.1	14.3	61.8	1	21.5	62
		V3 (WEEK 12) - V1 (WEEK 0)	26	-2.3	6.5		-14	-1.5	7
		V4 (WEEK 24) - V1 (WEEK 0)	22	-3.9	8.2		-20	-2.5	8
		V5 (WEEK 36) - V1 (WEEK 0)	21	-3.5	10.2		-25	-5.0	13
		V6 (WEEK 52) - V1 (WEEK 0)	27	-5.4	10.2		-36	-3.0	12
		V7 (WEEK 56) - V1 (WEEK 0)	21	-5.9	8.3		-21	-7.0	12
		V7 (WEEK 56) - V6 (WEEK 52)	22	1.2	6.3		-8	0.5	23

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Controlled Oral Word Association Test (COWAT) - FAS	Treatment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	Placebo	SCREENING	31	21.9	8.9	40.4	4	22.0	40
		V1 (WEEK 0)	31	22.0	9.5	43.1	5	22.0	41
		V3 (WEEK 12)	30	21.1	9.8	46.3	2	22.0	43
		V4 (WEEK 24)	30	20.4	10.9	53.8	3	23.0	43
		V5 (WEEK 36)	28	21.3	9.6	44.9	1	21.5	36
		V6 (WEEK 52)	31	17.9	9.7	54.3	2	18.0	43
		V7 (WEEK 56)	27	20.3	11.1	54.8	4	20.0	53
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.5	5.9		-10	-1.5	11
		V4 (WEEK 24) - V1 (WEEK 0)	30	-2.2	7.1		-19	-2.5	11
		V5 (WEEK 36) - V1 (WEEK 0)	28	-2.3	5.4		-13	-2.5	11
		V6 (WEEK 52) - V1 (WEEK 0)	31	-4.1	5.6		-19	-4.0	10
		V7 (WEEK 56) - V1 (WEEK 0)	27	-3.5	8.3		-16	-5.0	17
		V7 (WEEK 56) - V6 (WEEK 52)	27	0.7	5.9		-10	1.0	17

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Category Fluency Test (CFT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	ACI-91	SCREENING	32	11.6	5.1	43.7	3	10.5	24
		V1 (WEEK 0)	31	11.5	4.2	36.0	4	12.0	20
		V3 (WEEK 12)	27	8.8	4.4	50.3	0	9.0	18
		V4 (WEEK 24)	23	8.1	3.7	45.6	3	8.0	16
		V5 (WEEK 36)	22	8.2	3.4	41.6	3	8.0	16
		V6 (WEEK 52)	28	6.8	3.0	44.1	2	6.5	15
		V7 (WEEK 56)	22	8.3	5.8	69.7	1	8.0	21
		V3 (WEEK 12) - V1 (WEEK 0)	26	-2.2	3.0		-9	-2.5	4
		V4 (WEEK 24) - V1 (WEEK 0)	22	-3.2	2.0		-7	-3.0	0
		V5 (WEEK 36) - V1 (WEEK 0)	21	-3.3	2.7		-8	-4.0	2
		V6 (WEEK 52) - V1 (WEEK 0)	27	-4.5	2.7		-11	-5.0	0
		V7 (WEEK 56) - V1 (WEEK 0)	21	-3.3	3.7		-10	-4.0	7
		V7 (WEEK 56) - V6 (WEEK 52)	22	1.7	4.1		-3	1.0	13

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Category Fluency Test (CFT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	Placebo	SCREENING	31	9.0	4.4	49.3	2	9.0	21
		V1 (WEEK 0)	31	9.3	4.8	51.6	1	10.0	21
		V3 (WEEK 12)	30	9.8	3.8	39.1	1	10.0	17
		V4 (WEEK 24)	30	9.3	4.4	48.0	1	9.0	20
		V5 (WEEK 36)	28	8.7	3.8	43.8	0	9.5	18
		V6 (WEEK 52)	31	7.6	3.5	45.5	2	8.0	14
		V7 (WEEK 56)	27	7.9	3.5	44.2	1	8.0	15
		V3 (WEEK 12) - V1 (WEEK 0)	30	0.6	3.5		-6	0.5	9
		V4 (WEEK 24) - V1 (WEEK 0)	30	-0.2	3.0		-6	-0.5	10
		V5 (WEEK 36) - V1 (WEEK 0)	28	-1.1	2.9		-6	-1.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	31	-1.7	3.3		-10	-1.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	27	-1.9	3.8		-9	-2.0	6
		V7 (WEEK 56) - V6 (WEEK 52)	27	0.1	2.7		-5	1.0	6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails A Derived Upper Limit	ACI-91	SCREENING	31	90.5	56.1	62.0	29	70.0	180
		V1 (WEEK 0)	28	83.2	47.4	56.9	21	72.5	180
		V3 (WEEK 12)	24	92.6	49.7	53.6	31	81.0	180
		V4 (WEEK 24)	22	100.2	48.5	48.4	35	95.0	180
		V5 (WEEK 36)	22	114.1	56.4	49.4	40	115.0	180
		V6 (WEEK 52)	25	110.4	55.1	49.9	35	105.0	180
		V7 (WEEK 56)	21	118.2	58.4	49.4	33	125.0	180
		V3 (WEEK 12) - V1 (WEEK 0)	23	9.4	34.0		-56	0.0	87
		V4 (WEEK 24) - V1 (WEEK 0)	21	12.7	33.7		-66	10.0	76
		V5 (WEEK 36) - V1 (WEEK 0)	21	30.4	38.3		-35	30.0	111
		V6 (WEEK 52) - V1 (WEEK 0)	24	29.0	52.2		-74	25.5	131
		V7 (WEEK 56) - V1 (WEEK 0)	20	36.9	50.5		-41	26.0	131
		V7 (WEEK 56) - V6 (WEEK 52)	21	9.0	44.3		-94	0.0	101

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails A Derived Upper Limit	Placebo	SCREENING	29	79.5	44.2	55.6	31	69.0	180
		V1 (WEEK 0)	29	83.3	47.1	56.5	25	65.0	180
		V3 (WEEK 12)	29	92.6	52.8	57.1	30	69.0	180
		V4 (WEEK 24)	28	92.3	48.9	53.0	25	75.0	180
		V5 (WEEK 36)	27	94.8	50.7	53.5	33	87.0	180
		V6 (WEEK 52)	30	97.7	52.9	54.1	32	76.0	180
		V7 (WEEK 56)	25	92.9	49.3	53.0	33	79.0	180
		V3 (WEEK 12) - V1 (WEEK 0)	28	5.0	20.9		-36	1.0	67
		V4 (WEEK 24) - V1 (WEEK 0)	27	12.3	30.8		-41	5.0	104
		V5 (WEEK 36) - V1 (WEEK 0)	26	9.7	24.4		-33	6.0	57
		V6 (WEEK 52) - V1 (WEEK 0)	29	11.6	27.5		-33	5.0	72
		V7 (WEEK 56) - V1 (WEEK 0)	24	14.9	27.9		-37	14.0	73
		V7 (WEEK 56) - V6 (WEEK 52)	25	1.0	19.3		-35	0.0	45

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails B Derived Upper Limit	ACI-91	SCREENING	27	222.7	86.0	38.6	87	270.0	300
		V1 (WEEK 0)	23	185.9	81.8	44.0	50	160.0	300
		V3 (WEEK 12)	21	203.9	89.2	43.7	71	205.0	300
		V4 (WEEK 24)	18	206.6	88.1	42.7	87	204.0	300
		V5 (WEEK 36)	17	210.7	84.7	40.2	84	200.0	300
		V6 (WEEK 52)	21	228.3	79.9	35.0	50	252.0	300
		V7 (WEEK 56)	16	190.0	86.0	45.3	70	185.0	300
		V3 (WEEK 12) - V1 (WEEK 0)	19	15.8	40.9		-70	0.0	85
		V4 (WEEK 24) - V1 (WEEK 0)	16	13.3	31.1		-30	4.0	114
		V5 (WEEK 36) - V1 (WEEK 0)	15	28.9	49.3		-34	4.0	175
		V6 (WEEK 52) - V1 (WEEK 0)	19	36.7	62.9		-63	34.0	164
		V7 (WEEK 56) - V1 (WEEK 0)	15	12.8	57.8		-55	0.0	146
		V7 (WEEK 56) - V6 (WEEK 52)	16	-22.6	46.1		-110	0.0	50

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails B Derived Upper Limit	Placebo	SCREENING	24	202.5	72.7	35.9	89	195.0	300
		V1 (WEEK 0)	25	192.1	81.2	42.2	60	199.0	300
		V3 (WEEK 12)	25	210.0	79.2	37.7	75	209.0	300
		V4 (WEEK 24)	23	198.7	78.6	39.6	94	175.0	300
		V5 (WEEK 36)	21	204.4	75.0	36.7	97	195.0	300
		V6 (WEEK 52)	26	222.3	75.8	34.1	102	235.5	300
		V7 (WEEK 56)	19	193.5	74.9	38.7	95	173.0	300
		V3 (WEEK 12) - V1 (WEEK 0)	22	14.4	59.7		-78	5.0	230
		V4 (WEEK 24) - V1 (WEEK 0)	20	-5.6	62.0		-185	0.0	93
		V5 (WEEK 36) - V1 (WEEK 0)	21	11.0	32.2		-56	0.0	63
		V6 (WEEK 52) - V1 (WEEK 0)	23	22.1	71.7		-185	11.0	230
		V7 (WEEK 56) - V1 (WEEK 0)	18	13.3	49.0		-127	13.0	86
		V7 (WEEK 56) - V6 (WEEK 52)	19	-9.8	34.0		-103	-7.0	58

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Simple Reaction Time (SRT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Simple Reaction Time (SRT)	ACI-91	SCREENING	30	599.5	299.5	50.0	296	505.5	1445
		V1 (WEEK 0)	28	674.8	445.4	66.0	300	435.0	1687
		V3 (WEEK 12)	24	834.0	448.4	53.8	299	662.5	1752
		V4 (WEEK 24)	20	784.6	431.9	55.1	310	706.0	1895
		V5 (WEEK 36)	20	940.1	609.1	64.8	285	666.5	2123
		V6 (WEEK 52)	25	901.1	459.7	51.0	328	852.0	2053
		V7 (WEEK 56)	20	968.2	679.2	70.2	304	731.0	2569
		V3 (WEEK 12) - V1 (WEEK 0)	22	131.4	288.3		-588	61.0	637
		V4 (WEEK 24) - V1 (WEEK 0)	18	87.1	380.6		-570	24.5	830
		V5 (WEEK 36) - V1 (WEEK 0)	17	232.7	306.1		-360	229.0	811
		V6 (WEEK 52) - V1 (WEEK 0)	22	185.9	311.6		-588	157.5	620
		V7 (WEEK 56) - V1 (WEEK 0)	17	259.8	401.6		-325	111.0	1122
		V7 (WEEK 56) - V6 (WEEK 52)	20	69.5	304.9		-249	-31.0	1054

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Simple Reaction Time (SRT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Simple Reaction Time (SRT)	Placebo	SCREENING	28	648.9	403.3	62.2	290	507.0	1859
		V1 (WEEK 0)	27	614.6	412.2	67.1	255	461.0	1859
		V3 (WEEK 12)	24	563.6	321.5	57.1	228	472.0	1544
		V4 (WEEK 24)	26	596.0	305.0	51.2	312	484.5	1343
		V5 (WEEK 36)	26	648.4	460.9	71.1	336	507.0	2284
		V6 (WEEK 52)	27	641.1	361.8	56.4	307	549.0	1832
		V7 (WEEK 56)	18	729.8	509.6	69.8	251	468.5	1977
		V3 (WEEK 12) - V1 (WEEK 0)	24	-20.7	225.3		-495	-8.0	513
		V4 (WEEK 24) - V1 (WEEK 0)	26	-24.1	353.7		-1314	36.5	511
		V5 (WEEK 36) - V1 (WEEK 0)	26	77.7	364.8		-377	44.0	1634
		V6 (WEEK 52) - V1 (WEEK 0)	27	26.6	327.0		-1314	73.0	687
		V7 (WEEK 56) - V1 (WEEK 0)	18	145.9	277.4		-206	39.5	828
		V7 (WEEK 56) - V6 (WEEK 52)	18	52.4	220.8		-294	22.0	819

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Choice Reaction Time – GNG (CRTGNG)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Go/NoGo (CRTGNG)	ACI-91	SCREENING	27	542.9	112.3	20.7	369	521.0	792
		V1 (WEEK 0)	27	506.3	84.6	16.7	401	486.0	697
		V3 (WEEK 12)	22	572.1	172.4	30.1	376	513.5	1076
		V4 (WEEK 24)	19	558.8	111.7	20.0	387	559.0	832
		V5 (WEEK 36)	19	588.9	103.9	17.6	386	592.0	820
		V6 (WEEK 52)	24	605.2	165.2	27.3	416	560.5	1076
		V7 (WEEK 56)	19	572.0	104.0	18.2	412	573.0	765
		V3 (WEEK 12) - V1 (WEEK 0)	19	48.9	106.3		-184	24.0	289
		V4 (WEEK 24) - V1 (WEEK 0)	16	42.1	114.7		-138	26.0	266
		V5 (WEEK 36) - V1 (WEEK 0)	16	82.4	82.6		-46	68.5	203
		V6 (WEEK 52) - V1 (WEEK 0)	20	88.3	105.8		-138	74.5	319
		V7 (WEEK 56) - V1 (WEEK 0)	17	69.8	98.9		-72	52.0	313
		V7 (WEEK 56) - V6 (WEEK 52)	19	-4.9	111.6		-341	12.0	163

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Choice Reaction Time – GNG (CRTGNG)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Go/NoGo (CRTGNG)	Placebo	SCREENING	24	526.2	112.2	21.3	362	509.0	925
		V1 (WEEK 0)	25	507.6	100.7	19.8	368	478.0	774
		V3 (WEEK 12)	24	500.9	122.4	24.4	340	469.5	921
		V4 (WEEK 24)	23	481.7	81.8	17.0	354	453.0	663
		V5 (WEEK 36)	25	512.1	116.8	22.8	359	481.0	757
		V6 (WEEK 52)	27	533.9	105.1	19.7	373	509.0	832
		V7 (WEEK 56)	17	508.4	111.6	21.9	378	475.0	715
		V3 (WEEK 12) - V1 (WEEK 0)	23	-7.3	77.5		-180	-13.0	147
		V4 (WEEK 24) - V1 (WEEK 0)	22	-24.1	95.3		-253	-23.5	151
		V5 (WEEK 36) - V1 (WEEK 0)	24	3.8	65.5		-132	-15.0	147
		V6 (WEEK 52) - V1 (WEEK 0)	25	28.6	82.4		-195	40.0	216
		V7 (WEEK 56) - V1 (WEEK 0)	17	15.6	79.3		-90	1.0	182
		V7 (WEEK 56) - V6 (WEEK 52)	17	-20.2	65.8		-162	-10.0	92

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Choice Reaction Time – MSO	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	ACI-91	SCREENING	29	1027.1	322.2	31.4	514	915.0	1687
		V1 (WEEK 0)	30	1040.9	329.0	31.6	555	978.0	1887
		V3 (WEEK 12)	23	1003.0	342.0	34.1	567	1025.0	1773
		V4 (WEEK 24)	20	996.8	277.6	27.8	595	908.0	1536
		V5 (WEEK 36)	20	1086.2	261.0	24.0	663	1148.5	1437
		V6 (WEEK 52)	24	1023.5	338.6	33.1	483	990.0	1773
		V7 (WEEK 56)	20	993.2	234.3	23.6	545	968.5	1436
		V3 (WEEK 12) - V1 (WEEK 0)	22	7.5	308.1		-721	-10.0	830
		V4 (WEEK 24) - V1 (WEEK 0)	19	26.1	191.1		-250	6.0	416
		V5 (WEEK 36) - V1 (WEEK 0)	19	100.8	219.6		-371	53.0	455
		V6 (WEEK 52) - V1 (WEEK 0)	23	33.8	312.9		-653	11.0	639
		V7 (WEEK 56) - V1 (WEEK 0)	19	10.6	167.7		-310	-9.0	395
		V7 (WEEK 56) - V6 (WEEK 52)	20	-14.0	275.9		-583	-20.0	554

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Choice Reaction Time – MSO	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	Placebo	SCREENING	24	911.8	275.4	30.2	589	835.0	1663
		V1 (WEEK 0)	26	958.5	373.2	38.9	602	833.0	1700
		V3 (WEEK 12)	24	855.1	303.8	35.5	527	791.0	1637
		V4 (WEEK 24)	25	924.3	348.3	37.7	522	849.0	1692
		V5 (WEEK 36)	23	947.9	323.2	34.1	503	951.0	1580
		V6 (WEEK 52)	27	934.5	301.8	32.3	497	824.0	1612
		V7 (WEEK 56)	19	819.6	309.6	37.8	500	720.0	1666
		V3 (WEEK 12) - V1 (WEEK 0)	23	-163.7	298.6		-909	-140.0	215
		V4 (WEEK 24) - V1 (WEEK 0)	24	-86.5	338.6		-899	-49.0	345
		V5 (WEEK 36) - V1 (WEEK 0)	22	-17.2	196.6		-547	-10.0	326
		V6 (WEEK 52) - V1 (WEEK 0)	26	-29.1	364.6		-1006	0.0	740
		V7 (WEEK 56) - V1 (WEEK 0)	19	-21.6	145.5		-239	-27.0	267
		V7 (WEEK 56) - V6 (WEEK 52)	19	-81.6	206.8		-735	-13.0	183

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Easy)-Derived	ACI-91	SCREENING	32	7.5	2.9	39.0	2	8.0	12
		V1 (WEEK 0)	31	8.6	2.8	32.0	1	9.0	12
		V3 (WEEK 12)	27	7.5	3.1	40.8	1	8.0	12
		V4 (WEEK 24)	21	8.0	2.9	36.8	2	8.0	12
		V5 (WEEK 36)	20	8.5	3.2	37.5	3	9.5	12
		V6 (WEEK 52)	28	8.0	3.4	42.8	1	9.0	12
		V7 (WEEK 56)	20	8.6	3.6	41.4	1	9.0	12
		V3 (WEEK 12) - V1 (WEEK 0)	26	-0.9	3.9		-11	0.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	20	-0.9	3.2		-8	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	19	-0.2	3.0		-5	0.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.6	3.3		-9	0.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	19	-0.3	3.3		-7	0.0	6
		V7 (WEEK 56) - V6 (WEEK 52)	20	-0.1	2.7		-7	1.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Easy)-Derived	Placebo	SCREENING	29	6.4	3.7	57.2	0	7.0	12
		V1 (WEEK 0)	28	7.6	3.7	47.9	0	9.0	12
		V3 (WEEK 12)	25	8.1	3.3	40.6	1	8.0	12
		V4 (WEEK 24)	25	8.7	3.4	39.5	0	9.0	12
		V5 (WEEK 36)	25	8.7	3.5	39.8	0	10.0	12
		V6 (WEEK 52)	27	7.6	3.9	51.8	0	8.0	12
		V7 (WEEK 56)	24	8.4	3.9	46.2	0	9.5	12
		V3 (WEEK 12) - V1 (WEEK 0)	24	0.8	2.2		-4	0.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	25	1.0	2.4		-4	1.0	7
		V5 (WEEK 36) - V1 (WEEK 0)	25	1.0	2.4		-7	1.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	26	0.4	2.7		-7	0.5	6
		V7 (WEEK 56) - V1 (WEEK 0)	24	0.8	2.9		-7	1.0	6
		V7 (WEEK 56) - V6 (WEEK 52)	24	0.4	1.8		-4	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Hard)-Derived	ACI-91	SCREENING	32	2.1	2.6	125.6	0	1.0	9
		V1 (WEEK 0)	31	3.0	3.3	110.2	0	2.0	11
		V3 (WEEK 12)	27	2.0	2.5	126.3	0	1.0	8
		V4 (WEEK 24)	21	2.5	2.7	107.3	0	2.0	8
		V5 (WEEK 36)	20	1.7	2.3	132.4	0	0.0	7
		V6 (WEEK 52)	28	1.9	2.7	137.5	0	1.0	9
		V7 (WEEK 56)	20	2.1	2.6	125.1	0	1.0	8
		V3 (WEEK 12) - V1 (WEEK 0)	26	-0.9	2.4		-8	0.0	2
		V4 (WEEK 24) - V1 (WEEK 0)	20	-0.2	1.2		-2	0.0	2
		V5 (WEEK 36) - V1 (WEEK 0)	19	-1.3	1.8		-7	-1.0	1
		V6 (WEEK 52) - V1 (WEEK 0)	27	-1.0	2.5		-8	0.0	2
		V7 (WEEK 56) - V1 (WEEK 0)	19	-1.1	1.9		-7	0.0	1
		V7 (WEEK 56) - V6 (WEEK 52)	20	-0.4	0.8		-2	0.0	2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Hard)-Derived	Placebo	SCREENING	29	1.3	2.2	167.1	0	0.0	7
		V1 (WEEK 0)	28	2.5	3.6	143.4	0	0.0	11
		V3 (WEEK 12)	25	2.1	3.1	151.3	0	0.0	10
		V4 (WEEK 24)	25	2.8	3.6	127.9	0	0.0	9
		V5 (WEEK 36)	25	2.2	3.1	139.0	0	0.0	10
		V6 (WEEK 52)	27	1.8	2.5	136.7	0	0.0	7
		V7 (WEEK 56)	24	2.9	3.3	114.8	0	1.0	9
		V3 (WEEK 12) - V1 (WEEK 0)	24	-0.6	1.5		-6	0.0	1
		V4 (WEEK 24) - V1 (WEEK 0)	25	0.0	1.6		-5	0.0	4
		V5 (WEEK 36) - V1 (WEEK 0)	25	-0.6	1.3		-4	0.0	1
		V6 (WEEK 52) - V1 (WEEK 0)	26	-0.8	1.9		-5	0.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	24	-0.0	2.3		-5	0.0	7
		V7 (WEEK 56) - V6 (WEEK 52)	24	0.8	1.5		-1	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Total)-Derived	ACI-91	SCREENING	32	9.6	4.7	48.9	2	9.0	20
		V1 (WEEK 0)	31	11.6	5.1	44.1	2	12.0	23
		V3 (WEEK 12)	27	9.5	4.2	44.5	2	10.0	18
		V4 (WEEK 24)	21	10.4	4.6	44.1	2	11.0	18
		V5 (WEEK 36)	20	10.2	4.1	40.4	3	10.5	18
		V6 (WEEK 52)	28	10.0	4.7	47.4	1	10.5	20
		V7 (WEEK 56)	20	10.7	4.6	43.4	1	11.0	18
		V3 (WEEK 12) - V1 (WEEK 0)	26	-1.8	5.5		-17	-1.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	20	-1.1	3.2		-6	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	19	-1.4	4.0		-8	-1.0	7
		V6 (WEEK 52) - V1 (WEEK 0)	27	-1.6	4.6		-17	-1.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	19	-1.4	4.3		-11	0.0	7
		V7 (WEEK 56) - V6 (WEEK 52)	20	-0.4	3.0		-7	-0.5	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treatment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Total)-Derived	Placebo	SCREENING	29	7.7	5.2	67.9	0	7.0	18
		V1 (WEEK 0)	28	10.1	6.1	59.7	0	10.0	22
		V3 (WEEK 12)	25	10.2	5.4	53.4	1	9.0	22
		V4 (WEEK 24)	25	11.5	5.7	49.4	0	12.0	21
		V5 (WEEK 36)	25	11.0	5.7	51.9	0	12.0	21
		V6 (WEEK 52)	27	9.4	5.6	59.9	0	9.0	19
		V7 (WEEK 56)	24	11.3	6.4	57.1	0	11.0	21
		V3 (WEEK 12) - V1 (WEEK 0)	24	0.1	2.7		-6	0.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	25	1.0	2.7		-4	1.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	25	0.4	2.7		-7	0.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	26	-0.4	3.4		-7	0.0	7
		V7 (WEEK 56) - V1 (WEEK 0)	24	0.8	3.7		-7	1.0	9
		V7 (WEEK 56) - V6 (WEEK 52)	24	1.2	2.7		-4	1.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Delayed Trial (Sum Easy/Hard)	ACI-91	SCREENING	32	3.0	2.2	73.8	0	3.0	8
		V1 (WEEK 0)	31	3.6	2.1	58.9	0	4.0	7
		V3 (WEEK 12)	26	3.2	2.2	69.8	0	2.5	8
		V4 (WEEK 24)	21	3.1	1.8	59.5	1	3.0	7
		V5 (WEEK 36)	20	3.3	2.0	59.9	0	3.0	7
		V6 (WEEK 52)	27	2.5	2.1	84.9	0	2.0	8
		V7 (WEEK 56)	20	2.8	2.3	84.2	0	2.5	7
		V3 (WEEK 12) - V1 (WEEK 0)	25	-0.3	1.8		-5	0.0	3
		V4 (WEEK 24) - V1 (WEEK 0)	20	-0.6	1.5		-3	-1.0	3
		V5 (WEEK 36) - V1 (WEEK 0)	19	-0.5	1.6		-4	0.0	2
		V6 (WEEK 52) - V1 (WEEK 0)	26	-1.1	1.6		-4	-1.0	2
		V7 (WEEK 56) - V1 (WEEK 0)	19	-1.2	2.1		-6	0.0	1
		V7 (WEEK 56) - V6 (WEEK 52)	20	-0.1	1.6		-5	0.5	2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Delayed Trial (Sum Easy/Hard)	Placebo	SCREENING	25	3.1	2.3	74.8	0	2.0	8
		V1 (WEEK 0)	27	3.3	2.2	68.4	0	3.0	8
		V3 (WEEK 12)	25	3.2	2.3	72.2	0	3.0	8
		V4 (WEEK 24)	24	3.2	2.0	62.3	0	3.0	7
		V5 (WEEK 36)	24	3.5	2.6	73.0	0	3.5	8
		V6 (WEEK 52)	26	2.9	2.5	85.7	0	2.0	8
		V7 (WEEK 56)	23	3.3	2.6	76.7	0	3.0	8
		V3 (WEEK 12) - V1 (WEEK 0)	24	0.0	1.4		-2	0.0	3
		V4 (WEEK 24) - V1 (WEEK 0)	24	-0.3	1.3		-3	0.0	2
		V5 (WEEK 36) - V1 (WEEK 0)	24	0.0	1.7		-3	0.0	3
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.4	2.0		-6	0.0	3
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.2	1.6		-3	0.0	3
		V7 (WEEK 56) - V6 (WEEK 52)	23	0.3	1.9		-2	0.0	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	ACI-91	SCREENING	32	17.9	6.7	37.5	9	17.0	34
		V1 (WEEK 0)	32	18.2	6.8	37.1	8	16.5	36
		V3 (WEEK 12)	28	23.5	9.0	38.4	9	22.5	45
		V4 (WEEK 24)	24	24.8	9.7	39.1	9	25.0	46
		V5 (WEEK 36)	22	26.5	9.9	37.5	12	24.5	45
		V6 (WEEK 52)	29	29.0	12.7	43.7	12	26.0	61
		V7 (WEEK 56)	22	26.5	12.7	48.0	10	21.5	56
		V3 (WEEK 12) - V1 (WEEK 0)	28	4.5	6.9		-5	3.5	23
		V4 (WEEK 24) - V1 (WEEK 0)	24	6.8	8.4		-7	6.0	31
		V5 (WEEK 36) - V1 (WEEK 0)	22	8.4	8.8		-1	6.0	36
		V6 (WEEK 52) - V1 (WEEK 0)	29	10.1	9.9		-5	8.0	32
		V7 (WEEK 56) - V1 (WEEK 0)	22	8.3	10.6		-4	5.5	35
		V7 (WEEK 56) - V6 (WEEK 52)	22	-1.9	6.4		-12	-2.0	11

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	Placebo	SCREENING	31	18.6	6.8	36.3	9	18.0	37
		V1 (WEEK 0)	31	19.8	8.1	40.8	9	19.0	43
		V3 (WEEK 12)	31	19.1	8.9	46.4	7	18.0	48
		V4 (WEEK 24)	31	21.5	9.9	45.7	7	21.0	47
		V5 (WEEK 36)	29	21.4	10.2	47.7	9	19.0	48
		V6 (WEEK 52)	31	25.5	10.2	40.2	7	22.0	45
		V7 (WEEK 56)	27	23.6	10.9	46.5	9	20.0	49
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.7	5.4		-15	0.0	13
		V4 (WEEK 24) - V1 (WEEK 0)	31	1.8	6.0		-10	1.0	18
		V5 (WEEK 36) - V1 (WEEK 0)	29	2.2	6.1		-7	2.0	21
		V6 (WEEK 52) - V1 (WEEK 0)	31	5.7	8.1		-9	6.0	22
		V7 (WEEK 56) - V1 (WEEK 0)	27	4.3	7.5		-5	2.0	21
		V7 (WEEK 56) - V6 (WEEK 52)	27	-1.0	4.4		-8	-1.0	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Modified Total ADAS-cog (Subtests 1-12)	ACI-91	SCREENING	32	26.0	8.0	30.7	10	25.0	43
		V1 (WEEK 0)	32	26.9	7.6	28.2	13	25.0	46
		V3 (WEEK 12)	28	32.5	9.9	30.3	14	32.0	55
		V4 (WEEK 24)	24	34.1	10.5	30.7	13	33.0	55
		V5 (WEEK 36)	22	35.6	10.8	30.3	20	34.5	55
		V6 (WEEK 52)	29	38.4	13.0	33.8	22	36.0	71
		V7 (WEEK 56)	22	35.8	13.4	37.5	15	31.0	66
		V3 (WEEK 12) - V1 (WEEK 0)	28	4.8	7.4		-7	3.0	25
		V4 (WEEK 24) - V1 (WEEK 0)	24	7.2	8.4		-10	6.5	30
		V5 (WEEK 36) - V1 (WEEK 0)	22	8.6	9.1		-2	6.0	38
		V6 (WEEK 52) - V1 (WEEK 0)	29	10.7	9.8		-6	9.0	32
		V7 (WEEK 56) - V1 (WEEK 0)	22	8.8	10.7		-4	5.5	35
		V7 (WEEK 56) - V6 (WEEK 52)	22	-2.1	6.5		-12	-2.0	11

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Modified Total ADAS-cog (Subtests 1-12)	Placebo	SCREENING	31	27.1	7.8	28.9	13	27.0	47
		V1 (WEEK 0)	31	28.5	8.9	31.3	16	27.0	53
		V3 (WEEK 12)	31	28.0	9.6	34.5	14	27.0	58
		V4 (WEEK 24)	31	30.4	10.9	35.9	12	29.0	57
		V5 (WEEK 36)	29	30.1	11.1	37.1	15	28.0	58
		V6 (WEEK 52)	31	34.8	10.5	30.2	15	31.0	55
		V7 (WEEK 56)	27	32.3	11.8	36.5	16	30.0	59
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.5	5.5		-16	1.0	13
		V4 (WEEK 24) - V1 (WEEK 0)	31	1.9	6.5		-14	2.0	18
		V5 (WEEK 36) - V1 (WEEK 0)	29	2.2	6.5		-9	1.0	21
		V6 (WEEK 52) - V1 (WEEK 0)	31	6.4	8.7		-11	7.0	25
		V7 (WEEK 56) - V1 (WEEK 0)	27	4.5	8.3		-8	3.0	24
		V7 (WEEK 56) - V6 (WEEK 52)	27	-1.5	4.9		-9	-2.0	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Mini-Mental State Examination (MMSE)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
MMSE Score (Derived)	ACI-91	SCREENING	32	21.8	2.8	13.1	17	21.5	26
		V1 (WEEK 0)	32	22.6	2.9	12.9	18	23.0	28
		V4 (WEEK 24)	24	19.5	4.7	24.0	11	20.0	26
		V6 (WEEK 52)	26	18.1	5.7	31.2	5	20.0	26
		V4 (WEEK 24) - V1 (WEEK 0)	24	-2.9	3.9		-11	-2.0	2
		V6 (WEEK 52) - V1 (WEEK 0)	26	-4.5	4.5		-16	-4.0	2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Mini-Mental State Examination (MMSE)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
MMSE Score (Derived)	Placebo	SCREENING	31	21.6	2.3	10.7	18	21.0	26
		V1 (WEEK 0)	31	22.4	2.8	12.7	18	22.0	27
		V4 (WEEK 24)	31	21.3	4.7	21.9	7	21.0	27
		V6 (WEEK 52)	31	19.6	5.0	25.8	8	19.0	28
		V4 (WEEK 24) - V1 (WEEK 0)	31	-1.1	3.3		-12	-1.0	3
		V6 (WEEK 52) - V1 (WEEK 0)	31	-2.8	3.5		-11	-2.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Composite NTB z-score	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NTB composite z-score	ACI-91	SCREENING	23	26.3	7.4	27.9	14	25.6	42
		V1 (WEEK 0)	19	28.5	6.0	21.1	20	27.8	43
		V3 (WEEK 12)	16	27.3	6.4	23.6	19	27.6	42
		V4 (WEEK 24)	13	25.7	6.1	23.8	17	25.0	37
		V5 (WEEK 36)	16	26.0	6.2	23.7	16	25.3	35
		V6 (WEEK 52)	19	25.0	5.3	21.2	16	24.2	35
		V7 (WEEK 56)	15	27.4	7.4	26.9	19	26.4	41
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.3	3.5		-7	0.3	6
		V4 (WEEK 24) - V1 (WEEK 0)	9	-0.1	2.0		-3	-0.4	2
		V5 (WEEK 36) - V1 (WEEK 0)	11	-0.3	3.1		-7	-0.5	3
		V6 (WEEK 52) - V1 (WEEK 0)	13	-2.1	3.7		-9	-2.2	3
		V7 (WEEK 56) - V1 (WEEK 0)	12	0.1	4.8		-7	0.4	7
		V7 (WEEK 56) - V6 (WEEK 52)	15	1.1	4.2		-5	-0.2	12

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Composite NTB z-score	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NTB composite z-score	Placebo	SCREENING	17	26.7	6.0	22.5	19	27.3	44
		V1 (WEEK 0)	18	27.8	5.9	21.3	17	27.9	43
		V3 (WEEK 12)	17	29.3	6.7	22.7	19	29.5	46
		V4 (WEEK 24)	17	28.9	6.2	21.6	16	29.2	45
		V5 (WEEK 36)	15	29.7	6.3	21.3	17	29.7	43
		V6 (WEEK 52)	20	27.6	5.7	20.5	18	26.9	38
		V7 (WEEK 56)	14	30.0	6.0	20.1	18	32.5	37
		V3 (WEEK 12) - V1 (WEEK 0)	15	1.8	2.3		-3	2.1	5
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.9	2.0		-3	0.9	4
		V5 (WEEK 36) - V1 (WEEK 0)	14	2.1	2.6		-2	2.2	7
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.0	4.6		-11	1.2	6
		V7 (WEEK 56) - V1 (WEEK 0)	13	1.0	6.1		-10	1.7	11
		V7 (WEEK 56) - V6 (WEEK 52)	13	1.5	3.0		-3	0.7	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
CDR Sum Of Boxes	ACI-91	V1 (WEEK 0)	32	5.2	2.3	43.7	1	5.0	11
		V3 (WEEK 12)	28	6.4	2.8	42.8	2	6.0	12
		V4 (WEEK 24)	24	7.0	3.0	43.2	2	7.0	16
		V5 (WEEK 36)	22	7.8	3.5	45.5	2	7.0	15
		V6 (WEEK 52)	30	8.6	3.8	43.7	2	8.5	18
		V3 (WEEK 12) - V1 (WEEK 0)	28	1.1	1.6		-1	0.5	5
		V4 (WEEK 24) - V1 (WEEK 0)	24	1.8	2.9		-1	0.8	13
		V5 (WEEK 36) - V1 (WEEK 0)	22	2.4	2.9		-2	2.0	11
		V6 (WEEK 52) - V1 (WEEK 0)	30	3.4	3.2		-2	2.8	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Intention-To-Treat Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
CDR Sum Of Boxes	Placebo	V1 (WEEK 0)	31	5.0	2.4	47.6	1	4.0	11
		V3 (WEEK 12)	31	5.5	2.7	49.2	1	4.5	11
		V4 (WEEK 24)	31	5.8	2.9	50.3	1	5.0	13
		V5 (WEEK 36)	28	6.0	3.0	49.8	1	5.8	15
		V6 (WEEK 52)	31	6.6	3.1	47.2	1	6.5	15
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.5	1.4		-2	0.0	6
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.8	1.6		-2	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	28	1.2	2.0		-2	0.5	8
		V6 (WEEK 52) - V1 (WEEK 0)	31	1.6	2.2		-3	1.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Disability Assessment in Dementia (DAD) Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
DAD Percentage Total Score	ACI-91	V1 (WEEK 0)	32	74.5	22.6	30.4	23	77.9	100
		V3 (WEEK 12)	28	65.1	24.8	38.2	23	70.5	100
		V4 (WEEK 24)	24	61.7	27.3	44.3	8	70.0	100
		V5 (WEEK 36)	22	60.2	24.5	40.7	10	58.8	100
		V6 (WEEK 52)	31	57.4	27.7	48.3	0	57.5	100
		V3 (WEEK 12) - V1 (WEEK 0)	28	-8.4	15.7		-70	-3.8	20
		V4 (WEEK 24) - V1 (WEEK 0)	24	-12.7	20.5		-87	-7.5	15
		V5 (WEEK 36) - V1 (WEEK 0)	22	-13.0	14.0		-50	-10.0	5
		V6 (WEEK 52) - V1 (WEEK 0)	31	-16.5	21.8		-95	-16.8	25

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Disability Assessment in Dementia (DAD) Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
DAD Percentage Total Score	Placebo	V1 (WEEK 0)	31	77.2	18.7	24.2	43	80.0	100
		V3 (WEEK 12)	31	74.0	19.6	26.5	33	73.3	100
		V4 (WEEK 24)	31	70.9	20.5	28.8	15	70.0	100
		V5 (WEEK 36)	29	69.5	23.0	33.0	13	74.4	100
		V6 (WEEK 52)	31	69.9	21.3	30.5	3	73.0	100
		V3 (WEEK 12) - V1 (WEEK 0)	31	-3.3	10.6		-31	-2.5	23
		V4 (WEEK 24) - V1 (WEEK 0)	31	-6.3	12.0		-32	-3.3	28
		V5 (WEEK 36) - V1 (WEEK 0)	29	-7.4	14.5		-38	-7.4	24
		V6 (WEEK 52) - V1 (WEEK 0)	31	-7.3	14.1		-43	-5.0	24

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Frequency*Severity)	ACI-91	V1 (WEEK 0)	32	10.4	12.9	124.1	0	6.5	54
		V2 (WEEK 4)	31	11.8	12.9	109.2	0	8.0	47
		V3 (WEEK 12)	29	13.7	12.5	91.4	0	10.0	44
		V4 (WEEK 24)	24	10.2	10.3	100.8	0	8.0	48
		V5 (WEEK 36)	22	8.1	7.6	93.7	0	6.5	25
		V6 (WEEK 52)	32	12.6	11.6	92.2	0	9.5	46
		V7 (WEEK 56)	22	10.2	8.1	79.2	0	9.5	37
		V2 (WEEK 4) - V1 (WEEK 0)	31	1.1	7.5		-16	0.0	23
		V3 (WEEK 12) - V1 (WEEK 0)	29	2.3	10.6		-21	0.0	30
		V4 (WEEK 24) - V1 (WEEK 0)	24	-0.2	6.6		-20	0.5	9
		V5 (WEEK 36) - V1 (WEEK 0)	22	-2.3	12.5		-51	0.0	13
		V6 (WEEK 52) - V1 (WEEK 0)	32	2.2	13.0		-40	3.0	34
		V7 (WEEK 56) - V1 (WEEK 0)	22	-0.2	12.1		-40	2.5	25
		V7 (WEEK 56) - V6 (WEEK 52)	22	-1.9	4.5		-13	-1.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Frequency*Severity)	Placebo	V1 (WEEK 0)	31	8.3	10.6	128.9	0	5.0	46
		V2 (WEEK 4)	31	7.8	8.8	113.2	0	4.0	33
		V3 (WEEK 12)	31	7.0	10.0	143.3	0	4.0	40
		V4 (WEEK 24)	31	10.2	10.8	106.2	0	6.0	39
		V5 (WEEK 36)	29	10.6	10.7	101.1	0	6.0	47
		V6 (WEEK 52)	31	10.4	9.7	93.3	0	8.0	44
		V7 (WEEK 56)	28	10.6	13.1	122.9	0	7.5	50
		V2 (WEEK 4) - V1 (WEEK 0)	31	-0.5	5.7		-13	0.0	11
		V3 (WEEK 12) - V1 (WEEK 0)	31	-1.3	5.2		-15	0.0	8
		V4 (WEEK 24) - V1 (WEEK 0)	31	1.9	6.7		-12	0.0	15
		V5 (WEEK 36) - V1 (WEEK 0)	29	2.3	8.5		-19	0.0	22
		V6 (WEEK 52) - V1 (WEEK 0)	31	2.2	7.7		-18	2.0	20
		V7 (WEEK 56) - V1 (WEEK 0)	28	3.2	8.4		-9	0.5	25
		V7 (WEEK 56) - V6 (WEEK 52)	28	0.9	6.2		-14	0.0	14

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Distress)	ACI-91	V1 (WEEK 0)	32	6.4	8.1	127.0	0	3.0	32
		V2 (WEEK 4)	31	6.3	7.3	116.5	0	4.0	27
		V3 (WEEK 12)	29	7.7	9.3	120.7	0	5.0	44
		V4 (WEEK 24)	24	5.8	8.8	152.3	0	4.0	44
		V5 (WEEK 36)	22	3.5	5.1	144.5	0	2.0	22
		V6 (WEEK 52)	32	6.6	6.0	90.4	0	5.0	21
		V7 (WEEK 56)	22	4.7	4.2	89.6	0	4.0	16
		V2 (WEEK 4) - V1 (WEEK 0)	31	-0.3	5.1		-10	-1.0	21
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.7	5.9		-8	0.0	18
		V4 (WEEK 24) - V1 (WEEK 0)	24	0.0	4.7		-13	0.0	12
		V5 (WEEK 36) - V1 (WEEK 0)	22	-2.1	7.6		-32	0.0	5
		V6 (WEEK 52) - V1 (WEEK 0)	32	0.2	7.7		-28	0.5	18
		V7 (WEEK 56) - V1 (WEEK 0)	22	-0.9	7.8		-28	0.0	13
		V7 (WEEK 56) - V6 (WEEK 52)	22	-1.0	2.5		-7	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Intention-To-Treat Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Distress)	Placebo	V1 (WEEK 0)	31	6.0	7.1	117.9	0	3.0	26
		V2 (WEEK 4)	31	4.8	6.0	124.6	0	3.0	19
		V3 (WEEK 12)	31	4.1	5.3	128.8	0	3.0	21
		V4 (WEEK 24)	31	6.9	6.7	96.9	0	5.0	22
		V5 (WEEK 36)	29	5.8	5.9	101.1	0	4.0	20
		V6 (WEEK 52)	31	6.3	6.3	100.4	0	5.0	25
		V7 (WEEK 56)	28	5.8	7.5	129.6	0	3.5	27
		V2 (WEEK 4) - V1 (WEEK 0)	31	-1.2	5.0		-18	0.0	9
		V3 (WEEK 12) - V1 (WEEK 0)	31	-1.9	4.9		-20	0.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.9	4.7		-19	1.0	9
		V5 (WEEK 36) - V1 (WEEK 0)	29	0.1	5.1		-16	0.0	8
		V6 (WEEK 52) - V1 (WEEK 0)	31	0.3	5.0		-16	0.0	10
		V7 (WEEK 56) - V1 (WEEK 0)	28	0.8	3.9		-7	0.0	12
		V7 (WEEK 56) - V6 (WEEK 52)	28	0.2	3.1		-6	0.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Controlled Oral Word Association Test (COWAT) - FAS	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	ACI-91	SCREENING	17	28.9	17.3	59.9	7	24.0	70
		V1 (WEEK 0)	17	29.9	15.1	50.4	11	28.0	75
		V3 (WEEK 12)	17	28.9	14.0	48.4	1	28.0	61
		V4 (WEEK 24)	16	28.8	13.4	46.6	9	27.0	68
		V5 (WEEK 36)	17	27.6	14.6	52.9	3	25.0	59
		V6 (WEEK 52)	16	24.3	13.0	53.5	2	25.5	43
		V7 (WEEK 56)	17	25.3	15.2	60.2	1	23.0	62
		V3 (WEEK 12) - V1 (WEEK 0)	17	-1.0	6.4		-14	0.0	7
		V4 (WEEK 24) - V1 (WEEK 0)	16	-2.3	7.4		-18	-1.0	8
		V5 (WEEK 36) - V1 (WEEK 0)	17	-2.3	10.2		-25	-2.0	13
		V6 (WEEK 52) - V1 (WEEK 0)	16	-6.0	11.4		-36	-3.5	12
		V7 (WEEK 56) - V1 (WEEK 0)	17	-4.6	8.4		-21	-6.0	12
		V7 (WEEK 56) - V6 (WEEK 52)	16	1.7	6.7		-8	0.5	23

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Controlled Oral Word Association Test (COWAT) - FAS	Treatment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	Placebo	SCREENING	24	23.8	6.8	28.6	13	23.0	38
		V1 (WEEK 0)	24	25.1	7.9	31.4	11	25.5	41
		V3 (WEEK 12)	23	23.8	8.9	37.2	7	23.0	43
		V4 (WEEK 24)	24	22.7	10.3	45.3	4	25.0	43
		V5 (WEEK 36)	24	23.0	8.8	38.2	8	23.0	36
		V6 (WEEK 52)	24	20.5	8.9	43.7	6	21.5	43
		V7 (WEEK 56)	24	21.5	11.0	51.1	4	22.5	53
		V3 (WEEK 12) - V1 (WEEK 0)	23	-1.0	6.2		-10	-3.0	11
		V4 (WEEK 24) - V1 (WEEK 0)	24	-2.5	7.7		-19	-2.5	11
		V5 (WEEK 36) - V1 (WEEK 0)	24	-2.1	5.6		-13	-3.0	11
		V6 (WEEK 52) - V1 (WEEK 0)	24	-4.7	6.2		-19	-4.0	10
		V7 (WEEK 56) - V1 (WEEK 0)	24	-3.6	8.7		-16	-5.5	17
		V7 (WEEK 56) - V6 (WEEK 52)	24	1.0	6.2		-10	1.0	17

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Category Fluency Test (CFT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	ACI-91	SCREENING	17	12.4	5.2	42.1	5	10.0	23
		V1 (WEEK 0)	17	11.9	4.3	36.2	5	13.0	20
		V3 (WEEK 12)	17	10.1	4.5	45.1	0	11.0	18
		V4 (WEEK 24)	16	9.3	3.7	40.1	3	9.0	16
		V5 (WEEK 36)	17	9.0	3.5	38.7	3	9.0	16
		V6 (WEEK 52)	16	7.3	2.5	34.7	3	7.5	11
		V7 (WEEK 56)	17	9.4	5.8	61.9	1	10.0	21
		V3 (WEEK 12) - V1 (WEEK 0)	17	-1.8	3.5		-9	-1.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	16	-2.9	2.0		-7	-2.5	0
		V5 (WEEK 36) - V1 (WEEK 0)	17	-2.9	2.7		-8	-3.0	2
		V6 (WEEK 52) - V1 (WEEK 0)	16	-5.1	2.8		-11	-5.0	0
		V7 (WEEK 56) - V1 (WEEK 0)	17	-2.5	3.4		-7	-3.0	7
		V7 (WEEK 56) - V6 (WEEK 52)	16	2.6	4.1		-2	1.5	13

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Category Fluency Test (CFT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Total Words Acceptable	Placebo	SCREENING	24	9.4	4.7	49.6	2	9.0	21
		V1 (WEEK 0)	24	10.0	4.7	46.7	1	11.0	21
		V3 (WEEK 12)	23	10.1	3.9	39.1	1	10.0	17
		V4 (WEEK 24)	24	9.8	4.6	46.7	1	10.0	20
		V5 (WEEK 36)	24	8.9	3.9	43.6	0	10.0	18
		V6 (WEEK 52)	24	8.0	3.4	42.4	2	8.0	14
		V7 (WEEK 56)	24	7.7	3.5	45.7	1	8.0	15
		V3 (WEEK 12) - V1 (WEEK 0)	23	0.1	3.7		-6	0.0	9
		V4 (WEEK 24) - V1 (WEEK 0)	24	-0.3	3.2		-6	-0.5	10
		V5 (WEEK 36) - V1 (WEEK 0)	24	-1.1	2.9		-6	-1.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	24	-2.0	3.3		-10	-1.0	3
		V7 (WEEK 56) - V1 (WEEK 0)	24	-2.3	3.7		-9	-2.5	6
		V7 (WEEK 56) - V6 (WEEK 52)	24	-0.3	2.4		-5	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails A Derived Upper Limit	ACI-91	SCREENING	17	77.7	52.0	66.9	30	58.0	180
		V1 (WEEK 0)	17	79.7	47.9	60.1	21	69.0	180
		V3 (WEEK 12)	16	79.3	46.5	58.6	31	69.0	180
		V4 (WEEK 24)	16	91.8	49.7	54.1	35	84.5	180
		V5 (WEEK 36)	17	103.2	57.4	55.6	40	87.0	180
		V6 (WEEK 52)	14	89.4	49.2	55.1	35	70.5	180
		V7 (WEEK 56)	16	100.6	55.9	55.6	33	94.0	180
		V3 (WEEK 12) - V1 (WEEK 0)	16	-1.1	16.5		-26	0.0	24
		V4 (WEEK 24) - V1 (WEEK 0)	16	11.4	29.4		-33	7.0	76
		V5 (WEEK 36) - V1 (WEEK 0)	17	23.5	36.6		-35	15.0	111
		V6 (WEEK 52) - V1 (WEEK 0)	14	23.2	45.0		-74	25.5	120
		V7 (WEEK 56) - V1 (WEEK 0)	16	27.1	46.8		-41	7.0	111
		V7 (WEEK 56) - V6 (WEEK 52)	14	-0.1	41.9		-94	-2.0	50

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails A Derived Upper Limit	Placebo	SCREENING	24	79.3	47.2	59.5	31	67.0	180
		V1 (WEEK 0)	23	78.0	43.0	55.1	25	62.0	180
		V3 (WEEK 12)	23	89.5	52.1	58.2	30	69.0	180
		V4 (WEEK 24)	23	90.9	49.5	54.5	25	80.0	180
		V5 (WEEK 36)	24	89.4	51.1	57.2	33	77.5	180
		V6 (WEEK 52)	22	88.2	49.9	56.6	32	68.0	180
		V7 (WEEK 56)	23	93.1	51.0	54.8	33	79.0	180
		V3 (WEEK 12) - V1 (WEEK 0)	22	6.3	18.6		-20	2.5	67
		V4 (WEEK 24) - V1 (WEEK 0)	22	12.8	22.9		-11	5.0	71
		V5 (WEEK 36) - V1 (WEEK 0)	23	7.5	19.8		-33	5.0	47
		V6 (WEEK 52) - V1 (WEEK 0)	22	14.2	26.8		-20	6.0	72
		V7 (WEEK 56) - V1 (WEEK 0)	22	15.1	27.3		-37	14.0	73
		V7 (WEEK 56) - V6 (WEEK 52)	22	0.9	20.5		-35	0.0	45

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails B Derived Upper Limit	ACI-91	SCREENING	15	196.2	87.3	44.5	87	190.0	300
		V1 (WEEK 0)	15	173.9	89.7	51.6	50	150.0	300
		V3 (WEEK 12)	15	185.9	91.6	49.3	71	189.0	300
		V4 (WEEK 24)	14	182.9	85.7	46.9	87	153.5	300
		V5 (WEEK 36)	14	195.9	85.4	43.6	84	165.0	300
		V6 (WEEK 52)	12	189.3	84.7	44.7	50	176.5	300
		V7 (WEEK 56)	14	178.6	85.3	47.8	70	179.5	300
		V3 (WEEK 12) - V1 (WEEK 0)	15	12.0	39.2		-70	0.0	69
		V4 (WEEK 24) - V1 (WEEK 0)	14	13.9	33.2		-30	4.0	114
		V5 (WEEK 36) - V1 (WEEK 0)	14	26.8	50.4		-34	4.0	175
		V6 (WEEK 52) - V1 (WEEK 0)	12	42.0	75.5		-63	42.0	164
		V7 (WEEK 56) - V1 (WEEK 0)	14	13.6	59.8		-55	0.0	146
		V7 (WEEK 56) - V6 (WEEK 52)	12	-22.2	47.6		-110	0.0	50

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Trails B Derived Upper Limit	Placebo	SCREENING	20	191.2	71.4	37.3	89	180.0	300
		V1 (WEEK 0)	20	182.4	77.1	42.3	60	159.0	300
		V3 (WEEK 12)	20	193.5	78.0	40.3	75	166.5	300
		V4 (WEEK 24)	19	183.1	74.7	40.8	94	160.0	300
		V5 (WEEK 36)	18	188.4	68.8	36.5	97	183.5	300
		V6 (WEEK 52)	18	194.6	74.5	38.3	102	172.0	300
		V7 (WEEK 56)	17	180.9	68.7	38.0	95	166.0	300
		V3 (WEEK 12) - V1 (WEEK 0)	18	2.8	36.8		-78	5.0	96
		V4 (WEEK 24) - V1 (WEEK 0)	17	-3.4	60.6		-185	0.0	93
		V5 (WEEK 36) - V1 (WEEK 0)	18	9.8	33.0		-56	3.0	63
		V6 (WEEK 52) - V1 (WEEK 0)	17	13.2	63.9		-185	18.0	101
		V7 (WEEK 56) - V1 (WEEK 0)	16	11.5	50.9		-127	13.0	86
		V7 (WEEK 56) - V6 (WEEK 52)	17	-10.9	35.8		-103	-12.0	58

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Simple Reaction Time (SRT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Simple Reaction Time (SRT)	ACI-91	SCREENING	16	635.7	379.0	59.6	296	455.0	1445
		V1 (WEEK 0)	15	831.1	545.1	65.6	300	516.0	1687
		V3 (WEEK 12)	16	889.6	523.8	58.9	299	849.5	1752
		V4 (WEEK 24)	15	782.9	470.7	60.1	310	668.0	1895
		V5 (WEEK 36)	16	1014.7	663.4	65.4	285	845.5	2123
		V6 (WEEK 52)	16	930.5	550.0	59.1	328	697.5	2053
		V7 (WEEK 56)	16	1025.4	752.6	73.4	304	777.0	2569
		V3 (WEEK 12) - V1 (WEEK 0)	15	93.2	308.7		-588	36.0	637
		V4 (WEEK 24) - V1 (WEEK 0)	14	33.2	333.6		-570	-5.0	677
		V5 (WEEK 36) - V1 (WEEK 0)	14	262.3	314.6		-360	264.5	811
		V6 (WEEK 52) - V1 (WEEK 0)	14	196.1	237.7		-76	118.5	620
		V7 (WEEK 56) - V1 (WEEK 0)	14	269.1	430.4		-325	94.5	1122
		V7 (WEEK 56) - V6 (WEEK 52)	16	94.9	322.0		-249	-22.5	1054

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Simple Reaction Time (SRT)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Simple Reaction Time (SRT)	Placebo	SCREENING	21	666.6	428.8	64.3	290	508.0	1859
		V1 (WEEK 0)	21	561.7	371.3	66.1	255	456.0	1859
		V3 (WEEK 12)	20	523.0	268.4	51.3	228	445.5	1364
		V4 (WEEK 24)	21	591.6	287.5	48.6	312	486.0	1316
		V5 (WEEK 36)	21	646.7	496.0	76.7	336	503.0	2284
		V6 (WEEK 52)	19	638.7	396.9	62.2	307	500.0	1832
		V7 (WEEK 56)	15	703.8	519.3	73.8	251	453.0	1977
		V3 (WEEK 12) - V1 (WEEK 0)	20	-47.2	200.3		-495	-24.0	257
		V4 (WEEK 24) - V1 (WEEK 0)	21	29.9	239.8		-716	38.0	511
		V5 (WEEK 36) - V1 (WEEK 0)	21	85.0	387.5		-377	42.0	1634
		V6 (WEEK 52) - V1 (WEEK 0)	19	70.6	193.2		-193	18.0	687
		V7 (WEEK 56) - V1 (WEEK 0)	15	125.1	293.8		-206	32.0	828
		V7 (WEEK 56) - V6 (WEEK 52)	15	49.6	240.2		-294	23.0	819

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Choice Reaction Time – GNG (CRTGNG)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Go/NoGo (CRTGNG)	ACI-91	SCREENING	14	557.9	135.2	24.2	369	509.5	792
		V1 (WEEK 0)	14	505.4	98.3	19.4	410	460.5	697
		V3 (WEEK 12)	15	568.5	187.5	33.0	376	490.0	1076
		V4 (WEEK 24)	15	546.5	119.4	21.9	387	555.0	832
		V5 (WEEK 36)	16	592.4	112.1	18.9	386	603.0	820
		V6 (WEEK 52)	15	581.5	137.8	23.7	416	559.0	982
		V7 (WEEK 56)	15	558.9	110.6	19.8	412	528.0	765
		V3 (WEEK 12) - V1 (WEEK 0)	13	31.4	100.5		-184	22.0	211
		V4 (WEEK 24) - V1 (WEEK 0)	13	19.5	107.3		-138	16.0	247
		V5 (WEEK 36) - V1 (WEEK 0)	14	75.9	84.1		-46	53.5	203
		V6 (WEEK 52) - V1 (WEEK 0)	13	81.4	110.8		-138	74.0	319
		V7 (WEEK 56) - V1 (WEEK 0)	14	55.4	99.1		-72	20.0	313
		V7 (WEEK 56) - V6 (WEEK 52)	14	-18.7	122.5		-341	-7.5	163

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Choice Reaction Time – GNG (CRTGNG)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Go/NoGo (CRTGNG)	Placebo	SCREENING	19	526.8	123.0	23.3	362	506.0	925
		V1 (WEEK 0)	21	502.4	109.3	21.7	368	465.0	774
		V3 (WEEK 12)	19	496.3	128.2	25.8	340	469.0	921
		V4 (WEEK 24)	19	465.2	67.7	14.6	354	451.0	588
		V5 (WEEK 36)	20	505.1	126.7	25.1	359	465.0	757
		V6 (WEEK 52)	18	529.6	113.0	21.3	373	485.5	832
		V7 (WEEK 56)	15	494.4	104.7	21.2	378	467.0	694
		V3 (WEEK 12) - V1 (WEEK 0)	19	-6.7	71.8		-180	-13.0	147
		V4 (WEEK 24) - V1 (WEEK 0)	19	-37.7	89.9		-253	-26.0	86
		V5 (WEEK 36) - V1 (WEEK 0)	20	5.6	66.3		-132	-15.0	147
		V6 (WEEK 52) - V1 (WEEK 0)	18	33.3	91.0		-195	42.0	216
		V7 (WEEK 56) - V1 (WEEK 0)	15	9.4	74.7		-90	1.0	182
		V7 (WEEK 56) - V6 (WEEK 52)	14	-29.6	65.2		-162	-7.0	33

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Choice Reaction Time – MSO	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	ACI-91	SCREENING	15	979.2	355.8	36.3	514	829.0	1687
		V1 (WEEK 0)	16	985.6	328.0	33.3	681	910.0	1887
		V3 (WEEK 12)	15	958.6	323.0	33.7	567	964.0	1592
		V4 (WEEK 24)	16	968.6	257.9	26.6	595	899.0	1536
		V5 (WEEK 36)	16	1054.4	259.2	24.6	663	1092.0	1396
		V6 (WEEK 52)	16	926.8	287.2	31.0	483	866.0	1461
		V7 (WEEK 56)	16	937.9	198.2	21.1	545	933.0	1316
		V3 (WEEK 12) - V1 (WEEK 0)	14	47.1	258.8		-239	-10.0	830
		V4 (WEEK 24) - V1 (WEEK 0)	15	45.3	181.8		-250	58.0	416
		V5 (WEEK 36) - V1 (WEEK 0)	15	112.5	170.0		-69	53.0	455
		V6 (WEEK 52) - V1 (WEEK 0)	15	15.2	319.0		-653	-2.0	639
		V7 (WEEK 56) - V1 (WEEK 0)	15	-2.1	103.2		-160	-9.0	185
		V7 (WEEK 56) - V6 (WEEK 52)	16	11.2	300.8		-583	16.5	554

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Choice Reaction Time – MSO	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	Placebo	SCREENING	18	898.3	258.8	28.8	589	842.5	1663
		V1 (WEEK 0)	20	887.3	321.9	36.3	602	778.5	1624
		V3 (WEEK 12)	19	812.1	270.4	33.3	527	777.0	1502
		V4 (WEEK 24)	20	867.8	330.3	38.1	522	774.0	1655
		V5 (WEEK 36)	19	873.1	279.5	32.0	503	808.0	1566
		V6 (WEEK 52)	19	877.9	285.8	32.6	497	798.0	1612
		V7 (WEEK 56)	16	781.3	290.5	37.2	500	694.0	1666
		V3 (WEEK 12) - V1 (WEEK 0)	18	-140.3	253.5		-748	-131.0	215
		V4 (WEEK 24) - V1 (WEEK 0)	19	-66.1	317.4		-899	-20.0	345
		V5 (WEEK 36) - V1 (WEEK 0)	18	-40.0	198.4		-547	-47.5	326
		V6 (WEEK 52) - V1 (WEEK 0)	19	-3.7	380.0		-1006	51.0	740
		V7 (WEEK 56) - V1 (WEEK 0)	16	-14.4	156.3		-239	-26.0	267
		V7 (WEEK 56) - V6 (WEEK 52)	16	-81.4	225.2		-735	-8.5	183

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Easy)-Derived	ACI-91	SCREENING	17	6.9	2.9	41.5	2	7.0	12
		V1 (WEEK 0)	17	8.4	2.4	28.8	3	9.0	12
		V3 (WEEK 12)	17	8.4	2.5	29.7	2	9.0	12
		V4 (WEEK 24)	15	8.7	2.8	32.5	3	9.0	12
		V5 (WEEK 36)	17	8.8	3.1	35.4	3	10.0	12
		V6 (WEEK 52)	16	8.6	3.2	37.9	1	10.0	12
		V7 (WEEK 56)	16	9.3	3.4	36.5	1	11.0	12
		V3 (WEEK 12) - V1 (WEEK 0)	17	0.0	3.0		-6	0.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.1	3.0		-8	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	17	0.4	2.6		-3	0.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.1	2.5		-5	0.5	4
		V7 (WEEK 56) - V1 (WEEK 0)	16	0.6	2.7		-5	0.5	6
		V7 (WEEK 56) - V6 (WEEK 52)	15	0.9	1.6		-2	1.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Easy)-Derived	Placebo	SCREENING	22	6.7	3.5	52.5	1	7.0	12
		V1 (WEEK 0)	22	7.9	3.4	43.6	1	9.0	12
		V3 (WEEK 12)	19	8.3	2.9	35.4	1	8.0	12
		V4 (WEEK 24)	20	9.1	2.9	32.4	1	9.5	12
		V5 (WEEK 36)	21	8.7	3.6	41.6	0	10.0	12
		V6 (WEEK 52)	20	8.1	3.6	44.0	0	8.0	12
		V7 (WEEK 56)	21	8.5	3.9	46.4	0	10.0	12
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.3	2.0		-4	0.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	20	1.0	2.7		-4	1.0	7
		V5 (WEEK 36) - V1 (WEEK 0)	21	1.0	2.5		-7	1.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	20	0.6	2.5		-4	0.5	6
		V7 (WEEK 56) - V1 (WEEK 0)	21	0.8	3.1		-7	1.0	6
		V7 (WEEK 56) - V6 (WEEK 52)	20	0.6	1.9		-4	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Hard)-Derived	ACI-91	SCREENING	17	2.4	2.6	109.3	0	2.0	8
		V1 (WEEK 0)	17	3.0	3.1	104.7	0	2.0	9
		V3 (WEEK 12)	17	2.6	2.8	107.6	0	1.0	8
		V4 (WEEK 24)	15	3.0	2.8	91.7	0	2.0	8
		V5 (WEEK 36)	17	1.8	2.3	130.7	0	0.0	7
		V6 (WEEK 52)	16	2.6	3.1	118.7	0	1.0	9
		V7 (WEEK 56)	16	2.3	2.8	118.9	0	1.5	8
		V3 (WEEK 12) - V1 (WEEK 0)	17	-0.4	1.7		-4	0.0	2
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.1	1.2		-2	0.0	2
		V5 (WEEK 36) - V1 (WEEK 0)	17	-1.2	1.8		-7	-1.0	1
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.6	2.3		-7	0.0	2
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.9	1.9		-7	0.0	1
		V7 (WEEK 56) - V6 (WEEK 52)	15	-0.3	0.9		-2	0.0	2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Hard)-Derived	Placebo	SCREENING	22	1.6	2.4	149.8	0	0.0	7
		V1 (WEEK 0)	22	2.6	3.4	130.1	0	0.5	10
		V3 (WEEK 12)	19	2.5	3.4	136.3	0	1.0	10
		V4 (WEEK 24)	20	3.1	3.8	122.0	0	0.5	9
		V5 (WEEK 36)	21	2.3	3.1	137.8	0	0.0	10
		V6 (WEEK 52)	20	2.1	2.5	120.0	0	0.5	7
		V7 (WEEK 56)	21	3.0	3.4	114.6	0	1.0	9
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.4	1.1		-3	0.0	1
		V4 (WEEK 24) - V1 (WEEK 0)	20	0.2	1.3		-2	0.0	4
		V5 (WEEK 36) - V1 (WEEK 0)	21	-0.5	1.1		-3	0.0	1
		V6 (WEEK 52) - V1 (WEEK 0)	20	-0.9	2.1		-5	0.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	21	0.2	2.2		-5	0.0	7
		V7 (WEEK 56) - V6 (WEEK 52)	20	1.1	1.5		-1	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Total)-Derived	ACI-91	SCREENING	17	9.3	4.7	50.1	2	9.0	19
		V1 (WEEK 0)	17	11.4	4.7	41.6	3	12.0	21
		V3 (WEEK 12)	17	11.1	3.7	33.3	2	12.0	18
		V4 (WEEK 24)	15	11.7	4.3	37.2	4	13.0	18
		V5 (WEEK 36)	17	10.6	4.1	38.7	3	11.0	18
		V6 (WEEK 52)	16	11.2	4.7	41.6	2	11.5	20
		V7 (WEEK 56)	16	11.6	4.5	38.5	1	12.5	18
		V3 (WEEK 12) - V1 (WEEK 0)	17	-0.4	3.9		-8	-1.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.1	2.7		-6	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	17	-0.8	3.8		-8	-1.0	7
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.6	3.4		-7	-0.5	5
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.3	3.7		-8	0.5	7
		V7 (WEEK 56) - V6 (WEEK 52)	15	0.6	2.1		-3	1.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Sum Trial 1-3 (Total)-Derived	Placebo	SCREENING	22	8.3	5.3	63.8	1	7.0	18
		V1 (WEEK 0)	22	10.5	5.7	54.2	1	11.0	20
		V3 (WEEK 12)	19	10.7	5.4	50.2	1	9.0	22
		V4 (WEEK 24)	20	12.2	5.3	43.8	1	12.0	21
		V5 (WEEK 36)	21	11.0	5.9	53.8	0	12.0	21
		V6 (WEEK 52)	20	10.2	5.2	51.3	0	11.0	18
		V7 (WEEK 56)	21	11.4	6.5	56.7	0	12.0	21
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.1	2.2		-4	-1.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	20	1.2	2.7		-4	1.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	21	0.5	2.6		-7	0.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	20	-0.3	3.4		-6	-0.5	7
		V7 (WEEK 56) - V1 (WEEK 0)	21	1.0	3.8		-7	1.0	9
		V7 (WEEK 56) - V6 (WEEK 52)	20	1.7	2.7		-4	2.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Delayed Trial (Sum Easy/Hard)	ACI-91	SCREENING	17	3.1	2.3	76.2	0	3.0	8
		V1 (WEEK 0)	17	3.8	2.0	52.5	0	4.0	7
		V3 (WEEK 12)	17	3.9	2.4	62.4	0	4.0	8
		V4 (WEEK 24)	15	3.5	2.0	55.4	1	4.0	7
		V5 (WEEK 36)	17	3.4	2.1	63.2	0	3.0	7
		V6 (WEEK 52)	16	2.8	2.5	87.3	0	3.0	8
		V7 (WEEK 56)	16	3.2	2.3	72.6	0	3.5	7
		V3 (WEEK 12) - V1 (WEEK 0)	17	0.1	1.7		-2	0.0	3
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.3	1.4		-2	0.0	3
		V5 (WEEK 36) - V1 (WEEK 0)	17	-0.5	1.6		-4	0.0	2
		V6 (WEEK 52) - V1 (WEEK 0)	16	-1.2	1.8		-4	-1.0	2
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.8	1.8		-5	0.0	1
		V7 (WEEK 56) - V6 (WEEK 52)	15	0.3	1.0		-1	1.0	2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
PAL Delayed Trial (Sum Easy/Hard)	Placebo	SCREENING	20	3.2	2.4	74.9	0	2.0	8
		V1 (WEEK 0)	22	3.5	2.2	64.9	0	3.0	8
		V3 (WEEK 12)	20	3.3	2.5	74.9	0	3.0	8
		V4 (WEEK 24)	20	3.2	2.0	63.0	0	3.0	7
		V5 (WEEK 36)	20	3.5	2.6	76.1	0	3.5	8
		V6 (WEEK 52)	19	3.1	2.5	80.3	0	3.0	8
		V7 (WEEK 56)	20	3.4	2.4	69.7	0	3.5	7
		V3 (WEEK 12) - V1 (WEEK 0)	20	-0.2	1.3		-2	0.0	3
		V4 (WEEK 24) - V1 (WEEK 0)	20	-0.5	1.3		-3	0.0	2
		V5 (WEEK 36) - V1 (WEEK 0)	20	-0.2	1.7		-3	0.0	3
		V6 (WEEK 52) - V1 (WEEK 0)	19	-0.6	2.1		-6	-1.0	3
		V7 (WEEK 56) - V1 (WEEK 0)	20	-0.3	1.6		-3	0.0	3
		V7 (WEEK 56) - V6 (WEEK 52)	19	0.5	2.0		-2	0.0	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	ACI-91	SCREENING	17	17.8	7.1	40.2	9	19.0	34
		V1 (WEEK 0)	17	18.6	6.3	33.8	11	18.0	35
		V3 (WEEK 12)	17	20.9	7.4	35.5	9	21.0	37
		V4 (WEEK 24)	17	22.1	9.4	42.4	9	22.0	44
		V5 (WEEK 36)	17	25.0	9.8	39.3	12	23.0	45
		V6 (WEEK 52)	17	27.4	12.7	46.2	12	26.0	61
		V7 (WEEK 56)	17	24.1	12.5	51.9	10	21.0	56
		V3 (WEEK 12) - V1 (WEEK 0)	17	2.2	5.3		-5	1.0	11
		V4 (WEEK 24) - V1 (WEEK 0)	17	3.5	5.5		-7	3.0	13
		V5 (WEEK 36) - V1 (WEEK 0)	17	6.4	6.2		-1	5.0	19
		V6 (WEEK 52) - V1 (WEEK 0)	17	8.8	8.2		-5	8.0	26
		V7 (WEEK 56) - V1 (WEEK 0)	17	5.4	8.1		-4	3.0	21
		V7 (WEEK 56) - V6 (WEEK 52)	17	-3.4	4.8		-12	-3.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	Placebo	SCREENING	24	18.2	7.0	38.5	9	18.0	37
		V1 (WEEK 0)	24	19.0	7.4	38.7	9	18.0	38
		V3 (WEEK 12)	24	18.8	9.0	48.1	7	17.5	48
		V4 (WEEK 24)	24	19.5	9.2	47.3	7	18.5	47
		V5 (WEEK 36)	24	20.2	9.8	48.6	9	17.5	48
		V6 (WEEK 52)	24	23.9	10.1	42.3	7	21.0	45
		V7 (WEEK 56)	24	23.7	11.1	46.8	10	20.0	49
		V3 (WEEK 12) - V1 (WEEK 0)	24	-0.3	3.8		-7	0.0	10
		V4 (WEEK 24) - V1 (WEEK 0)	24	0.4	4.6		-10	0.5	9
		V5 (WEEK 36) - V1 (WEEK 0)	24	1.2	5.1		-7	0.5	15
		V6 (WEEK 52) - V1 (WEEK 0)	24	4.9	7.9		-9	6.0	22
		V7 (WEEK 56) - V1 (WEEK 0)	24	4.7	7.7		-5	2.5	21
		V7 (WEEK 56) - V6 (WEEK 52)	24	-0.2	4.0		-7	-1.0	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Modified Total ADAS-cog (Subtests 1-12)	ACI-91	SCREENING	17	25.9	8.7	33.4	10	27.0	43
		V1 (WEEK 0)	17	27.5	7.4	26.9	14	27.0	45
		V3 (WEEK 12)	17	29.9	8.4	28.2	14	31.0	47
		V4 (WEEK 24)	17	31.4	10.4	33.1	13	32.0	54
		V5 (WEEK 36)	17	34.0	10.7	31.5	20	33.0	55
		V6 (WEEK 52)	17	36.9	13.1	35.4	22	36.0	71
		V7 (WEEK 56)	17	33.2	13.3	40.0	15	30.0	66
		V3 (WEEK 12) - V1 (WEEK 0)	17	2.4	5.6		-7	1.0	11
		V4 (WEEK 24) - V1 (WEEK 0)	17	3.8	5.6		-10	3.0	13
		V5 (WEEK 36) - V1 (WEEK 0)	17	6.5	6.3		-2	5.0	19
		V6 (WEEK 52) - V1 (WEEK 0)	17	9.4	8.2		-6	9.0	26
		V7 (WEEK 56) - V1 (WEEK 0)	17	5.7	8.1		-4	3.0	21
		V7 (WEEK 56) - V6 (WEEK 52)	17	-3.6	4.8		-11	-4.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Modified Total ADAS-cog (Subtests 1-12)	Placebo	SCREENING	24	26.6	8.2	30.8	13	27.0	47
		V1 (WEEK 0)	24	27.7	8.3	30.0	16	26.5	48
		V3 (WEEK 12)	24	27.8	9.8	35.2	16	27.0	58
		V4 (WEEK 24)	24	28.1	10.3	36.7	12	26.0	57
		V5 (WEEK 36)	24	28.8	10.7	37.1	15	26.5	58
		V6 (WEEK 52)	24	33.3	10.4	31.1	15	31.0	55
		V7 (WEEK 56)	24	32.5	11.9	36.7	17	29.0	59
		V3 (WEEK 12) - V1 (WEEK 0)	24	0.1	3.8		-6	1.0	10
		V4 (WEEK 24) - V1 (WEEK 0)	24	0.4	5.1		-14	1.0	11
		V5 (WEEK 36) - V1 (WEEK 0)	24	1.1	5.6		-9	1.0	15
		V6 (WEEK 52) - V1 (WEEK 0)	24	5.6	8.7		-11	7.0	25
		V7 (WEEK 56) - V1 (WEEK 0)	24	4.8	8.6		-8	2.5	24
		V7 (WEEK 56) - V6 (WEEK 52)	24	-0.8	4.7		-8	-1.5	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Mini-Mental State Examination (MMSE)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
MMSE Score (Derived)	ACI-91	SCREENING	17	21.5	2.8	12.9	17	21.0	26
		V1 (WEEK 0)	17	22.5	2.6	11.6	19	23.0	28
		V4 (WEEK 24)	17	20.8	3.7	17.7	13	22.0	26
		V6 (WEEK 52)	17	18.4	5.3	28.6	5	20.0	26
		V4 (WEEK 24) - V1 (WEEK 0)	17	-1.6	2.6		-7	-1.0	2
		V6 (WEEK 52) - V1 (WEEK 0)	17	-4.1	4.1		-16	-4.0	1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Mini-Mental State Examination (MMSE)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
MMSE Score (Derived)	Placebo	SCREENING	24	21.9	2.3	10.4	18	22.0	26
		V1 (WEEK 0)	24	22.6	3.0	13.2	18	23.0	27
		V4 (WEEK 24)	24	21.9	4.6	21.1	7	22.5	27
		V6 (WEEK 52)	24	20.2	5.4	26.5	8	21.0	28
		V4 (WEEK 24) - V1 (WEEK 0)	24	-0.7	3.2		-12	0.0	3
		V6 (WEEK 52) - V1 (WEEK 0)	24	-2.4	3.6		-11	-2.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Composite NTB z-score	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NTB composite z-score	ACI-91	SCREENING	12	27.9	7.5	27.0	16	28.1	38
		V1 (WEEK 0)	12	29.0	5.3	18.4	20	29.8	36
		V3 (WEEK 12)	12	29.4	5.8	19.8	19	29.6	42
		V4 (WEEK 24)	11	26.7	6.2	23.1	17	25.9	37
		V5 (WEEK 36)	14	26.6	6.4	24.0	16	26.9	35
		V6 (WEEK 52)	11	26.5	5.2	19.8	19	28.5	35
		V7 (WEEK 56)	14	27.9	7.4	26.4	19	27.6	41
		V3 (WEEK 12) - V1 (WEEK 0)	11	0.6	3.5		-7	0.7	6
		V4 (WEEK 24) - V1 (WEEK 0)	9	-0.1	2.0		-3	-0.4	2
		V5 (WEEK 36) - V1 (WEEK 0)	11	-0.3	3.1		-7	-0.5	3
		V6 (WEEK 52) - V1 (WEEK 0)	10	-2.0	3.7		-9	-1.1	3
		V7 (WEEK 56) - V1 (WEEK 0)	12	0.1	4.8		-7	0.4	7
		V7 (WEEK 56) - V6 (WEEK 52)	11	0.6	3.2		-5	-0.2	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Composite NTB z-score	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NTB composite z-score	Placebo	SCREENING	15	26.8	6.4	23.9	19	28.0	44
		V1 (WEEK 0)	16	28.3	6.0	21.2	17	28.7	43
		V3 (WEEK 12)	16	29.6	6.7	22.8	19	29.9	46
		V4 (WEEK 24)	15	29.0	6.5	22.4	16	29.2	45
		V5 (WEEK 36)	12	30.8	6.2	20.2	17	30.2	43
		V6 (WEEK 52)	15	28.4	6.0	21.2	18	27.5	38
		V7 (WEEK 56)	13	29.8	6.3	21.0	18	32.8	37
		V3 (WEEK 12) - V1 (WEEK 0)	14	1.6	2.3		-3	2.1	5
		V4 (WEEK 24) - V1 (WEEK 0)	13	0.5	1.7		-3	0.5	4
		V5 (WEEK 36) - V1 (WEEK 0)	12	1.7	2.6		-2	1.7	7
		V6 (WEEK 52) - V1 (WEEK 0)	14	-0.5	4.9		-11	0.7	6
		V7 (WEEK 56) - V1 (WEEK 0)	12	0.7	6.2		-10	1.2	11
		V7 (WEEK 56) - V6 (WEEK 52)	12	1.5	3.1		-3	0.6	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
CDR Sum Of Boxes	ACI-91	V1 (WEEK 0)	17	5.5	2.3	41.9	1	6.0	10
		V3 (WEEK 12)	16	6.0	2.7	44.6	2	6.0	12
		V4 (WEEK 24)	17	6.5	2.6	39.6	2	7.0	12
		V5 (WEEK 36)	17	7.4	3.5	46.5	2	7.0	15
		V6 (WEEK 52)	17	8.2	3.5	42.3	2	8.0	14
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.6	1.2		-1	0.0	3
		V4 (WEEK 24) - V1 (WEEK 0)	17	1.0	1.7		-1	0.5	5
		V5 (WEEK 36) - V1 (WEEK 0)	17	1.9	2.0		-1	1.5	5
		V6 (WEEK 52) - V1 (WEEK 0)	17	2.7	1.9		-1	2.5	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
CDR Sum Of Boxes	Placebo	V1 (WEEK 0)	24	4.8	2.3	48.9	1	4.3	11
		V3 (WEEK 12)	24	4.9	2.4	49.5	1	4.5	11
		V4 (WEEK 24)	24	5.1	2.6	51.6	1	4.5	11
		V5 (WEEK 36)	23	5.4	2.5	45.9	1	5.0	11
		V6 (WEEK 52)	24	5.9	2.9	48.5	1	5.5	11
		V3 (WEEK 12) - V1 (WEEK 0)	24	0.1	0.9		-2	0.0	2
		V4 (WEEK 24) - V1 (WEEK 0)	24	0.4	1.2		-2	0.0	4
		V5 (WEEK 36) - V1 (WEEK 0)	23	0.8	1.6		-2	0.5	5
		V6 (WEEK 52) - V1 (WEEK 0)	24	1.2	1.8		-3	0.8	5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Disability Assessment in Dementia (DAD) Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
DAD Percentage Total Score	ACI-91	V1 (WEEK 0)	17	71.2	24.9	34.9	23	77.5	100
		V3 (WEEK 12)	16	67.1	24.0	35.8	23	75.1	100
		V4 (WEEK 24)	17	62.7	26.7	42.6	13	72.5	100
		V5 (WEEK 36)	17	61.3	25.0	40.7	10	60.0	100
		V6 (WEEK 52)	17	56.5	26.2	46.3	5	57.5	94
		V3 (WEEK 12) - V1 (WEEK 0)	16	-4.2	9.6		-23	-2.5	20
		V4 (WEEK 24) - V1 (WEEK 0)	17	-8.5	13.5		-28	-7.5	15
		V5 (WEEK 36) - V1 (WEEK 0)	17	-9.9	12.2		-42	-10.0	5
		V6 (WEEK 52) - V1 (WEEK 0)	17	-14.7	15.7		-50	-8.3	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Disability Assessment in Dementia (DAD) Scale	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
DAD Percentage Total Score	Placebo	V1 (WEEK 0)	24	77.1	17.0	22.0	50	80.0	100
		V3 (WEEK 12)	24	74.8	18.6	24.9	38	72.9	100
		V4 (WEEK 24)	24	72.5	17.9	24.7	35	72.5	100
		V5 (WEEK 36)	24	70.8	20.5	29.0	33	74.0	100
		V6 (WEEK 52)	23	73.3	18.4	25.1	40	74.4	100
		V3 (WEEK 12) - V1 (WEEK 0)	24	-2.3	10.4		-31	-1.6	23
		V4 (WEEK 24) - V1 (WEEK 0)	24	-4.5	11.1		-26	-2.5	28
		V5 (WEEK 36) - V1 (WEEK 0)	24	-6.3	14.9		-38	-6.4	24
		V6 (WEEK 52) - V1 (WEEK 0)	23	-4.3	13.3		-38	-2.5	24

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Frequency*Severity)	ACI-91	V1 (WEEK 0)	17	12.4	14.8	119.0	0	7.0	54
		V2 (WEEK 4)	17	14.2	12.4	87.3	0	11.0	44
		V3 (WEEK 12)	17	12.5	11.4	91.1	0	10.0	41
		V4 (WEEK 24)	17	11.4	11.6	101.9	0	8.0	48
		V5 (WEEK 36)	17	8.3	7.7	92.6	0	7.0	25
		V6 (WEEK 52)	17	13.1	11.2	85.8	0	10.0	46
		V7 (WEEK 56)	17	11.2	8.4	75.4	0	10.0	37
		V2 (WEEK 4) - V1 (WEEK 0)	17	1.8	8.6		-16	1.0	23
		V3 (WEEK 12) - V1 (WEEK 0)	17	0.1	9.6		-14	0.0	30
		V4 (WEEK 24) - V1 (WEEK 0)	17	-1.0	7.3		-20	0.0	7
		V5 (WEEK 36) - V1 (WEEK 0)	17	-4.1	13.6		-51	0.0	13
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.6	15.8		-40	1.0	34
		V7 (WEEK 56) - V1 (WEEK 0)	17	-1.2	13.6		-40	1.0	25
		V7 (WEEK 56) - V6 (WEEK 52)	17	-1.9	5.1		-13	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Frequency*Severity)	Placebo	V1 (WEEK 0)	24	7.4	10.2	138.4	0	4.5	46
		V2 (WEEK 4)	24	7.1	8.8	123.8	0	4.0	33
		V3 (WEEK 12)	24	5.7	8.5	149.9	0	4.0	40
		V4 (WEEK 24)	24	8.3	9.8	118.4	0	5.0	34
		V5 (WEEK 36)	24	9.0	8.5	93.5	0	5.5	27
		V6 (WEEK 52)	23	9.0	7.7	86.4	0	8.0	28
		V7 (WEEK 56)	24	9.8	11.1	113.6	0	7.5	40
		V2 (WEEK 4) - V1 (WEEK 0)	24	-0.3	5.1		-13	0.0	10
		V3 (WEEK 12) - V1 (WEEK 0)	24	-1.7	5.6		-15	0.0	8
		V4 (WEEK 24) - V1 (WEEK 0)	24	0.9	5.9		-12	0.0	14
		V5 (WEEK 36) - V1 (WEEK 0)	24	1.7	7.4		-19	0.0	21
		V6 (WEEK 52) - V1 (WEEK 0)	23	1.9	7.4		-18	2.0	20
		V7 (WEEK 56) - V1 (WEEK 0)	24	2.4	7.4		-9	0.5	20
		V7 (WEEK 56) - V6 (WEEK 52)	23	0.9	6.4		-14	0.0	14

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

 14FEB2013

Per Protocol Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Distress)	ACI-91	V1 (WEEK 0)	17	6.5	8.3	127.1	0	3.0	32
		V2 (WEEK 4)	17	7.1	7.7	108.9	0	4.0	27
		V3 (WEEK 12)	17	7.5	10.5	140.7	0	4.0	44
		V4 (WEEK 24)	17	6.4	10.1	157.9	0	4.0	44
		V5 (WEEK 36)	17	3.8	5.6	146.9	0	2.0	22
		V6 (WEEK 52)	17	6.4	5.2	82.0	0	5.0	19
		V7 (WEEK 56)	17	5.4	4.2	77.9	0	5.0	16
		V2 (WEEK 4) - V1 (WEEK 0)	17	0.5	6.5		-10	0.0	21
		V3 (WEEK 12) - V1 (WEEK 0)	17	0.9	4.4		-6	0.0	12
		V4 (WEEK 24) - V1 (WEEK 0)	17	-0.1	5.4		-13	0.0	12
		V5 (WEEK 36) - V1 (WEEK 0)	17	-2.7	8.5		-32	0.0	5
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.2	9.0		-28	2.0	12
		V7 (WEEK 56) - V1 (WEEK 0)	17	-1.1	8.9		-28	0.0	13
		V7 (WEEK 56) - V6 (WEEK 52)	17	-0.9	2.7		-7	0.0	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.1: Clinical efficacy, descriptive statistics

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Per Protocol Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Treat-ment	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
NPI Total score (Distress)	Placebo	V1 (WEEK 0)	24	5.3	6.4	119.7	0	3.0	26
		V2 (WEEK 4)	24	4.4	6.1	138.6	0	2.5	19
		V3 (WEEK 12)	24	3.7	5.2	139.9	0	3.0	21
		V4 (WEEK 24)	24	6.4	6.9	107.3	0	3.5	22
		V5 (WEEK 36)	24	5.8	5.6	96.5	0	4.0	20
		V6 (WEEK 52)	23	5.4	6.2	114.8	0	4.0	25
		V7 (WEEK 56)	24	6.2	7.7	124.0	0	4.0	27
		V2 (WEEK 4) - V1 (WEEK 0)	24	-1.0	3.4		-9	0.0	6
		V3 (WEEK 12) - V1 (WEEK 0)	24	-1.6	3.2		-11	0.0	2
		V4 (WEEK 24) - V1 (WEEK 0)	24	1.1	2.7		-4	0.5	8
		V5 (WEEK 36) - V1 (WEEK 0)	24	0.5	4.3		-11	0.0	8
		V6 (WEEK 52) - V1 (WEEK 0)	23	0.4	4.2		-10	0.0	10
		V7 (WEEK 56) - V1 (WEEK 0)	24	0.9	4.2		-7	0.0	12
		V7 (WEEK 56) - V6 (WEEK 52)	23	0.8	2.9		-3	0.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

 14FEB2013

Intention-To-Treat Population

Controlled Oral Word Association Test (COWAT) - FAS	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Total Words Acceptable	-4.55	-4.40	-0.15	-4.10	3.80	0.282

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

 14FEB2013

Intention-To-Treat Population

Category Fluency Test (CFT)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Total Words Acceptable	-4.00	-2.14	-1.86	-3.08	-0.64	0.152

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Trails A Derived Upper Limit	28.87	11.58	17.30	-4.51	39.10	0.055
Trails B Derived Upper Limit	36.00	22.95	13.05	-24.97	51.06	0.764

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Intention-To-Treat Population

Simple Reaction Time (SRT)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Simple Reaction Time (SRT)	199.32	2.98	196.33	26.27	366.40	0.785

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Intention-To-Treat Population

Choice Reaction Time - GNG (CRTGNG)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Choice Reaction Time - Go/NoGo (CRTGNG)	88.36	28.91	59.45	2.88	116.02	0.485

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Choice Reaction Time – MSO	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	43.12	-42.46	85.58	-81.72	252.87	0.575

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
PAL Sum Trial 1-3 (Easy)-Derived	-0.40	0.24	-0.64	-2.27	0.98	0.741
PAL Sum Trial 1-3 (Hard)-Derived	-0.90	-0.86	-0.04	-1.01	0.93	0.924
PAL Sum Trial 1-3 (Total)-Derived	-1.29	-0.61	-0.68	-2.69	1.33	0.557

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
PAL Delayed Trial (Sum Easy/Hard)	-1.05	-0.41	-0.64	-1.64	0.35	0.294

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Modified Total ADAS-cog (Subtests 1-12)	10.75	6.45	4.30	-0.47	9.07	0.352
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	10.16	5.76	4.40	-0.29	9.08	0.624

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Mini-Mental State Examination (MMSE)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
MMSE Score (Derived)	-4.51	-2.74	-1.77	-3.85	0.32	0.777

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Composite NTB z-score	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
NTB composite z-score	-1.96	-0.11	-1.85	-4.88	1.18	0.666

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
CDR Sum Of Boxes	3.37	1.59	1.78	0.36	3.21	0.201

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Disability Assessment in Dementia (DAD) Scale	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
DAD Percentage Total Score	-16.89	-7.12	-9.76	-19.06	-0.46	0.853

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Intention-To-Treat Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
NPI Total score (Distress)	0.34	0.22	0.12	-2.38	2.62	0.191
NPI Total score (Frequency*Severity)	2.82	1.79	1.03	-3.51	5.57	0.231

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Controlled Oral Word Association Test (COWAT) - FAS	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Total Words Acceptable	-4.70	-5.01	0.30	-4.89	5.50	0.309

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Category Fluency Test (CFT)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Total Words Acceptable	-4.31	-2.44	-1.87	-3.39	-0.36	0.585

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Trails A Derived Upper Limit	21.71	13.96	7.75	-17.03	32.52	0.212
Trails B Derived Upper Limit	35.77	17.97	17.80	-32.40	67.99	0.828

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Simple Reaction Time (SRT)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Simple Reaction Time (SRT)	191.90	61.77	130.14	-30.82	291.09	0.781

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Choice Reaction Time – GNG (CRTGNG)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Choice Reaction Time - Go/NoGo (CRTGNG)	81.97	31.75	50.22	-24.57	125.01	0.757

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Choice Reaction Time – MSO	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	31.27	-18.98	50.26	-153.63	254.15	0.854

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
PAL Sum Trial 1-3 (Easy)-Derived	-0.01	0.44	-0.45	-2.19	1.30	0.579
PAL Sum Trial 1-3 (Hard)-Derived	-0.52	-0.90	0.39	-0.86	1.63	0.924
PAL Sum Trial 1-3 (Total)-Derived	-0.43	-0.47	0.05	-2.14	2.23	0.934

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
PAL Delayed Trial (Sum Easy/Hard)	-1.17	-0.62	-0.54	-1.88	0.80	0.389

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
Modified Total ADAS-cog (Subtests 1-12)	9.39	5.60	3.79	-1.53	9.11	0.122
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	8.92	4.90	4.02	-0.94	8.98	0.156

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Mini-Mental State Examination (MMSE)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
MMSE Score (Derived)	-4.04	-2.39	-1.64	-4.06	0.77	0.946

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Composite NTB z-score	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
NTB composite z-score	-2.02	-0.47	-1.54	-5.27	2.18	0.645

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
CDR Sum Of Boxes	2.55	1.16	1.39	0.21	2.57	0.858

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

Per Protocol Population

Disability Assessment in Dementia (DAD) Scale	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
DAD Percentage Total Score	-15.24	-3.65	-11.58	-20.92	-2.24	0.320

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.2: Clinical efficacy, ANCOVA estimates for change from baseline

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Per Protocol Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value treatment effect
NPI Total score (Distress)	0.58	0.24	0.34	-2.66	3.34	0.041
NPI Total score (Frequency*Severity)	3.07	0.83	2.24	-3.32	7.80	0.142

Change from baseline at Week 52 (Visit 6)
ANCOVA with treatment as a fixed effect, baseline as a covariate, treatment by baseline as interaction term.
The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Controlled Oral Word Association Test (COWAT) - FAS	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Total Words Acceptable	-3.00	-4.00	0.00	-4.00	3.00	0.932

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Category Fluency Test (CFT)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Total Words Acceptable	-5.00	-1.00	-3.00	-5.00	-2.00	<.001

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Trails A Derived Upper Limit	25.50	5.00	14.00	-4.00	35.00	0.171
Trails B Derived Upper Limit	34.00	11.00	7.00	-25.00	49.00	0.612

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

			ACI-91 - Placebo	95% Confidence intervals		
Simple Reaction Time (SRT)	Median ACI-91	Median Placebo	Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Simple Reaction Time (SRT)	157.50	73.00	142.00	-7.00	321.00	0.056

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Choice Reaction Time – GNG (CRTGNG)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Choice Reaction Time - Go/NoGo (CRTGNG)	74.50	40.00	55.00	6.00	98.00	0.029

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Choice Reaction Time – MSO	Median ACI-91	Median Placebo	ACI-91 - Placebo Hodges-Lehman estimate	95% Confidence intervals Lower Limit	Upper Limit	p-value Wilcoxon test
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	11.00	0.00	31.50	-129.00	213.00	0.659

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
PAL Sum Trial 1-3 (Easy)-Derived	0.00	0.50	1.00	-1.00	2.00	0.374
PAL Sum Trial 1-3 (Hard)-Derived	0.00	0.00	0.00	-1.00	0.00	0.573
PAL Sum Trial 1-3 (Total)-Derived	-1.00	0.00	1.00	-1.00	3.00	0.447

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
PAL Delayed Trial (Sum Easy/Hard)	-1.00	0.00	1.00	0.00	2.00	0.124

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Median ACI-91	Median Placebo	ACI-91 - Placebo Hodges-Lehman estimate	95% Confidence intervals Lower Limit	Upper Limit	p-value Wilcoxon test
Modified Total ADAS-cog (Subtests 1-12)	9.00	7.00	4.00	-1.00	9.00	0.173
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	8.00	6.00	4.00	-1.00	8.00	0.136

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Mini-Mental State Examination (MMSE)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
MMSE Score (Derived)	-4.00	-2.00	-1.00	-3.00	1.00	0.209

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Composite NTB z-score	Median ACI-91	Median Placebo	ACI-91 - Placebo Hodges-Lehman estimate	95% Confidence intervals Lower Limit	Upper Limit	p-value Wilcoxon test
NTB composite z-score	-2.15	1.17	-2.51	-5.60	0.79	0.103

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Intention-To-Treat Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
CDR Sum Of Boxes	2.75	1.00	1.50	0.50	2.50	0.017

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Disability Assessment in Dementia (DAD) Scale	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
DAD Percentage Total Score	-16.80	-5.00	7.50	0.00	15.97	0.071

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Intention-To-Treat Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
NPI Total score (Distress)	0.50	0.00	0.00	-2.00	2.00	0.934
NPI Total score (Frequency*Severity)	3.00	2.00	-1.00	-4.00	3.00	0.539

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Controlled Oral Word Association Test (COWAT) - FAS	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Total Words Acceptable	-3.50	-4.00	0.00	-6.00	6.00	0.901

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

 14FEB2013

Per Protocol Population

Category Fluency Test (CFT)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Total Words Acceptable	-5.00	-1.00	-3.00	-5.00	-1.00	0.005

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Trails A Derived Upper Limit	25.50	6.00	8.50	-14.00	34.00	0.408
Trails B Derived Upper Limit	42.00	18.00	21.00	-33.00	88.00	0.464

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

			95% Confidence intervals ACI-91 - Placebo			
Simple Reaction Time (SRT)	Median ACI-91	Median Placebo	Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Simple Reaction Time (SRT)	118.50	18.00	90.50	-20.00	245.00	0.101

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Per Protocol Population

Choice Reaction Time - GNG (CRTGNG)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Choice Reaction Time - Go/NoGo (CRTGNG)	74.00	42.00	39.50	-20.00	98.00	0.133

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Choice Reaction Time – MSO	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	-2.00	51.00	-4.00	-210.00	216.00	0.959

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
PAL Sum Trial 1-3 (Easy)-Derived	0.50	0.50	0.00	-2.00	1.00	0.735
PAL Sum Trial 1-3 (Hard)-Derived	0.00	0.00	0.00	0.00	1.00	0.231
PAL Sum Trial 1-3 (Total)-Derived	-0.50	-0.50	0.00	-3.00	2.00	0.936

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Per Protocol Population

Wechsler Verbal Paired Associates Test – delayed (WVPATd) Paired Associative Learning	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
PAL Delayed Trial (Sum Easy/Hard)	-1.00	-1.00	-1.00	-2.00	1.00	0.389

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Alzheimer's Disease Assessment Scale (ADAS-cog)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
Modified Total ADAS-cog (Subtests 1-12)	9.00	7.00	3.00	-2.00	9.00	0.228
Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	8.00	6.00	3.50	-1.00	9.00	0.168

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Mini-Mental State Examination (MMSE)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
MMSE Score (Derived)	-4.00	-2.00	-1.00	-4.00	1.00	0.197

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Composite NTB z-score	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
NTB composite z-score	-1.11	0.72	-1.75	-5.25	2.51	0.334

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

Per Protocol Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
CDR Sum Of Boxes	2.50	0.75	1.50	0.00	2.50	0.023

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Disability Assessment in Dementia (DAD) Scale	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
DAD Percentage Total Score	-8.33	-2.50	-8.33	-18.44	0.00	0.034

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.3: Clinical efficacy, non-parametric 95% confidence intervals for treatment differences

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Per Protocol Population

Disability Assessment – Neuropsychiatric Inventory (NPI)	Median ACI-91	Median Placebo	95% Confidence intervals ACI-91 - Placebo Hodges-Lehman estimate	Lower Limit	Upper Limit	p-value Wilcoxon test
NPI Total score (Distress)	2.00	0.00	0.00	-2.00	4.00	0.619
NPI Total score (Frequency*Severity)	1.00	2.00	0.00	-5.00	5.00	0.978

Change from baseline at Week 52 (Visit 6)
Hodges-Lehman estimates with 95% confidence intervals are based on changes from baseline at Visit 6

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Controlled Oral Word Association Test (COWAT) - FAS	Total Words Acceptable	OVERALL	-3.07	-2.77	-0.30	-3.53	2.94	0.855
		V3 (WEEK 12)	-1.63	-1.16	-0.47	-4.27	3.33	0.808
		V4 (WEEK 24)	-3.20	-2.67	-0.53	-4.44	3.37	0.788
		V5 (WEEK 36)	-2.34	-2.67	0.33	-3.63	4.30	0.869
		V6 (WEEK 52)	-5.10	-4.58	-0.52	-4.28	3.24	0.786
Category Fluency Test (CFT)	Total Words Acceptable	OVERALL	-2.91	-0.90	-2.02	-2.96	-1.07	<.001
		V3 (WEEK 12)	-1.87	0.20	-2.08	-3.42	-0.74	0.003
		V4 (WEEK 24)	-2.82	-0.49	-2.33	-3.73	-0.94	0.001
		V5 (WEEK 36)	-2.84	-1.27	-1.57	-3.00	-0.15	0.031
		V6 (WEEK 52)	-4.12	-2.04	-2.08	-3.40	-0.76	0.002
Trail Making Tests A (TMA) and B (TMB)	Trails A Derived Upper Limit	OVERALL	21.95	9.44	12.51	-2.88	27.89	0.109
		V3 (WEEK 12)	12.05	4.61	7.44	-10.90	25.78	0.424
		V4 (WEEK 24)	15.66	12.21	3.45	-15.25	22.16	0.715
		V5 (WEEK 36)	31.04	9.29	21.75	2.97	40.52	0.024
		V6 (WEEK 52)	29.05	11.66	17.38	-0.75	35.52	0.060

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
Trail Making Tests A (TMA) and B (TMB)	Trails B Derived Upper Limit	OVERALL	24.70	14.77	9.93	-17.48	37.34	0.468
		V3 (WEEK 12)	15.45	15.74	-0.29	-32.64	32.06	0.986
		V4 (WEEK 24)	17.84	1.62	16.22	-17.46	49.90	0.342
		V5 (WEEK 36)	29.16	18.85	10.31	-23.53	44.16	0.547
		V6 (WEEK 52)	36.34	22.87	13.48	-18.69	45.65	0.408
Simple Reaction Time (SRT)	Simple Reaction Time (SRT)	OVERALL	183.20	-19.75	202.95	50.26	355.64	0.010
		V3 (WEEK 12)	158.61	-78.57	237.18	55.48	418.88	0.011
		V4 (WEEK 24)	103.46	-35.39	138.85	-46.79	324.49	0.141
		V5 (WEEK 36)	257.64	22.50	235.14	47.38	422.91	0.015
		V6 (WEEK 52)	213.11	12.47	200.64	21.82	379.46	0.028
Choice Reaction Time - GNG (CRTGNG)	Choice Reaction Time - Go/NoGo (CRTGNG)	OVERALL	66.11	-1.24	67.35	27.48	107.22	0.001
		V3 (WEEK 12)	47.36	-9.85	57.22	2.41	112.03	0.041
		V4 (WEEK 24)	43.57	-26.01	69.57	12.07	127.08	0.018
		V5 (WEEK 36)	85.48	1.95	83.52	26.87	140.17	0.004
		V6 (WEEK 52)	88.04	28.96	59.08	5.76	112.40	0.030

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
Choice Reaction Time - MSO	Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	OVERALL	45.06	-68.37	113.44	-2.40	229.27	0.055
		V3 (WEEK 12)	13.40	-144.60	158.00	8.05	307.95	0.039
		V4 (WEEK 24)	24.11	-68.63	92.74	-60.64	246.12	0.234
		V5 (WEEK 36)	98.90	-21.03	119.93	-35.65	275.51	0.130
		V6 (WEEK 52)	43.85	-39.22	83.07	-62.67	228.81	0.261
Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	PAL Sum Trial 1-3 (Easy)-Derived	OVERALL	-0.48	0.54	-1.02	-2.37	0.32	0.132
		V3 (WEEK 12)	-0.72	0.51	-1.23	-2.77	0.31	0.117
		V4 (WEEK 24)	-0.56	0.74	-1.29	-2.88	0.30	0.110
		V5 (WEEK 36)	-0.20	0.76	-0.95	-2.55	0.65	0.241
		V6 (WEEK 52)	-0.46	0.15	-0.62	-2.14	0.90	0.423
	PAL Sum Trial 1-3 (Hard)-Derived	OVERALL	-0.94	-0.53	-0.41	-1.14	0.32	0.262
		V3 (WEEK 12)	-0.89	-0.63	-0.25	-1.14	0.64	0.581
		V4 (WEEK 24)	-0.47	-0.02	-0.45	-1.37	0.48	0.344

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	PAL Sum Trial 1-3 (Hard)-Derived	V5 (WEEK 36)	-1.47	-0.59	-0.88	-1.82	0.06	0.066
		V6 (WEEK 52)	-0.93	-0.86	-0.07	-0.95	0.81	0.877
	PAL Sum Trial 1-3 (Total)-Derived	OVERALL	-1.45	0.03	-1.48	-3.14	0.17	0.078
		V3 (WEEK 12)	-1.62	-0.10	-1.52	-3.44	0.41	0.121
		V4 (WEEK 24)	-1.07	0.73	-1.80	-3.79	0.18	0.075
		V5 (WEEK 36)	-1.71	0.18	-1.89	-3.89	0.11	0.064
		V6 (WEEK 52)	-1.41	-0.69	-0.72	-2.62	1.17	0.453
Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning	PAL Delayed Trial (Sum Easy/Hard)	OVERALL	-0.62	-0.17	-0.45	-1.08	0.18	0.156
		V3 (WEEK 12)	-0.30	-0.01	-0.30	-1.16	0.57	0.499
		V4 (WEEK 24)	-0.59	-0.27	-0.31	-1.22	0.60	0.497
		V5 (WEEK 36)	-0.53	0.02	-0.54	-1.46	0.38	0.243
		V6 (WEEK 52)	-1.05	-0.40	-0.65	-1.50	0.20	0.133

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Alzheimer's Disease Assessment Scale (ADAS-cog)	Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	OVERALL	7.36	2.28	5.08	1.76	8.41	0.003
		V3 (WEEK 12)	4.26	-0.64	4.90	1.00	8.79	0.014
		V4 (WEEK 24)	6.56	1.82	4.75	0.76	8.74	0.020
		V5 (WEEK 36)	8.57	2.21	6.35	2.28	10.43	0.002
		V6 (WEEK 52)	10.05	5.72	4.34	0.46	8.21	0.028
	Modified Total ADAS-cog (Subtests 1-12)	OVERALL	7.72	2.51	5.22	1.78	8.66	0.004
		V3 (WEEK 12)	4.47	-0.48	4.95	0.91	8.99	0.017
		V4 (WEEK 24)	6.98	1.91	5.07	0.93	9.21	0.017
		V5 (WEEK 36)	8.76	2.20	6.56	2.33	10.79	0.003
		V6 (WEEK 52)	10.68	6.39	4.29	0.27	8.30	0.037
Mini-Mental State Examination (MMSE)	MMSE Score (Derived)	OVERALL	-3.65	-1.92	-1.72	-3.51	0.06	0.058
		V4 (WEEK 24)	-2.79	-1.08	-1.71	-3.74	0.32	0.097
		V6 (WEEK 52)	-4.50	-2.76	-1.74	-3.74	0.26	0.087

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
Composite NTB z-score	NTB composite z-score	OVERALL	-0.60	1.30	-1.90	-3.59	-0.21	0.029
		V3 (WEEK 12)	0.48	1.96	-1.48	-3.89	0.92	0.223
		V4 (WEEK 24)	-0.28	1.02	-1.30	-3.89	1.29	0.321
		V5 (WEEK 36)	-0.58	2.22	-2.80	-5.29	-0.31	0.028
		V6 (WEEK 52)	-2.03	-0.01	-2.02	-4.33	0.28	0.084
Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	CDR Sum Of Boxes	OVERALL	2.20	1.01	1.19	0.14	2.25	0.028
		V3 (WEEK 12)	1.09	0.46	0.63	-0.56	1.83	0.296
		V4 (WEEK 24)	1.67	0.76	0.91	-0.31	2.12	0.142
		V5 (WEEK 36)	2.68	1.23	1.45	0.21	2.69	0.022
		V6 (WEEK 52)	3.37	1.59	1.78	0.60	2.96	0.003
Disability Assessment in Dementia (DAD) Scale	DAD Percentage Total Score	OVERALL	-12.21	-5.92	-6.29	-13.86	1.28	0.102
		V3 (WEEK 12)	-7.31	-3.02	-4.30	-12.65	4.06	0.311
		V4 (WEEK 24)	-10.53	-6.08	-4.45	-12.95	4.04	0.302
		V5 (WEEK 36)	-14.24	-7.50	-6.74	-15.36	1.89	0.125
		V6 (WEEK 52)	-16.77	-7.10	-9.67	-17.94	-1.41	0.022

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Intention-To-Treat Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Disability Assessment - Neuropsychiatric Inventory (NPI)	NPI Total score (Frequency*Severity)	OVERALL	1.06	0.54	0.51	-2.05	3.08	0.690
		V2 (WEEK 4)	1.54	-0.89	2.43	-1.39	6.25	0.211
		V3 (WEEK 12)	2.84	-1.66	4.50	0.62	8.38	0.023
		V4 (WEEK 24)	0.13	1.50	-1.37	-5.42	2.69	0.507
		V5 (WEEK 36)	-1.77	2.01	-3.78	-7.97	0.41	0.077
		V6 (WEEK 52)	2.53	1.75	0.78	-3.01	4.57	0.686
	NPI Total score (Distress)	OVERALL	-0.22	-0.39	0.17	-1.42	1.76	0.829
		V2 (WEEK 4)	-0.14	-1.24	1.10	-1.35	3.55	0.378
		V3 (WEEK 12)	0.98	-1.95	2.93	0.43	5.42	0.022
		V4 (WEEK 24)	-0.10	0.89	-0.99	-3.60	1.62	0.455
		V5 (WEEK 36)	-2.14	0.10	-2.25	-4.95	0.45	0.103
		V6 (WEEK 52)	0.31	0.24	0.07	-2.37	2.50	0.956

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Controlled Oral Word Association Test (COWAT) - FAS	Total Words Acceptable	OVERALL	-2.33	-3.07	0.74	-3.13	4.61	0.701
		V3 (WEEK 12)	-0.39	-1.64	1.24	-3.39	5.88	0.596
		V4 (WEEK 24)	-1.88	-2.92	1.05	-3.62	5.71	0.658
		V5 (WEEK 36)	-1.69	-2.59	0.90	-3.71	5.51	0.700
		V6 (WEEK 52)	-5.36	-5.13	-0.23	-4.89	4.43	0.922
Category Fluency Test (CFT)	Total Words Acceptable	OVERALL	-2.76	-1.14	-1.62	-2.79	-0.45	0.008
		V3 (WEEK 12)	-1.45	-0.22	-1.23	-2.91	0.44	0.147
		V4 (WEEK 24)	-2.53	-0.60	-1.93	-3.62	-0.24	0.026
		V5 (WEEK 36)	-2.51	-1.43	-1.08	-2.74	0.58	0.202
		V6 (WEEK 52)	-4.55	-2.31	-2.25	-3.94	-0.56	0.010
Trail Making Tests A (TMA) and B (TMB)	Trails A Derived Upper Limit	OVERALL	16.18	10.17	6.02	-8.55	20.58	0.408
		V3 (WEEK 12)	1.80	5.65	-3.85	-21.93	14.23	0.674
		V4 (WEEK 24)	14.36	13.04	1.32	-16.77	19.42	0.885
		V5 (WEEK 36)	23.60	7.54	16.07	-1.68	33.81	0.075
		V6 (WEEK 52)	24.97	14.45	10.53	-8.02	29.08	0.263

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Trail Making Tests A (TMA) and B (TMB)	Trails B Derived Upper Limit	OVERALL	23.26	7.25	16.00	-9.13	41.14	0.204
		V3 (WEEK 12)	12.12	5.97	6.15	-26.44	38.73	0.708
		V4 (WEEK 24)	14.42	-2.46	16.88	-16.59	50.34	0.319
		V5 (WEEK 36)	27.34	11.38	15.97	-17.17	49.11	0.341
		V6 (WEEK 52)	39.16	14.13	25.03	-9.61	59.67	0.154
Simple Reaction Time (SRT)	Simple Reaction Time (SRT)	OVERALL	156.16	21.72	134.45	-15.49	284.38	0.077
		V3 (WEEK 12)	122.51	-64.87	187.38	-6.27	381.02	0.058
		V4 (WEEK 24)	36.74	13.95	22.79	-171.51	217.09	0.816
		V5 (WEEK 36)	265.81	69.05	196.76	2.46	391.06	0.047
		V6 (WEEK 52)	199.60	68.74	130.86	-66.25	327.97	0.191
Choice Reaction Time - GNG (CRTGNG)	Choice Reaction Time - Go/NoGo (CRTGNG)	OVERALL	52.30	-3.86	56.16	14.98	97.34	0.009
		V3 (WEEK 12)	31.54	-9.09	40.62	-20.03	101.27	0.187
		V4 (WEEK 24)	19.69	-40.14	59.83	-0.83	120.48	0.053
		V5 (WEEK 36)	76.45	3.04	73.41	14.56	132.27	0.015
		V6 (WEEK 52)	81.54	30.74	50.80	-10.42	112.01	0.103

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	ACI-91 - Placebo Difference	95% Confidence intervals Lower Limit	95% Confidence intervals Upper Limit	p-value
Choice Reaction Time – MSO	Choice Reaction Time - Maximum Stimulatory Output (CRTMSO)	OVERALL	60.62	-59.70	120.32	7.96	232.67	0.037
		V3 (WEEK 12)	46.98	-131.26	178.24	9.50	346.98	0.039
		V4 (WEEK 24)	52.83	-61.67	114.50	-49.76	278.76	0.170
		V5 (WEEK 36)	119.96	-30.93	150.90	-15.11	316.90	0.074
		V6 (WEEK 52)	22.70	-14.93	37.63	-126.63	201.88	0.650
Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	PAL Sum Trial 1-3 (Easy)-Derived	OVERALL	0.25	0.53	-0.28	-1.65	1.09	0.677
		V3 (WEEK 12)	0.08	0.18	-0.10	-1.73	1.53	0.902
		V4 (WEEK 24)	0.23	0.84	-0.61	-2.26	1.04	0.466
		V5 (WEEK 36)	0.49	0.87	-0.38	-1.99	1.23	0.641
		V6 (WEEK 52)	0.19	0.24	-0.05	-1.68	1.59	0.956
	PAL Sum Trial 1-3 (Hard)-Derived	OVERALL	-0.54	-0.40	-0.14	-0.83	0.55	0.689
		V3 (WEEK 12)	-0.34	-0.42	0.08	-0.89	1.05	0.876
		V4 (WEEK 24)	-0.09	0.19	-0.28	-1.27	0.71	0.579

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning	PAL Sum Trial 1-3 (Hard)-Derived	V5 (WEEK 36)	-1.23	-0.52	-0.71	-1.66	0.24	0.143
		V6 (WEEK 52)	-0.50	-0.86	0.36	-0.61	1.33	0.466
	PAL Sum Trial 1-3 (Total)-Derived	OVERALL	-0.32	0.17	-0.48	-1.97	1.01	0.514
		V3 (WEEK 12)	-0.28	-0.20	-0.08	-1.98	1.83	0.936
		V4 (WEEK 24)	0.10	1.07	-0.97	-2.91	0.97	0.323
		V5 (WEEK 36)	-0.75	0.38	-1.13	-3.01	0.75	0.235
		V6 (WEEK 52)	-0.34	-0.58	0.24	-1.67	2.15	0.803
Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning	PAL Delayed Trial (Sum Easy/Hard)	OVERALL	-0.44	-0.37	-0.07	-0.80	0.65	0.840
		V3 (WEEK 12)	0.08	-0.15	0.23	-0.81	1.27	0.662
		V4 (WEEK 24)	-0.31	-0.47	0.16	-0.91	1.23	0.765
		V5 (WEEK 36)	-0.45	-0.22	-0.23	-1.27	0.81	0.660
		V6 (WEEK 52)	-1.08	-0.63	-0.45	-1.51	0.61	0.403

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Alzheimer's Disease Assessment Scale (ADAS-cog)	Unmodified Total ADAS-cog (Subtests 1 2 3 5-12)	OVERALL	5.23	1.52	3.71	0.83	6.59	0.013
		V3 (WEEK 12)	2.26	-0.31	2.57	-1.13	6.28	0.171
		V4 (WEEK 24)	3.50	0.40	3.10	-0.60	6.81	0.100
		V5 (WEEK 36)	6.38	1.15	5.23	1.53	8.94	0.006
		V6 (WEEK 52)	8.79	4.86	3.94	0.23	7.64	0.037
	Modified Total ADAS-cog (Subtests 1-12)	OVERALL	5.52	1.80	3.72	0.61	6.83	0.020
		V3 (WEEK 12)	2.42	0.08	2.34	-1.61	6.28	0.243
		V4 (WEEK 24)	3.83	0.41	3.42	-0.53	7.36	0.089
		V5 (WEEK 36)	6.48	1.12	5.35	1.41	9.30	0.008
		V6 (WEEK 52)	9.36	5.58	3.78	-0.17	7.72	0.060
Mini-Mental State Examination (MMSE)	MMSE Score (Derived)	OVERALL	-2.84	-1.53	-1.31	-3.17	0.55	0.163
		V4 (WEEK 24)	-1.63	-0.68	-0.95	-3.12	1.21	0.378
		V6 (WEEK 52)	-4.04	-2.39	-1.66	-3.82	0.51	0.129

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Composite NTB z-score	NTB composite z-score	OVERALL	-0.52	0.92	-1.44	-3.14	0.26	0.093
		V3 (WEEK 12)	0.65	1.72	-1.07	-3.61	1.47	0.404
		V4 (WEEK 24)	-0.23	0.59	-0.81	-3.53	1.91	0.553
		V5 (WEEK 36)	-0.44	1.90	-2.33	-4.96	0.29	0.081
		V6 (WEEK 52)	-2.08	-0.53	-1.55	-4.15	1.06	0.240
Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale	CDR Sum Of Boxes	OVERALL	1.57	0.64	0.93	0.08	1.78	0.032
		V3 (WEEK 12)	0.70	0.15	0.54	-0.45	1.54	0.283
		V4 (WEEK 24)	0.99	0.38	0.61	-0.38	1.60	0.225
		V5 (WEEK 36)	1.93	0.85	1.08	0.09	2.07	0.033
		V6 (WEEK 52)	2.67	1.17	1.49	0.51	2.48	0.003
Disability Assessment in Dementia (DAD) Scale	DAD Percentage Total Score	OVERALL	-9.96	-4.04	-5.92	-12.68	0.84	0.084
		V3 (WEEK 12)	-5.36	-1.99	-3.37	-11.38	4.63	0.406
		V4 (WEEK 24)	-8.97	-4.23	-4.74	-12.67	3.19	0.239
		V5 (WEEK 36)	-10.32	-6.00	-4.32	-12.25	3.61	0.283
		V6 (WEEK 52)	-15.17	-3.94	-11.23	-19.20	-3.26	0.006

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.4: Clinical efficacy, ANCOVA estimates for repeated measure effects

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Per Protocol Population

Endpoint	Parameter	Visit	LSmeans ACI-91	LSmeans Placebo	95% Confidence intervals ACI-91 - Placebo Difference	Lower Limit	Upper Limit	p-value
Disability Assessment - Neuropsychiatric Inventory (NPI)	NPI Total score (Frequency*Severity)	OVERALL	0.81	-0.45	1.26	-1.24	3.75	0.314
		V2 (WEEK 4)	3.09	-1.17	4.26	-0.11	8.63	0.056
		V3 (WEEK 12)	1.44	-2.63	4.07	-0.29	8.44	0.067
		V4 (WEEK 24)	0.33	-0.00	0.33	-4.04	4.69	0.882
		V5 (WEEK 36)	-2.79	0.75	-3.54	-7.91	0.83	0.111
		V6 (WEEK 52)	1.97	0.81	1.17	-3.24	5.57	0.602
	NPI Total score (Distress)	OVERALL	-0.09	-0.29	0.21	-1.37	1.79	0.792
		V2 (WEEK 4)	0.75	-1.10	1.85	-1.17	4.87	0.228
		V3 (WEEK 12)	1.16	-1.77	2.93	-0.09	5.95	0.057
		V4 (WEEK 24)	0.10	0.94	-0.84	-3.86	2.18	0.583
		V5 (WEEK 36)	-2.49	0.32	-2.80	-5.82	0.21	0.068
		V6 (WEEK 52)	0.04	0.14	-0.10	-3.14	2.95	0.950

Change from baseline. V6 (WEEK 52) does also include assessments performed due to early termination
ANCOVA with treatment as a fixed effect, baseline as a covariate, time as a repeated measure effect and patient as a random effect. The complete SAS output incl. Shapiro-Wilk test for residuals is given in Appendix 16.1.9

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

Intention-To-Treat Population

Controlled Oral Word Association Test (COWAT) - FAS

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline Total Words Acceptable	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.289	0.578
			Clinical endpoint	26	-2.27	6.45	-14.00	7.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.150	0.724
			Clinical endpoint	30	-0.50	5.88	-10.00	11.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	0.035	0.898
			Clinical endpoint	27	-5.41	10.17	-36.00	12.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	0.196	0.394
			Clinical endpoint	31	-4.10	5.55	-19.00	10.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Category Fluency Test (CFT)

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline Total Words Acceptable	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.044	0.933
			Clinical endpoint	26	-2.23	3.04	-9.00	4.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.001	0.998
			Clinical endpoint	30	0.57	3.54	-6.00	9.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	-0.048	0.859
			Clinical endpoint	27	-4.48	2.67	-11.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	0.422	0.057
			Clinical endpoint	31	-1.68	3.31	-10.00	4.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Trail Making Tests A (TMA) and B (TMB)

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Trails A Change From Baseline Derived Upper Limit	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.300	0.564
			Clinical endpoint	23	9.43	33.98	-56.00	87.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.43	1.32	3.91	7.39	-0.119	0.823
			Clinical endpoint	28	5.04	20.88	-36.00	67.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	-0.341	0.196
			Clinical endpoint	24	29.04	52.18	-74.00	131.00		
		Placebo	Albumin CSF/Serum Ratio	19	5.30	1.85	0.79	9.15	-0.450	0.053
			Clinical endpoint	29	11.55	27.52	-33.00	72.00		
Trails B Change From Baseline Derived Upper Limit	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	6.82	1.00	5.95	8.30	0.111	0.859
			Clinical endpoint	19	15.79	40.89	-70.00	85.00		
		Placebo	Albumin CSF/Serum Ratio	3	5.02	1.06	3.91	6.03	-0.839	0.366
			Clinical endpoint	22	14.41	59.74	-78.00	230.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	13	5.48	2.82	2.33	13.26	0.043	0.890
			Clinical endpoint	19	36.68	62.94	-63.00	164.00		
		Placebo	Albumin CSF/Serum Ratio	15	5.00	1.90	0.79	9.15	-0.406	0.133
			Clinical endpoint	23	22.13	71.66	-185.00	230.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

			Simple Reaction Time (SRT)							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline SRT	V1 (WEEK 0)	ACI-91	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	28	0.00	0.00	0.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	27	0.00	0.00	0.00	0.00		
	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	7.15	0.93	5.95	8.30	0.672	0.214
			Clinical endpoint	22	131.36	288.30	-588.00	637.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.26	1.29	3.91	7.39	-0.271	0.557
			Clinical endpoint	24	-20.71	225.31	-495.00	513.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	14	4.82	1.57	2.33	7.44	-0.063	0.831
			Clinical endpoint	22	185.86	311.61	-588.00	620.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.32	1.89	0.79	9.15	-0.636	0.005
			Clinical endpoint	27	26.59	326.96	-1314.0	687.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Choice Reaction Time - GNG (CRTGNG)

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline CRTGNG	V1 (WEEK 0)	ACI-91	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	27	0.00	0.00	0.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	25	0.00	0.00	0.00	0.00		
	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	7.15	0.93	5.95	8.30	0.031	0.960
			Clinical endpoint	19	48.95	106.30	-184.00	289.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.26	1.29	3.91	7.39	0.096	0.838
			Clinical endpoint	23	-7.35	77.52	-180.00	147.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	14	4.78	1.57	2.33	7.44	-0.436	0.119
			Clinical endpoint	20	88.25	105.77	-138.00	319.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.32	1.89	0.79	9.15	-0.426	0.078
			Clinical endpoint	25	28.60	82.36	-195.00	216.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Choice Reaction Time - MSO

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline CRTMSO	V1 (WEEK 0)	ACI-91	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	30	0.00	0.00	0.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	26	0.00	0.00	0.00	0.00		
	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	7.15	0.93	5.95	8.30	0.644	0.241
			Clinical endpoint	22	7.45	308.07	-721.00	830.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.13	1.37	3.91	7.39	-0.334	0.518
			Clinical endpoint	23	-163.65	298.62	-909.00	215.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	15	4.81	1.51	2.33	7.44	-0.016	0.956
			Clinical endpoint	23	33.83	312.87	-653.00	639.00		
		Placebo	Albumin CSF/Serum Ratio	17	5.23	1.91	0.79	9.15	-0.031	0.906
			Clinical endpoint	26	-29.12	364.55	-1006.0	740.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline PAL Sum Trial 1-3 (Easy)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.058	0.914
			Clinical endpoint	26	-0.88	3.89	-11.00	4.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.01	0.94	3.91	6.04	-0.662	0.105
			Clinical endpoint	24	0.75	2.19	-4.00	5.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	-0.133	0.623
			Clinical endpoint	27	-0.63	3.30	-9.00	5.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.39	1.91	0.79	9.15	-0.152	0.548
			Clinical endpoint	26	0.38	2.73	-7.00	6.00		
Difference From Baseline PAL Sum Trial 1-3 (Hard)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.137	0.795
			Clinical endpoint	26	-0.92	2.40	-8.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.01	0.94	3.91	6.04	-0.481	0.275
			Clinical endpoint	24	-0.63	1.53	-6.00	1.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	-0.254	0.343
			Clinical endpoint	27	-0.96	2.47	-8.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.39	1.91	0.79	9.15	0.315	0.203
			Clinical endpoint	26	-0.81	1.94	-5.00	4.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline PAL Sum Trial 1-3 (Total)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.177	0.737
			Clinical endpoint	26	-1.81	5.54	-17.00	5.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.01	0.94	3.91	6.04	-0.706	0.076
			Clinical endpoint	24	0.13	2.66	-6.00	5.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	-0.280	0.293
			Clinical endpoint	27	-1.59	4.58	-17.00	5.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.39	1.91	0.79	9.15	0.035	0.890
			Clinical endpoint	26	-0.42	3.42	-7.00	7.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline PAL Delayed Trial (Sum Easy/Hard)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	-0.466	0.351
			Clinical endpoint	25	-0.32	1.77	-5.00	3.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.469	0.241
			Clinical endpoint	24	0.00	1.35	-2.00	3.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	16	5.37	2.57	2.33	13.26	-0.036	0.894
			Clinical endpoint	26	-1.08	1.57	-4.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.39	1.91	0.79	9.15	-0.061	0.809
			Clinical endpoint	25	-0.36	2.02	-6.00	3.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Alzheimer's Disease Assessment Scale (ADAS-cog)

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline Modified ADAS-cog	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.197	0.708
			Clinical endpoint	28	4.75	7.42	-7.00	25.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.772	0.025
			Clinical endpoint	31	-0.52	5.50	-16.00	13.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.126	0.631
			Clinical endpoint	29	10.69	9.81	-6.00	32.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.315	0.164
			Clinical endpoint	31	6.35	8.72	-11.00	25.00		
Difference From Baseline Unmodified ADAS-cog	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.278	0.593
			Clinical endpoint	28	4.54	6.93	-5.00	23.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.753	0.031
			Clinical endpoint	31	-0.68	5.35	-15.00	13.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.165	0.528
			Clinical endpoint	29	10.07	9.86	-5.00	32.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.317	0.161
			Clinical endpoint	31	5.68	8.10	-9.00	22.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

				Mini-Mental State Examination (MMSE)						
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline MMSE Score (Derived)	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.242	0.349
			Clinical endpoint	26	-4.46	4.46	-16.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.006	0.978
			Clinical endpoint	31	-2.77	3.47	-11.00	4.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline CDR	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	7.15	0.93	5.95	8.30	0.616	0.269
			Clinical endpoint	28	1.13	1.56	-1.00	4.50		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.117	0.784
			Clinical endpoint	31	0.47	1.40	-1.50	5.50		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.042	0.874
			Clinical endpoint	30	3.35	3.23	-1.50	14.50		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.231	0.315
			Clinical endpoint	31	1.60	2.15	-2.50	8.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

Intention-To-Treat Population

Disability Assessment in Dementia (DAD) Scale

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline DAD (%)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	5	7.15	0.93	5.95	8.30	-0.557	0.330
			Clinical endpoint	28	-8.41	15.68	-69.59	20.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	-0.026	0.950
			Clinical endpoint	31	-3.26	10.62	-31.39	23.33		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	-0.241	0.352
			Clinical endpoint	31	-16.53	21.81	-94.59	25.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.066	0.775
			Clinical endpoint	31	-7.34	14.07	-42.50	24.36		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Intention-To-Treat Population

			Disability Assessment - Neuropsychiatric Inventory (NPI)							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline NPI (Distress)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.554	0.254
			Clinical endpoint	29	0.69	5.88	-8.00	18.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.067	0.874
			Clinical endpoint	31	-1.90	4.88	-20.00	5.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.273	0.290
			Clinical endpoint	32	0.22	7.67	-28.00	18.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.228	0.321
			Clinical endpoint	31	0.29	4.98	-16.00	10.00		
Difference From Baseline NPI (Frequency Severity)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	6	6.96	0.96	5.95	8.30	0.545	0.263
			Clinical endpoint	29	2.31	10.65	-21.00	30.00		
		Placebo	Albumin CSF/Serum Ratio	8	5.31	1.21	3.91	7.39	0.047	0.912
			Clinical endpoint	31	-1.26	5.16	-15.00	8.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	17	5.36	2.49	2.33	13.26	0.046	0.862
			Clinical endpoint	32	2.19	13.04	-40.00	34.00		
		Placebo	Albumin CSF/Serum Ratio	21	5.35	1.77	0.79	9.15	-0.184	0.424
			Clinical endpoint	31	2.16	7.69	-18.00	20.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

Controlled Oral Word Association Test (COWAT) - FAS

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline Total Words Acceptable	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.487	0.513
			Clinical endpoint	17	-1.00	6.44	-14.00	7.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.467	0.291
			Clinical endpoint	23	-0.96	6.24	-10.00	11.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.074	0.819
			Clinical endpoint	16	-6.00	11.35	-36.00	12.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	0.197	0.404
			Clinical endpoint	24	-4.67	6.17	-19.00	10.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

Category Fluency Test (CFT)

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline Total Words Acceptable	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.991	0.009
			Clinical endpoint	17	-1.82	3.49	-9.00	4.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.027	0.954
			Clinical endpoint	23	0.09	3.74	-6.00	9.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.099	0.760
			Clinical endpoint	16	-5.06	2.82	-11.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	0.433	0.057
			Clinical endpoint	24	-2.00	3.31	-10.00	3.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

Trail Making Tests A (TMA) and B (TMB)

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Trails A Change From Baseline Derived Upper Limit	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.566	0.434
			Clinical endpoint	16	-1.13	16.51	-26.00	24.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.43	1.32	3.91	7.39	-0.119	0.823
			Clinical endpoint	22	6.27	18.58	-20.00	67.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.075	0.817
			Clinical endpoint	14	23.21	44.97	-74.00	120.00		
		Placebo	Albumin CSF/Serum Ratio	18	5.21	1.87	0.79	9.15	-0.462	0.054
			Clinical endpoint	22	14.18	26.77	-20.00	72.00		
Trails B Change From Baseline Derived Upper Limit	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.956	0.044
			Clinical endpoint	15	12.00	39.24	-70.00	69.00		
		Placebo	Albumin CSF/Serum Ratio	3	5.02	1.06	3.91	6.03	-0.839	0.366
			Clinical endpoint	18	2.83	36.84	-78.00	96.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	10	4.98	1.76	2.33	7.44	0.399	0.254
			Clinical endpoint	12	42.00	75.51	-63.00	164.00		
		Placebo	Albumin CSF/Serum Ratio	13	5.07	2.04	0.79	9.15	-0.410	0.164
			Clinical endpoint	17	13.18	63.87	-185.00	101.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

			Simple Reaction Time (SRT)							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline SRT	V1 (WEEK 0)	ACI-91	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	15	0.00	0.00	0.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	21	0.00	0.00	0.00	0.00		
	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	3	6.60	0.71	5.95	7.37	0.289	0.813
			Clinical endpoint	15	93.20	308.72	-588.00	637.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.43	1.32	3.91	7.39	0.003	0.995
			Clinical endpoint	20	-47.15	200.29	-495.00	257.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	11	4.78	1.70	2.33	7.44	-0.045	0.895
			Clinical endpoint	14	196.07	237.72	-76.00	620.00		
		Placebo	Albumin CSF/Serum Ratio	15	5.29	2.03	0.79	9.15	-0.669	0.006
			Clinical endpoint	19	70.58	193.25	-193.00	687.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

				Choice Reaction Time - GNG (CRTGNG)						
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline CRTGNG	V1 (WEEK 0)	ACI-91	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	14	0.00	0.00	0.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	21	0.00	0.00	0.00	0.00		
	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	3	6.60	0.71	5.95	7.37	0.425	0.721
			Clinical endpoint	13	31.38	100.54	-184.00	211.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.43	1.32	3.91	7.39	0.541	0.267
			Clinical endpoint	19	-6.68	71.82	-180.00	147.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	10	4.73	1.78	2.33	7.44	-0.460	0.181
			Clinical endpoint	13	81.38	110.76	-138.00	319.00		
		Placebo	Albumin CSF/Serum Ratio	14	5.20	2.08	0.79	9.15	-0.391	0.167
			Clinical endpoint	18	33.28	90.97	-195.00	216.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

Choice Reaction Time - MSO

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline CRTMSO	V1 (WEEK 0)	ACI-91	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	16	0.00	0.00	0.00	0.00		
		Placebo	Albumin CSF/Serum Ratio	0						
			Clinical endpoint	20	0.00	0.00	0.00	0.00		
	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	3	6.60	0.71	5.95	7.37	0.985	0.111
			Clinical endpoint	14	47.07	258.82	-239.00	830.00		
		Placebo	Albumin CSF/Serum Ratio	5	5.31	1.44	3.91	7.39	-0.222	0.720
			Clinical endpoint	18	-140.33	253.54	-748.00	215.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	11	4.78	1.70	2.33	7.44	-0.190	0.577
			Clinical endpoint	15	15.20	318.95	-653.00	639.00		
		Placebo	Albumin CSF/Serum Ratio	15	5.29	2.03	0.79	9.15	-0.032	0.909
			Clinical endpoint	19	-3.74	380.00	-1006.0	740.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

			Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline PAL Sum Trial 1-3 (Easy)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.559	0.441
			Clinical endpoint	17	0.00	2.96	-6.00	4.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.15	0.95	3.91	6.04	-0.584	0.223
			Clinical endpoint	19	0.32	2.00	-4.00	5.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.221	0.490
			Clinical endpoint	16	-0.06	2.46	-5.00	4.00		
		Placebo	Albumin CSF/Serum Ratio	16	5.31	2.00	0.79	9.15	-0.053	0.845
			Clinical endpoint	20	0.55	2.52	-4.00	6.00		
Difference From Baseline PAL Sum Trial 1-3 (Hard)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.144	0.856
			Clinical endpoint	17	-0.35	1.73	-4.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.15	0.95	3.91	6.04	-0.458	0.362
			Clinical endpoint	19	-0.42	1.12	-3.00	1.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.541	0.069
			Clinical endpoint	16	-0.56	2.28	-7.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	16	5.31	2.00	0.79	9.15	0.311	0.241
			Clinical endpoint	20	-0.85	2.06	-5.00	4.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

Wechsler Verbal Paired Associates Test (WVPAT) Paired Associative Learning

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline PAL Sum Trial 1-3 (Total)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.542	0.458
			Clinical endpoint	17	-0.35	3.89	-8.00	5.00		
		Placebo	Albumin CSF/Serum Ratio	6	5.15	0.95	3.91	6.04	-0.644	0.167
			Clinical endpoint	19	-0.11	2.16	-4.00	5.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.601	0.039
			Clinical endpoint	16	-0.63	3.40	-7.00	5.00		
		Placebo	Albumin CSF/Serum Ratio	16	5.31	2.00	0.79	9.15	0.141	0.602
			Clinical endpoint	20	-0.30	3.44	-6.00	7.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

			Wechsler Verbal Paired Associates Test - delayed (WVPATd) Paired Associative Learning							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline PAL Delayed Trial (Sum Easy/Hard)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.880	0.120
			Clinical endpoint	17	0.06	1.68	-2.00	3.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.358	0.431
			Clinical endpoint	20	-0.15	1.31	-2.00	3.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.377	0.227
			Clinical endpoint	16	-1.19	1.80	-4.00	2.00		
		Placebo	Albumin CSF/Serum Ratio	15	5.23	2.04	0.79	9.15	0.015	0.959
			Clinical endpoint	19	-0.58	2.06	-6.00	3.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

			Alzheimer's Disease Assessment Scale (ADAS-cog)							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline Modified ADAS-cog	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.360	0.640
			Clinical endpoint	17	2.41	5.61	-7.00	11.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.753	0.051
			Clinical endpoint	24	0.08	3.79	-6.00	10.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	0.281	0.377
			Clinical endpoint	17	9.35	8.24	-6.00	26.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	-0.315	0.176
			Clinical endpoint	24	5.58	8.69	-11.00	25.00		
Difference From Baseline Unmodified ADAS-cog	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.419	0.581
			Clinical endpoint	17	2.24	5.34	-5.00	11.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.710	0.074
			Clinical endpoint	24	-0.29	3.79	-7.00	10.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	0.268	0.400
			Clinical endpoint	17	8.76	8.24	-5.00	26.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	-0.317	0.173
			Clinical endpoint	24	4.88	7.85	-9.00	22.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

			Mini-Mental State Examination (MMSE)							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline MMSE Score (Derived)	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.106	0.743
			Clinical endpoint	17	-4.06	4.05	-16.00	1.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	-0.009	0.970
			Clinical endpoint	24	-2.38	3.62	-11.00	4.00		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

Clinical Dementia Rating (CDR) Sum of Boxes Rating Scale

Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline CDR	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	3	6.60	0.71	5.95	7.37	0.980	0.127
			Clinical endpoint	16	0.56	1.15	-1.00	3.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.442	0.321
			Clinical endpoint	24	0.15	0.87	-1.50	2.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	0.283	0.373
			Clinical endpoint	17	2.68	1.87	-0.50	7.00		
		Placebo	Albumin CSF/Serum Ratio	20	5.35	1.82	0.79	9.15	-0.237	0.314
			Clinical endpoint	24	1.17	1.79	-2.50	4.50		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

Per Protocol Population

			Disability Assessment in Dementia (DAD) Scale							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline DAD (%)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	3	6.60	0.71	5.95	7.37	-0.475	0.685
			Clinical endpoint	16	-4.16	9.55	-22.50	20.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	-0.231	0.618
			Clinical endpoint	24	-2.30	10.39	-31.39	23.33		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	-0.352	0.261
			Clinical endpoint	17	-14.71	15.65	-49.84	7.50		
		Placebo	Albumin CSF/Serum Ratio	19	5.40	1.85	0.79	9.15	-0.094	0.701
			Clinical endpoint	23	-4.27	13.33	-37.50	24.36		

Table 14.2.2.5: Correlation analysis of Albumin CSF/Serum Ratio with Change from Baseline in Clinical efficacy

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Per Protocol Population

			Disability Assessment - Neuropsychiatric Inventory (NPI)							
Clinical efficacy	Visit	Treat-ment	Variable	N	Mean	SD	Minimum	Maximum	Coefficient of Correlation	p-Value
Difference From Baseline NPI (Distress)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	-0.308	0.692
			Clinical endpoint	17	0.94	4.37	-6.00	12.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.142	0.761
			Clinical endpoint	24	-1.63	3.24	-11.00	2.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	0.272	0.392
			Clinical endpoint	17	-0.18	8.96	-28.00	12.00		
		Placebo	Albumin CSF/Serum Ratio	19	5.40	1.85	0.79	9.15	-0.229	0.347
			Clinical endpoint	23	0.39	4.22	-10.00	10.00		
Difference From Baseline NPI (Frequency Severity)	V3 (WEEK 12)	ACI-91	Albumin CSF/Serum Ratio	4	6.45	0.66	5.95	7.37	0.175	0.825
			Clinical endpoint	17	0.12	9.61	-14.00	30.00		
		Placebo	Albumin CSF/Serum Ratio	7	5.47	1.21	3.91	7.39	0.079	0.866
			Clinical endpoint	24	-1.71	5.57	-15.00	8.00		
	V6 (WEEK 52)	ACI-91	Albumin CSF/Serum Ratio	12	4.86	1.64	2.33	7.44	0.091	0.779
			Clinical endpoint	17	0.65	15.82	-40.00	34.00		
		Placebo	Albumin CSF/Serum Ratio	19	5.40	1.85	0.79	9.15	-0.185	0.449
			Clinical endpoint	23	1.91	7.37	-18.00	20.00		

Table 14.2.3.1: Pharmacokinetic assessments, descriptive statistics

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PK Population

Concentration	Treatment	Visit	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91 in plasma [ng/mL]	ACI-91	V1 (WEEK 0)	2	156.77	220.94	140.93	0.547	156.8	313
		V3 (WEEK 12)	24	125.16	48.39	38.66	46.3	120.0	224
		V6 (WEEK 52)	18	126.77	58.24	45.94	31.4	127.0	229
ACI-91 in CSF [ng/mL]	ACI-91	V1 (WEEK 0)	16	0.96	3.43	355.30	0	0.0	13.8
		V3 (WEEK 12)	6	13.94	5.40	38.76	5.82	15.4	19.4
		V6 (WEEK 52)	16	15.10	7.53	49.86	2.95	13.6	32.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.4.1: Albumin CSF/Serum Ratio, descriptive statistics

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Intention-To-Treat Population

Parameter	Treat-ment	Visit	N	Mean	SD	CV	Minimum	Median	Maximum
CSF albumin index	ACI-91	V1 (WEEK 0)	32	6.14	2.42	39.48	1.52	5.81	11.84
		V3 (WEEK 12)	6	6.96	0.96	13.78	5.95	6.93	8.30
		V6 (WEEK 52)	17	5.36	2.49	46.46	2.33	5.10	13.26
	Placebo	V1 (WEEK 0)	29	6.01	2.57	42.84	2.92	5.28	14.11
		V3 (WEEK 12)	8	5.31	1.21	22.74	3.91	5.40	7.39
		V6 (WEEK 52)	21	5.35	1.77	33.16	0.79	5.53	9.15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.2.5: Drug compliance, frequency table

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Safety Population

	Compliant (80-120%)		Not compliant#	
Treatment	N	%	N	%
ACI-91	22	68.8	10	31.3
Placebo	25	80.6	6	19.4
Total	47	74.6	16	25.4

Not compliant includes also patients with missing compliance due to missing visit 6

Table 14.3.1.1: Adverse events during study

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	002	1	TEAE	HEADACHE	2009-04-24	08:00	2009-04-28	12:00	4 4.00	1	MODERATE	NO
			TEAE	DIARRHOEA	2009-05-05	22:30	2009-05-05	23:50	1.33	12	MILD	NO
			TEAE	DIARRHOEA	2009-05-07	22:30	2009-05-07	23:59	1.48	14	MILD	NO
			TEAE	DIARRHOEA	2009-05-08	22:00	2009-05-08	23:59	1.98	15	MILD	NO
			TEAE	DIARRHOEA	2009-05-10	22:30	2009-05-10	23:59	1.48	17	MILD	NO
	004	1	TEAE	BACK PAIN	2009-07-24	08:00	2009-07-31	22:00	7 14.00	8	MILD	NO
	006	2	TEAE	HEADACHE	2010-11-10	09:00	2010-11-10	11:00	2.00	257	MILD	NO
	010	1	TEAE	ARTHRALGIA	2009-10-04	07:00	2009-11-20	07:00	47 0.00	75	MILD	NO
			TEAE	DELUSIONAL DISORDER, UNSPECIFIED TYPE	2009-10-16	10:00	2009-11-05	07:00	19 21.00	87	MILD	NO
			TEAE	DEEP VEIN THROMBOSIS	2009-11-04	08:30				106	MODERATE	NO
	012	1	TEAE	SCIATICA	2010-09-09	07:00				52	MODERATE	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	002	1	TEAE	HEADACHE	YES	RESOLVED	CONCOMITANT THERAPY	
			TEAE	DIARRHOEA	YES	RESOLVED	NONE	
			TEAE	DIARRHOEA	YES	RESOLVED	NONE	
			TEAE	DIARRHOEA	YES	RESOLVED	NONE	
			TEAE	DIARRHOEA	YES	RESOLVED	NONE	
	004	1	TEAE	BACK PAIN	NO	RESOLVED	NONE	
	006	2	TEAE	HEADACHE	NO	RESOLVED	CONCOMITANT THERAPY	
	010	1	TEAE	ARTHRALGIA	NO	RESOLVED WITH SEQUELAE	CONCOMITANT THERAPY, OTHER	ORTHOPADIC CHECK, DEGENERATIVE MENISCOPATHY
			TEAE	DELUSIONAL DISORDER, UNSPECIFIED TYPE	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	DEEP VEIN THROMBOSIS	NO	ONGOING	CONCOMITANT THERAPY, OTHER	ANGIOLOGICAL CHECK
	012	1	TEAE	SCIATICA	NO	ONGOING	CONCOMITANT THERAPY	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	012	1	TEAE	HEPATIC ENZYME INCREASED	2010-10-14	09:15	2010-11-29	08:45	45 23.50	87	MILD	NO
			TEAE	BRADYCARDIA	2010-10-14	09:30				87	MILD	NO
	014	4	TEAE	PROCEDURAL HEADACHE	2009-11-02	13:00	2009-11-03	09:00	20.00	0	MILD	NO
			TEAE	UPPER LIMB FRACTURE	2010-01-09	11:00	2010-02-09	11:00	31 0.00	68	MILD	NO
	015	4	TEAE	ADVERSE DRUG REACTION	2010-04	00:00	2010-05-15	00:00			MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	012	1	TEAE	HEPATIC ENZYME INCREASED	NO	RESOLVED	OTHER	GP INFORMED,WHO CONTROLLED THE INCREASED SGPT AND SGOT WITH NORMALIZED VALUES AT 29.11.2010
			TEAE	BRADYCARDIA	NO	ONGOING	OTHER	GP INFORMED, WHO DECIDED TO CONTROLL THE BRADYCARDIA BECAUSE OF NORMAL VALUES IN HER CONSULTING ROOM AND IN THE CASE OF ONGOING TO ARRANGE A CARDIOLOGICAL CHECK
	014	4	TEAE	PROCEDURAL HEADACHE	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	UPPER LIMB FRACTURE	NO	RESOLVED	OTHER	LIMB FIXATION
	015	4	TEAE	ADVERSE DRUG REACTION	NO	RESOLVED	CONCOMITANT THERAPY, OTHER	RAMIPRIL WAS STOPPED AT 14/05/2010, CHANGE OF HYPERTENSION MEDICATION INTO CANDESARTAN

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	017	5	TEAE	DECREASED APPETITE	2009-08-06	00:00	2009-10-28	00:00	84	1	MODERATE	NO
			TEAE	WEIGHT DECREASED	2009-08-06	00:00	2009-10-14	00:00	70	1	MODERATE	NO
			TEAE	DRY MOUTH	2009-08-06	00:00	2009-10-28	00:00	84	1	MILD	NO
			TEAE	COGNITIVE DISORDER	2009-08-09	00:00	2009-09-02	00:00	25	4	MODERATE	NO
			TEAE	MUSCULOSKELETAL PAIN	2009-09-23	00:00	2009-09-26	00:00	4	49	MILD	NO
			TEAE	FUNGAL SKIN INFECTION	2009-10-28	00:00	2009-11-25	00:00	29	84	MILD	NO
			TEAE	VOMITING	2009-12-20	00:00	2009-12-24	00:00	5	137	MILD	NO
			TEAE	MUSCULOSKELETAL PAIN	2010-07-26	08:00	2010-07-30	23:00	4 15.00	355	MILD	NO
	019	5	TEAE	DRY MOUTH	2010-05-11	08:00	2011-01-04	08:00	238 0.00	153	MILD	NO
	023	4	PTSS	DISOMFORT	2010-07-20	08:00	2011-08-11	08:00	387 0.00	0	MILD	NO
			PTSS	COCCYDYNIA	2010-07-20	08:00	2010-07-20	20:00	12.00	0	MILD	NO
			TEAE	DRY MOUTH	2010-07-21	08:00	2010-08-07	08:00	17 0.00	1	MILD	NO
			TEAE	TINEA PEDIS	2010-08-17	09:00				28	MILD	NO
			TEAE	DIARRHOEA	2010-08-24	17:00	2010-08-24	17:30	0.50	35	MILD	NO
			TEAE	SINUSITIS	2010-12-09	08:30	2010-12-10	18:30	1 10.00	142	MILD	NO
			TEAE	POLLAKIURIA	2011-01-07	NK:NK				171	MILD	NO
			TEAE	CYSTITIS	2011-01-26	08:00	2011-01-29	20:00	3 12.00	190	MILD	NO
			TEAE	ELECTROCARDIOGRAM QT PROLONGED	2011-03-21	12:22				244		NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken
ACI-91	017	5	TEAE	DECREASED APPETITE	YES	RESOLVED	NONE
			TEAE	WEIGHT DECREASED	YES	RESOLVED	NONE
			TEAE	DRY MOUTH	YES	RESOLVED	NONE
			TEAE	COGNITIVE DISORDER	YES	RESOLVED	NONE
			TEAE	MUSCULOSKELETAL PAIN	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	FUNGAL SKIN INFECTION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	VOMITING	NO	RESOLVED	NONE
			TEAE	MUSCULOSKELETAL PAIN	NO	RESOLVED	CONCOMITANT THERAPY
	019	5	TEAE	DRY MOUTH	YES	RESOLVED	NONE
	023	4	PTSS	DISOMFORT	NO	RESOLVED	NONE
			PTSS	COCCYDYNIA	NO	RESOLVED	NONE
			TEAE	DRY MOUTH	NO	RESOLVED	NONE
			TEAE	TINEA PEDIS	NO	ONGOING	CONCOMITANT THERAPY
			TEAE	DIARRHOEA	NO	RESOLVED	NONE
			TEAE	SINUSITIS	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	POLLAKIURIA	NO	ONGOING	CONCOMITANT THERAPY
			TEAE	CYSTITIS	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	ELECTROCARDIOGRAM QT PROLONGED		LOST TO FU	NONE

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	023	4	TEAE	ELECTROCARDIOGRAM QT PROLONGED	2011-07-18	14:10				363		NO
	027	20	TEAE	FATIGUE	2010-11-09	NK:NK	2011-06-01	NK:NK	205	19	MILD	NO
			TEAE	BENIGN NEOPLASM OF ADRENAL GLAND	2011-02-11	00:00				113	MILD	NO
			TEAE	PULMONARY MASS	2011-02-11	00:00				113	MILD	NO
			TEAE	EMPHYSEMA	2011-02-11	00:00				113	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-04-12	00:00	2011-04-22	00:00	11	173	MILD	NO
			TEAE	PNEUMONIA	2011-07-22	00:00	2011-08-01	00:00	11	274	MODERATE	YES
			TEAE	DERMATITIS ATOPIC	2011-07-22	00:00				274	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-10-25	00:00	2011-10-30	00:00	6	369	MILD	NO
	030	8	TEAE	DRY MOUTH	2010-04-01	NK:NK				7	MILD	NO
			TEAE	HEADACHE	2010-04-07	NK:NK	2010-04-07	NK:NK	1	13	MILD	NO
			TEAE	URINARY TRACT INFECTION	2010-06-17	NK:NK	2010-06-28	NK:NK	12	84	MILD	NO
			TEAE	HEADACHE	2010-08-19	10:00	2010-08-22	10:00	3 0.00	147	MILD	NO
			TEAE	HYPOAESTHESIA	2010-09-03	NK:NK	2011-03-14	13:30	193	162	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	023	4	TEAE	ELECTROCARDIOGRAM QT PROLONGED		LOST TO FU	NONE	
	027	20	TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	BENIGN NEOPLASM OF ADRENAL GLAND	NO	ONGOING	OTHER	EXAMINATION AT ENDOCRINOLOGY
			TEAE	PULMONARY MASS	NO	ONGOING	OTHER	SEND TO THE PULMONARY WARD
			TEAE	EMPHYSEMA	NO	ONGOING	NONE	
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	PNEUMONIA	NO	RESOLVED	HOSPITALIZATION, CONCOMITANT THERAPY	
			TEAE	DERMATITIS ATOPIC	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	NONE	
	030	8	TEAE	DRY MOUTH	YES	ONGOING	NONE	
			TEAE	HEADACHE	NO	RESOLVED	NONE	
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	HEADACHE	NO	RESOLVED	NONE	
			TEAE	HYPOAESTHESIA	NO	RESOLVED	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Serious
ACI-91	030	8	TEAE	ATAXIA	2010-09-03	NK:NK				162	MODERATE	NO
			TEAE	CHEST PAIN	2011-01-25	09:30	2011-02-01	15:00	7 5.50	306	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-02-11	10:00	2011-02-11	15:00	5.00	323	MILD	NO
			TEAE	DYSPNOEA	2011-02-28	11:00	2011-02-28	16:00	5.00	340	MILD	NO
			TEAE	DYSPNOEA	2011-03-05	09:00	2011-03-05	15:00	6.00	345	MILD	NO
			TEAE	TREMOR	2011-03-14	12:30	2011-03-14	12:45	0.25	354	MILD	YES
			TEAE	URINARY TRACT INFECTION	2011-03-14	14:00				354	MILD	NO
			TEAE	VOMITING	2011-03-28	NK:NK	2011-03-30	NK:NK	3	368	MODERATE	YES
			TEAE	VERTIGO	2011-03-28	NK:NK	2011-03-30	NK:NK	3	368	MODERATE	YES
	033	9	TEAE	FATIGUE	2010-05-29	00:00	2010-05-29	00:00	1	206	MILD	NO
	042	12	TEAE	AGITATION	2010-08	00:00					MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2010-01-15	10:00	2010-01-17	10:00	2 0.00	1	MILD	NO
			TEAE	DIARRHOEA	2010-01-27	09:00	2010-01-27	12:00	3.00	13	MILD	NO
			PTSS	DISORIENTATION	2009-12	17:00	2009-12	23:00			MILD	NO
	043	12	TEAE	ANAEMIA	2010-07	00:00					MILD	NO
			TEAE	CONSTIPATION	2010-05	00:00					MILD	NO
			TEAE	PARKINSONISM	2010-04	00:00					MILD	YES
			TEAE	HALLUCINATION	2009-12-29	00:00				41	MILD	YES

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Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken
ACI-91	030	8	TEAE	ATAXIA	NO	ONGOING	NONE
			TEAE	CHEST PAIN	NO	RESOLVED	NONE
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE
			TEAE	DYSPNOEA	NO	RESOLVED	NONE
			TEAE	DYSPNOEA	NO	RESOLVED	NONE
			TEAE	TREMOR	YES	RESOLVED	HOSPITALIZATION
			TEAE	URINARY TRACT INFECTION	NO	ONGOING	NONE
			TEAE	VOMITING	NO	RESOLVED	HOSPITALIZATION
			TEAE	VERTIGO	NO	RESOLVED	HOSPITALIZATION
	033	9	TEAE	FATIGUE	YES	RESOLVED	NONE
	042	12	TEAE	AGITATION	NO	ONGOING	CONCOMITANT THERAPY
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE
			TEAE	DIARRHOEA	NO	RESOLVED	NONE
			PTSS	DISORIENTATION	NO	RESOLVED	NONE
	043	12	TEAE	ANAEMIA	NO	ONGOING	NONE
			TEAE	CONSTIPATION	NO	ONGOING	CONCOMITANT THERAPY
			TEAE	PARKINSONISM	NO	ONGOING	HOSPITALIZATION
			TEAE	HALLUCINATION	YES	ONGOING	HOSPITALIZATION, CONCOMITANT THERAPY

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	043	12	TEAE	RESTLESSNESS	2009-12-30	00:00				42	MILD	NO
			TEAE	INTERTRIGO	2010-01-27	00:00	2010-05	00:00		70	MILD	NO
			TEAE	CIRCULATORY COLLAPSE	2010-04-30	00:00	2010-04-30	00:00	1	163	MODERATE	YES
			TEAE	SKIN LACERATION	2010-04-30	00:00	2010-05	00:00		163	MODERATE	YES
			TEAE	HYPOTENSION	2010-04-30	00:00	2010-04-30	17:00	17.00	163	MODERATE	YES
			TEAE	PYREXIA	2010-07-03	00:00	2010-07-04	00:00	2	227	MODERATE	NO
			TEAE	CONTUSION	2010-07-05	00:00	2010-08	00:00		229	MODERATE	YES
			TEAE	C-REACTIVE PROTEIN INCREASED	2010-07-05	00:00				229	MILD	NO
			TEAE	GENERAL PHYSICAL HEALTH DETERIORATION	2010-07-26	00:00				250	SEVERE	NO
			TEAE	PNEUMONIA ASPIRATION	2010-08-11	NK:NK	2010-08-12	NK:NK	2	266	SEVERE	YES
	046	11	TEAE	EXTRASYSTOLES	2010-01-11	00:00	2010-04-07	00:00	87	0	MODERATE	NO
			TEAE	HAEMATOMA	2010-04-07	00:00	2010-07-07	00:00	92	86	MILD	NO
			TEAE	RESTLESSNESS	2010-11-02	00:00				295	MILD	NO
			TEAE	CYSTIC LYMPHANGIOMA	2011-01-12	10:30				366	MILD	NO
			TEAE	BACTERIAL TEST	2011-02-07	00:00				392	MILD	NO
			TEAE	PROTEINURIA	2011-02-07	00:00				392	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	043	12	TEAE	RESTLESSNESS	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	INTERTRIGO	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	CIRCULATORY COLLAPSE	NO	RESOLVED	HOSPITALIZATION	
			TEAE	SKIN LACERATION	NO	RESOLVED WITH SEQUELAE	HOSPITALIZATION	
			TEAE	HYPOTENSION	NO	RESOLVED	HOSPITALIZATION	
			TEAE	PYREXIA	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	CONTUSION	NO	RESOLVED	HOSPITALIZATION, CONCOMITANT THERAPY, OTHER	PUNCTURE OF HAEMATOMA
			TEAE	C-REACTIVE PROTEIN INCREASED	NO	ONGOING	NONE	
			TEAE	GENERAL PHYSICAL HEALTH DETERIORATION	NO	ONGOING	STUDY DISCONTINUED PERMANENTLY	
			TEAE	PNEUMONIA ASPIRATION	NO	DEATH	HOSPITALIZATION	
	046	11	TEAE	EXTRASYSTOLES	NO	RESOLVED	NONE	
			TEAE	HAEMATOMA	NO	RESOLVED	NONE	
			TEAE	RESTLESSNESS	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	CYSTIC LYMPHANGIOMA	NO	ONGOING	OTHER	CONTROLLED
			TEAE	BACTERIAL TEST	NO	ONGOING	NONE	
			TEAE	PROTEINURIA	NO	ONGOING	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	048	11	TEAE	SYNCOPE	2011-08-04	00:00	2011-08-06	00:00	3	255	MILD	YES
	050	21	TEAE	MALAISE	2010-11-24	06:30	2010-11-24	17:45	11.25	28	MILD	NO
			TEAE	DIZZINESS	2010-11-26	06:20	2010-11-26	18:00	11.67	30	MILD	NO
			TEAE	NERVOUSNESS	2010-11-28	07:15	2010-11-28	18:30	11.25	32	MILD	NO
			TEAE	FATIGUE	2010-12-04	07:10	2010-12-04	18:10	11.00	38	MILD	NO
			TEAE	NAUSEA	2010-12-05	06:30	2010-12-05	17:00	10.50	39	MILD	NO
			TEAE	FATIGUE	2010-12-06	06:50	2010-12-06	17:30	10.67	40	MILD	NO
			TEAE	MALAISE	2010-12-09	07:10	2010-12-09	17:30	10.33	43	MILD	NO
			TEAE	MALAISE	2010-12-11	06:50	2010-12-11	17:40	10.83	45	MILD	NO
			TEAE	FATIGUE	2010-12-13	06:30	2010-12-13	17:10	10.67	47	MILD	NO
			TEAE	MALAISE	2011-01-22	07:15	2011-01-22	19:00	11.75	87	MILD	NO
			TEAE	BACK PAIN	2011-01-29	06:50	2011-01-29	18:10	11.33	94	MILD	NO
			TEAE	MALAISE	2011-01-30	07:10	2011-01-30	18:00	10.83	95	MILD	NO
			TEAE	HYPOAESTHESIA	2011-02-02	06:55	2011-02-03	18:15	1 11.33	98	MILD	NO
			TEAE	BONE PAIN	2011-02-14	06:30	2011-02-14	17:30	11.00	110	MILD	NO
			TEAE	FATIGUE	2011-02-15	06:50	2011-02-16	17:30	1 10.67	111	MILD	NO
			TEAE	ARTHRALGIA	2011-02-16	07:00	2011-02-16	17:30	10.50	112	MILD	NO
			TEAE	TOOTHACHE	2011-02-17	06:55	2011-02-17	18:10	11.25	113	MILD	NO
			TEAE	ARTHRALGIA	2011-02-19	07:15	2011-02-19	17:50	10.58	115	MILD	NO
			TEAE	ARTHRALGIA	2011-02-23	06:50	2011-02-23	17:30	10.67	119	MILD	NO
			TEAE	HOT FLUSH	2011-02-24	09:30	2011-02-24	18:10	8.67	120	MILD	NO
			TEAE	ARTHRALGIA	2011-02-26	06:45	2011-02-26	18:10	11.42	122	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	048	11	TEAE	SYNCOPE	NO	RESOLVED	HOSPITALIZATION	
	050	21	TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	DIZZINESS	NO	RESOLVED	NONE	
			TEAE	NERVOUSNESS	NO	RESOLVED	NONE	
			TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	NAUSEA	NO	RESOLVED	NONE	
			TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	BACK PAIN	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	HYPOAESTHESIA	NO	RESOLVED	NONE	
			TEAE	BONE PAIN	NO	RESOLVED	NONE	
			TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	TOOTHACHE	NO	RESOLVED	OTHER	VISIT TO THE DENTIST
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	HOT FLUSH	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	050	21	TEAE	HOT FLUSH	2011-02-27	10:00	2011-02-27	18:30	8.50	123	MILD	NO
			TEAE	HOT FLUSH	2011-03-02	11:00	2011-03-02	17:50	6.83	126	MILD	NO
			TEAE	ARTHRALGIA	2011-03-06	06:50	2011-03-06	17:30	10.67	130	MILD	NO
			TEAE	MUSCLE SPASMS	2011-03-08	07:10	2011-03-08	17:50	10.67	132	MILD	NO
			TEAE	ARTHRALGIA	2011-03-08	07:10	2011-03-08	17:50	10.67	132	MILD	NO
			TEAE	MUSCLE SPASMS	2011-03-14	06:30	2011-03-14	18:40	12.17	138	MILD	NO
			TEAE	MAJOR DEPRESSION	2011-03-15	07:00	2011-03-15	17:45	10.75	139	MILD	NO
			TEAE	BLADDER PAIN	2011-03-22	07:10	2011-03-22	18:30	11.33	146	MILD	NO
			TEAE	ARTHRALGIA	2011-03-25	06:50	2011-03-25	17:50	11.00	149	MILD	NO
			TEAE	BLADDER PAIN	2011-03-30	07:00	2011-03-30	18:30	11.50	154	MILD	NO
			TEAE	ARTHRALGIA	2011-03-31	07:00	2011-03-31	19:00	12.00	155	MILD	NO
			TEAE	BLADDER PAIN	2011-04-01	07:30	2011-04-01	18:10	10.67	156	MILD	NO
			TEAE	MALAISE	2011-04-02	07:10	2011-04-02	18:40	11.50	157	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-04-13	07:10	2011-04-13	17:30	10.33	168	MILD	NO
			TEAE	FATIGUE	2011-04-20	07:00	2011-04-20	18:50	11.83	175	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-04-24	06:55	2011-04-24	19:20	12.42	179	MILD	NO
			TEAE	VOMITING	2011-05-05	07:00	2011-05-07	18:10	2 11.17	190	MODERATE	NO
			TEAE	FATIGUE	2011-05-25	06:30	2011-05-25	17:30	11.00	210	MILD	NO
			TEAE	MALAISE	2011-05-29	07:00	2011-05-29	19:10	12.17	214	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-06-06	06:50	2011-06-09	17:30	3 10.67	222	MILD	NO
			TEAE	MALAISE	2011-06-06	08:00	2011-06-09	20:00	3 12.00	222	MILD	NO
			TEAE	COUGH	2011-06-07	06:50	2011-06-09	17:30	2 10.67	223	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	050	21	TEAE	HOT FLUSH	NO	RESOLVED	NONE	
			TEAE	HOT FLUSH	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	MUSCLE SPASMS	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	MUSCLE SPASMS	NO	RESOLVED	NONE	
			TEAE	MAJOR DEPRESSION	NO	RESOLVED	NONE	
			TEAE	BLADDER PAIN	NO	RESOLVED	OTHER	PATIENT VISITED PRACTITIONER.
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	BLADDER PAIN	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	BLADDER PAIN	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	VOMITING	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	FATIGUE	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	COUGH	NO	RESOLVED	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	050	21	TEAE	URINARY TRACT INFECTION	2011-06-09	06:50	2011-06-11	17:50	2 11.00	225	MILD	NO
			TEAE	EAR PAIN	2011-06-11	07:00	2011-06-12	18:00	1 11.00	227	MILD	NO
			TEAE	FATIGUE	2011-06-12	08:55	2011-06-12	18:00	9.08	228	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-06-13	07:50	2011-06-13	19:00	11.17	229	MILD	NO
			TEAE	EAR PAIN	2011-06-14	07:30	2011-06-14	18:30	11.00	230	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-06-14	07:30	2011-06-15	18:30	1 11.00	230	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-06-15	08:10	2011-06-15	18:30	10.33	231	MILD	NO
			TEAE	EAR PAIN	2011-06-17	07:45	2011-06-17	18:00	10.25	233	MILD	NO
			TEAE	BLADDER PAIN	2011-06-18	08:10	2011-06-18	17:30	9.33	234	MILD	NO
			TEAE	EAR PAIN	2011-06-19	07:10	2011-06-19	18:20	11.17	235	MILD	NO
			TEAE	EAR PAIN	2011-06-21	06:45	2011-06-21	17:30	10.75	237	MILD	NO
			TEAE	EAR PAIN	2011-06-23	07:00	2011-06-23	17:50	10.83	239	MILD	NO
			TEAE	EAR PAIN	2011-06-27	07:05	2011-06-27	17:50	10.75	243	MILD	NO
			TEAE	ELECTROCARDIOGRAM LOW VOLTAGE	2011-07-04	11:56	2011-10-24	09:35	111 21.65	250	MILD	NO
			TEAE	NAUSEA	2011-07-24	06:45	2011-07-24	18:30	11.75	270	MILD	NO
			TEAE	FATIGUE	2011-08-02	06:50	2011-08-03	17:50	1 11.00	279	MILD	NO
			TEAE	MALAISE	2011-08-08	06:50	2011-08-08	18:05	11.25	285	MILD	NO
			TEAE	MALAISE	2011-08-16	07:00	2011-08-17	19:00	1 12.00	293	MILD	NO
			TEAE	MALAISE	2011-08-21	07:00	2011-08-21	19:00	12.00	298	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken
ACI-91	050	21	TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	FATIGUE	NO	RESOLVED	NONE
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	BLADDER PAIN	NO	RESOLVED	NONE
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	EAR PAIN	NO	RESOLVED	NONE
			TEAE	ELECTROCARDIOGRAM LOW VOLTAGE	NO	RESOLVED	NONE
			TEAE	NAUSEA	NO	RESOLVED	NONE
			TEAE	FATIGUE	NO	RESOLVED	NONE
			TEAE	MALAISE	NO	RESOLVED	NONE
			TEAE	MALAISE	NO	RESOLVED	NONE
			TEAE	MALAISE	NO	RESOLVED	NONE

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	050	21	TEAE	MALAISE	2011-08-25	07:00	2011-08-25	19:00	12.00	302	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-08-27	07:00	2011-08-28	19:00	1 12.00	304	MILD	NO
			TEAE	ASTHENIA	2011-08-30	07:00	2011-08-30	19:00	12.00	307	MILD	NO
			TEAE	SKIN LACERATION	2011-08-31	07:10	2011-08-31	17:30	10.33	308	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-09-04	07:00	2011-09-04	19:00	12.00	312	MILD	NO
			TEAE	ASTHENIA	2011-09-05	07:00	2011-09-08	19:00	3 12.00	313	MILD	NO
			TEAE	MALAISE	2011-09-08	07:00	2011-09-08	19:00	12.00	316	MILD	NO
			TEAE	ASTHENIA	2011-09-10	07:00	2011-09-10	19:00	12.00	318	MILD	NO
			TEAE	ASTHENIA	2011-09-12	07:00	2011-09-12	19:00	12.00	320	MILD	NO
			TEAE	HYPOAESTHESIA	2011-09-14	07:00	2011-09-14	19:00	12.00	322	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-09-19	07:00	2011-09-22	19:00	3 12.00	327	MILD	NO
			TEAE	ARTHRALGIA	2011-10-03	07:00	2011-10-04	19:00	1 12.00	341	MILD	NO
			TEAE	FACIAL PALSY	2011-10-07	03:00	2011-10-07	04:00	1.00	345	MILD	NO
			TEAE	ARTHRALGIA	2011-10-11	07:00	2011-10-11	19:00	12.00	349	MILD	NO
			TEAE	MALAISE	2011-10-11	07:00	2011-10-11	19:00	12.00	349	MILD	NO
			TEAE	ARTHRALGIA	2011-10-14	07:00	2011-10-14	19:00	12.00	352	MILD	NO
			TEAE	ABDOMINAL PAIN UPPER	2011-10-18	07:00	2011-10-18	19:00	12.00	356	MILD	NO
			TEAE	ARTHRALGIA	2011-10-21	07:00	2011-10-21	19:00	12.00	359	MILD	NO
			TEAE	VOMITING	2011-10-24	08:00	2011-10-28	18:00	4 10.00	362	MODERATE	NO
			TEAE	NASOPHARYNGITIS	2011-12-08	08:00				407	MILD	NO
			TEAE	DIARRHOEA	2011-12-08	08:00				407	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	050	21	TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	ASTHENIA	NO	RESOLVED	NONE	
			TEAE	SKIN LACERATION	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	ASTHENIA	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	ASTHENIA	NO	RESOLVED	NONE	
			TEAE	ASTHENIA	NO	RESOLVED	NONE	
			TEAE	HYPOAESTHESIA	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	FACIAL PALSY	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	MALAISE	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	ABDOMINAL PAIN UPPER	NO	RESOLVED	NONE	
			TEAE	ARTHRALGIA	NO	RESOLVED	NONE	
			TEAE	VOMITING	NO	RESOLVED	CONCOMITANT THERAPY, OTHER	EXAMINATION IN THE DEPARTMENT OF NEUROLOGY, LABORATORY
			TEAE	NASOPHARYNGITIS	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	DIARRHOEA	NO	ONGOING	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	050	21	TEAE	VOMITING	2011-12-08	08:00				407	MILD	NO
	052	21	TEAE	HEADACHE	2010-11-01	07:00	2010-11-01	18:00	11.00	4	MILD	NO
			TEAE	JOINT SPRAIN	2011-02-28	12:00	2011-03-01	12:00	1 0.00	123	MILD	NO
	055	5	TEAE	HYPERSENSITIVITY	2010-03-30	09:00	2010-03-31	09:00	1 0.00	1	MILD	NO
	057	1	TEAE	HERPES ZOSTER	2011-04-06	08:00	2011-04-13	22:00	7 14.00	230	MODERATE	YES
	066	16	TEAE	DIARRHOEA	2010-09-18	09:00	2010-09-20	13:00	2 4.00	9	MILD	NO
			TEAE	RESTLESSNESS	2010-09-23	18:00	2011-02-03	NK:NK	134	14	MODERATE	NO
			TEAE	DRY MOUTH	2010-10-01	NK:NK	2011-01-06	NK:NK	98	22	MILD	NO
			TEAE	ENDODONTIC PROCEDURE	2010-11-02	NK:NK	2010-11-02	NK:NK	1	54	MILD	NO
			TEAE	AGGRESSION	2010-12-14	NK:NK	2010-12-19	NK:NK	6	96	MODERATE	NO
			TEAE	AGGRESSION	2010-12-20	NK:NK	2011-01-04	NK:NK	16	102	SEVERE	NO
			TEAE	VOMITING	2010-12-21	NK:NK	2010-12-21	NK:NK	1	103	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	050	21	TEAE	VOMITING	NO	ONGOING	NONE	
	052	21	TEAE	HEADACHE	NO	RESOLVED	NONE	
			TEAE	JOINT SPRAIN	NO	RESOLVED	NONE	
	055	5	TEAE	HYPERSENSITIVITY	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	
	057	1	TEAE	HERPES ZOSTER	NO	RESOLVED	HOSPITALIZATION, CONCOMITANT THERAPY	
	066	16	TEAE	DIARRHOEA	YES	RESOLVED	NONE	
			TEAE	RESTLESSNESS	YES	RESOLVED	CONCOMITANT THERAPY	
			TEAE	DRY MOUTH	YES	RESOLVED	NONE	
			TEAE	ENDODONTIC PROCEDURE	NO	RESOLVED	CONCOMITANT THERAPY, OTHER	SURGERY
			TEAE	AGGRESSION	NO	RESOLVED WITH SEQUELAE	CONCOMITANT THERAPY	
			TEAE	AGGRESSION	NO	RESOLVED WITH SEQUELAE		
			TEAE	VOMITING	NO	RESOLVED	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	066	16	TEAE	AGGRESSION	2011-01-05	NK:NK	2011-02-03	NK:NK	30	118	SEVERE	YES
			TEAE	AGGRESSION	2011-02-04	NK:NK				148	MILD	NO
	067	16	TEAE	HEADACHE	2010-11-19	08:30	2011-01-03	NK:NK	46	1	MODERATE	NO
			TEAE	NAUSEA	2010-11-19	08:30	2011-01-01	NK:NK	44	1	MODERATE	NO
			TEAE	ABNORMAL DREAMS	2010-11-19	20:30	2011-01-03	NK:NK	46	1	MODERATE	NO
			TEAE	DRY MOUTH	2010-11-20	NK:NK	2010-12-06	NK:NK	17	2	MODERATE	NO
			TEAE	VOMITING	2010-11-29	NK:NK	2011-01-01	NK:NK	34	11	MILD	NO
	071	18	TEAE	CATARACT	2010-12	NK:NK	2010-12-15	NK:NK			MILD	NO
			TEAE	DIARRHOEA	2010-11-14	NK:NK	2010-11-16	NK:NK	3	5	MILD	NO
			TEAE	CORNEAL SCAR	2011-02-03	NK:NK	2011-02-07	NK:NK	5	86	MILD	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	066	16	TEAE	AGGRESSION	NO	RESOLVED WITH SEQUELAE	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
			TEAE	AGGRESSION	NO	ONGOING	CONCOMITANT THERAPY	
	067	16	TEAE	HEADACHE	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	
			TEAE	NAUSEA	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	
			TEAE	ABNORMAL DREAMS	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	
			TEAE	DRY MOUTH	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	
			TEAE	VOMITING	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	
	071	18	TEAE	CATARACT	NO	RESOLVED WITH SEQUELAE	OTHER	AMULANT OPERATION
			TEAE	DIARRHOEA	NO	RESOLVED	NONE	
			TEAE	CORNEAL SCAR	NO	RESOLVED WITH SEQUELAE	OTHER	NEW OPERATION PLANNED

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd	hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	071	18	TEAE	GAMMA-GLUTAMYLTRANSFERASE INCREASED	2011-02-03	10:07	2011-04-12	10:10	68	0.05	86	MODERATE	NO
			TEAE	EYE OPERATION	2011-02-07	NK:NK	2011-02-09	NK:NK	3		90	MILD	YES
			TEAE	HYPERTENSION	2011-02-13	NK:NK	2011-02-13	NK:NK	1		96	MODERATE	NO
			TEAE	ACNE	2011-03-01	NK:NK	2011-05-04	NK:NK	65		112	MODERATE	NO
			TEAE	HYPERTENSION	2011-11-17	11:45	2011-12-05	12:10	18	0.42	373	MILD	NO
	080	13	TEAE	PSYCHOTIC DISORDER	2010-12	NK:NK	2011-02-26	NK:NK				MILD	NO
			TEAE	DEPRESSION	2010-12	NK:NK	2011-05	NK:NK				MODERATE	NO
			TEAE	DISORIENTATION	2010-12	NK:NK						MODERATE	NO
			TEAE	TONGUE DISORDER	2010-11-24	NK:NK					6	MODERATE	NO
			TEAE	BLOOD CREATININE INCREASED	2010-12-29	NK:NK	2011-02-09	NK:NK	43		41	MODERATE	NO
			TEAE	WHITE BLOOD CELLS URINE	2010-12-29	NK:NK	2011-02-09	NK:NK	43		41	MILD	NO
			TEAE	DISORIENTATION	2011-02-26	NK:NK	2011-05	NK:NK			100	SEVERE	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	071	18	TEAE	GAMMA-GLUTAMYLTRANSFERASE INCREASED	YES	RESOLVED	NONE	
			TEAE	EYE OPERATION	NO	RESOLVED WITH SEQUELAE	HOSPITALIZATION	
			TEAE	HYPERTENSION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	ACNE	NO	RESOLVED	NONE	
			TEAE	HYPERTENSION	NO	RESOLVED	NONE	
	080	13	TEAE	PSYCHOTIC DISORDER	YES	RESOLVED WITH SEQUELAE	NONE	
			TEAE	DEPRESSION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	DISORIENTATION	NO	ONGOING	CONCOMITANT THERAPY, OTHER	EXTRA VISIT 29-DEC-2010
			TEAE	TONGUE DISORDER	YES	ONGOING	NONE	
			TEAE	BLOOD CREATININE INCREASED	YES	RESOLVED	NONE	
			TEAE	WHITE BLOOD CELLS URINE	NO	RESOLVED	NONE	
			TEAE	DISORIENTATION	YES	RESOLVED	STUDY DISCONTINUED PERMANENTLY	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
ACI-91	080	13	TEAE	PSYCHOTIC DISORDER	2011-02-26	NK:NK	2011-05	NK:NK		100	SEVERE	YES
			TEAE	CONSTIPATION	2011-02-27	NK:NK				101	MILD	NO
	081	17	TEAE	SUBDURAL HAEMATOMA	2011-09-05	14:00	2011-09-20	09:00	14 19.00	326	MILD	YES
	087	16	TEAE	DEMENTIA	2011-01-01	NK:NK				33	MODERATE	NO
			TEAE	DIARRHOEA	2011-05-01	NK:NK				153	MODERATE	NO
			TEAE	INCONTINENCE	2011-11-01	NK:NK				337	MILD	NO
	089	5	TEAE	SYNCOPE	2011-01-06	17:20	2011-01-06	17:22	0.03	51	MILD	NO
			TEAE	ATRIOVENTRICULAR BLOCK FIRST DEGREE	2011-02-07	11:30	2011-02-16	10:35	8 23.08	83	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-11-14	08:00	2011-11-21	NK:NK	8	363	MILD	NO
	097	12	TEAE	HAEMATOMA	2011-02-04	00:00				79	MILD	NO
			TEAE	BRONCHITIS	2011-02-16	00:00				91	MODERATE	YES

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
ACI-91	080	13	TEAE	PSYCHOTIC DISORDER	YES	RESOLVED	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
			TEAE	CONSTIPATION	NO	ONGOING	CONCOMITANT THERAPY	
	081	17	TEAE	SUBDURAL HAEMATOMA	NO	RESOLVED	OTHER	MRI, SUBDURAL HEMATOMA RESOLVED
	087	16	TEAE	DEMENTIA	YES	ONGOING	CONCOMITANT THERAPY	
			TEAE	DIARRHOEA	NO	ONGOING	NONE	
			TEAE	INCONTINENCE	NO	ONGOING	NONE	
	089	5	TEAE	SYNCOPE	NO	RESOLVED	NONE	
			TEAE	ATRIOVENTRICULAR BLOCK FIRST DEGREE	NO	RESOLVED	NONE	
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	OTHER	REFERRAL TO GP FOR FOLLOW-UP
	097	12	TEAE	HAEMATOMA	NO	ONGOING	NONE	
			TEAE	BRONCHITIS	NO	ONGOING	HOSPITALIZATION, CONCOMITANT THERAPY	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	001	1	TEAE	DIZZINESS	2009-04-11	08:00	2009-04-13	08:00	2 0.00	2	MILD	NO
			TEAE	NAUSEA	2009-05-16	21:00	2009-05-17	08:00	11.00	37	MILD	NO
			TEAE	HYPERTENSION	2009-06-18	08:00				70	MILD	NO
			TEAE	ABDOMINAL DISCOMFORT	2009-07-25	08:30				107	MILD	NO
			TEAE	ESSENTIAL TREMOR	2009-12-10	NK:NK				245	MILD	NO
			TEAE	URINARY TRACT INFECTION	2010-02-05	08:00	2010-02-10	20:00	5 12.00	302	MILD	NO
	003	1	TEAE	ADVERSE DRUG REACTION	2009-07-03	08:50	2009-07-03	17:30	8.67	36	SEVERE	NO
			TEAE	DEPRESSION	2009-10-01	08:00	2009-11-01	08:00	31 0.00	126	MILD	NO
	011	1	TEAE	BUNDLE BRANCH BLOCK RIGHT	2010-05-06	12:47				161	MILD	NO
			TEAE	URINARY TRACT INFECTION	2010-12-27	NK:NK	2010-12-31	NK:NK	5	396	MILD	NO
	016	4	TEAE	DIZZINESS	2010-04-16	00:00	2010-04-22	00:00	7	46	MODERATE	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
Placebo	001	1	TEAE	DIZZINESS	YES	RESOLVED	NONE	
			TEAE	NAUSEA	YES	RESOLVED	NONE	
			TEAE	HYPERTENSION	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	ABDOMINAL DISCOMFORT	NO	ONGOING	OTHER	CHECK BY THE INTERNIST, NO PATHOLOGICAL RESULT
			TEAE	ESSENTIAL TREMOR	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY	
	003	1	TEAE	ADVERSE DRUG REACTION	NO	RESOLVED	IMP DISCONTINUED AND RESTARTED, CONCOMITANT THERAPY	
			TEAE	DEPRESSION	NO	RESOLVED	CONCOMITANT THERAPY	
	011	1	TEAE	BUNDLE BRANCH BLOCK RIGHT	NO	ONGOING	OTHER	GENERAL PRACTICIONER INFORMED
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY	
	016	4	TEAE	DIZZINESS	NO	RESOLVED	OTHER	DONEPEZIL 10 MG AFTER LUNCH INSTEAD OF IN THE MORNING

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	016	4	TEAE	DIZZINESS	2010-05-20	06:50	2010-05-20	18:50	12.00	80	MILD	NO
			TEAE	EPILEPSY	2011-02-28	11:30				364	MILD	NO
	024	4	TEAE	CATARACT OPERATION	2010-11-30	09:00	2010-11-30	12:00	3.00	106	MILD	NO
			TEAE	TOOTH INFECTION	2011-01-28	09:00	2011-02-01	21:00	4 12.00	165	MILD	NO
			TEAE	VENTRICULAR EXTRASYSTOLES	2011-08-08	13:59				357	MILD	NO
	028	20	TEAE	MONOCYTOSIS	2011-02-23	NK:NK				89	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-02-23	NK:NK	2011-03-10	NK:NK	16	89	MILD	NO

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
Placebo	016	4	TEAE	DIZZINESS	NO	RESOLVED	NONE	
			TEAE	EPILEPSY	NO	ONGOING	CONCOMITANT THERAPY	
	024	4	TEAE	CATARACT OPERATION	NO	RESOLVED	OTHER	OUT PATIENT MINIMAL SURGERY
			TEAE	TOOTH INFECTION	NO	RESOLVED	OTHER	ANTIBIOTIC THERAPY PO. (SEE CONCOMITANT MEDICATION)
			TEAE	VENTRICULAR EXTRASYSTOLES			OTHER	PATIENT HAS TO PERFORM CARDIOLOGIC EXAMINATIONS (ECG, ULTRASOUND, ERGOMETRIC ECG, 24H ECG) ACCORDING TO THE RECOMMENDATION OF OUR CONSULTING CARDIOLOGIST.
	028	20	TEAE	MONOCYTOSIS	NO	ONGOING	OTHER	BLOOD COUNT TO HÄMATOLOGY DEPARTMENT
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY	

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	028	20	TEAE	PNEUMONIA	2011-03-02	NK:NK	2011-03-17	NK:NK	16	96	MODERATE	YES
	029	8	PTSS	PAIN IN EXTREMITY	2010-01-28	17:45	2010-01-29	12:00	18.25	-1	MILD	NO
			PTSS	HEADACHE	2010-01-29	10:00	2010-01-29	15:00	5.00	0	SEVERE	NO
			TEAE	WHITE BLOOD CELLS URINE POSITIVE	2010-01-29	15:00				0	MILD	NO
			TEAE	MUSCLE SPASMS	2010-01-29	21:00	2010-01-29	NK:NK	1	0	MILD	NO
			TEAE	MUSCULOSKELETAL PAIN	2010-01-30	11:00	2010-01-30	NK:NK	1	1	MILD	NO
			TEAE	TINNITUS	2010-02-01	NK:NK	2010-02-01	NK:NK	1	3	MILD	NO
			TEAE	GASTRITIS	2010-02-03	NK:NK	2010-02-10	NK:NK	8	5	MODERATE	NO
			TEAE	VOMITING	2010-02-03	01:30	2010-02-10	NK:NK	8	5	MODERATE	NO
			TEAE	URINARY TRACT INFECTION	2010-07-05	10:30	2010-08-13	NK:NK	40	157	SEVERE	NO
			TEAE	ABDOMINAL DISTENSION	2010-08-24	19:30	2010-08-24	22:00	2.50	207	MILD	NO
			TEAE	URINARY TRACT INFECTION	2010-09-30	11:00	2010-10-06	NK:NK	7	244	MILD	NO
			TEAE	URINARY SEDIMENT PRESENT	2011-02-01	10:45				368	MILD	NO
			TEAE	NEUTROPHIL COUNT INCREASED	2011-02-23	NK:NK				390	MILD	NO
			TEAE	URINARY TRACT INFECTION	2011-02-23	NK:NK				390	MILD	NO

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken
Placebo	028	20	TEAE	PNEUMONIA	NO	RESOLVED	HOSPITALIZATION, CONCOMITANT THERAPY
	029	8	PTSS	PAIN IN EXTREMITY	NO	RESOLVED	CONCOMITANT THERAPY
			PTSS	HEADACHE	NO	RESOLVED	NONE
			TEAE	WHITE BLOOD CELLS URINE POSITIVE	NO	ONGOING	NONE
			TEAE	MUSCLE SPASMS	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	MUSCULOSKELETAL PAIN	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	TINNITUS	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	GASTRITIS	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	VOMITING	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	ABDOMINAL DISTENSION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	URINARY SEDIMENT PRESENT	NO	ONGOING	NONE
			TEAE	NEUTROPHIL COUNT INCREASED	NO	ONGOING	NONE
			TEAE	URINARY TRACT INFECTION	NO	ONGOING	NONE

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	031	8	TEAE	PARAESTHESIA	2010-07	NK:NK					MILD	NO
			TEAE	BACK PAIN	2010-05-20	18:00	2010-05-22	18:00	2 0.00	0	MILD	NO
			TEAE	MUSCULOSKELETAL PAIN	2010-10-26	06:00	2010-11-30	NK:NK	36	159	MODERATE	NO
			TEAE	DISORIENTATION	2011-05-18	NK:NK	2011-06-06	NK:NK	20	363	MILD	NO
			TEAE	INSOMNIA	2011-05-18	NK:NK				363	MODERATE	NO
	034	9	TEAE	NAUSEA	2010-03-26	00:00	2010-03-26	00:00	1	8	MILD	NO
			TEAE	MALAISE	2010-04-29	00:00	2010-04-29	00:00	1	42	MILD	NO
	041	12	TEAE	GASTRITIS	2009-10-17	14:00	2009-11-03	00:00	16 10.00	8	MILD	NO
			TEAE	HYPERTENSION	2010-01-11	00:00				94	MILD	NO
	045	11	PTSS	RASH	2009-12-21	00:00				0	MILD	NO
			TEAE	GASTROINTESTINAL INFECTION	2010-01-30	07:30	2010-02-04	12:00	5 4.50	40	MODERATE	NO
			TEAE	LIPOMA	2010-02-10	00:00				51	MILD	NO
			TEAE	VITREOUS DISORDER	2010-05-06	00:00	2010-05-17	00:00	12	136	MILD	NO
	049	21	PTSS	URINARY TRACT INFECTION	2010-10-24	00:00	2010-11-21	23:59	28 23.98	-3	MILD	NO
			TEAE	AGGRESSION	2010-11-01	08:00	2010-11-04	18:30	3 10.50	5	MILD	NO

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treatment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
Placebo	031	8	TEAE	PARAESTHESIA	NO	ONGOING	NONE	
			TEAE	BACK PAIN	NO	RESOLVED	NONE	
			TEAE	MUSCULOSKELETAL PAIN	NO	RESOLVED	CONCOMITANT THERAPY, OTHER	PHYSIOTHERAPY
			TEAE	DISORIENTATION	NO	RESOLVED	NONE	
			TEAE	INSOMNIA	NO	ONGOING	CONCOMITANT THERAPY	
	034	9	TEAE	NAUSEA	NO	RESOLVED	NONE	
			TEAE	MALAISE	YES	RESOLVED	NONE	
	041	12	TEAE	GASTRITIS	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	HYPERTENSION	NO	ONGOING	CONCOMITANT THERAPY	
	045	11	PTSS	RASH	NO	ONGOING	NONE	
			TEAE	GASTROINTESTINAL INFECTION	NO	RESOLVED	IMP DISCONTINUED AND RESTARTED	
			TEAE	LIPOMA	NO	ONGOING	NONE	
			TEAE	VITREOUS DISORDER	NO	RESOLVED	IMP DISCONTINUED AND RESTARTED	
	049	21	PTSS	URINARY TRACT INFECTION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	AGGRESSION	NO	RESOLVED	NONE	

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	049	21	TEAE	AGGRESSION	2010-11-08	07:30	2010-11-08	18:30	11.00	12	MILD	NO
			TEAE	THERMAL BURN	2010-11-19	00:00	2010-11-19	23:59	23.98	23	MILD	NO
			TEAE	AGGRESSION	2010-12-18	09:00	2010-12-18	19:30	10.50	52	MILD	NO
			TEAE	AGGRESSION	2011-01-13	07:30	2011-01-13	17:00	9.50	78	MILD	NO
			TEAE	AGGRESSION	2011-01-26	16:00	2011-01-26	21:00	5.00	91	MILD	NO
			TEAE	NASOPHARYNGITIS	2011-01-30	07:30	2011-01-30	18:00	10.50	95	MILD	NO
			TEAE	AGGRESSION	2011-02-03	07:30	2011-02-06	18:00	3 10.50	99	MILD	NO
			TEAE	DECREASED APPETITE	2011-03-18	08:00	2011-03-19	18:00	1 10.00	142	MILD	NO
			TEAE	VOMITING	2011-05-08	07:00	2011-05-08	10:00	3.00	193	MILD	NO
			TEAE	NAUSEA	2011-05-08	07:00	2011-05-08	10:00	3.00	193	MILD	NO
			TEAE	APATHY	2011-05-08	08:00	2011-05-09	20:00	1 12.00	193	MILD	NO
			TEAE	VITAMIN D DEFICIENCY	2011-05-27	10:47				212	MILD	NO
			TEAE	DECREASED APPETITE	2011-09-01	07:30	2011-09-05	18:00	4 10.50	309	MILD	NO
			TEAE	ABNORMAL BEHAVIOUR	2011-09-06	00:00				314	SEVERE	YES
			TEAE	HYPOKALAEMIA	2011-09-06	08:00	2011-10-14	23:59	38 15.98	314	MILD	NO
			TEAE	VITAMIN B COMPLEX DEFICIENCY	2011-09-06	08:00				314	MILD	NO

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
Placebo	049	21	TEAE	AGGRESSION	NO	RESOLVED	NONE	
			TEAE	THERMAL BURN	NO	RESOLVED	OTHER	VISIT AT DEPARTMENT OF DERMATOLOGY
			TEAE	AGGRESSION	NO	RESOLVED	NONE	
			TEAE	AGGRESSION	NO	RESOLVED	NONE	
			TEAE	AGGRESSION	NO	RESOLVED	NONE	
			TEAE	NASOPHARYNGITIS	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	AGGRESSION	NO	RESOLVED	NONE	
			TEAE	DECREASED APPETITE	NO	RESOLVED	NONE	
			TEAE	VOMITING	NO	RESOLVED	NONE	
			TEAE	NAUSEA	NO	RESOLVED	NONE	
			TEAE	APATHY	NO	RESOLVED	NONE	
			TEAE	VITAMIN D DEFICIENCY	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	DECREASED APPETITE	NO	RESOLVED	NONE	
			TEAE	ABNORMAL BEHAVIOUR	NO	ONGOING	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
			TEAE	HYPOKALAEMIA	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	VITAMIN B COMPLEX DEFICIENCY	NO	ONGOING	CONCOMITANT THERAPY	

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	049	21	TEAE	PELVIC VENOUS THROMBOSIS	2011-09-10	08:00	2011-09-19	18:00	9 10.00	318	SEVERE	YES
	051	21	TEAE	ANXIETY	2011-03-02	20:00	2011-03-03	08:00	12.00	125	MILD	NO
			TEAE	ANXIETY	2011-04-12	07:00	2011-07-05	19:00	84 12.00	166	MILD	NO
			TEAE	ELECTROCARDIOGRAM POOR R-WAVE PROGRESSION	2011-04-12	13:37	2011-07-05	13:47	84 0.17	166	MILD	NO
	056	5	TEAE	SPINAL COLUMN STENOSIS	2010-05-03	00:00	2010-07-05	00:00	64	12	MODERATE	YES
	058	1	TEAE	HYPERTENSION	2011-03-23	NK:NK				86	MILD	NO
			TEAE	NASOPHARYNGITIS	2011-06-04	08:00	2011-06-10	22:00	6 14.00	159	MILD	NO
			TEAE	SINUSITIS	2011-10-13	08:00	2011-10-16	22:00	3 14.00	290	MILD	NO
			TEAE	BACTERIURIA	2011-12-06	08:00	2011-12-13	10:00	7 2.00	344	MILD	NO
			TEAE	COGNITIVE DISORDER	2011-12-13	08:00	2012-01-10	08:00	28 0.00	351	MILD	NO
	059	1	TEAE	INFLUENZA	2011-02-13	NK:NK	2011-02-15	NK:NK	3	46	MILD	NO

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
Placebo	049	21	TEAE	PELVIC VENOUS THROMBOSIS	NO	RESOLVED	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	
	051	21	TEAE	ANXIETY	NO	RESOLVED	NONE	
			TEAE	ANXIETY	NO	RESOLVED	NONE	
			TEAE	ELECTROCARDIOGRAM POOR R-WAVE PROGRESSION	NO	RESOLVED	NONE	
	056	5	TEAE	SPINAL COLUMN STENOSIS	NO	RESOLVED	HOSPITALIZATION, CONCOMITANT THERAPY, OTHER	SURGERY OF SPINAL CANAL STENOSIS
	058	1	TEAE	HYPERTENSION	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	NASOPHARYNGITIS	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	SINUSITIS	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	BACTERIURIA	NO	RESOLVED	NONE	
			TEAE	COGNITIVE DISORDER	YES	RESOLVED WITH SEQUELAE	NONE	
	059	1	TEAE	INFLUENZA	NO	RESOLVED	CONCOMITANT THERAPY	

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Start of AE Date yyyy-mm-dd	Start of AE Time	Stop of AE Date yyyy-mm-dd	Stop of AE Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	059	1	TEAE	HERPES ZOSTER	2011-05-30	08:00	2011-06-09	22:00	10 14.00	152	MODERATE	NO
			TEAE	HEADACHE	2011-05-31	08:00	2011-05-31	22:00	14.00	153	MILD	NO
			TEAE	BACK PAIN	2011-09-13	08:00	2011-09-17	22:00	4 14.00	258	MILD	NO
			TEAE	DEPRESSION	2011-08	08:00					MILD	NO
	065	16	TEAE	CONSTIPATION	2011-04	NK:NK					MILD	NO
			TEAE	FEELING HOT	2010-11-10	NK:NK	2010-12-12	NK:NK	33	72	MILD	NO
			TEAE	PAIN IN EXTREMITY	2011-01-16	NK:NK				139	MILD	NO
			TEAE	ALCOHOLISM	2011-03-16	NK:NK	2011-04-14	NK:NK	30	198	MODERATE	YES
			TEAE	DEMENTIA	2011-03-16	NK:NK	2011-04-14	NK:NK	30	198	MODERATE	YES
	068	16	TEAE	HAEMATURIA	2011-02-10	NK:NK	2011-05-03	NK:NK	83	80	MILD	NO
			TEAE	WEIGHT DECREASED	2011-08-10	NK:NK				261	MODERATE	NO
			TEAE	INCONTINENCE	2011-10-01	NK:NK				313	MODERATE	NO
			TEAE	FACE INJURY	2011-11-14	NK:NK	2011-11-14	NK:NK	1	357	MILD	NO
	079	13	TEAE	NASOPHARYNGITIS	2010-11-05	NK:NK	2010-11-30	NK:NK	26	91	MILD	NO
			TEAE	DIARRHOEA	2011-07-16	NK:NK	2011-07-17	NK:NK	2	344	MILD	NO

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken
Placebo	059	1	TEAE	HERPES ZOSTER	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	HEADACHE	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	BACK PAIN	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	DEPRESSION	NO	ONGOING	CONCOMITANT THERAPY
	065	16	TEAE	CONSTIPATION	NO	ONGOING	CONCOMITANT THERAPY
			TEAE	FEELING HOT	NO	RESOLVED	NONE
			TEAE	PAIN IN EXTREMITY	NO	ONGOING	NONE
			TEAE	ALCOHOLISM	NO	RESOLVED	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY
			TEAE	DEMENTIA	NO	RESOLVED	HOSPITALIZATION, CONCOMITANT THERAPY
	068	16	TEAE	HAEMATURIA	NO	RESOLVED	NONE
			TEAE	WEIGHT DECREASED	NO	ONGOING	NONE
			TEAE	INCONTINENCE	NO	ONGOING	NONE
			TEAE	FACE INJURY	NO	RESOLVED	NONE
	079	13	TEAE	NASOPHARYNGITIS	NO	RESOLVED	CONCOMITANT THERAPY
			TEAE	DIARRHOEA	NO	RESOLVED	NONE

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Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	___Start of AE___ Date yyyy-mm-dd	Time	___Stop of AE____ Date yyyy-mm-dd	Time	Duration ddd hh.hh	Days of onset*	Severity	Ser-ious
Placebo	086	21	TEAE	NASOPHARYNGITIS	2010-12-02	00:00	2010-12-03	00:00	2	35	MILD	NO
			TEAE	SINUS ARRHYTHMIA	2011-04-12	12:04	2011-07-05	12:02	83 23.97	166	MILD	NO
			TEAE	BUNDLE BRANCH BLOCK LEFT	2011-10-25	11:49				362	MILD	NO
			TEAE	CATARACT OPERATION	2011-11-02	07:30	2011-11-05	19:30	3 12.00	370	SEVERE	NO
	088	16	TEAE	AGGRESSION	2010-12-20	NK:NK	2011-02-10	NK:NK	53	11	MILD	NO
			TEAE	AGGRESSION	2011-02-10	NK:NK	2011-07-01	NK:NK	142	63	MODERATE	NO
			TEAE	AGITATION	2011-05-04	NK:NK				146	MILD	NO
			TEAE	DEMENTIA ALZHEIMER'S TYPE	2011-07-26	NK:NK	2011-08-23	NK:NK	29	229	MILD	YES
			TEAE	NASOPHARYNGITIS	2012-01-04	NK:NK	2012-01-14	NK:NK	11	391	MODERATE	NO
			TEAE	SYNCOPE	2012-01-13	NK:NK	2012-01-13	NK:NK	1	400	MODERATE	NO

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.1: Adverse events during study

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Safety Population

Treat-ment	Random No.	Site ID	#	Preferred term	Relation to IMP	Outcome	Action taken	Other action
Placebo	086	21	TEAE	NASOPHARYNGITIS	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	SINUS ARRHYTHMIA	NO	RESOLVED	NONE	
			TEAE	BUNDLE BRANCH BLOCK LEFT	NO	ONGOING	NONE	
			TEAE	CATARACT OPERATION	NO	RESOLVED		PLANNED SURGERY AND PLANNED HOSPITALIZATION
	088	16	TEAE	AGGRESSION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	AGGRESSION	NO	RESOLVED	CONCOMITANT THERAPY	
			TEAE	AGITATION	NO	ONGOING	CONCOMITANT THERAPY	
			TEAE	DEMENTIA ALZHEIMER'S TYPE	YES	RESOLVED WITH SEQUELAE	HOSPITALIZATION, CONCOMITANT THERAPY	
			TEAE	NASOPHARYNGITIS	NO	RESOLVED	NONE	
			TEAE	SYNCOPE	NO	RESOLVED	NONE	

* relative to day 1/week 0; # PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

PTSS (Pre-Treatment Signs & Symptoms)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32) F	ACI-91 (n=32) N	ACI-91 (n=32) %	Placebo (n=31) F	Placebo (n=31) N	Placebo (n=31) %	Total (n=63) F	Total (n=63) N	Total (n=63) %
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	COCCYDYNIA	1	1	3.1				1	1	1.6
	PAIN IN EXTREMITY				1	1	3.2	1	1	1.6
	TOTAL	1	1	3.1	1	1	3.2	2	2	3.2
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISOMFORT	1	1	3.1				1	1	1.6
	TOTAL	1	1	3.1				1	1	1.6
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION				1	1	3.2	1	1	1.6
	TOTAL				1	1	3.2	1	1	1.6
NERVOUS SYSTEM DISORDERS	HEADACHE				1	1	3.2	1	1	1.6
	TOTAL				1	1	3.2	1	1	1.6
PSYCHIATRIC DISORDERS	DISORIENTATION	1	1	3.1				1	1	1.6
	TOTAL	1	1	3.1				1	1	1.6
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH				1	1	3.2	1	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

PTSS (Pre-Treatment Signs & Symptoms)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	TOTAL				1	1	3.2	1	1	1.6
TOTAL		3	2	6.3	4	3	9.7	7	5	7.9

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32) F	ACI-91 (n=32) N	ACI-91 (n=32) %	Placebo (n=31) F	Placebo (n=31) N	Placebo (n=31) %	Total (n=63) F	Total (n=63) N	Total (n=63) %
GASTROINTESTINAL DISORDERS	DIARRHOEA	10	7	21.9	1	1	3.2	11	8	12.7
	ABDOMINAL PAIN UPPER	10	3	9.4				10	3	4.8
	VOMITING	7	5	15.6	2	2	6.5	9	7	11.1
	DRY MOUTH	6	6	18.8				6	6	9.5
	NAUSEA	3	2	6.3	3	3	9.7	6	5	7.9
	CONSTIPATION	2	2	6.3	1	1	3.2	3	3	4.8
	GASTRITIS				2	2	6.5	2	2	3.2
	ABDOMINAL DISCOMFORT				1	1	3.2	1	1	1.6
	ABDOMINAL DISTENSION				1	1	3.2	1	1	1.6
	TONGUE DISORDER	1	1	3.1				1	1	1.6
	TOOTHACHE	1	1	3.1				1	1	1.6
	TOTAL	40	13	40.6	11	7	22.6	51	20	31.7
PSYCHIATRIC DISORDERS	AGGRESSION	4	1	3.1	8	2	6.5	12	3	4.8
	DEPRESSION	1	1	3.1	2	2	6.5	3	3	4.8
	DISORIENTATION	2	1	3.1	1	1	3.2	3	2	3.2
	RESTLESSNESS	3	3	9.4				3	3	4.8
	AGITATION	1	1	3.1	1	1	3.2	2	2	3.2
	ANXIETY				2	1	3.2	2	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	2	1	3.1				2	1	1.6
	ABNORMAL BEHAVIOUR				1	1	3.2	1	1	1.6
	ABNORMAL DREAMS	1	1	3.1				1	1	1.6
	ALCOHOLISM				1	1	3.2	1	1	1.6
	APATHY				1	1	3.2	1	1	1.6
	DELUSIONAL DISORDER, UNSPECIFIED TYPE	1	1	3.1				1	1	1.6
	HALLUCINATION	1	1	3.1				1	1	1.6
	INSOMNIA				1	1	3.2	1	1	1.6
	MAJOR DEPRESSION	1	1	3.1				1	1	1.6
	NERVOUSNESS	1	1	3.1				1	1	1.6
	TOTAL	18	8	25.0	18	7	22.6	36	15	23.8
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	14	1	3.1	1	1	3.2	15	2	3.2
	FATIGUE	10	3	9.4				10	3	4.8
	ASTHENIA	4	1	3.1				4	1	1.6
	ADVERSE DRUG REACTION	1	1	3.1	1	1	3.2	2	2	3.2
	CHEST PAIN	1	1	3.1				1	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING HOT				1	1	3.2	1	1	1.6
	GENERAL PHYSICAL HEALTH DETERIORATION	1	1	3.1				1	1	1.6
	PYREXIA	1	1	3.1				1	1	1.6
	TOTAL	32	6	18.8	3	3	9.7	35	9	14.3
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	8	4	12.5	6	4	12.9	14	8	12.7
	NASOPHARYNGITIS	1	1	3.1	5	5	16.1	6	6	9.5
	HERPES ZOSTER	1	1	3.1	1	1	3.2	2	2	3.2
	PNEUMONIA	1	1	3.1	1	1	3.2	2	2	3.2
	SINUSITIS	1	1	3.1	1	1	3.2	2	2	3.2
	BACTERIURIA				1	1	3.2	1	1	1.6
	BRONCHITIS	1	1	3.1				1	1	1.6
	CYSTITIS	1	1	3.1				1	1	1.6
	FUNGAL SKIN INFECTION	1	1	3.1				1	1	1.6
	GASTROINTESTINAL INFECTION				1	1	3.2	1	1	1.6
	INFLUENZA				1	1	3.2	1	1	1.6
	TINEA PEDIS	1	1	3.1				1	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
INFECTIONS AND INFESTATIONS	TOOTH INFECTION				1	1	3.2	1	1	1.6
	TOTAL	16	8	25.0	18	12	38.7	34	20	31.7
NERVOUS SYSTEM DISORDERS	HEADACHE	6	5	15.6	1	1	3.2	7	6	9.5
	DIZZINESS	1	1	3.1	3	2	6.5	4	3	4.8
	HYPOAESTHESIA	3	2	6.3				3	2	3.2
	SYNCOPE	2	2	6.3	1	1	3.2	3	3	4.8
	COGNITIVE DISORDER	1	1	3.1	1	1	3.2	2	2	3.2
	DEMENTIA	1	1	3.1	1	1	3.2	2	2	3.2
	ATAXIA	1	1	3.1				1	1	1.6
	DEMENTIA ALZHEIMER'S TYPE				1	1	3.2	1	1	1.6
	EPILEPSY				1	1	3.2	1	1	1.6
	ESSENTIAL TREMOR				1	1	3.2	1	1	1.6
	FACIAL PALSY	1	1	3.1				1	1	1.6
	PARAESTHESIA				1	1	3.2	1	1	1.6
	PARKINSONISM	1	1	3.1				1	1	1.6
	SCIATICA	1	1	3.1				1	1	1.6
	TREMOR	1	1	3.1				1	1	1.6
	TOTAL	19	12	37.5	11	7	22.6	30	19	30.2

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32) F	N	%	Placebo (n=31) F	N	%	Total (n=63) F	N	%
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	13	2	6.3				13	2	3.2
	BACK PAIN	2	2	6.3	2	2	6.5	4	4	6.3
	MUSCULOSKELETAL PAIN	2	1	3.1	2	2	6.5	4	3	4.8
	MUSCLE SPASMS	2	1	3.1	1	1	3.2	3	2	3.2
	BONE PAIN	1	1	3.1				1	1	1.6
	PAIN IN EXTREMITY				1	1	3.2	1	1	1.6
	SPINAL COLUMN STENOSIS				1	1	3.2	1	1	1.6
	TOTAL	20	4	12.5	7	5	16.1	27	9	14.3
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	2	1	3.1				2	1	1.6
	WEIGHT DECREASED	1	1	3.1	1	1	3.2	2	2	3.2
	BACTERIAL TEST	1	1	3.1				1	1	1.6
	BLOOD CREATININE INCREASED	1	1	3.1				1	1	1.6
	C-REACTIVE PROTEIN INCREASED	1	1	3.1				1	1	1.6
	ELECTROCARDIOGRAM LOW VOLTAGE	1	1	3.1				1	1	1.6
	ELECTROCARDIOGRAM POOR R-WAVE PROGRESSION				1	1	3.2	1	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	1	1	3.1				1	1	1.6
	HEPATIC ENZYME INCREASED	1	1	3.1				1	1	1.6
	NEUTROPHIL COUNT INCREASED				1	1	3.2	1	1	1.6
	URINARY SEDIMENT PRESENT				1	1	3.2	1	1	1.6
	WHITE BLOOD CELLS URINE	1	1	3.1				1	1	1.6
	WHITE BLOOD CELLS URINE POSITIVE				1	1	3.2	1	1	1.6
	TOTAL	10	8	25.0	5	3	9.7	15	11	17.5
VASCULAR DISORDERS	HYPERTENSION	2	1	3.1	3	3	9.7	5	4	6.3
	HOT FLUSH	3	1	3.1				3	1	1.6
	HAEMATOMA	2	2	6.3				2	2	3.2
	CIRCULATORY COLLAPSE	1	1	3.1				1	1	1.6
	DEEP VEIN THROMBOSIS	1	1	3.1				1	1	1.6
	HYPOTENSION	1	1	3.1				1	1	1.6
	PELVIC VENOUS THROMBOSIS				1	1	3.2	1	1	1.6
	TOTAL	10	6	18.8	4	4	12.9	14	10	15.9

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	2	2	6.3				2	2	3.2
	CONTUSION	1	1	3.1				1	1	1.6
	CORNEAL SCAR	1	1	3.1				1	1	1.6
	FACE INJURY				1	1	3.2	1	1	1.6
	JOINT SPRAIN	1	1	3.1				1	1	1.6
	PROCEDURAL HEADACHE	1	1	3.1				1	1	1.6
	SUBDURAL HAEMATOMA	1	1	3.1				1	1	1.6
	THERMAL BURN				1	1	3.2	1	1	1.6
	UPPER LIMB FRACTURE	1	1	3.1				1	1	1.6
	TOTAL	8	6	18.8	2	2	6.5	10	8	12.7
EAR AND LABYRINTH DISORDERS	EAR PAIN	7	1	3.1				7	1	1.6
	TINNITUS				1	1	3.2	1	1	1.6
	VERTIGO	1	1	3.1				1	1	1.6
	TOTAL	8	2	6.3	1	1	3.2	9	3	4.8
RENAL AND URINARY DISORDERS	BLADDER PAIN	4	1	3.1				4	1	1.6
	INCONTINENCE	1	1	3.1	1	1	3.2	2	2	3.2

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
RENAL AND URINARY DISORDERS	HAEMATURIA				1	1	3.2	1	1	1.6
	POLLAKIURIA	1	1	3.1				1	1	1.6
	PROTEINURIA	1	1	3.1				1	1	1.6
	TOTAL	7	4	12.5	2	1	3.2	9	5	7.9
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	1	1	3.1				1	1	1.6
	BRADYCARDIA	1	1	3.1				1	1	1.6
	BUNDLE BRANCH BLOCK LEFT				1	1	3.2	1	1	1.6
	BUNDLE BRANCH BLOCK RIGHT				1	1	3.2	1	1	1.6
	EXTRASYSTOLES	1	1	3.1				1	1	1.6
	SINUS ARRHYTHMIA				1	1	3.2	1	1	1.6
	VENTRICULAR EXTRASYSTOLES				1	1	3.2	1	1	1.6
	TOTAL	3	3	9.4	4	3	9.7	7	6	9.5
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	1	1	3.1	2	1	3.2	3	2	3.2
	HYPOKALAEMIA				1	1	3.2	1	1	1.6
	VITAMIN B COMPLEX DEFICIENCY				1	1	3.2	1	1	1.6
	VITAMIN D DEFICIENCY				1	1	3.2	1	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
METABOLISM AND NUTRITION DISORDERS	TOTAL	1	1	3.1	5	1	3.2	6	2	3.2
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	2	1	3.1				2	1	1.6
	COUGH	1	1	3.1				1	1	1.6
	EMPHYSEMA	1	1	3.1				1	1	1.6
	PNEUMONIA ASPIRATION	1	1	3.1				1	1	1.6
	PULMONARY MASS	1	1	3.1				1	1	1.6
	TOTAL	6	4	12.5				6	4	6.3
SURGICAL AND MEDICAL PROCEDURES	CATARACT OPERATION				2	2	6.5	2	2	3.2
	ENDODONTIC PROCEDURE	1	1	3.1				1	1	1.6
	EYE OPERATION	1	1	3.1				1	1	1.6
	TOTAL	2	2	6.3	2	2	6.5	4	4	6.3
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ACNE	1	1	3.1				1	1	1.6
	DERMATITIS ATOPIC	1	1	3.1				1	1	1.6
	INTERTRIGO	1	1	3.1				1	1	1.6
	TOTAL	3	3	9.4				3	3	4.8

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	1	1	3.1				1	1	1.6
	MONOCYTOSIS				1	1	3.2	1	1	1.6
	TOTAL	1	1	3.1	1	1	3.2	2	2	3.2
EYE DISORDERS	CATARACT	1	1	3.1				1	1	1.6
	VITREOUS DISORDER				1	1	3.2	1	1	1.6
	TOTAL	1	1	3.1	1	1	3.2	2	2	3.2
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	BENIGN NEOPLASM OF ADRENAL GLAND	1	1	3.1				1	1	1.6
	LIPOMA				1	1	3.2	1	1	1.6
	TOTAL	1	1	3.1	1	1	3.2	2	2	3.2
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	CYSTIC LYMPHANGIOMA	1	1	3.1				1	1	1.6
	TOTAL	1	1	3.1				1	1	1.6
IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	1	1	3.1				1	1	1.6
	TOTAL	1	1	3.1				1	1	1.6

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.2: Frequency of all adverse events

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Safety Population

TEAEs (Treatment Emergent Adverse Events)

System organ class (MedDRA version 12.1)	Preferred Term (MedDRA version 12.1)	ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
TOTAL		208	29	90.6	96	21	67.7	304	50	79.4

F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.3: Frequency of related TEAEs by severity

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Safety Population

MedDRA (version 12.1) System organ class/ Preferred term	ACI-91 (n=32)											
	Mild			Moderate			Severe			Missing		
	F	N	%	F	N	%	F	N	%	F	N	%
GASTROINTESTINAL DISORDERS	10	6	18.8	3	2	6.3						
DIARRHOEA	5	2	6.3									
DRY MOUTH	4	4	12.5	1	1	3.1						
NAUSEA				1	1	3.1						
TONGUE DISORDER				1	1	3.1						
VOMITING	1	1	3.1									
PSYCHIATRIC DISORDERS	2	2	6.3	2	2	6.3	2	1	3.1			
PSYCHOTIC DISORDER	1	1	3.1				1	1	3.1			
ABNORMAL DREAMS				1	1	3.1						
DISORIENTATION							1	1	3.1			
HALLUCINATION	1	1	3.1									
RESTLESSNESS				1	1	3.1						
INVESTIGATIONS				3	3	9.4				2	1	3.1
ELECTROCARDIOGRAM QT PROLONGED*										2	1	3.1
BLOOD CREATININE INCREASED				1	1	3.1						
GAMMA-GLUTAMYLTRANSFERASE INCREASED				1	1	3.1						
WEIGHT DECREASED				1	1	3.1						

Includes also TEAEs with missing relationship (marked with *)
F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.3: Frequency of related TEAEs by severity

14FEB2013

Safety Population

MedDRA (version 12.1) System organ class/ Preferred term	ACI-91 (n=32)											
	Mild			Moderate			Severe			Missing		
	F	N	%	F	N	%	F	N	%	F	N	%
NERVOUS SYSTEM DISORDERS	1	1	3.1	4	4	12.5						
HEADACHE				2	2	6.3						
COGNITIVE DISORDER				1	1	3.1						
DEMENTIA				1	1	3.1						
TREMOR	1	1	3.1									
GENERAL DISORDERS AND ADMINISTRATION SITE C	1	1	3.1									
FATIGUE	1	1	3.1									
IMMUNE SYSTEM DISORDERS	1	1	3.1									
HYPERSENSITIVITY	1	1	3.1									
METABOLISM AND NUTRITION DISORDERS				1	1	3.1						
DECREASED APPETITE				1	1	3.1						
TOTAL	15	10	31.3	13	7	21.9	2	1	3.1	2	1	3.1

Includes also TEAEs with missing relationship (marked with *)
F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.3: Frequency of related TEAEs by severity

 14FEB2013

Safety Population

MedDRA (version 12.1) System organ class/ Preferred term	Placebo (n=31)											
	Mild			Moderate			Severe			Missing		
	F	N	%	F	N	%	F	N	%	F	N	%
NERVOUS SYSTEM DISORDERS	3	3	9.7									
COGNITIVE DISORDER	1	1	3.2									
DEMENTIA ALZHEIMER'S TYPE	1	1	3.2									
DIZZINESS	1	1	3.2									
CARDIAC DISORDERS	1	1	3.2									
VENTRICULAR EXTRASYSTOLES*	1	1	3.2									
GASTROINTESTINAL DISORDERS	1	1	3.2									
NAUSEA	1	1	3.2									
GENERAL DISORDERS AND ADMINISTRATION SITE C	1	1	3.2									
MALAISE	1	1	3.2									
TOTAL	6	5	16.1									

Includes also TEAEs with missing relationship (marked with *)
F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.3: Frequency of related TEAEs by severity

 14FEB2013

Safety Population

Total (n=63)

MedDRA (version 12.1) System organ class/ Preferred term	Mild			Moderate			Severe			Missing		
	F	N	%	F	N	%	F	N	%	F	N	%
GASTROINTESTINAL DISORDERS	11	7	11.1	3	2	3.2						
DIARRHOEA	5	2	3.2									
DRY MOUTH	4	4	6.3	1	1	1.6						
NAUSEA	1	1	1.6	1	1	1.6						
TONGUE DISORDER				1	1	1.6						
VOMITING	1	1	1.6									
NERVOUS SYSTEM DISORDERS	4	4	6.3	4	4	6.3						
COGNITIVE DISORDER	1	1	1.6	1	1	1.6						
HEADACHE				2	2	3.2						
DEMENTIA				1	1	1.6						
DEMENTIA ALZHEIMER'S TYPE	1	1	1.6									
DIZZINESS	1	1	1.6									
TREMOR	1	1	1.6									
PSYCHIATRIC DISORDERS	2	2	3.2	2	2	3.2	2	1	1.6			
PSYCHOTIC DISORDER	1	1	1.6				1	1	1.6			
ABNORMAL DREAMS				1	1	1.6						
DISORIENTATION							1	1	1.6			

Includes also TEAEs with missing relationship (marked with *)
F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.3: Frequency of related TEAEs by severity

 14FEB2013

Safety Population

MedDRA (version 12.1) System organ class/ Preferred term	Total (n=63)											
	Mild			Moderate			Severe			Missing		
	F	N	%	F	N	%	F	N	%	F	N	%
HALLUCINATION	1	1	1.6									
RESTLESSNESS				1	1	1.6						
INVESTIGATIONS				3	3	4.8				2	1	1.6
ELECTROCARDIOGRAM QT PROLONGED*										2	1	1.6
BLOOD CREATININE INCREASED				1	1	1.6						
GAMMA-GLUTAMYLTRANSFERASE INCREASED				1	1	1.6						
WEIGHT DECREASED				1	1	1.6						
GENERAL DISORDERS AND ADMINISTRATION SITE C	2	2	3.2									
FATIGUE	1	1	1.6									
MALAISE	1	1	1.6									
CARDIAC DISORDERS	1	1	1.6									
VENTRICULAR EXTRASYSTOLES*	1	1	1.6									
IMMUNE SYSTEM DISORDERS	1	1	1.6									
HYPERSENSITIVITY	1	1	1.6									

Includes also TEAEs with missing relationship (marked with *)
F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.3: Frequency of related TEAEs by severity

 14FEB2013

Safety Population

MedDRA (version 12.1) System organ class/ Preferred term	Total (n=63)											
	Mild			Moderate			Severe			Missing		
	F	N	%	F	N	%	F	N	%	F	N	%
METABOLISM AND NUTRITION DISORDERS				1	1	1.6						
DECREASED APPETITE				1	1	1.6						
TOTAL	21	15	23.8	13	7	11.1	2	1	1.6	2	1	1.6

Includes also TEAEs with missing relationship (marked with *)
F = number of adverse events, N/% = number/percent of patients with adverse events

Table 14.3.1.4: Characteristics of adverse events

 14FEB2013

Safety Population

		ACI-91 (n=32)			Placebo (n=31)			Total (n=63)		
		F	N	%	F	N	%	F	N	%
PTSS		3	2	6.3	4	3	9.7	7	5	7.9
TEAE		208	29	90.6	96	21	67.7	304	50	79.4
Deaths		1	1	3.1				1	1	1.6
Serious TEAEs		18	10	31.3	7	5	16.1	25	15	23.8
TEAEs causing discontinuation		10	5	15.6	3	2	6.5	13	7	11.1
Severity of TEAEs	MILD	165	28	87.5	75	20	64.5	240	48	76.2
	MODERATE	35	16	50.0	16	10	32.3	51	26	41.3
	SEVERE	6	3	9.4	5	4	12.9	11	7	11.1
	MISSING	2	1	3.1				2	1	1.6
Relation to IMP of TEAEs	NO	176	24	75.0	90	21	67.7	266	45	71.4
	YES	30	12	37.5	5	4	12.9	35	16	25.4
	MISSING	2	1	3.1	1	1	3.2	3	2	3.2

F = number of adverse events, N/% = number/percent of patients with adverse events
PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	System organ class	Preferred term	Start date yyyy-mm-dd	Stop date yyyy-mm-dd
ACI-91	027	20	TEAE	PNEUMONIA	INFECTIONS AND INFESTATIONS	PNEUMONIA	2011-07-22	2011-08-01
	030	8	TEAE	UPPER LIMB SHAKING	NERVOUS SYSTEM DISORDERS	TREMOR	2011-03-14	2011-03-14
			TEAE	NAUSEA AND VOMITING	GASTROINTESTINAL DISORDERS	VOMITING	2011-03-28	2011-03-30
			TEAE	VERTIGO	EAR AND LABYRINTH DISORDERS	VERTIGO	2011-03-28	2011-03-30
	043	12	TEAE	PARKINSON SYNDROME	NERVOUS SYSTEM DISORDERS	PARKINSONISM	2010-04	
			TEAE	VISIONS	PSYCHIATRIC DISORDERS	HALLUCINATION	2009-12-29	
			TEAE	COLLAPSE AND DOWNFALL	VASCULAR DISORDERS	CIRCULATORY COLLAPSE	2010-04-30	2010-04-30
			TEAE	HEAD LACERATION	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	2010-04-30	2010-05
			TEAE	HYPOTENSIVE EPISODE	VASCULAR DISORDERS	HYPOTENSION	2010-04-30	2010-04-30
			TEAE	DOWNFALL WITH CONTUSION AND RESULTING HAEMATOMA OF RIGHT THIGH	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	2010-07-05	2010-08

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach
# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Duration ddd hh.hh	Severity	Ser-ious	Relation to IMP	Outcome
ACI-91	027	20	TEAE	PNEUMONIA	11	MODERATE	YES	NO	RESOLVED
	030	8	TEAE	UPPER LIMB SHAKING	0.25	MILD	YES	YES	RESOLVED
			TEAE	NAUSEA AND VOMITING	3	MODERATE	YES	NO	RESOLVED
			TEAE	VERTIGO	3	MODERATE	YES	NO	RESOLVED
	043	12	TEAE	PARKINSON SYNDROME		MILD	YES	NO	ONGOING
			TEAE	VISIONS		MILD	YES	YES	ONGOING
			TEAE	COLLAPSE AND DOWNFALL	1	MODERATE	YES	NO	RESOLVED
			TEAE	HEAD LACERATION		MODERATE	YES	NO	RESOLVED WITH SEQUELAE
			TEAE	HYPOTENSIVE EPISODE	17.00	MODERATE	YES	NO	RESOLVED
			TEAE	DOWNFALL WITH CONTUSION AND RESULTING HAEMATOMA OF RIGHT THIGH		MODERATE	YES	NO	RESOLVED

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Action taken	Other action	Date of 1st dose of study drug
ACI-91	027	20	TEAE	PNEUMONIA	HOSPITALIZATION, CONCOMITANT THERAPY		22OCT2010
	030	8	TEAE	UPPER LIMB SHAKING	HOSPITALIZATION		25MAR2010
			TEAE	NAUSEA AND VOMITING	HOSPITALIZATION		25MAR2010
			TEAE	VERTIGO	HOSPITALIZATION		25MAR2010
	043	12	TEAE	PARKINSON SYNDROME	HOSPITALIZATION		19NOV2009
			TEAE	VISIONS	HOSPITALIZATION, CONCOMITANT THERAPY		19NOV2009
			TEAE	COLLAPSE AND DOWNFALL	HOSPITALIZATION		19NOV2009
			TEAE	HEAD LACERATION	HOSPITALIZATION		19NOV2009
			TEAE	HYPOTENSIVE EPISODE	HOSPITALIZATION		19NOV2009
			TEAE	DOWNFALL WITH CONTUSION AND RESULTING HAEMATOMA OF RIGHT THIGH	HOSPITALIZATION, CONCOMITANT THERAPY, OTHER	PUNCTURE OF HAEMATOMA	19NOV2009

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	System organ class	Preferred term	Start date yyyy-mm-dd	Stop date yyyy-mm-dd
ACI-91	043	12	TEAE	WORSENING OF GENERAL CONDITION	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GENERAL PHYSICAL HEALTH DETERIORATION	2010-07-26	
			TEAE	ASPIRATION PNEUMONIA	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONIA ASPIRATION	2010-08-11	2010-08-12
	048	11	TEAE	SYNCOPE	NERVOUS SYSTEM DISORDERS	SYNCOPE	2011-08-04	2011-08-06
	055	5	TEAE	ALLERGIC REACTION (FATIGUE, NAUSEA, DYSAESTHESIA (WHOLE BODY), PHARYNGAL STING)	IMMUNE SYSTEM DISORDERS	HYPERSENSITIVITY	2010-03-30	2010-03-31
	057	1	TEAE	VARIZELLA ZOSTER INFECTION	INFECTIONS AND INFESTATIONS	HERPES ZOSTER	2011-04-06	2011-04-13
	066	16	TEAE	WORSENING OF AGGRESSION	PSYCHIATRIC DISORDERS	AGGRESSION	2011-01-05	2011-02-03

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Duration ddd hh.hh	Severity	Ser-ious	Relation to IMP	Outcome
ACI-91	043	12	TEAE	WORSENING OF GENERAL CONDITION		SEVERE	NO	NO	ONGOING
			TEAE	ASPIRATION PNEUMONIA	2	SEVERE	YES	NO	DEATH
	048	11	TEAE	SYNCOPE	3	MILD	YES	NO	RESOLVED
	055	5	TEAE	ALLERGIC REACTION (FATIGUE, NAUSEA, DYSAESTHESIA (WHOLE BODY), PHARYNGAL STING)	1 0.00	MILD	NO	YES	RESOLVED
	057	1	TEAE	VARIZELLA ZOSTER INFECTION	7 14.00	MODERATE	YES	NO	RESOLVED
	066	16	TEAE	WORSENING OF AGGRESSION	30	SEVERE	YES	NO	RESOLVED WITH SEQUELAE

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Action taken	Date of 1st dose of study drug
ACI-91	043	12	TEAE	WORSENING OF GENERAL CONDITION	STUDY DISCONTINUED PERMANENTLY	19NOV2009
			TEAE	ASPIRATION PNEUMONIA	HOSPITALIZATION	19NOV2009
	048	11	TEAE	SYNCOPE	HOSPITALIZATION	22NOV2010
	055	5	TEAE	ALLERGIC REACTION (FATIGUE, NAUSEA, DYSAESTHESIA (WHOLE BODY), PHARYNGAL STING)	STUDY DISCONTINUED PERMANENTLY	29MAR2010
	057	1	TEAE	VARIZELLA ZOSTER INFECTION	HOSPITALIZATION, CONCOMITANT THERAPY	20AUG2010
	066	16	TEAE	WORSENING OF AGGRESSION	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	14SEP2010

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	System organ class	Preferred term	Start date yyyy-mm-dd	Stop date yyyy-mm-dd
ACI-91	067	16	TEAE	HEADACHE	NERVOUS SYSTEM DISORDERS	HEADACHE	2010-11-19	2011-01-03
			TEAE	NAUSEA	GASTROINTESTINAL DISORDERS	NAUSEA	2010-11-19	2011-01-01
			TEAE	BAD DREAMS	PSYCHIATRIC DISORDERS	ABNORMAL DREAMS	2010-11-19	2011-01-03
			TEAE	XEROSTOMIA	GASTROINTESTINAL DISORDERS	DRY MOUTH	2010-11-20	2010-12-06
			TEAE	VOMITING	GASTROINTESTINAL DISORDERS	VOMITING	2010-11-29	2011-01-01
	071	18	TEAE	SURGERY TO REMOVE CICATRICE AFTER KATARACT EXCISION	SURGICAL AND MEDICAL PROCEDURES	EYE OPERATION	2011-02-07	2011-02-09
	080	13	TEAE	FURTHER WORSENING OF ORIENTATION	PSYCHIATRIC DISORDERS	DISORIENTATION	2011-02-26	2011-05
			TEAE	WORSENING PYCHOSIS (DELUSIONS AND HALLUZINATIONS)	PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	2011-02-26	2011-05

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Duration ddd hh.hh	Severity	Ser-ious	Relation to IMP	Outcome
ACI-91	067	16	TEAE	HEADACHE	46	MODERATE	NO	YES	RESOLVED
			TEAE	NAUSEA	44	MODERATE	NO	YES	RESOLVED
			TEAE	BAD DREAMS	46	MODERATE	NO	YES	RESOLVED
			TEAE	XEROSTOMIA	17	MODERATE	NO	YES	RESOLVED
			TEAE	VOMITING	34	MILD	NO	YES	RESOLVED
	071	18	TEAE	SURGERY TO REMOVE CICATRICE AFTER KATARACT EXCISION	3	MILD	YES	NO	RESOLVED WITH SEQUELAE
	080	13	TEAE	FURTHER WORSENING OF ORIENTATION		SEVERE	NO	YES	RESOLVED
			TEAE	WORSENING PYCHOSIS (DELUSIONS AND HALLUZINATIONS)		SEVERE	YES	YES	RESOLVED

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Action taken	Date of 1st dose of study drug
ACI-91	067	16	TEAE	HEADACHE	STUDY DISCONTINUED PERMANENTLY	19NOV2010
			TEAE	NAUSEA	STUDY DISCONTINUED PERMANENTLY	19NOV2010
			TEAE	BAD DREAMS	STUDY DISCONTINUED PERMANENTLY	19NOV2010
			TEAE	XEROSTOMIA	STUDY DISCONTINUED PERMANENTLY	19NOV2010
			TEAE	VOMITING	STUDY DISCONTINUED PERMANENTLY	19NOV2010
	071	18	TEAE	SURGERY TO REMOVE CICATRICE AFTER KATARACT EXCISION	HOSPITALIZATION	10NOV2010
	080	13	TEAE	FURTHER WORSENING OF ORIENTATION	STUDY DISCONTINUED PERMANENTLY	20NOV2010
			TEAE	WORSENING PYCHOSIS (DELUSIONS AND HALLUZINATIONS)	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY	20NOV2010

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Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	System organ class	Preferred term	Start date yyyy-mm-dd	Stop date yyyy-mm-dd
ACI-91	081	17	TEAE	FALL, SUBDURAL HEMATOMA	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SUBDURAL HAEMATOMA	2011-09-05	2011-09-20
	097	12	TEAE	BRONCHOPULMONAL FEBRILE INFEKTION	INFECTIONS AND INFESTATIONS	BRONCHITIS	2011-02-16	
Placebo	003	1	TEAE	NAUSEA AND EMESIS DUE TO RIVASTIGMIN	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ADVERSE DRUG REACTION	2009-07-03	2009-07-03
	028	20	TEAE	COUGH-PNEUMONIA	INFECTIONS AND INFESTATIONS	PNEUMONIA	2011-03-02	2011-03-17
	045	11	TEAE	ORTHOSTATIC SYNCOPE WITH GASTROINTESTINAL INFECTION	INFECTIONS AND INFESTATIONS	GASTROINTESTINAL INFECTION	2010-01-30	2010-02-04
			TEAE	ABLATION OF VITREOUS BODY	EYE DISORDERS	VITREOUS DISORDER	2010-05-06	2010-05-17

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Duration ddd hh.hh	Severity	Ser-ious	Relation to IMP	Outcome
ACI-91	081	17	TEAE	FALL, SUBDURAL HEMATOMA	14 19.00	MILD	YES	NO	RESOLVED
	097	12	TEAE	BRONCHOPULMONAL FEBRILE INFEKTION		MODERATE	YES	NO	ONGOING
Placebo	003	1	TEAE	NAUSEA AND EMESIS DUE TO RIVASTIGMIN	8.67	SEVERE	NO	NO	RESOLVED
	028	20	TEAE	COUGH-PNEUMONIA	16	MODERATE	YES	NO	RESOLVED
	045	11	TEAE	ORTHOSTATIC SYNCOPE WITH GASTROINTESTINAL INFECTION	5 4.50	MODERATE	NO	NO	RESOLVED
			TEAE	ABLATION OF VITREOUS BODY	12	MILD	NO	NO	RESOLVED

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Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Action taken	Other action	Date of 1st dose of study drug
ACI-91	081	17	TEAE	FALL, SUBDURAL HEMATOMA	OTHER	MRI, SUBDURAL HEMATOMA RESOLVED	14OCT2010
	097	12	TEAE	BRONCHOPULMONAL FEBRILE INFEKTION	HOSPITALIZATION, CONCOMITANT THERAPY		19NOV2010
Placebo	003	1	TEAE	NAUSEA AND EMESIS DUE TO RIVASTIGMIN	IMP DISCONTINUED AND RESTARTED, CONCOMITANT THERAPY		28MAY2009
	028	20	TEAE	COUGH-PNEUMONIA	HOSPITALIZATION, CONCOMITANT THERAPY		27NOV2010
	045	11	TEAE	ORTHOSTATIC SYNCOPE WITH GASTROINTESTINAL INFECTION	IMP DISCONTINUED AND RESTARTED		22DEC2009
			TEAE	ABLATION OF VITREOUS BODY	IMP DISCONTINUED AND RESTARTED		22DEC2009

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach
# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	System organ class	Preferred term	Start date yyyy-mm-dd	Stop date yyyy-mm-dd
Placebo	049	21	TEAE	INCREASING PSYCHOPATHOLOGICAL SYMPTOMS	PSYCHIATRIC DISORDERS	ABNORMAL BEHAVIOUR	2011-09-06	
			TEAE	PELVIC VEIN THROMBOSIS	VASCULAR DISORDERS	PELVIC VENOUS THROMBOSIS	2011-09-10	2011-09-19
	056	5	TEAE	WORSENING OF CHRONIC BACK PAIN DUE TO SPINAL CANAL STENOSIS	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL COLUMN STENOSIS	2010-05-03	2010-07-05
	065	16	TEAE	RELAPSE OF ALCOHOL DEPENDENCE	PSYCHIATRIC DISORDERS	ALCOHOLISM	2011-03-16	2011-04-14
			TEAE	WORSENING OF DEMENTIA	NERVOUS SYSTEM DISORDERS	DEMENTIA	2011-03-16	2011-04-14
	088	16	TEAE	PROGRESSION OF ALZHEIMERS DISEASE	NERVOUS SYSTEM DISORDERS	DEMENTIA ALZHEIMER'S TYPE	2011-07-26	2011-08-23

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Duration ddd hh.hh	Severity	Ser-ious	Relation to IMP	Outcome
Placebo	049	21	TEAE	INCREASING PSYCHOPATHOLOGICAL SYMPTOMS		SEVERE	YES	NO	ONGOING
			TEAE	PELVIC VEIN THROMBOSIS	9 10.00	SEVERE	YES	NO	RESOLVED
	056	5	TEAE	WORSENING OF CHRONIC BACK PAIN DUE TO SPINAL CANAL STENOSIS	64	MODERATE	YES	NO	RESOLVED
	065	16	TEAE	RELAPSE OF ALCOHOL DEPENDENCE	30	MODERATE	YES	NO	RESOLVED
			TEAE	WORSENING OF DEMENTIA	30	MODERATE	YES	NO	RESOLVED
	088	16	TEAE	PROGRESSION OF ALZHEIMERS DISEASE	29	MILD	YES	YES	RESOLVED WITH SEQUELAE

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16=Leipzig, 17=Hannover, 18=Nürnberg, 20=Graz, 21=Innsbruck, 22=Linz, 23=Villach
# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.2.1: Listing of deaths, other serious and significant adverse events

 14FEB2013

Safety Population

Treat-ment	Random No.	Site ID	#	Adverse event	Action taken	Other action	Date of 1st dose of study drug
Placebo	049	21	TEAE	INCREASING PSYCHOPATHOLOGICAL SYMPTOMS	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY		28OCT2010
			TEAE	PELVIC VEIN THROMBOSIS	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY		28OCT2010
	056	5	TEAE	WORSENING OF CHRONIC BACK PAIN DUE TO SPINAL CANAL STENOSIS	HOSPITALIZATION, CONCOMITANT THERAPY, OTHER	SURGERY OF SPINAL CANAL STENOSIS	21APR2010
	065	16	TEAE	RELAPSE OF ALCOHOL DEPENDENCE	HOSPITALIZATION, STUDY DISCONTINUED PERMANENTLY, CONCOMITANT THERAPY		31AUG2010
			TEAE	WORSENING OF DEMENTIA	HOSPITALIZATION, CONCOMITANT THERAPY		31AUG2010
	088	16	TEAE	PROGRESSION OF ALZHEIMERS DISEASE	HOSPITALIZATION, CONCOMITANT THERAPY		10DEC2010

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# PTSS = Pre-Treatment Sign & Symptom, TEAE = Treatment Emergent Adverse Event

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
SODIUM	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)	1	3.1	31	96.9		
		V3 (WEEK 12)	1	3.4	28	96.6		
		V4 (WEEK 24)	1	4.3	22	95.7		
		V5 (WEEK 36)			22	100.0		
		V6 (WEEK 52)	1	4.0	24	96.0		
		V7 (WEEK 56)			23	100.0		
	Placebo	SCREENING	1	3.2	30	96.8		
		V1 (WEEK 0)	1	3.2	30	96.8		
		V3 (WEEK 12)	1	3.2	30	96.8		
		V4 (WEEK 24)			31	100.0		
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)	1	3.7	26	96.3		
		V7 (WEEK 56)			26	96.3	1	3.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
POTASSIUM	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)			32	100.0		
		V3 (WEEK 12)	1	3.4	28	96.6		
		V4 (WEEK 24)	1	4.3	22	95.7		
		V5 (WEEK 36)			20	90.9	2	9.1
		V6 (WEEK 52)			25	100.0		
		V7 (WEEK 56)			22	95.7	1	4.3
	Placebo	SCREENING			31	100.0		
		V1 (WEEK 0)			30	96.8	1	3.2
		V3 (WEEK 12)			31	100.0		
		V4 (WEEK 24)	1	3.2	30	96.8		
		V5 (WEEK 36)	1	3.4	28	96.6		
		V6 (WEEK 52)	1	3.7	26	96.3		
		V7 (WEEK 56)			26	96.3	1	3.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
CHLORIDE	ACI-91	SCREENING	2	6.3	28	87.5	2	6.3
		V1 (WEEK 0)	1	3.1	30	93.8	1	3.1
		V3 (WEEK 12)			26	89.7	3	10.3
		V4 (WEEK 24)	1	4.3	20	87.0	2	8.7
		V5 (WEEK 36)	2	9.1	20	90.9		
		V6 (WEEK 52)	1	4.0	19	76.0	5	20.0
		V7 (WEEK 56)			20	87.0	3	13.0
	Placebo	SCREENING	1	3.2	30	96.8		
		V1 (WEEK 0)	2	6.5	26	83.9	3	9.7
		V3 (WEEK 12)	2	6.7	27	90.0	1	3.3
		V4 (WEEK 24)			27	87.1	4	12.9
		V5 (WEEK 36)	1	3.4	26	89.7	2	6.9
		V6 (WEEK 52)			24	88.9	3	11.1
		V7 (WEEK 56)			23	85.2	4	14.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
BICARBONATE	ACI-91	SCREENING	6	18.8	23	71.9	3	9.4
		V1 (WEEK 0)	3	9.4	26	81.3	3	9.4
		V3 (WEEK 12)	4	13.8	23	79.3	2	6.9
		V4 (WEEK 24)	2	8.7	20	87.0	1	4.3
		V5 (WEEK 36)	4	18.2	17	77.3	1	4.5
		V6 (WEEK 52)			24	96.0	1	4.0
		V7 (WEEK 56)	1	4.3	21	91.3	1	4.3
	Placebo	SCREENING	3	9.7	27	87.1	1	3.2
		V1 (WEEK 0)	3	9.7	27	87.1	1	3.2
		V3 (WEEK 12)	2	6.5	27	87.1	2	6.5
		V4 (WEEK 24)	2	6.5	26	83.9	3	9.7
		V5 (WEEK 36)	3	10.3	25	86.2	1	3.4
		V6 (WEEK 52)	1	3.7	25	92.6	1	3.7
		V7 (WEEK 56)			25	92.6	2	7.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
UREA	ACI-91	SCREENING			30	93.8	2	6.3
		V1 (WEEK 0)			31	96.9	1	3.1
		V3 (WEEK 12)			26	89.7	3	10.3
		V4 (WEEK 24)			21	91.3	2	8.7
		V5 (WEEK 36)			19	86.4	3	13.6
		V6 (WEEK 52)			23	92.0	2	8.0
		V7 (WEEK 56)			20	87.0	3	13.0
	Placebo	SCREENING			31	100.0		
		V1 (WEEK 0)			31	100.0		
		V3 (WEEK 12)			31	100.0		
		V4 (WEEK 24)			31	100.0		
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)			27	100.0		
		V7 (WEEK 56)			27	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
CREATININE	ACI-91	SCREENING			26	81.3	6	18.8
		V1 (WEEK 0)			23	71.9	9	28.1
		V3 (WEEK 12)			22	75.9	7	24.1
		V4 (WEEK 24)			17	73.9	6	26.1
		V5 (WEEK 36)			15	68.2	7	31.8
		V6 (WEEK 52)	1	4.0	21	84.0	3	12.0
		V7 (WEEK 56)	1	4.3	14	60.9	8	34.8
	Placebo	SCREENING			31	100.0		
		V1 (WEEK 0)			28	90.3	3	9.7
		V3 (WEEK 12)			29	93.5	2	6.5
		V4 (WEEK 24)			30	96.8	1	3.2
		V5 (WEEK 36)			26	89.7	3	10.3
		V6 (WEEK 52)	1	3.7	23	85.2	3	11.1
		V7 (WEEK 56)	1	3.7	22	81.5	4	14.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
CALCIUM	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)			32	100.0		
		V3 (WEEK 12)			29	100.0		
		V4 (WEEK 24)			23	100.0		
		V5 (WEEK 36)			22	100.0		
		V6 (WEEK 52)			25	100.0		
		V7 (WEEK 56)			23	100.0		
	Placebo	SCREENING			31	100.0		
		V1 (WEEK 0)			31	100.0		
		V3 (WEEK 12)			31	100.0		
		V4 (WEEK 24)			29	93.5	2	6.5
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)			27	100.0		
		V7 (WEEK 56)			27	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
PHOSPHATE	ACI-91	SCREENING	1	3.1	31	96.9		
		V1 (WEEK 0)			32	100.0		
		V3 (WEEK 12)			29	100.0		
		V4 (WEEK 24)			23	100.0		
		V5 (WEEK 36)	1	4.5	21	95.5		
		V6 (WEEK 52)	1	4.0	24	96.0		
		V7 (WEEK 56)	1	4.3	22	95.7		
	Placebo	SCREENING	1	3.2	30	96.8		
		V1 (WEEK 0)	1	3.2	30	96.8		
		V3 (WEEK 12)	1	3.3	29	96.7		
		V4 (WEEK 24)			31	100.0		
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)	1	3.7	26	96.3		
		V7 (WEEK 56)			27	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
GLUCOSE	ACI-91	SCREENING			20	62.5	12	37.5
		V1 (WEEK 0)			20	62.5	12	37.5
		V3 (WEEK 12)			13	44.8	16	55.2
		V4 (WEEK 24)			17	73.9	6	26.1
		V5 (WEEK 36)			10	45.5	12	54.5
		V6 (WEEK 52)			15	60.0	10	40.0
		V7 (WEEK 56)			13	56.5	10	43.5
	Placebo	SCREENING			21	67.7	10	32.3
		V1 (WEEK 0)			16	51.6	15	48.4
		V3 (WEEK 12)	1	3.3	20	66.7	9	30.0
		V4 (WEEK 24)			17	54.8	14	45.2
		V5 (WEEK 36)			21	72.4	8	27.6
		V6 (WEEK 52)			13	48.1	14	51.9
		V7 (WEEK 56)			16	59.3	11	40.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
TOTAL BILIRUBIN	ACI-91	SCREENING			31	96.9	1	3.1
		V1 (WEEK 0)			30	93.8	2	6.3
		V3 (WEEK 12)			27	93.1	2	6.9
		V4 (WEEK 24)			22	95.7	1	4.3
		V5 (WEEK 36)			19	86.4	3	13.6
		V6 (WEEK 52)			25	100.0		
		V7 (WEEK 56)			23	100.0		
	Placebo	SCREENING			29	93.5	2	6.5
		V1 (WEEK 0)			30	96.8	1	3.2
		V3 (WEEK 12)			30	96.8	1	3.2
		V4 (WEEK 24)			31	100.0		
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)			25	92.6	2	7.4
		V7 (WEEK 56)			27	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
TOTAL PROTEIN	ACI-91	SCREENING			31	96.9	1	3.1
		V1 (WEEK 0)			32	100.0		
		V3 (WEEK 12)	1	3.4	28	96.6		
		V4 (WEEK 24)			23	100.0		
		V5 (WEEK 36)			22	100.0		
		V6 (WEEK 52)			25	100.0		
		V7 (WEEK 56)			23	100.0		
	Placebo	SCREENING	1	3.2	28	90.3	2	6.5
		V1 (WEEK 0)			31	100.0		
		V3 (WEEK 12)			30	100.0		
		V4 (WEEK 24)	1	3.2	30	96.8		
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)			27	100.0		
		V7 (WEEK 56)	1	3.7	26	96.3		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
ALBUMIN	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)			32	100.0		
		V3 (WEEK 12)			29	100.0		
		V4 (WEEK 24)			23	100.0		
		V5 (WEEK 36)			22	100.0		
		V6 (WEEK 52)			25	100.0		
		V7 (WEEK 56)			23	100.0		
	Placebo	SCREENING			31	100.0		
		V1 (WEEK 0)			31	100.0		
		V3 (WEEK 12)			31	100.0		
		V4 (WEEK 24)			30	96.8	1	3.2
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)			27	100.0		
		V7 (WEEK 56)			27	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
SGOT (AST)	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)			30	93.8	2	6.3
		V3 (WEEK 12)			23	79.3	6	20.7
		V4 (WEEK 24)			19	82.6	4	17.4
		V5 (WEEK 36)			19	86.4	3	13.6
		V6 (WEEK 52)			24	96.0	1	4.0
		V7 (WEEK 56)			23	100.0		
	Placebo	SCREENING			30	96.8	1	3.2
		V1 (WEEK 0)			30	96.8	1	3.2
		V3 (WEEK 12)			29	93.5	2	6.5
		V4 (WEEK 24)			30	96.8	1	3.2
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)			26	96.3	1	3.7
		V7 (WEEK 56)			26	96.3	1	3.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
SGPT (ALT)	ACI-91	SCREENING			31	96.9	1	3.1
		V1 (WEEK 0)			30	93.8	2	6.3
		V3 (WEEK 12)			23	79.3	6	20.7
		V4 (WEEK 24)			18	78.3	5	21.7
		V5 (WEEK 36)			20	90.9	2	9.1
		V6 (WEEK 52)			24	96.0	1	4.0
		V7 (WEEK 56)			22	95.7	1	4.3
	Placebo	SCREENING			30	96.8	1	3.2
		V1 (WEEK 0)			30	96.8	1	3.2
		V3 (WEEK 12)			30	96.8	1	3.2
		V4 (WEEK 24)			28	90.3	3	9.7
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)			26	96.3	1	3.7
		V7 (WEEK 56)			26	96.3	1	3.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
ALKALINE PHOSPHATASE	ACI-91	SCREENING	1	3.1	29	90.6	2	6.3
		V1 (WEEK 0)	1	3.1	28	87.5	3	9.4
		V3 (WEEK 12)	2	6.9	25	86.2	2	6.9
		V4 (WEEK 24)	2	8.7	19	82.6	2	8.7
		V5 (WEEK 36)	2	9.1	19	86.4	1	4.5
		V6 (WEEK 52)	2	8.0	20	80.0	3	12.0
		V7 (WEEK 56)	2	8.7	20	87.0	1	4.3
	Placebo	SCREENING	1	3.2	28	90.3	2	6.5
		V1 (WEEK 0)			30	96.8	1	3.2
		V3 (WEEK 12)			30	96.8	1	3.2
		V4 (WEEK 24)			30	96.8	1	3.2
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)			25	92.6	2	7.4
		V7 (WEEK 56)			27	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
GAMMA-GT	ACI-91	SCREENING			29	90.6	3	9.4
		V1 (WEEK 0)			28	87.5	4	12.5
		V3 (WEEK 12)			25	86.2	4	13.8
		V4 (WEEK 24)			20	87.0	3	13.0
		V5 (WEEK 36)			19	86.4	3	13.6
		V6 (WEEK 52)			24	96.0	1	4.0
		V7 (WEEK 56)			20	87.0	3	13.0
	Placebo	SCREENING			30	96.8	1	3.2
		V1 (WEEK 0)			31	100.0		
		V3 (WEEK 12)			27	87.1	4	12.9
		V4 (WEEK 24)			29	93.5	2	6.5
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)			26	96.3	1	3.7
		V7 (WEEK 56)			26	96.3	1	3.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
CHOLESTEROL	ACI-91	SCREENING			22	68.8	10	31.3
		V1 (WEEK 0)			24	75.0	8	25.0
		V3 (WEEK 12)			19	65.5	10	34.5
		V4 (WEEK 24)			16	69.6	7	30.4
		V5 (WEEK 36)			13	59.1	9	40.9
		V6 (WEEK 52)			19	76.0	6	24.0
		V7 (WEEK 56)			16	69.6	7	30.4
	Placebo	SCREENING			21	67.7	10	32.3
		V1 (WEEK 0)			21	67.7	10	32.3
		V3 (WEEK 12)			20	64.5	11	35.5
		V4 (WEEK 24)			23	74.2	8	25.8
		V5 (WEEK 36)			21	72.4	8	27.6
		V6 (WEEK 52)			20	74.1	7	25.9
		V7 (WEEK 56)			17	63.0	10	37.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
TRIGLYCERIDES	ACI-91	SCREENING	1	3.1	23	71.9	8	25.0
		V1 (WEEK 0)			26	81.3	6	18.8
		V3 (WEEK 12)	1	3.4	22	75.9	6	20.7
		V4 (WEEK 24)			21	91.3	2	8.7
		V5 (WEEK 36)	1	4.5	19	86.4	2	9.1
		V6 (WEEK 52)			22	88.0	3	12.0
		V7 (WEEK 56)			19	82.6	4	17.4
	Placebo	SCREENING			27	87.1	4	12.9
		V1 (WEEK 0)			26	83.9	5	16.1
		V3 (WEEK 12)			24	80.0	6	20.0
		V4 (WEEK 24)			25	80.6	6	19.4
		V5 (WEEK 36)			21	72.4	8	27.6
		V6 (WEEK 52)			19	70.4	8	29.6
		V7 (WEEK 56)			21	77.8	6	22.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.1: Blood chemistry, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
URIC ACID	ACI-91	SCREENING			25	78.1	7	21.9
		V1 (WEEK 0)			26	81.3	6	18.8
		V3 (WEEK 12)			21	72.4	8	27.6
		V4 (WEEK 24)			16	69.6	7	30.4
		V5 (WEEK 36)			14	63.6	8	36.4
		V6 (WEEK 52)			17	68.0	8	32.0
		V7 (WEEK 56)			15	65.2	8	34.8
	Placebo	SCREENING			26	83.9	5	16.1
		V1 (WEEK 0)			26	83.9	5	16.1
		V3 (WEEK 12)			24	77.4	7	22.6
		V4 (WEEK 24)			28	90.3	3	9.7
		V5 (WEEK 36)			24	82.8	5	17.2
		V6 (WEEK 52)			22	81.5	5	18.5
		V7 (WEEK 56)			23	85.2	4	14.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
SODIUM	mmol/L	046	Female	ACI-91	V1 (WEEK 0)	1	130	L	NO	135 - 150
					V3 (WEEK 12)	87	131	L	NO	135 - 150
					V4 (WEEK 24)	178	133	L	NO	135 - 150
		056	Female	Placebo	SCREENING	-21	134	L	NO	135 - 150
					V1 (WEEK 0)	1	133	L	NO	135 - 150
					V3 (WEEK 12)	84	133	L	NO	135 - 150
					V6 (WEEK 52)	364	134	L	NO	135 - 150
		081	Male	ACI-91	V6 (WEEK 52)	376	133	L	NO	135 - 150
		088	Female	Placebo	V7 (WEEK 56)	404	146	H	NO	136 - 145
POTASSIUM	mmol/L	001	Female	Placebo	V5 (WEEK 36)	246	3.5	L	NO	3.6 - 5.4
					V6 (WEEK 52)	365	3.5	L	NO	3.6 - 5.4
		002	Female	ACI-91	V5 (WEEK 36)	258	5.5	H	NO	3.6 - 5.4
					V7 (WEEK 56)	393	5.5	H	NO	3.6 - 5.4
		031	Male	Placebo	V7 (WEEK 56)	391	5.5	H	NO	3.6 - 5.4

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
POTASSIUM	mmol/L	033	Female	ACI-91	V3 (WEEK 12)	78	3.2	L	NO	3.6 - 5.4
					V4 (WEEK 24)	169	3.1	L	NO	3.6 - 5.4
		034	Female	Placebo	V4 (WEEK 24)	175	3.5	L	NO	3.6 - 5.4
		046	Female	ACI-91	V5 (WEEK 36)	255	5.9	H	NO	3.6 - 5.4
		079	Female	Placebo	V1 (WEEK 0)	1	5.5	H	NO	3.6 - 5.4
CHLORIDE	mmol/L	002	Female	ACI-91	SCREENING	-7	106	H	NO	95 - 105
		005	Female	Placebo	V1 (WEEK 0)	1	107	H	NO	95 - 105
					V4 (WEEK 24)	168	107	H	NO	95 - 105
		006	Male	ACI-91	V5 (WEEK 36)	252	93	L	NO	95 - 105
		011	Female	Placebo	V1 (WEEK 0)	1	94	L	NO	95 - 105
		015	Female	ACI-91	V3 (WEEK 12)	85	106	H	NO	95 - 105
		018	Female	Placebo	V5 (WEEK 36)	247	106	H	NO	95 - 105

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHLORIDE	mmol/L	019	Male	ACI-91	V1 (WEEK 0)	1	107	H	NO	95 - 105
					V4 (WEEK 24)	168	107	H	NO	95 - 105
					V7 (WEEK 56)	399	106	H	NO	95 - 105
		023	Male	ACI-91	V3 (WEEK 12)	86	107	H	NO	95 - 105
					V6 (WEEK 52)	364	106	H	NO	95 - 105
					V7 (WEEK 56)	388	106	H		95 - 105
		024	Male	Placebo	V6 (WEEK 52)	358	108	H		95 - 105
					V7 (WEEK 56)	393	106	H	NO	95 - 105
		028	Female	Placebo	V4 (WEEK 24)	180	106	H	NO	95 - 105
		030	Female	ACI-91	V3 (WEEK 12)	85	106	H	NO	95 - 105
					V6 (WEEK 52)	355	106	H	NO	95 - 105
		033	Female	ACI-91	SCREENING	-7	93	L	NO	95 - 105
		045	Male	Placebo	V4 (WEEK 24)	169	107	H	NO	95 - 105
		046	Female	ACI-91	V1 (WEEK 0)	1	90	L	NO	95 - 105

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHLORIDE	mmol/L	046	Female	ACI-91	V4 (WEEK 24)	178	93	L	NO	95 - 105
					V5 (WEEK 36)	255	93	L	NO	95 - 105
		047	Male	Placebo	V7 (WEEK 56)	393	107	H	NO	95 - 105
		049	Female	Placebo	SCREENING	-51	94	L	NO	95 - 105
		050	Female	ACI-91	V7 (WEEK 56)	391	106	H	NO	95 - 105
		051	Female	Placebo	V6 (WEEK 52)	363	107	H	NO	95 - 105
		056	Female	Placebo	V1 (WEEK 0)	1	92	L	NO	95 - 105
					V5 (WEEK 36)	259	93	L	NO	95 - 105
		058	Male	Placebo	V4 (WEEK 24)	166	106	H	NO	95 - 105
		066	Male	ACI-91	SCREENING	-31	106	H	NO	95 - 105
		069	Male	Placebo	V1 (WEEK 0)	1	106	H	NO	95 - 105
		071	Female	ACI-91	V6 (WEEK 52)	374	106	H	NO	95 - 105

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHLORIDE	mmol/L	072	Female	Placebo	V3 (WEEK 12)	85	94	L	NO	95 - 105
		079	Female	Placebo	V6 (WEEK 52)	320	106	H	NO	95 - 105
		081	Male	ACI-91	V6 (WEEK 52)	376	94	L	NO	95 - 105
		082	Male	Placebo	V3 (WEEK 12)	84	93	L	NO	95 - 105
		083	Female	ACI-91	SCREENING	-15	94	L	NO	95 - 105
					V4 (WEEK 24)	168	106	H	NO	95 - 105
					V6 (WEEK 52)	365	106	H	NO	95 - 105
		084	Female	Placebo	V1 (WEEK 0)	1	106	H	NO	95 - 105
		086	Female	Placebo	V7 (WEEK 56)	391	106	H	NO	95 - 105
		088	Female	Placebo	V3 (WEEK 12)	83	107	H	NO	95 - 105
					V5 (WEEK 36)	264	108	H	NO	95 - 105
					V7 (WEEK 56)	404	109	H	NO	98 - 107
		089	Female	ACI-91	V6 (WEEK 52)	364	106	H	NO	95 - 105

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BICARBONATE	mmol/L	001	Female	Placebo	V1 (WEEK 0)	1	20.5	L	NO	22.0 - 29.0
		002	Female	ACI-91	V3 (WEEK 12)	85	18.4	L	NO	22.0 - 29.0
		004	Male	ACI-91	V1 (WEEK 0)	1	19.6	L	NO	22.0 - 29.0
		006	Male	ACI-91	V3 (WEEK 12)	85	21.8	L	NO	22.0 - 29.0
		009	Female	Placebo	V1 (WEEK 0)	1	20.0	L	NO	22.0 - 29.0
					V5 (WEEK 36)	246	19.8	L	NO	22.0 - 29.0
					V6 (WEEK 52)	361	20.8	L	NO	22.0 - 29.0
		010	Male	ACI-91	SCREENING	-26	20.0	L	NO	22.0 - 29.0
		011	Female	Placebo	V5 (WEEK 36)	253	19.7	L	NO	22.0 - 29.0
		012	Male	ACI-91	SCREENING	-32	30.0	H	NO	22.0 - 29.0
					V1 (WEEK 0)	1	29.8	H	NO	22.0 - 29.0
					V5 (WEEK 36)	257	29.2	H	NO	22.0 - 29.0
		015	Female	ACI-91	V3 (WEEK 12)	85	20.3	L	NO	22.0 - 29.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BICARBONATE	mmol/L	015	Female	ACI-91	V4 (WEEK 24)	162	20.5	L	NO	22.0 - 29.0
					V7 (WEEK 56)	394	21.6	L	NO	22.0 - 29.0
		017	Male	ACI-91	SCREENING	-22	19.6	L	NO	22.0 - 29.0
					V5 (WEEK 36)	252	21.1	L	NO	22.0 - 29.0
		018	Female	Placebo	V3 (WEEK 12)	86	31.1	H	NO	22.0 - 29.0
					V5 (WEEK 36)	247	29.3	H	NO	22.0 - 29.0
					V7 (WEEK 56)	387	29.5	H	NO	22.0 - 29.0
		027	Female	ACI-91	V4 (WEEK 24)	174	29.2	H	NO	22.0 - 29.0
		029	Female	Placebo	V1 (WEEK 0)	1	29.1	H	NO	22.0 - 29.0
					V3 (WEEK 12)	82	20.7	L	NO	22.0 - 29.0
		030	Female	ACI-91	V1 (WEEK 0)	1	21.8	L	NO	22.0 - 29.0
		032	Female	ACI-91	V3 (WEEK 12)	82	31.1	H	NO	22.0 - 29.0
		033	Female	ACI-91	V5 (WEEK 36)	261	21.3	L	NO	22.0 - 29.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BICARBONATE	mmol/L	042	Female	ACI-91	SCREENING	-29	29.7	H	NO	22.0 - 29.0
		045	Male	Placebo	V4 (WEEK 24)	169	19.5	L	NO	22.0 - 29.0
		046	Female	ACI-91	V1 (WEEK 0)	1	20.6	L	NO	22.0 - 29.0
					V3 (WEEK 12)	87	19.0	L	NO	22.0 - 29.0
		047	Male	Placebo	SCREENING	-21	20.5	L	NO	22.0 - 29.0
		048	Male	ACI-91	SCREENING	-5	30.3	H	NO	22.0 - 29.0
		051	Female	Placebo	V4 (WEEK 24)	167	29.3	H	NO	22.0 - 29.0
					V5 (WEEK 36)	251	21.9	L	NO	22.0 - 29.0
		052	Female	ACI-91	SCREENING	-52	20.9	L	NO	22.0 - 29.0
		059	Male	Placebo	V3 (WEEK 12)	93	21.3	L	NO	22.0 - 29.0
		065	Male	Placebo	SCREENING	-20	19.8	L	NO	22.0 - 29.0
					V1 (WEEK 0)	1	17.6	L	NO	22.0 - 29.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BICARBONATE	mmol/L	066	Male	ACI-91	SCREENING	-31	18.2	L	NO	22.0 - 29.0
		069	Male	Placebo	SCREENING	-13	21.0	L	NO	22.0 - 29.0
					V6 (WEEK 52)	373	29.3	H	NO	22.0 - 29.0
		071	Female	ACI-91	V5 (WEEK 36)	253	21.9	L	NO	22.0 - 29.0
		072	Female	Placebo	V4 (WEEK 24)	169	29.8	H	NO	22.0 - 29.0
					V7 (WEEK 56)	393	29.8	H	NO	22.0 - 29.0
		079	Female	Placebo	SCREENING	-18	29.1	H	NO	22.0 - 29.0
					V4 (WEEK 24)	175	29.3	H	NO	22.0 - 29.0
		082	Male	Placebo	V3 (WEEK 12)	84	30.0	H	NO	22.0 - 29.0
		083	Female	ACI-91	SCREENING	-15	21.3	L	NO	22.0 - 29.0
		084	Female	Placebo	V4 (WEEK 24)	175	20.2	L	NO	22.0 - 29.0
		087	Female	ACI-91	V4 (WEEK 24)	169	20.4	L	NO	22.0 - 29.0
					V5 (WEEK 36)	255	21.8	L	NO	22.0 - 29.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BICARBONATE	mmol/L	089	Female	ACI-91	V1 (WEEK 0)	1	29.7	H	NO	22.0 - 29.0
					V3 (WEEK 12)	84	31.5	H	NO	22.0 - 29.0
					V6 (WEEK 52)	364	31.0	H	NO	22.0 - 29.0
					V7 (WEEK 56)	394	33.1	H	NO	22.0 - 29.0
		093	Female	ACI-91	SCREENING	-3	21.1	L	NO	22.0 - 29.0
		097	Male	ACI-91	V1 (WEEK 0)	1	29.1	H	NO	22.0 - 29.0
UREA	mmol/L	005	Female	Placebo	V5 (WEEK 36)	258	8.68	H	NO	< 8.40
		017	Male	ACI-91	V7 (WEEK 56)	392	8.52	H	NO	< 8.40
		019	Male	ACI-91	SCREENING	-21	9.02	H	NO	< 8.40
					V1 (WEEK 0)	1	11.36	H	NO	< 8.40
					V3 (WEEK 12)	85	8.52	H	NO	< 8.40
					V4 (WEEK 24)	168	9.69	H	NO	< 8.40
					V5 (WEEK 36)	259	9.02	H	NO	< 8.40
					V6 (WEEK 52)	364	8.52	H	NO	< 8.40
					V7 (WEEK 56)	399	9.85	H	NO	< 8.40

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
UREA	mmol/L	046	Female	ACI-91	SCREENING	-28	13.69	H	YES	< 8.40
					V3 (WEEK 12)	87	12.02	H	NO	< 8.40
					V4 (WEEK 24)	178	9.35	H	NO	< 8.40
					V5 (WEEK 36)	255	9.69	H	NO	< 8.40
					V6 (WEEK 52)	367	9.35	H	NO	< 8.40
					V7 (WEEK 56)	393	12.36	H	NO	< 8.40
		057	Female	ACI-91	V3 (WEEK 12)	82	10.52	H	NO	< 8.40
		093	Female	ACI-91	V5 (WEEK 36)	258	8.52	H	NO	< 8.40
CREATININE	µmol/L	015	Female	ACI-91	V5 (WEEK 36)	248	87	H	NO	45.1 - 84.0
					V7 (WEEK 56)	394	90	H	NO	45.1 - 84.0
		017	Male	ACI-91	V7 (WEEK 56)	392	115	H	NO	< 106
		018	Female	Placebo	V6 (WEEK 52)	366	88	H	NO	45.1 - 84.0
		019	Male	ACI-91	V4 (WEEK 24)	168	112	H	NO	< 106
					V5 (WEEK 36)	259	112	H	NO	< 106

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CREATININE	µmol/L	029	Female	Placebo	V6 (WEEK 52)	369	89	H	NO	45.1 - 84.0
					V7 (WEEK 56)	391	94	H	NO	45.1 - 84.0
		045	Male	Placebo	V3 (WEEK 12)	85	111	H	NO	< 106
		046	Female	ACI-91	SCREENING	-28	146	H	YES	< 97
					V1 (WEEK 0)	1	103	H	NO	< 97
					V3 (WEEK 12)	87	117	H	NO	< 97
					V4 (WEEK 24)	178	111	H	NO	< 97
					V5 (WEEK 36)	255	132	H	YES	< 97
					V6 (WEEK 52)	367	119	H	YES	45.1 - 84.0
					V7 (WEEK 56)	393	157	H	YES	45.1 - 84.0
		047	Male	Placebo	V5 (WEEK 36)	254	107	H	NO	59.2 - 103.4
		048	Male	ACI-91	V1 (WEEK 0)	1	104	H	NO	59.2 - 103.4
					V3 (WEEK 12)	86	109	H	NO	59.2 - 103.4
					V4 (WEEK 24)	176	113	H	NO	59.2 - 103.4
					V6 (WEEK 52)	360	107	H	NO	59.2 - 103.4
					V7 (WEEK 56)	395	108	H	NO	59.2 - 103.4

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CREATININE	µmol/L	049	Female	Placebo	V1 (WEEK 0)	1	90	H	NO	45.1 - 84.0
		050	Female	ACI-91	V1 (WEEK 0)	1	86	H	NO	45.1 - 84.0
					V3 (WEEK 12)	83	89	H	NO	45.1 - 84.0
					V4 (WEEK 24)	167	88	H	NO	45.1 - 84.0
					V5 (WEEK 36)	251	86	H	NO	45.1 - 84.0
		051	Female	Placebo	V1 (WEEK 0)	1	88	H	NO	45.1 - 84.0
					V3 (WEEK 12)	97	92	H	NO	45.1 - 84.0
					V4 (WEEK 24)	167	111	H	NO	45.1 - 84.0
					V5 (WEEK 36)	251	85	H	NO	45.1 - 84.0
					V6 (WEEK 52)	363	97	H	NO	45.1 - 84.0
					V7 (WEEK 56)	391	101	H	NO	45.1 - 84.0
		055	Female	ACI-91	V1 (WEEK 0)	1	97	H	NO	< 97
		066	Male	ACI-91	V3 (WEEK 12)	83	105	H	NO	59.2 - 103.4
		067	Female	ACI-91	SCREENING	-16	88	H	NO	45.1 - 84.0
					V1 (WEEK 0)	1	85	H	NO	45.1 - 84.0
					V7 (WEEK 56)	111	88	H	NO	45.1 - 84.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CREATININE	µmol/L	068	Male	Placebo	V6 (WEEK 52)	372	57	L	NO	59.2 - 103.4
					V7 (WEEK 56)	414	50	L	NO	61.9 - 106.1
		081	Male	ACI-91	V6 (WEEK 52)	376	56	L	NO	59.2 - 103.4
					V7 (WEEK 56)	405	55	L	NO	59.2 - 103.4
		083	Female	ACI-91	V1 (WEEK 0)	1	87	H	NO	45.1 - 84.0
					V6 (WEEK 52)	365	97	H	NO	45.1 - 84.0
					V7 (WEEK 56)	392	88	H	NO	45.1 - 84.0
		084	Female	Placebo	V7 (WEEK 56)	394	87	H	NO	45.1 - 84.0
		086	Female	Placebo	V1 (WEEK 0)	1	88	H	NO	45.1 - 84.0
		087	Female	ACI-91	SCREENING	-20	91	H	NO	45.1 - 84.0
					V1 (WEEK 0)	1	89	H	NO	45.1 - 84.0
					V3 (WEEK 12)	81	87	H	NO	45.1 - 84.0
					V4 (WEEK 24)	169	95	H	NO	45.1 - 84.0
					V5 (WEEK 36)	255	94	H	NO	45.1 - 84.0
					V7 (WEEK 56)	395	96	H	NO	45.1 - 84.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CREATININE	µmol/L	088	Female	Placebo	V5 (WEEK 36)	264	85	H	NO	45.1 - 84.0
					V7 (WEEK 56)	404	85	H	NO	44.2 - 79.6
		089	Female	ACI-91	SCREENING	-28	85	H	NO	45.1 - 84.0
					V1 (WEEK 0)	1	88	H	NO	45.1 - 84.0
					V3 (WEEK 12)	84	86	H	NO	45.1 - 84.0
					V4 (WEEK 24)	168	87	H	NO	45.1 - 84.0
					V5 (WEEK 36)	252	85	H	NO	45.1 - 84.0
		093	Female	ACI-91	SCREENING	-3	94	H	NO	45.1 - 84.0
					V5 (WEEK 36)	258	103	H	NO	45.1 - 84.0
					V7 (WEEK 56)	392	96	H	NO	45.1 - 84.0
		097	Male	ACI-91	SCREENING	-21	111	H	NO	59.2 - 103.4
					V1 (WEEK 0)	1	114	H	NO	59.2 - 103.4
					V3 (WEEK 12)	85	111	H	NO	59.2 - 103.4
CALCIUM	mmol/L	003	Female	Placebo	V4 (WEEK 24)	169	2.9	H	NO	2.1 - 2.7
		031	Male	Placebo	V4 (WEEK 24)	174	2.8	H	NO	2.1 - 2.7

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
PHOSPHATE	mmol/L	006	Male	ACI-91	SCREENING	-32	0.7	L	NO	0.8 - 1.6
		019	Male	ACI-91	V7 (WEEK 56)	399	0.7	L	NO	0.8 - 1.6
		034	Female	Placebo	V1 (WEEK 0)	1	0.6	L	NO	0.8 - 1.6
		041	Male	Placebo	SCREENING	-16	0.7	L	NO	0.8 - 1.6
					V3 (WEEK 12)	89	0.7	L	NO	0.8 - 1.6
		059	Male	Placebo	V6 (WEEK 52)	345	0.7	L	NO	0.8 - 1.6
		071	Female	ACI-91	V5 (WEEK 36)	253	0.5	L	NO	0.8 - 1.6
		083	Female	ACI-91	V6 (WEEK 52)	365	0.5	L	NO	0.8 - 1.6
GLUCOSE	mmol/L	001	Female	Placebo	SCREENING	-7	5.78	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.28	H	NO	2.78 - 5.55
					V3 (WEEK 12)	90	5.67	H	NO	2.78 - 5.55
		003	Female	Placebo	SCREENING	-21	5.67	H	NO	2.78 - 5.55
					V4 (WEEK 24)	169	6.00	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	004	Male	ACI-91	V3 (WEEK 12)	92	5.89	H	NO	2.78 - 5.55
		005	Female	Placebo	V1 (WEEK 0)	1	6.00	H	NO	2.78 - 5.55
					V7 (WEEK 56)	400	5.84	H	NO	2.78 - 5.55
		006	Male	ACI-91	SCREENING	-32	7.17	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.62	H	NO	2.78 - 5.55
					V3 (WEEK 12)	85	6.23	H	NO	2.78 - 5.55
					V4 (WEEK 24)	169	7.01	H	NO	2.78 - 5.55
					V5 (WEEK 36)	252	7.23	H	NO	2.78 - 5.55
					V7 (WEEK 56)	390	7.45	H	NO	2.78 - 5.55
		009	Female	Placebo	V3 (WEEK 12)	94	2.00	L	NO	2.78 - 5.55
					V4 (WEEK 24)	178	19.24	H	NO	2.78 - 5.55
					V6 (WEEK 52)	361	13.73	H	NO	2.78 - 5.55
					V7 (WEEK 56)	389	9.34	H	NO	2.78 - 5.55
		011	Female	Placebo	V1 (WEEK 0)	1	7.84	H	NO	2.78 - 5.55
					V3 (WEEK 12)	85	6.45	H	NO	2.78 - 5.55
					V4 (WEEK 24)	162	6.06	H	NO	2.78 - 5.55
					V5 (WEEK 36)	253	6.17	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	011	Female	Placebo	V6 (WEEK 52)	366	6.34	H	NO	2.78 - 5.55
					V7 (WEEK 56)	397	6.06	H	NO	2.78 - 5.55
		012	Male	ACI-91	SCREENING	-32	7.95	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	9.23	H	NO	2.78 - 5.55
					V3 (WEEK 12)	88	8.73	H	NO	2.78 - 5.55
					V5 (WEEK 36)	257	7.90	H	NO	2.78 - 5.55
					V6 (WEEK 52)	361	7.45	H	NO	2.78 - 5.55
					V7 (WEEK 56)	396	7.01	H	NO	2.78 - 5.55
		013	Female	Placebo	V5 (WEEK 36)	247	5.78	H	NO	2.78 - 5.55
					V6 (WEEK 52)	366	5.67	H	NO	2.78 - 5.55
		014	Male	ACI-91	V5 (WEEK 36)	256	6.95	H	NO	2.78 - 5.55
		015	Female	ACI-91	V3 (WEEK 12)	85	5.62	H	NO	2.78 - 5.55
		016	Male	Placebo	SCREENING	-28	5.56	H	NO	2.78 - 5.55
					V6 (WEEK 52)	365	5.78	H	NO	2.78 - 5.55
					V7 (WEEK 56)	403	6.12	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	017	Male	ACI-91	V1 (WEEK 0)	1	5.89	H	NO	2.78 - 5.55
					V7 (WEEK 56)	392	5.78	H	NO	2.78 - 5.55
		018	Female	Placebo	V1 (WEEK 0)	1	5.62	H	NO	2.78 - 5.55
					V6 (WEEK 52)	366	5.73	H	NO	2.78 - 5.55
		019	Male	ACI-91	SCREENING	-21	6.45	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	7.17	H	NO	2.78 - 5.55
					V3 (WEEK 12)	85	6.06	H	NO	2.78 - 5.55
					V4 (WEEK 24)	168	6.67	H	NO	2.78 - 5.55
					V5 (WEEK 36)	259	6.00	H	NO	2.78 - 5.55
					V6 (WEEK 52)	364	6.89	H	NO	2.78 - 5.55
					V7 (WEEK 56)	399	6.95	H	NO	2.78 - 5.55
		023	Male	ACI-91	V1 (WEEK 0)	1	6.06	H	NO	2.78 - 5.55
					V3 (WEEK 12)	86	6.67	H	NO	2.78 - 5.55
					V4 (WEEK 24)	177	6.95	H	NO	2.78 - 5.55
					V5 (WEEK 36)	245	6.78	H	NO	2.78 - 5.55
		024	Male	Placebo	SCREENING	-31	5.73	H	NO	2.78 - 5.55
					V3 (WEEK 12)	87	5.84	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	024	Male	Placebo	V5 (WEEK 36)	246	6.39	H	NO	2.78 - 5.55
					V7 (WEEK 56)	393	6.78	H	NO	2.78 - 5.55
		027	Female	ACI-91	V3 (WEEK 12)	92	5.78	H	NO	2.78 - 5.55
					V5 (WEEK 36)	259	5.95	H	NO	2.78 - 5.55
		028	Female	Placebo	V1 (WEEK 0)	1	6.28	H	NO	2.78 - 5.55
					V3 (WEEK 12)	89	5.73	H	NO	2.78 - 5.55
					V4 (WEEK 24)	180	6.28	H	NO	2.78 - 5.55
					V6 (WEEK 52)	364	6.28	H	NO	2.78 - 5.55
		029	Female	Placebo	SCREENING	-3	7.84	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	7.06	H	NO	2.78 - 5.55
					V3 (WEEK 12)	82	7.34	H	NO	2.78 - 5.55
					V4 (WEEK 24)	158	8.34	H	NO	2.78 - 5.55
					V5 (WEEK 36)	245	6.06	H	NO	2.78 - 5.55
					V6 (WEEK 52)	369	7.73	H	NO	2.78 - 5.55
					V7 (WEEK 56)	391	7.78	H	NO	2.78 - 5.55
		030	Female	ACI-91	SCREENING	-7	5.56	H	NO	2.78 - 5.55
					V4 (WEEK 24)	163	6.34	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	030	Female	ACI-91	V6 (WEEK 52)	355	5.95	H	NO	2.78 - 5.55
		031	Male	Placebo	V4 (WEEK 24)	174	6.28	H	NO	2.78 - 5.55
					V5 (WEEK 36)	251	7.73	H	NO	2.78 - 5.55
		033	Female	ACI-91	SCREENING	-7	5.56	H	NO	2.78 - 5.55
					V3 (WEEK 12)	78	5.84	H	NO	2.78 - 5.55
		034	Female	Placebo	SCREENING	-22	7.34	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.28	H	NO	2.78 - 5.55
					V3 (WEEK 12)	83	7.01	H	NO	2.78 - 5.55
					V4 (WEEK 24)	175	7.45	H	NO	2.78 - 5.55
					V5 (WEEK 36)	258	6.23	H	NO	2.78 - 5.55
					V6 (WEEK 52)	363	7.90	H	NO	2.78 - 5.55
					V7 (WEEK 56)	399	5.95	H	NO	2.78 - 5.55
		041	Male	Placebo	V1 (WEEK 0)	1	7.73	H	NO	2.78 - 5.55
					V4 (WEEK 24)	167	5.89	H	NO	2.78 - 5.55
					V6 (WEEK 52)	363	6.28	H	NO	2.78 - 5.55
		042	Female	ACI-91	V3 (WEEK 12)	126	6.12	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	042	Female	ACI-91	V5 (WEEK 36)	252	6.67	H	NO	2.78 - 5.55
					V7 (WEEK 56)	391	6.06	H	NO	2.78 - 5.55
		043	Male	ACI-91	SCREENING	-28	7.34	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.56	H	NO	2.78 - 5.55
					V3 (WEEK 12)	85	5.73	H	NO	2.78 - 5.55
					V4 (WEEK 24)	176	6.84	H	NO	2.78 - 5.55
		044	Female	Placebo	V4 (WEEK 24)	176	5.56	H	NO	2.78 - 5.55
					V6 (WEEK 52)	365	6.39	H	NO	2.78 - 5.55
		046	Female	ACI-91	SCREENING	-28	6.28	H	NO	2.78 - 5.55
					V3 (WEEK 12)	87	6.51	H	NO	2.78 - 5.55
					V5 (WEEK 36)	255	7.90	H	NO	2.78 - 5.55
					V6 (WEEK 52)	367	5.78	H	NO	2.78 - 5.55
					V7 (WEEK 56)	393	6.12	H	NO	2.78 - 5.55
		047	Male	Placebo	V7 (WEEK 56)	393	5.95	H	NO	2.78 - 5.55
		048	Male	ACI-91	SCREENING	-5	7.56	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.23	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	048	Male	ACI-91	V3 (WEEK 12)	86	5.84	H	NO	2.78 - 5.55
					V5 (WEEK 36)	247	6.67	H	NO	2.78 - 5.55
					V6 (WEEK 52)	360	7.84	H	NO	2.78 - 5.55
					V7 (WEEK 56)	395	8.01	H	NO	2.78 - 5.55
		051	Female	Placebo	V4 (WEEK 24)	167	6.51	H	NO	2.78 - 5.55
		052	Female	ACI-91	V3 (WEEK 12)	82	5.84	H	NO	2.78 - 5.55
					V6 (WEEK 52)	362	6.06	H	NO	2.78 - 5.55
					V7 (WEEK 56)	390	5.67	H	NO	2.78 - 5.55
		055	Female	ACI-91	V6 (WEEK 52)	30	6.51	H	NO	2.78 - 5.55
		056	Female	Placebo	V1 (WEEK 0)	1	5.56	H	NO	2.78 - 5.55
					V5 (WEEK 36)	259	5.56	H	NO	2.78 - 5.55
		059	Male	Placebo	SCREENING	-2	7.67	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	8.28	H	NO	2.78 - 5.55
					V3 (WEEK 12)	93	6.84	H	NO	2.78 - 5.55
					V4 (WEEK 24)	161	7.73	H	NO	2.78 - 5.55
					V5 (WEEK 36)	254	6.51	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	059	Male	Placebo	V6 (WEEK 52)	345	5.95	H	NO	2.78 - 5.55
					V7 (WEEK 56)	380	6.84	H	NO	2.78 - 5.55
		065	Male	Placebo	SCREENING	-20	6.17	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	5.67	H	NO	2.78 - 5.55
					V3 (WEEK 12)	85	6.28	H	NO	2.78 - 5.55
					V4 (WEEK 24)	141	7.06	H	NO	2.78 - 5.55
		066	Male	ACI-91	V1 (WEEK 0)	1	6.28	H	NO	2.78 - 5.55
		067	Female	ACI-91	SCREENING	-16	5.73	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.23	H	NO	2.78 - 5.55
					V6 (WEEK 52)	69	5.73	H	NO	2.78 - 5.55
					V7 (WEEK 56)	111	7.01	H	NO	2.78 - 5.55
		069	Male	Placebo	SCREENING	-13	6.23	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.28	H	NO	2.78 - 5.55
					V3 (WEEK 12)	93	5.89	H	NO	2.78 - 5.55
					V6 (WEEK 52)	373	5.73	H	NO	2.78 - 5.55
		071	Female	ACI-91	SCREENING	-20	9.06	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	071	Female	ACI-91	V5 (WEEK 36)	253	6.45	H	NO	2.78 - 5.55
		079	Female	Placebo	SCREENING	-18	5.62	H	NO	2.78 - 5.55
					V4 (WEEK 24)	175	6.56	H	NO	2.78 - 5.55
					V7 (WEEK 56)	348	5.56	H	NO	2.78 - 5.55
		080	Female	ACI-91	SCREENING	-10	5.67	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	5.73	H	NO	2.78 - 5.55
					V3 (WEEK 12)	84	5.62	H	NO	2.78 - 5.55
		081	Male	ACI-91	V1 (WEEK 0)	1	6.12	H	NO	2.78 - 5.55
		082	Male	Placebo	V1 (WEEK 0)	1	8.06	H	NO	2.78 - 5.55
					V4 (WEEK 24)	175	5.73	H	NO	2.78 - 5.55
					V6 (WEEK 52)	364	6.62	H	NO	2.78 - 5.55
					V7 (WEEK 56)	407	6.34	H	NO	2.78 - 5.55
		083	Female	ACI-91	V6 (WEEK 52)	365	10.95	H	NO	2.78 - 5.55
		084	Female	Placebo	V1 (WEEK 0)	1	5.56	H	NO	2.78 - 5.55

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	086	Female	Placebo	V1 (WEEK 0)	1	5.84	H	NO	2.78 - 5.55
					V6 (WEEK 52)	363	5.78	H	NO	2.78 - 5.55
		087	Female	ACI-91	SCREENING	-20	9.06	H	NO	2.78 - 5.55
					V1 (WEEK 0)	1	6.89	H	NO	2.78 - 5.55
					V3 (WEEK 12)	81	7.28	H	NO	2.78 - 5.55
					V4 (WEEK 24)	169	6.67	H	NO	2.78 - 5.55
					V5 (WEEK 36)	255	7.12	H	NO	2.78 - 5.55
					V6 (WEEK 52)	365	7.12	H	NO	2.78 - 5.55
					V7 (WEEK 56)	395	8.23	H	NO	2.78 - 5.55
		093	Female	ACI-91	V5 (WEEK 36)	258	7.23	H	NO	2.78 - 5.55
		097	Male	ACI-91	V3 (WEEK 12)	85	8.40	H	NO	2.78 - 5.55
TOTAL BILIRUBIN	µmol/L	003	Female	Placebo	V3 (WEEK 12)	90	20.5	H	NO	< 17.0
		006	Male	ACI-91	SCREENING	-32	17.1	H	NO	< 17.0
					V1 (WEEK 0)	1	23.9	H	NO	< 17.0
					V3 (WEEK 12)	85	17.1	H	NO	< 17.0
					V4 (WEEK 24)	169	18.8	H	NO	< 17.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TOTAL BILIRUBIN	µmol/L	006	Male	ACI-91	V5 (WEEK 36)	252	17.1	H	NO	< 17.0
		029	Female	Placebo	SCREENING	-3	17.1	H	NO	< 17.0
					V1 (WEEK 0)	1	17.1	H	NO	< 17.0
		048	Male	ACI-91	V1 (WEEK 0)	1	17.1	H	NO	< 17.0
					V5 (WEEK 36)	247	17.1	H	NO	< 17.0
		056	Female	Placebo	V5 (WEEK 36)	259	23.9	H	NO	< 17.0
					V6 (WEEK 52)	364	22.2	H	NO	< 17.0
		066	Male	ACI-91	V3 (WEEK 12)	83	17.1	H	NO	< 17.0
		069	Male	Placebo	SCREENING	-13	20.5	H	NO	< 17.0
					V6 (WEEK 52)	373	17.1	H	NO	< 17.0
		071	Female	ACI-91	V5 (WEEK 36)	253	18.8	H	NO	< 17.0
TOTAL PROTEIN	g/L	018	Female	Placebo	SCREENING	-20	82	H	NO	61.0 - 81.0
		029	Female	Placebo	V4 (WEEK 24)	158	60	L	NO	61.0 - 81.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TOTAL PROTEIN	g/L	046	Female	ACI-91	V3 (WEEK 12)	87	59	L	NO	61.0 - 81.0
		068	Male	Placebo	V7 (WEEK 56)	414	64	L	NO	66 - 87
		072	Female	Placebo	SCREENING	-20	83	H	NO	61.0 - 81.0
		082	Male	Placebo	SCREENING	-8	60	L	NO	61.0 - 81.0
		087	Female	ACI-91	SCREENING	-20	83	H	NO	61.0 - 81.0
ALBUMIN	g/L	031	Male	Placebo	V4 (WEEK 24)	174	57.0	H	NO	35.0 - 55.0
SGOT (AST)	U/L	002	Female	ACI-91	V1 (WEEK 0)	1	40	H	NO	10 - 35
					V4 (WEEK 24)	169	40	H	NO	10 - 35
					V5 (WEEK 36)	258	45	H	NO	10 - 35
					V6 (WEEK 52)	365	39	H	NO	10 - 35
		009	Female	Placebo	V3 (WEEK 12)	94	42	H	NO	10 - 35
		012	Male	ACI-91	V3 (WEEK 12)	88	73	H	YES	10 - 50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
SGOT (AST)	U/L	015	Female	ACI-91	V3 (WEEK 12)	85	37	H	NO	10 - 35
		027	Female	ACI-91	V1 (WEEK 0)	1	37	H	NO	10 - 35
					V3 (WEEK 12)	92	40	H	NO	10 - 35
					V5 (WEEK 36)	259	36	H	NO	10 - 35
		042	Female	ACI-91	V3 (WEEK 12)	126	49	H	NO	10 - 35
		043	Male	ACI-91	V3 (WEEK 12)	85	53	H	NO	10 - 50
		049	Female	Placebo	V3 (WEEK 12)	84	36	H	NO	10 - 35
		050	Female	ACI-91	V4 (WEEK 24)	167	37	H	NO	10 - 35
		057	Female	ACI-91	V4 (WEEK 24)	170	40	H	NO	10 - 35
		065	Male	Placebo	V4 (WEEK 24)	141	71	H	NO	10 - 50
		079	Female	Placebo	SCREENING	-18	42	H	NO	10 - 35
					V1 (WEEK 0)	1	38	H	NO	10 - 35
					V6 (WEEK 52)	320	36	H	NO	10 - 35

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
SGOT (AST)	U/L	079	Female	Placebo	V7 (WEEK 56)	348	36	H	NO	10 - 35
		087	Female	ACI-91	V3 (WEEK 12)	81	45	H	NO	10 - 35
					V4 (WEEK 24)	169	38	H	NO	10 - 35
		093	Female	ACI-91	V5 (WEEK 36)	258	37	H	NO	10 - 35
SGPT (ALT)	U/L	002	Female	ACI-91	SCREENING	-7	41	H	NO	< 35
					V1 (WEEK 0)	1	41	H	NO	< 35
					V3 (WEEK 12)	85	35	H	NO	< 35
					V4 (WEEK 24)	169	40	H	NO	< 35
					V5 (WEEK 36)	258	61	H	NO	< 35
					V6 (WEEK 52)	365	40	H	NO	< 35
		009	Female	Placebo	V3 (WEEK 12)	94	56	H	NO	< 35
		012	Male	ACI-91	V3 (WEEK 12)	88	150	H	YES	< 50
		030	Female	ACI-91	V4 (WEEK 24)	163	39	H	NO	< 35
					V7 (WEEK 56)	383	48	H	NO	< 35

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
SGPT (ALT)	U/L	033	Female	ACI-91	V3 (WEEK 12)	78	37	H	NO	< 35
		042	Female	ACI-91	V3 (WEEK 12)	126	86	H	NO	< 35
					V4 (WEEK 24)	168	50	H	NO	< 35
		057	Female	ACI-91	V1 (WEEK 0)	1	39	H	NO	< 35
					V4 (WEEK 24)	170	55	H	NO	< 35
		065	Male	Placebo	V4 (WEEK 24)	141	93	H	NO	< 50
		069	Male	Placebo	V4 (WEEK 24)	164	66	H	NO	< 50
		071	Female	ACI-91	V3 (WEEK 12)	87	55	H	NO	< 35
		079	Female	Placebo	SCREENING	-18	53	H	NO	< 35
					V1 (WEEK 0)	1	55	H	NO	< 35
					V4 (WEEK 24)	175	37	H	NO	< 35
					V5 (WEEK 36)	249	38	H	NO	< 35
					V6 (WEEK 52)	320	50	H	NO	< 35
					V7 (WEEK 56)	348	43	H	NO	< 35

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
SGPT (ALT)	U/L	087	Female	ACI-91	V3 (WEEK 12)	81	59	H	NO	< 35
					V4 (WEEK 24)	169	42	H	NO	< 35
		093	Female	ACI-91	V5 (WEEK 36)	258	44	H	NO	< 35
ALKALINE PHOSPHATASE	U/L	014	Male	ACI-91	SCREENING	-26	24	L	NO	40 - 130
					V1 (WEEK 0)	1	22	L	NO	40 - 130
					V3 (WEEK 12)	85	20	L	NO	40 - 130
					V4 (WEEK 24)	172	23	L	NO	40 - 130
					V5 (WEEK 36)	256	20	L	NO	40 - 130
					V6 (WEEK 52)	361	23	L	NO	40 - 130
					V7 (WEEK 56)	396	22	L	NO	40 - 130
		019	Male	ACI-91	V3 (WEEK 12)	85	35	L	NO	40 - 130
					V4 (WEEK 24)	168	39	L	NO	40 - 130
					V6 (WEEK 52)	364	38	L	NO	40 - 130
					V7 (WEEK 56)	399	39	L	NO	40 - 130
		027	Female	ACI-91	V4 (WEEK 24)	174	112	H	NO	35 - 105
		028	Female	Placebo	V3 (WEEK 12)	89	113	H	NO	35 - 105

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
ALKALINE PHOSPHATASE	U/L	031	Male	Placebo	V6 (WEEK 52)	363	134	H	NO	40 - 130
		033	Female	ACI-91	SCREENING	-7	128	H	NO	35 - 105
					V1 (WEEK 0)	1	126	H	NO	35 - 105
					V6 (WEEK 52)	372	110	H	NO	35 - 105
		046	Female	ACI-91	V1 (WEEK 0)	1	153	H	NO	35 - 105
		048	Male	ACI-91	V5 (WEEK 36)	247	39	L	NO	40 - 130
		052	Female	ACI-91	SCREENING	-52	152	H	NO	35 - 105
					V1 (WEEK 0)	1	158	H	NO	35 - 105
					V3 (WEEK 12)	82	148	H	NO	35 - 105
					V4 (WEEK 24)	166	156	H	NO	35 - 105
					V5 (WEEK 36)	250	152	H	NO	35 - 105
					V6 (WEEK 52)	362	135	H	NO	35 - 105
					V7 (WEEK 56)	390	150	H	NO	35 - 105
		067	Female	ACI-91	V6 (WEEK 52)	69	106	H	NO	35 - 105
		071	Female	ACI-91	V3 (WEEK 12)	87	132	H	NO	35 - 105

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
ALKALINE PHOSPHATASE	U/L	072	Female	Placebo	SCREENING	-20	110	H	NO	35 - 105
					V6 (WEEK 52)	360	110	H	NO	35 - 105
		079	Female	Placebo	V4 (WEEK 24)	175	109	H	NO	35 - 105
		082	Male	Placebo	SCREENING	-8	38	L	NO	40 - 130
		088	Female	Placebo	SCREENING	-9	132	H	NO	35 - 105
					V1 (WEEK 0)	1	146	H	NO	35 - 105
					V5 (WEEK 36)	264	126	H	NO	35 - 105
GAMMA-GT	U/L	001	Female	Placebo	V5 (WEEK 36)	246	44	H	NO	< 40
					V6 (WEEK 52)	365	46	H	NO	< 40
					V7 (WEEK 56)	393	58	H	NO	< 40
		003	Female	Placebo	SCREENING	-21	75	H	NO	< 40
					V3 (WEEK 12)	90	55	H	NO	< 40
		009	Female	Placebo	V3 (WEEK 12)	94	46	H	NO	< 40
		027	Female	ACI-91	V1 (WEEK 0)	1	40	H	NO	< 40

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GAMMA-GT	U/L	027	Female	ACI-91	V3 (WEEK 12)	92	48	H	NO	< 40
					V4 (WEEK 24)	174	62	H	NO	< 40
					V5 (WEEK 36)	259	54	H	NO	< 40
					V7 (WEEK 56)	407	40	H	NO	< 40
		041	Male	Placebo	V3 (WEEK 12)	89	102	H	NO	< 60
		046	Female	ACI-91	SCREENING	-28	64	H	NO	< 40
					V1 (WEEK 0)	1	51	H	NO	< 40
		052	Female	ACI-91	SCREENING	-52	153	H	NO	< 40
					V1 (WEEK 0)	1	175	H	NO	< 40
					V3 (WEEK 12)	82	149	H	NO	< 40
					V4 (WEEK 24)	166	168	H	NO	< 40
					V5 (WEEK 36)	250	160	H	NO	< 40
					V6 (WEEK 52)	362	160	H	NO	< 40
					V7 (WEEK 56)	390	143	H	NO	< 40
		065	Male	Placebo	V4 (WEEK 24)	141	75	H	NO	< 60
		066	Male	ACI-91	SCREENING	-31	199	H	NO	< 60

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GAMMA-GT	U/L	066	Male	ACI-91	V1 (WEEK 0)	1	203	H	NO	< 60
					V3 (WEEK 12)	83	164	H	NO	< 60
		069	Male	Placebo	V3 (WEEK 12)	93	78	H	NO	< 60
					V4 (WEEK 24)	164	116	H	NO	< 60
		071	Female	ACI-91	V3 (WEEK 12)	87	262	H	YES	< 40
					V4 (WEEK 24)	177	62	H	NO	< 40
					V5 (WEEK 36)	253	50	H	NO	< 40
					V7 (WEEK 56)	392	40	H	NO	< 40
CHOLESTEROL	mmol/L	001	Female	Placebo	V3 (WEEK 12)	90	7.10	H	NO	< 6.50
		003	Female	Placebo	SCREENING	-21	6.81	H	NO	< 6.50
					V3 (WEEK 12)	90	6.86	H	NO	< 6.50
		004	Male	ACI-91	SCREENING	-29	7.30	H	NO	< 6.50
					V3 (WEEK 12)	92	6.79	H	NO	< 6.50
		006	Male	ACI-91	SCREENING	-32	6.76	H	NO	< 6.50
					V1 (WEEK 0)	1	7.43	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	006	Male	ACI-91	V3 (WEEK 12)	85	7.90	H	NO	< 6.50
					V4 (WEEK 24)	169	6.73	H	NO	< 6.50
					V5 (WEEK 36)	252	6.97	H	NO	< 6.50
					V6 (WEEK 52)	364	6.89	H	NO	< 6.50
					V7 (WEEK 56)	390	6.97	H	NO	< 6.50
		011	Female	Placebo	SCREENING	-21	6.55	H	NO	< 6.50
					V1 (WEEK 0)	1	6.76	H	NO	< 6.50
					V4 (WEEK 24)	162	6.68	H	NO	< 6.50
					V5 (WEEK 36)	253	6.63	H	NO	< 6.50
					V6 (WEEK 52)	366	6.84	H	NO	< 6.50
		016	Male	Placebo	SCREENING	-28	6.79	H	YES	< 6.50
					V1 (WEEK 0)	1	6.97	H	YES	< 6.50
					V4 (WEEK 24)	162	7.20	H	NO	< 6.50
					V5 (WEEK 36)	253	8.00	H	NO	< 6.50
					V6 (WEEK 52)	365	8.16	H	NO	< 6.50
					V7 (WEEK 56)	403	8.73	H	NO	< 6.50
		024	Male	Placebo	V3 (WEEK 12)	87	6.66	H	NO	< 6.50
					V4 (WEEK 24)	171	6.86	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	024	Male	Placebo	V7 (WEEK 56)	393	7.61	H	NO	< 6.50
		028	Female	Placebo	SCREENING	-8	7.98	H	NO	< 6.50
					V1 (WEEK 0)	1	7.43	H	NO	< 6.50
					V3 (WEEK 12)	89	7.67	H	NO	< 6.50
					V4 (WEEK 24)	180	6.99	H	NO	< 6.50
					V5 (WEEK 36)	273	7.17	H	NO	< 6.50
					V6 (WEEK 52)	364	7.80	H	NO	< 6.50
					V7 (WEEK 56)	390	7.43	H	NO	< 6.50
		030	Female	ACI-91	V4 (WEEK 24)	163	6.92	H	NO	< 6.50
					V5 (WEEK 36)	253	6.66	H	NO	< 6.50
		032	Female	ACI-91	SCREENING	-10	6.66	H	YES	< 6.50
					V3 (WEEK 12)	82	7.46	H	YES	< 6.50
		033	Female	ACI-91	V5 (WEEK 36)	261	7.10	H	NO	< 6.50
		034	Female	Placebo	V7 (WEEK 56)	399	6.50	H	NO	< 6.50
		042	Female	ACI-91	V5 (WEEK 36)	252	7.72	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	042	Female	ACI-91	V6 (WEEK 52)	364	8.21	H	NO	< 6.50
					V7 (WEEK 56)	391	7.49	H	NO	< 6.50
		046	Female	ACI-91	SCREENING	-28	9.14	H	YES	< 6.50
					V1 (WEEK 0)	1	7.23	H	NO	< 6.50
					V3 (WEEK 12)	87	6.73	H	NO	< 6.50
					V5 (WEEK 36)	255	7.07	H	NO	< 6.50
					V7 (WEEK 56)	393	7.38	H	NO	< 6.50
		048	Male	ACI-91	V1 (WEEK 0)	1	6.50	H	NO	< 6.50
		049	Female	Placebo	SCREENING	-51	7.98	H	NO	< 6.50
					V1 (WEEK 0)	1	7.54	H	NO	< 6.50
					V3 (WEEK 12)	84	7.82	H	NO	< 6.50
					V4 (WEEK 24)	168	7.51	H	NO	< 6.50
		050	Female	ACI-91	SCREENING	-51	8.00	H	NO	< 6.50
					V1 (WEEK 0)	1	6.73	H	NO	< 6.50
					V3 (WEEK 12)	83	7.51	H	NO	< 6.50
					V4 (WEEK 24)	167	7.20	H	NO	< 6.50
					V5 (WEEK 36)	251	7.02	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	050	Female	ACI-91	V6 (WEEK 52)	363	7.10	H	NO	< 6.50
					V7 (WEEK 56)	391	7.12	H	NO	< 6.50
		057	Female	ACI-91	V1 (WEEK 0)	1	6.66	H	NO	< 6.50
					V3 (WEEK 12)	82	6.50	H	NO	< 6.50
					V4 (WEEK 24)	170	6.50	H	NO	< 6.50
		058	Male	Placebo	SCREENING	-21	7.54	H	NO	< 6.50
					V1 (WEEK 0)	1	7.49	H	NO	< 6.50
					V3 (WEEK 12)	93	6.86	H	NO	< 6.50
					V4 (WEEK 24)	166	6.58	H	NO	< 6.50
					V5 (WEEK 36)	260	7.10	H	NO	< 6.50
					V6 (WEEK 52)	345	6.71	H	NO	< 6.50
					V7 (WEEK 56)	380	7.25	H	NO	< 5.18
		059	Male	Placebo	SCREENING	-2	7.04	H	NO	< 6.50
					V1 (WEEK 0)	1	6.76	H	NO	< 6.50
					V3 (WEEK 12)	93	6.66	H	NO	< 6.50
					V4 (WEEK 24)	161	7.10	H	NO	< 6.50
					V5 (WEEK 36)	254	6.92	H	NO	< 6.50
					V6 (WEEK 52)	345	6.53	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	059	Male	Placebo	V7 (WEEK 56)	380	6.86	H	NO	< 5.18
		065	Male	Placebo	V1 (WEEK 0)	1	7.46	H	NO	< 6.50
		068	Male	Placebo	V3 (WEEK 12)	81	6.89	H	NO	< 6.50
					V5 (WEEK 36)	262	7.17	H	NO	< 6.50
		069	Male	Placebo	SCREENING	-13	6.84	H	NO	< 6.50
					V1 (WEEK 0)	1	6.58	H	NO	< 6.50
					V3 (WEEK 12)	93	6.81	H	NO	< 6.50
					V5 (WEEK 36)	261	6.68	H	NO	< 6.50
					V6 (WEEK 52)	373	7.23	H	NO	< 6.50
					V7 (WEEK 56)	401	6.79	H	NO	< 5.18
		072	Female	Placebo	SCREENING	-20	7.51	H	NO	< 6.50
					V1 (WEEK 0)	1	6.63	H	NO	< 6.50
					V3 (WEEK 12)	85	6.60	H	NO	< 6.50
					V7 (WEEK 56)	393	6.16	H	NO	< 5.18
		080	Female	ACI-91	SCREENING	-10	7.38	H	NO	< 6.50
					V3 (WEEK 12)	84	7.15	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	080	Female	ACI-91	V6 (WEEK 52)	196	7.51	H	NO	< 6.50
		081	Male	ACI-91	SCREENING	-10	6.94	H	NO	< 6.50
					V1 (WEEK 0)	1	6.60	H	NO	< 6.50
					V4 (WEEK 24)	175	6.58	H	NO	< 6.50
					V5 (WEEK 36)	250	6.94	H	NO	< 6.50
		083	Female	ACI-91	V5 (WEEK 36)	258	6.50	H	NO	< 6.50
					V7 (WEEK 56)	392	7.72	H	NO	< 6.50
		086	Female	Placebo	SCREENING	-24	8.00	H	NO	< 6.50
					V1 (WEEK 0)	1	7.04	H	NO	< 6.50
					V3 (WEEK 12)	83	6.84	H	NO	< 6.50
					V4 (WEEK 24)	167	6.99	H	NO	< 6.50
					V5 (WEEK 36)	251	7.10	H	NO	< 6.50
					V6 (WEEK 52)	363	6.60	H	NO	< 6.50
					V7 (WEEK 56)	391	6.79	H	NO	< 6.50
		087	Female	ACI-91	SCREENING	-20	6.73	H	NO	< 6.50
					V3 (WEEK 12)	81	6.73	H	NO	< 6.50
					V4 (WEEK 24)	169	6.86	H	NO	< 6.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
CHOLESTEROL	mmol/L	087	Female	ACI-91	V6 (WEEK 52)	365	7.33	H	NO	< 6.50
					V7 (WEEK 56)	395	7.20	H	NO	< 6.50
		088	Female	Placebo	V7 (WEEK 56)	404	6.37	H	NO	< 5.18
		089	Female	ACI-91	SCREENING	-28	6.76	H	NO	< 6.50
					V1 (WEEK 0)	1	6.68	H	NO	< 6.50
					V3 (WEEK 12)	84	6.92	H	NO	< 6.50
					V4 (WEEK 24)	168	6.84	H	NO	< 6.50
					V5 (WEEK 36)	252	6.79	H	NO	< 6.50
		093	Female	ACI-91	SCREENING	-3	7.95	H	NO	< 6.50
					V1 (WEEK 0)	1	8.73	H	NO	< 6.50
					V3 (WEEK 12)	86	8.29	H	NO	< 6.50
					V6 (WEEK 52)	370	7.87	H	NO	< 6.50
					V7 (WEEK 56)	392	6.76	H	NO	< 6.50
TRIGLYCERIDES	mmol/L	001	Female	Placebo	V5 (WEEK 36)	246	2.49	H	NO	0.57 - 2.28
					V6 (WEEK 52)	365	3.06	H	NO	0.57 - 2.28
					V7 (WEEK 56)	393	2.91	H	NO	0.57 - 2.28

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TRIGLYCERIDES	mmol/L	005	Female	Placebo	SCREENING	-16	3.44	H	NO	0.57 - 2.28
					V6 (WEEK 52)	364	2.60	H	NO	0.57 - 2.28
		006	Male	ACI-91	V3 (WEEK 12)	85	2.33	H	NO	0.57 - 2.28
					V4 (WEEK 24)	169	2.29	H	NO	0.57 - 2.28
					V7 (WEEK 56)	390	2.58	H	NO	0.57 - 2.28
		010	Male	ACI-91	SCREENING	-26	2.31	H	NO	0.57 - 2.28
		012	Male	ACI-91	V3 (WEEK 12)	88	0.48	L	NO	0.57 - 2.28
					V5 (WEEK 36)	257	0.50	L	NO	0.57 - 2.28
		014	Male	ACI-91	SCREENING	-26	2.37	H	NO	0.57 - 2.28
					V3 (WEEK 12)	85	2.60	H	NO	0.57 - 2.28
		015	Female	ACI-91	V3 (WEEK 12)	85	2.84	H	NO	0.57 - 2.28
		016	Male	Placebo	V3 (WEEK 12)	80	3.09	H	NO	0.57 - 2.28
					V4 (WEEK 24)	162	3.48	H	NO	0.57 - 2.28
					V5 (WEEK 36)	253	2.99	H	NO	0.57 - 2.28
					V6 (WEEK 52)	365	3.02	H	NO	0.57 - 2.28

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TRIGLYCERIDES	mmol/L	016	Male	Placebo	V7 (WEEK 56)	403	3.65	H	NO	0.57 - 2.28
		019	Male	ACI-91	SCREENING	-21	2.36	H	NO	0.57 - 2.28
		023	Male	ACI-91	V1 (WEEK 0)	1	2.46	H	NO	0.57 - 2.28
		024	Male	Placebo	V5 (WEEK 36)	246	2.62	H	NO	0.57 - 2.28
					V6 (WEEK 52)	358	2.79	H		0.57 - 2.28
		027	Female	ACI-91	SCREENING	-21	2.84	H	NO	0.57 - 2.28
					V1 (WEEK 0)	1	3.15	H	NO	0.57 - 2.28
					V4 (WEEK 24)	174	3.92	H	NO	0.57 - 2.28
					V7 (WEEK 56)	407	2.47	H	NO	0.57 - 2.28
		028	Female	Placebo	V1 (WEEK 0)	1	2.38	H	NO	0.57 - 2.28
					V3 (WEEK 12)	89	4.07	H	NO	0.57 - 2.28
					V4 (WEEK 24)	180	3.52	H	NO	0.57 - 2.28
					V5 (WEEK 36)	273	2.60	H	NO	0.57 - 2.28
					V6 (WEEK 52)	364	2.74	H	NO	0.57 - 2.28
		029	Female	Placebo	SCREENING	-3	3.17	H	NO	0.57 - 2.28

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TRIGLYCERIDES	mmol/L	029	Female	Placebo	V1 (WEEK 0)	1	3.31	H	NO	0.57 - 2.28
					V3 (WEEK 12)	82	3.59	H	NO	0.57 - 2.28
					V4 (WEEK 24)	158	3.02	H	NO	0.57 - 2.28
					V5 (WEEK 36)	245	2.75	H	NO	0.57 - 2.28
					V6 (WEEK 52)	369	4.71	H	NO	0.57 - 2.28
					V7 (WEEK 56)	391	3.72	H	NO	0.57 - 2.28
		030	Female	ACI-91	V1 (WEEK 0)	1	2.50	H	NO	0.57 - 2.28
					V6 (WEEK 52)	355	2.79	H	NO	0.57 - 2.28
					V7 (WEEK 56)	383	3.73	H	NO	0.57 - 2.28
		033	Female	ACI-91	V1 (WEEK 0)	1	2.54	H	NO	0.57 - 2.28
		046	Female	ACI-91	SCREENING	-28	2.68	H	NO	0.57 - 2.28
					V5 (WEEK 36)	255	2.49	H	NO	0.57 - 2.28
		047	Male	Placebo	V3 (WEEK 12)	80	2.72	H	NO	0.57 - 2.28
					V4 (WEEK 24)	162	2.30	H	NO	0.57 - 2.28
		048	Male	ACI-91	SCREENING	-5	2.59	H	NO	0.57 - 2.28
					V1 (WEEK 0)	1	2.36	H	NO	0.57 - 2.28

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TRIGLYCERIDES	mmol/L	048	Male	ACI-91	V3 (WEEK 12)	86	2.71	H	NO	0.57 - 2.28
					V5 (WEEK 36)	247	2.49	H	NO	0.57 - 2.28
					V6 (WEEK 52)	360	2.85	H	NO	0.57 - 2.28
					V7 (WEEK 56)	395	3.55	H	NO	0.57 - 2.28
		051	Female	Placebo	V1 (WEEK 0)	1	2.39	H	NO	0.57 - 2.28
					V4 (WEEK 24)	167	2.98	H	NO	0.57 - 2.28
					V5 (WEEK 36)	251	2.55	H	NO	0.57 - 2.28
					V7 (WEEK 56)	391	2.61	H	NO	0.57 - 2.28
		055	Female	ACI-91	SCREENING	-21	3.53	H	NO	0.57 - 2.28
					V6 (WEEK 52)	30	2.87	H	NO	0.57 - 2.28
		059	Male	Placebo	SCREENING	-2	2.93	H	NO	0.57 - 2.28
					V3 (WEEK 12)	93	2.75	H	NO	0.57 - 2.28
					V4 (WEEK 24)	161	2.59	H	NO	0.57 - 2.28
					V5 (WEEK 36)	254	3.21	H	NO	0.57 - 2.28
					V7 (WEEK 56)	380	2.34	H	NO	< 2.28
		069	Male	Placebo	SCREENING	-13	2.47	H	NO	0.57 - 2.28
					V1 (WEEK 0)	1	3.42	H	NO	0.57 - 2.28

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
TRIGLYCERIDES	mmol/L	069	Male	Placebo	V3 (WEEK 12)	93	3.39	H	NO	0.57 - 2.28
					V5 (WEEK 36)	261	2.69	H	NO	0.57 - 2.28
					V6 (WEEK 52)	373	4.02	H	NO	0.57 - 2.28
					V7 (WEEK 56)	401	3.73	H	NO	< 2.28
		079	Female	Placebo	V1 (WEEK 0)	1	2.46	H	NO	0.57 - 2.28
					V6 (WEEK 52)	320	3.97	H	NO	0.57 - 2.28
		081	Male	ACI-91	SCREENING	-10	0.55	L	NO	0.57 - 2.28
		093	Female	ACI-91	SCREENING	-3	4.90	H	NO	0.57 - 2.28
					V1 (WEEK 0)	1	3.01	H	NO	0.57 - 2.28
					V3 (WEEK 12)	86	4.39	H	NO	0.57 - 2.28
		097	Male	ACI-91	V3 (WEEK 12)	85	2.66	H	NO	0.57 - 2.28
URIC ACID	µmol/L	006	Male	ACI-91	SCREENING	-32	416	H	NO	< 416
					V3 (WEEK 12)	85	428	H	NO	< 416
					V4 (WEEK 24)	169	434	H	NO	< 416
					V6 (WEEK 52)	364	422	H	NO	< 416
					V7 (WEEK 56)	390	416	H	NO	< 416

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
URIC ACID	µmol/L	015	Female	ACI-91	V3 (WEEK 12)	85	357	H	NO	< 357
					V5 (WEEK 36)	248	369	H	NO	< 357
		017	Male	ACI-91	V1 (WEEK 0)	1	446	H	NO	< 416
		019	Male	ACI-91	V4 (WEEK 24)	168	458	H	NO	< 416
					V5 (WEEK 36)	259	458	H	NO	< 416
					V6 (WEEK 52)	364	428	H	NO	< 416
					V7 (WEEK 56)	399	440	H	NO	< 416
		024	Male	Placebo	V4 (WEEK 24)	171	416	H	NO	< 416
					V6 (WEEK 52)	358	434	H		< 416
					V7 (WEEK 56)	393	452	H	NO	< 416
		027	Female	ACI-91	SCREENING	-21	440	H	NO	< 357
					V1 (WEEK 0)	1	470	H	NO	< 357
					V3 (WEEK 12)	92	416	H	NO	< 357
					V4 (WEEK 24)	174	440	H	NO	< 357
					V5 (WEEK 36)	259	416	H	NO	< 357
					V6 (WEEK 52)	370	434	H	NO	< 357
					V7 (WEEK 56)	407	404	H	NO	< 357

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
URIC ACID	µmol/L	030	Female	ACI-91	V3 (WEEK 12)	85	363	H	NO	< 357
					V4 (WEEK 24)	163	393	H	NO	< 357
					V5 (WEEK 36)	253	357	H	NO	< 357
					V6 (WEEK 52)	355	399	H	NO	< 357
		033	Female	ACI-91	SCREENING	-7	488	H	NO	< 357
					V1 (WEEK 0)	1	387	H	NO	< 357
					V3 (WEEK 12)	78	404	H	NO	< 357
					V4 (WEEK 24)	169	446	H	NO	< 357
					V5 (WEEK 36)	261	470	H	NO	< 357
					V6 (WEEK 52)	372	470	H	NO	< 357
					V7 (WEEK 56)	398	458	H	NO	< 357
		046	Female	ACI-91	SCREENING	-28	381	H	NO	< 357
					V6 (WEEK 52)	367	369	H	NO	< 357
					V7 (WEEK 56)	393	399	H	NO	< 357
		047	Male	Placebo	SCREENING	-21	470	H	NO	< 416
					V1 (WEEK 0)	1	422	H	NO	< 416
					V3 (WEEK 12)	80	422	H	NO	< 416
					V4 (WEEK 24)	162	464	H	NO	< 416

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
URIC ACID	µmol/L	047	Male	Placebo	V5 (WEEK 36)	254	482	H	NO	< 416
					V6 (WEEK 52)	360	470	H	NO	< 416
					V7 (WEEK 56)	393	452	H	NO	< 416
		048	Male	ACI-91	V3 (WEEK 12)	86	440	H	NO	< 416
					V4 (WEEK 24)	176	446	H	NO	< 416
					V5 (WEEK 36)	247	434	H	NO	< 416
					V7 (WEEK 56)	395	422	H	NO	< 416
		049	Female	Placebo	SCREENING	-51	363	H	NO	< 357
					V1 (WEEK 0)	1	375	H	NO	< 357
					V3 (WEEK 12)	84	381	H	NO	< 357
					V5 (WEEK 36)	252	369	H	NO	< 357
		051	Female	Placebo	SCREENING	-52	410	H	NO	< 357
					V1 (WEEK 0)	1	458	H	NO	< 357
					V3 (WEEK 12)	97	488	H	NO	< 357
					V4 (WEEK 24)	167	482	H	NO	< 357
					V5 (WEEK 36)	251	458	H	NO	< 357
					V6 (WEEK 52)	363	458	H	NO	< 357
					V7 (WEEK 56)	391	440	H	NO	< 357

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
URIC ACID	µmol/L	052	Female	ACI-91	SCREENING	-52	363	H	NO	< 357
		055	Female	ACI-91	V1 (WEEK 0)	1	375	H	NO	< 357
		058	Male	Placebo	V3 (WEEK 12)	93	416	H	NO	< 416
					V5 (WEEK 36)	260	422	H	NO	< 416
					V6 (WEEK 52)	345	446	H	NO	< 416
					V7 (WEEK 56)	380	440	H	NO	202 - 416
		065	Male	Placebo	SCREENING	-20	464	H	NO	< 416
					V1 (WEEK 0)	1	470	H	NO	< 416
		069	Male	Placebo	V3 (WEEK 12)	93	470	H	NO	< 416
		079	Female	Placebo	SCREENING	-18	369	H	NO	< 357
					V3 (WEEK 12)	96	369	H	NO	< 357
					V5 (WEEK 36)	249	381	H	NO	< 357
		080	Female	ACI-91	V6 (WEEK 52)	196	369	H	NO	< 357
		082	Male	Placebo	V6 (WEEK 52)	364	422	H	NO	< 416

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.2: Blood chemistry, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
URIC ACID	µmol/L	083	Female	ACI-91	SCREENING	-15	399	H	NO	< 357
					V1 (WEEK 0)	1	446	H	NO	< 357
		086	Female	Placebo	V1 (WEEK 0)	1	357	H	NO	< 357
					V3 (WEEK 12)	83	363	H	NO	< 357
		087	Female	ACI-91	V3 (WEEK 12)	81	399	H	NO	< 357
					V4 (WEEK 24)	169	410	H	NO	< 357
					V5 (WEEK 36)	255	416	H	NO	< 357
					V6 (WEEK 52)	365	369	H	NO	< 357
					V7 (WEEK 56)	395	357	H	NO	< 357
		093	Female	ACI-91	SCREENING	-3	404	H	NO	< 357
					V1 (WEEK 0)	1	393	H	NO	< 357
					V3 (WEEK 12)	86	381	H	NO	< 357
					V5 (WEEK 36)	258	446	H	NO	< 357
					V7 (WEEK 56)	392	399	H	NO	< 357

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.1.3: Blood chemistry, shift tables

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Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
SODIUM	ACI-91	LOW	0	0	1	3.1	0	0	0	0
		NORMAL	1	3.1	23	71.9	0	0	7	21.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	1	3.2	0	0	0	0	0	0
		NORMAL	0	0	26	83.9	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
POTASSIUM	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	25	78.1	0	0	7	21.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.2	25	80.6	0	0	4	12.9
		HIGH	0	0	1	3.2	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
CHLORIDE	ACI-91	LOW	0	0	1	3.1	0	0	0	0
		NORMAL	1	3.1	17	53.1	5	15.6	7	21.9
		HIGH	0	0	1	3.1	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	2	6.5	0	0	0	0
		NORMAL	0	0	19	61.3	3	9.7	4	12.9
		HIGH	0	0	3	9.7	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
BICARBONATE	ACI-91	LOW	0	0	2	6.3	0	0	1	3.1
		NORMAL	0	0	21	65.6	0	0	5	15.6
		HIGH	0	0	1	3.1	1	3.1	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	1	3.2	1	3.2	0	0	1	3.2
		NORMAL	0	0	23	74.2	1	3.2	3	9.7
		HIGH	0	0	1	3.2	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

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Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
UREA	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	23	71.9	1	3.1	7	21.9
		HIGH	0	0	0	0	1	3.1	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	27	87.1	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
CREATININE	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.1	16	50.0	0	0	6	18.8
		HIGH	0	0	5	15.6	3	9.4	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.2	22	71.0	2	6.5	3	9.7
		HIGH	0	0	1	3.2	1	3.2	1	3.2
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

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Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
CALCIUM	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	25	78.1	0	0	7	21.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	27	87.1	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
PHOSPHATE	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.1	24	75.0	0	0	7	21.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	1	3.2	0	0	0	0
		NORMAL	1	3.2	25	80.6	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
GLUCOSE	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	10	31.3	5	15.6	5	15.6
		HIGH	0	0	5	15.6	5	15.6	2	6.3
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	9	29.0	4	12.9	3	9.7
		HIGH	0	0	4	12.9	10	32.3	1	3.2
		MISSING	0	0	0	0	0	0	0	0
TOTAL BILIRUBIN	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	23	71.9	0	0	7	21.9
		HIGH	0	0	2	6.3	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	24	77.4	2	6.5	4	12.9
		HIGH	0	0	1	3.2	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
TOTAL PROTEIN	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	25	78.1	0	0	7	21.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	27	87.1	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
ALBUMIN	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	25	78.1	0	0	7	21.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	27	87.1	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
SGOT (AST)	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	23	71.9	0	0	7	21.9
		HIGH	0	0	1	3.1	1	3.1	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	26	83.9	0	0	4	12.9
		HIGH	0	0	0	0	1	3.2	0	0
		MISSING	0	0	0	0	0	0	0	0
SGPT (ALT)	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	24	75.0	0	0	6	18.8
		HIGH	0	0	0	0	1	3.1	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	26	83.9	0	0	4	12.9
		HIGH	0	0	0	0	1	3.2	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
ALKALINE PHOSPHATASE	ACI-91	LOW	1	3.1	0	0	0	0	0	0
		NORMAL	1	3.1	19	59.4	1	3.1	7	21.9
		HIGH	0	0	1	3.1	2	6.3	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	25	80.6	2	6.5	3	9.7
		HIGH	0	0	0	0	0	0	1	3.2
		MISSING	0	0	0	0	0	0	0	0
GAMMA-GT	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	22	68.8	0	0	6	18.8
		HIGH	0	0	2	6.3	1	3.1	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	26	83.9	1	3.2	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
CHOLESTEROL	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	15	46.9	3	9.4	6	18.8
		HIGH	0	0	4	12.5	3	9.4	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	19	61.3	0	0	2	6.5
		HIGH	0	0	1	3.2	7	22.6	2	6.5
		MISSING	0	0	0	0	0	0	0	0
TRIGLYCERIDES	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	18	56.3	1	3.1	7	21.9
		HIGH	0	0	4	12.5	2	6.3	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	18	58.1	4	12.9	4	12.9
		HIGH	0	0	1	3.2	4	12.9	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.3: Blood chemistry, shift tables

 14FEB2013

Safety Population

Parameter	Treat-ment	V1 (Week 0)	V6 (WEEK 52) Low N	Low %	Normal N	Normal %	High N	High %	Missing N	Missing %
URIC ACID	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	13	40.6	6	18.8	7	21.9
		HIGH	0	0	4	12.5	2	6.3	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	21	67.7	3	9.7	2	6.5
		HIGH	0	0	1	3.2	2	6.5	2	6.5
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
SODIUM	ACI-91	SCREENING			1	100.0
		V1 (WEEK 0)			2	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0
	Placebo	SCREENING			1	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
POTASSIUM	ACI-91	SCREENING			1	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)	1	100.0		
		V7 (WEEK 56)			3	100.0
	Placebo	V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
CHLORIDE	ACI-91	SCREENING			5	100.0
		V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			4	100.0
	Placebo	SCREENING			1	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			5	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
BICARBONATE	ACI-91	SCREENING			10	100.0
		V1 (WEEK 0)			7	100.0
		V3 (WEEK 12)			7	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			3	100.0
	Placebo	SCREENING			4	100.0
		V1 (WEEK 0)			4	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
UREA	ACI-91	SCREENING	1	33.3	2	66.7
		V1 (WEEK 0)			2	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			5	100.0
	Placebo	V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			1	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
CREATININE	ACI-91	SCREENING	1	14.3	6	85.7
		V1 (WEEK 0)			10	100.0
		V3 (WEEK 12)			8	100.0
		V4 (WEEK 24)			7	100.0
		V5 (WEEK 36)	1	12.5	7	87.5
		V6 (WEEK 52)	1	20.0	4	80.0
		V7 (WEEK 56)	1	9.1	10	90.9
	Placebo	V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			5	100.0
		V7 (WEEK 56)			6	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
CALCIUM	ACI-91	SCREENING			1	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			2	100.0
	Placebo	V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			1	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
PHOSPHATE	ACI-91	SCREENING			2	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			3	100.0
	Placebo	SCREENING			1	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			1	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
GLUCOSE	ACI-91	SCREENING			12	100.0
		V1 (WEEK 0)			13	100.0
		V3 (WEEK 12)			17	100.0
		V4 (WEEK 24)			7	100.0
		V5 (WEEK 36)			12	100.0
		V6 (WEEK 52)			11	100.0
		V7 (WEEK 56)			12	100.0
	Placebo	SCREENING			10	100.0
		V1 (WEEK 0)			15	100.0
		V3 (WEEK 12)			11	100.0
		V4 (WEEK 24)			15	100.0
		V5 (WEEK 36)			9	100.0
		V6 (WEEK 52)			15	100.0
		V7 (WEEK 56)			12	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
TOTAL BILIRUBIN	ACI-91	SCREENING			2	100.0
		V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			2	100.0
	Placebo	SCREENING			2	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			1	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
TOTAL PROTEIN	ACI-91	SCREENING			2	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			2	100.0
	Placebo	SCREENING			3	100.0
		V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
ALBUMIN	ACI-91	SCREENING			1	100.0
		V1 (WEEK 0)			2	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			2	100.0
	Placebo	V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			1	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			1	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
SGOT (AST)	ACI-91	SCREENING			1	100.0
		V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)	1	14.3	6	85.7
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0
	Placebo	SCREENING			1	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
SGPT (ALT)	ACI-91	SCREENING			2	100.0
		V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)	1	16.7	5	83.3
		V4 (WEEK 24)			6	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			3	100.0
	Placebo	SCREENING			1	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
ALKALINE PHOSPHATASE	ACI-91	SCREENING			4	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			5	100.0
	Placebo	SCREENING			3	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			1	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
GAMMA-GT	ACI-91	SCREENING			4	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)	1	25.0	3	75.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			4	100.0
	Placebo	SCREENING			1	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
CHOLESTEROL	ACI-91	SCREENING	2	18.2	9	81.8
		V1 (WEEK 0)			9	100.0
		V3 (WEEK 12)	1	9.1	10	90.9
		V4 (WEEK 24)			8	100.0
		V5 (WEEK 36)			10	100.0
		V6 (WEEK 52)			7	100.0
		V7 (WEEK 56)			9	100.0
	Placebo	SCREENING	1	10.0	9	90.0
		V1 (WEEK 0)	1	10.0	9	90.0
		V3 (WEEK 12)			11	100.0
		V4 (WEEK 24)			9	100.0
		V5 (WEEK 36)			9	100.0
		V6 (WEEK 52)			8	100.0
		V7 (WEEK 56)			10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
TRIGLYCERIDES	ACI-91	SCREENING			10	100.0
		V1 (WEEK 0)			7	100.0
		V3 (WEEK 12)			8	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			4	100.0
		V7 (WEEK 56)			6	100.0
	Placebo	SCREENING			4	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			7	100.0
		V4 (WEEK 24)			7	100.0
		V5 (WEEK 36)			9	100.0
		V6 (WEEK 52)			8	100.0
		V7 (WEEK 56)			7	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.1.4: Blood chemistry, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
URIC ACID	ACI-91	SCREENING			8	100.0
		V1 (WEEK 0)			7	100.0
		V3 (WEEK 12)			9	100.0
		V4 (WEEK 24)			8	100.0
		V5 (WEEK 36)			9	100.0
		V6 (WEEK 52)			9	100.0
		V7 (WEEK 56)			10	100.0
	Placebo	SCREENING			5	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			8	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			6	100.0
		V6 (WEEK 52)			5	100.0
		V7 (WEEK 56)			5	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
ERYTHROCYTES	ACI-91	SCREENING	4	12.5	27	84.4	1	3.1
		V1 (WEEK 0)	3	9.4	28	87.5	1	3.1
		V3 (WEEK 12)	4	13.8	25	86.2		
		V4 (WEEK 24)	4	18.2	18	81.8		
		V5 (WEEK 36)	2	9.1	18	81.8	2	9.1
		V6 (WEEK 52)	1	4.2	22	91.7	1	4.2
		V7 (WEEK 56)	3	13.0	20	87.0		
	Placebo	SCREENING	1	3.2	29	93.5	1	3.2
		V1 (WEEK 0)	1	3.3	29	96.7		
		V3 (WEEK 12)	2	6.5	29	93.5		
		V4 (WEEK 24)	1	3.2	29	93.5	1	3.2
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)	2	7.7	24	92.3		
		V7 (WEEK 56)	3	11.5	22	84.6	1	3.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
HEMOGLOBIN	ACI-91	SCREENING	2	6.3	30	93.8		
		V1 (WEEK 0)	2	6.3	29	90.6	1	3.1
		V3 (WEEK 12)	2	6.9	26	89.7	1	3.4
		V4 (WEEK 24)			22	100.0		
		V5 (WEEK 36)			20	90.9	2	9.1
		V6 (WEEK 52)	1	4.2	23	95.8		
		V7 (WEEK 56)	2	8.7	20	87.0	1	4.3
	Placebo	SCREENING	1	3.2	29	93.5	1	3.2
		V1 (WEEK 0)	1	3.3	29	96.7		
		V3 (WEEK 12)	1	3.2	29	93.5	1	3.2
		V4 (WEEK 24)	1	3.2	30	96.8		
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)	1	3.8	25	96.2		
		V7 (WEEK 56)			25	96.2	1	3.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
HEMATOCRIT	ACI-91	SCREENING			26	81.3	6	18.8
		V1 (WEEK 0)			21	65.6	11	34.4
		V3 (WEEK 12)			22	75.9	7	24.1
		V4 (WEEK 24)			17	77.3	5	22.7
		V5 (WEEK 36)			14	63.6	8	36.4
		V6 (WEEK 52)			19	79.2	5	20.8
		V7 (WEEK 56)			19	82.6	4	17.4
	Placebo	SCREENING			25	80.6	6	19.4
		V1 (WEEK 0)			25	83.3	5	16.7
		V3 (WEEK 12)			28	90.3	3	9.7
		V4 (WEEK 24)			26	83.9	5	16.1
		V5 (WEEK 36)			24	82.8	5	17.2
		V6 (WEEK 52)	1	3.8	20	76.9	5	19.2
		V7 (WEEK 56)			22	84.6	4	15.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
MCH (HbE)	ACI-91	SCREENING			26	81.3	6	18.8
		V1 (WEEK 0)			27	84.4	5	15.6
		V3 (WEEK 12)	1	3.4	23	79.3	5	17.2
		V4 (WEEK 24)	2	9.1	14	63.6	6	27.3
		V5 (WEEK 36)	1	4.5	19	86.4	2	9.1
		V6 (WEEK 52)	1	4.2	20	83.3	3	12.5
		V7 (WEEK 56)	1	4.3	18	78.3	4	17.4
	Placebo	SCREENING	2	6.5	26	83.9	3	9.7
		V1 (WEEK 0)	3	10.0	25	83.3	2	6.7
		V3 (WEEK 12)	2	6.5	27	87.1	2	6.5
		V4 (WEEK 24)	1	3.2	28	90.3	2	6.5
		V5 (WEEK 36)			28	96.6	1	3.4
		V6 (WEEK 52)			24	92.3	2	7.7
		V7 (WEEK 56)			24	92.3	2	7.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
MCHC	ACI-91	SCREENING	7	21.9	25	78.1		
		V1 (WEEK 0)	11	34.4	21	65.6		
		V3 (WEEK 12)	7	24.1	22	75.9		
		V4 (WEEK 24)	8	36.4	14	63.6		
		V5 (WEEK 36)	9	40.9	13	59.1		
		V6 (WEEK 52)	5	20.8	19	79.2		
		V7 (WEEK 56)	5	21.7	18	78.3		
	Placebo	SCREENING	16	51.6	15	48.4		
		V1 (WEEK 0)	12	40.0	18	60.0		
		V3 (WEEK 12)	13	41.9	18	58.1		
		V4 (WEEK 24)	11	35.5	20	64.5		
		V5 (WEEK 36)	18	62.1	11	37.9		
		V6 (WEEK 52)	9	34.6	17	65.4		
		V7 (WEEK 56)	6	23.1	20	76.9		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
MCV	ACI-91	SCREENING			16	50.0	16	50.0
		V1 (WEEK 0)			17	53.1	15	46.9
		V3 (WEEK 12)			13	44.8	16	55.2
		V4 (WEEK 24)			7	31.8	15	68.2
		V5 (WEEK 36)			9	40.9	13	59.1
		V6 (WEEK 52)	1	4.2	12	50.0	11	45.8
		V7 (WEEK 56)	1	4.3	14	60.9	8	34.8
	Placebo	SCREENING			22	71.0	9	29.0
		V1 (WEEK 0)	1	3.3	21	70.0	8	26.7
		V3 (WEEK 12)			22	71.0	9	29.0
		V4 (WEEK 24)			20	64.5	11	35.5
		V5 (WEEK 36)			21	72.4	8	27.6
		V6 (WEEK 52)			16	61.5	10	38.5
		V7 (WEEK 56)			16	61.5	10	38.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
THROMBOCYTES	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)			30	93.8	2	6.3
		V3 (WEEK 12)	1	3.4	25	86.2	3	10.3
		V4 (WEEK 24)	1	4.5	19	86.4	2	9.1
		V5 (WEEK 36)	3	13.6	19	86.4		
		V6 (WEEK 52)	1	4.2	19	79.2	4	16.7
		V7 (WEEK 56)			20	87.0	3	13.0
	Placebo	SCREENING	1	3.2	30	96.8		
		V1 (WEEK 0)	2	6.7	27	90.0	1	3.3
		V3 (WEEK 12)	7	22.6	23	74.2	1	3.2
		V4 (WEEK 24)	4	12.9	25	80.6	2	6.5
		V5 (WEEK 36)	5	17.2	24	82.8		
		V6 (WEEK 52)	4	15.4	21	80.8	1	3.8
		V7 (WEEK 56)	5	19.2	19	73.1	2	7.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
LEUKOCYTES	ACI-91	SCREENING			31	96.9	1	3.1
		V1 (WEEK 0)	1	3.1	29	90.6	2	6.3
		V3 (WEEK 12)			28	96.6	1	3.4
		V4 (WEEK 24)			21	95.5	1	4.5
		V5 (WEEK 36)			21	95.5	1	4.5
		V6 (WEEK 52)			23	95.8	1	4.2
		V7 (WEEK 56)			22	95.7	1	4.3
	Placebo	SCREENING	3	9.7	27	87.1	1	3.2
		V1 (WEEK 0)	4	13.3	24	80.0	2	6.7
		V3 (WEEK 12)	3	9.7	27	87.1	1	3.2
		V4 (WEEK 24)	3	9.7	26	83.9	2	6.5
		V5 (WEEK 36)	2	6.9	27	93.1		
		V6 (WEEK 52)	2	7.7	23	88.5	1	3.8
		V7 (WEEK 56)	3	11.5	22	84.6	1	3.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
NEUTROPHILS	ACI-91	SCREENING			26	81.3	6	18.8
		V1 (WEEK 0)			26	81.3	6	18.8
		V3 (WEEK 12)			22	75.9	7	24.1
		V4 (WEEK 24)			19	86.4	3	13.6
		V5 (WEEK 36)			18	81.8	4	18.2
		V6 (WEEK 52)			19	79.2	5	20.8
		V7 (WEEK 56)			18	78.3	5	21.7
	Placebo	SCREENING	2	6.5	24	77.4	5	16.1
		V1 (WEEK 0)	2	6.9	23	79.3	4	13.8
		V3 (WEEK 12)			25	80.6	6	19.4
		V4 (WEEK 24)			24	77.4	7	22.6
		V5 (WEEK 36)			21	72.4	8	27.6
		V6 (WEEK 52)			19	73.1	7	26.9
		V7 (WEEK 56)	2	7.7	19	73.1	5	19.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
LYMPHOCYTES	ACI-91	SCREENING	10	31.3	22	68.8		
		V1 (WEEK 0)	8	25.0	24	75.0		
		V3 (WEEK 12)	8	27.6	21	72.4		
		V4 (WEEK 24)	4	18.2	18	81.8		
		V5 (WEEK 36)	5	22.7	17	77.3		
		V6 (WEEK 52)	5	20.8	19	79.2		
		V7 (WEEK 56)	5	21.7	18	78.3		
	Placebo	SCREENING	7	22.6	23	74.2	1	3.2
		V1 (WEEK 0)	6	20.7	21	72.4	2	6.9
		V3 (WEEK 12)	5	16.1	26	83.9		
		V4 (WEEK 24)	7	22.6	24	77.4		
		V5 (WEEK 36)	7	24.1	22	75.9		
		V6 (WEEK 52)	6	23.1	20	76.9		
		V7 (WEEK 56)	4	15.4	21	80.8	1	3.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
MONOCYTES	ACI-91	SCREENING			31	96.9	1	3.1
		V1 (WEEK 0)			31	96.9	1	3.1
		V3 (WEEK 12)			27	93.1	2	6.9
		V4 (WEEK 24)			21	95.5	1	4.5
		V5 (WEEK 36)	2	9.1	20	90.9		
		V6 (WEEK 52)			23	95.8	1	4.2
		V7 (WEEK 56)			22	95.7	1	4.3
	Placebo	SCREENING			29	93.5	2	6.5
		V1 (WEEK 0)	2	6.9	24	82.8	3	10.3
		V3 (WEEK 12)	1	3.2	28	90.3	2	6.5
		V4 (WEEK 24)	2	6.5	25	80.6	4	12.9
		V5 (WEEK 36)	3	10.3	24	82.8	2	6.9
		V6 (WEEK 52)	1	3.8	24	92.3	1	3.8
		V7 (WEEK 56)	2	7.7	21	80.8	3	11.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
EOSINOPHILS	ACI-91	SCREENING	8	25.0	21	65.6	3	9.4
		V1 (WEEK 0)	6	18.8	23	71.9	3	9.4
		V3 (WEEK 12)	7	24.1	20	69.0	2	6.9
		V4 (WEEK 24)	4	18.2	17	77.3	1	4.5
		V5 (WEEK 36)	4	18.2	17	77.3	1	4.5
		V6 (WEEK 52)	5	20.8	17	70.8	2	8.3
		V7 (WEEK 56)	2	8.7	19	82.6	2	8.7
	Placebo	SCREENING	2	6.5	26	83.9	3	9.7
		V1 (WEEK 0)	4	13.8	24	82.8	1	3.4
		V3 (WEEK 12)	8	25.8	22	71.0	1	3.2
		V4 (WEEK 24)	7	22.6	23	74.2	1	3.2
		V5 (WEEK 36)	8	27.6	21	72.4		
		V6 (WEEK 52)	7	26.9	19	73.1		
		V7 (WEEK 56)	3	11.5	23	88.5		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.1: Hematology, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
BASOPHILS	ACI-91	SCREENING			31	96.9	1	3.1
		V1 (WEEK 0)			31	96.9	1	3.1
		V3 (WEEK 12)			27	93.1	2	6.9
		V4 (WEEK 24)			20	90.9	2	9.1
		V5 (WEEK 36)			18	81.8	4	18.2
		V6 (WEEK 52)			22	91.7	2	8.3
		V7 (WEEK 56)			20	87.0	3	13.0
	Placebo	SCREENING			29	93.5	2	6.5
		V1 (WEEK 0)			26	89.7	3	10.3
		V3 (WEEK 12)			28	90.3	3	9.7
		V4 (WEEK 24)			28	90.3	3	9.7
		V5 (WEEK 36)			29	100.0		
		V6 (WEEK 52)			26	100.0		
		V7 (WEEK 56)			25	96.2	1	3.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
ERYTHROCYTES	/pL	006	Male	ACI-91	SCREENING	-32	4.5	L	NO	4.6 - 6.1
					V1 (WEEK 0)	1	4.5	L	NO	4.6 - 6.1
					V3 (WEEK 12)	85	4.5	L	NO	4.6 - 6.1
					V4 (WEEK 24)	169	4.4	L	NO	4.6 - 6.1
					V5 (WEEK 36)	252	4.5	L	NO	4.6 - 6.1
		010	Male	ACI-91	SCREENING	-26	4.0	L	NO	4.2 - 5.7
					V1 (WEEK 0)	1	4.0	L	NO	4.2 - 5.7
					V3 (WEEK 12)	85	4.0	L	NO	4.2 - 5.7
		012	Male	ACI-91	SCREENING	-32	4.4	L	NO	4.6 - 6.1
					V3 (WEEK 12)	88	4.5	L	NO	4.6 - 6.1
					V7 (WEEK 56)	396	4.2	L	NO	4.6 - 6.1
		013	Female	Placebo	V1 (WEEK 0)	1	3.6	L	NO	3.8 - 5.3
					V7 (WEEK 56)	400	3.8	L	NO	3.9 - 5.2
		017	Male	ACI-91	V4 (WEEK 24)	169	4.3	L	NO	4.6 - 6.1
					V6 (WEEK 52)	364	4.3	L	NO	4.6 - 6.1
					V7 (WEEK 56)	392	4.4	L	NO	4.6 - 6.1

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
ERYTHROCYTES	/pL	019	Male	ACI-91	V4 (WEEK 24)	168	4.5	L	NO	4.6 - 6.1
					V5 (WEEK 36)	259	4.4	L	NO	4.6 - 6.1
		034	Female	Placebo	V7 (WEEK 56)	399	5.3	H	NO	3.9 - 5.2
		042	Female	ACI-91	V5 (WEEK 36)	252	5.8	H	NO	3.9 - 5.2
					V6 (WEEK 52)	364	5.3	H	NO	3.9 - 5.2
		044	Female	Placebo	V4 (WEEK 24)	176	5.6	H	NO	3.9 - 5.2
					V5 (WEEK 36)	260	5.4	H	NO	3.9 - 5.2
		046	Female	ACI-91	V5 (WEEK 36)	255	5.4	H	NO	3.9 - 5.2
		047	Male	Placebo	V7 (WEEK 56)	393	4.5	L	NO	4.6 - 6.1
		056	Female	Placebo	V3 (WEEK 12)	84	3.6	L	NO	3.9 - 5.2
		058	Male	Placebo	V6 (WEEK 52)	345	4.5	L	NO	4.6 - 6.1
					V7 (WEEK 56)	380	4.5	L	NO	4.6 - 6.1
		065	Male	Placebo	V4 (WEEK 24)	141	4.2	L	NO	4.6 - 6.1

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
ERYTHROCYTES	/pL	066	Male	ACI-91	SCREENING	-31	4.2	L	NO	4.6 - 6.1
					V1 (WEEK 0)	1	4.2	L	NO	4.6 - 6.1
					V3 (WEEK 12)	83	4.3	L	NO	4.6 - 6.1
		068	Male	Placebo	SCREENING	-27	4.5	L	NO	4.6 - 6.1
					V3 (WEEK 12)	81	4.5	L	NO	4.6 - 6.1
					V6 (WEEK 52)	372	4.4	L	NO	4.6 - 6.1
		072	Female	Placebo	SCREENING	-20	5.3	H	NO	3.9 - 5.2
		080	Female	ACI-91	SCREENING	-10	5.4	H	NO	3.9 - 5.2
					V1 (WEEK 0)	1	5.3	H	NO	3.9 - 5.2
		081	Male	ACI-91	V4 (WEEK 24)	175	4.2	L	NO	4.6 - 6.1
					V7 (WEEK 56)	405	4.5	L	NO	4.6 - 6.1
HEMOGLOBIN	mmol/L	010	Male	ACI-91	SCREENING	-26	7.8	L	NO	8.4 - 11.2
					V1 (WEEK 0)	1	7.8	L	NO	8.4 - 11.2
					V3 (WEEK 12)	85	7.8	L	NO	8.4 - 11.2
		012	Male	ACI-91	V7 (WEEK 56)	396	8.2	L	NO	8.5 - 10.9

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMOGLOBIN	mmol/L	024	Male	Placebo	V1 (WEEK 0)	1	8.4	L	NO	8.5 - 10.9
		030	Female	ACI-91	V5 (WEEK 36)	253	9.8	H	NO	6.9 - 9.7
					V7 (WEEK 56)	383	9.9	H	NO	6.9 - 9.7
		034	Female	Placebo	SCREENING	-22	9.9	H	NO	6.9 - 9.7
					V3 (WEEK 12)	83	9.8	H	NO	6.9 - 9.7
					V5 (WEEK 36)	258	10.0	H	NO	6.9 - 9.7
					V7 (WEEK 56)	399	10.4	H	NO	6.9 - 9.7
		042	Female	ACI-91	V5 (WEEK 36)	252	10.3	H	NO	6.9 - 9.7
		066	Male	ACI-91	SCREENING	-31	8.1	L	NO	8.5 - 10.9
					V1 (WEEK 0)	1	8.2	L	NO	8.5 - 10.9
					V3 (WEEK 12)	83	8.3	L	NO	8.5 - 10.9
		068	Male	Placebo	SCREENING	-27	8.4	L	NO	8.5 - 10.9
					V3 (WEEK 12)	81	8.4	L	NO	8.5 - 10.9
					V4 (WEEK 24)	163	8.4	L	NO	8.5 - 10.9
					V6 (WEEK 52)	372	8.1	L	NO	8.5 - 10.9

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMOGLOBIN	mmol/L	081	Male	ACI-91	V6 (WEEK 52)	376	8.4	L	NO	8.5 - 10.9
					V7 (WEEK 56)	405	8.1	L	NO	8.5 - 10.9
		093	Female	ACI-91	V1 (WEEK 0)	1	9.8	H	NO	6.9 - 9.7
					V3 (WEEK 12)	86	9.9	H	NO	6.9 - 9.7
HEMATOCRIT	L/L	001	Female	Placebo	V6 (WEEK 52)	365	0.46	H	NO	0.35 - 0.45
		002	Female	ACI-91	V5 (WEEK 36)	258	0.46	H	NO	0.35 - 0.45
					V6 (WEEK 52)	365	0.46	H	NO	0.35 - 0.45
		009	Female	Placebo	V1 (WEEK 0)	1	0.48	H	NO	0.35 - 0.47
					V6 (WEEK 52)	361	0.48	H	NO	0.35 - 0.45
					V7 (WEEK 56)	389	0.46	H	NO	0.35 - 0.45
		014	Male	ACI-91	V5 (WEEK 36)	256	0.53	H	NO	0.40 - 0.50
		015	Female	ACI-91	SCREENING	-32	0.46	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.47	H	NO	0.35 - 0.45
					V3 (WEEK 12)	85	0.47	H	NO	0.35 - 0.45
					V7 (WEEK 56)	394	0.47	H	NO	0.35 - 0.45

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMATOCRIT	L/L	016	Male	Placebo	V6 (WEEK 52)	365	0.51	H	NO	0.40 - 0.50
		023	Male	ACI-91	V1 (WEEK 0)	1	0.51	H	NO	0.40 - 0.50
		024	Male	Placebo	SCREENING	-31	0.52	H	NO	0.40 - 0.50
		028	Female	Placebo	V5 (WEEK 36)	273	0.48	H	NO	0.35 - 0.45
		029	Female	Placebo	V4 (WEEK 24)	158	0.46	H	NO	0.35 - 0.45
		030	Female	ACI-91	SCREENING	-7	0.46	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
					V3 (WEEK 12)	85	0.47	H	NO	0.35 - 0.45
					V4 (WEEK 24)	163	0.46	H	NO	0.35 - 0.45
					V5 (WEEK 36)	253	0.46	H	NO	0.35 - 0.45
					V6 (WEEK 52)	355	0.47	H	NO	0.35 - 0.45
					V7 (WEEK 56)	383	0.51	H	NO	0.35 - 0.45
		034	Female	Placebo	SCREENING	-22	0.47	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
					V3 (WEEK 12)	83	0.51	H	NO	0.35 - 0.45

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMATOCRIT	L/L	034	Female	Placebo	V4 (WEEK 24)	175	0.46	H	NO	0.35 - 0.45
					V5 (WEEK 36)	258	0.47	H	NO	0.35 - 0.45
					V6 (WEEK 52)	363	0.46	H	NO	0.35 - 0.45
					V7 (WEEK 56)	399	0.50	H	NO	0.35 - 0.45
		042	Female	ACI-91	V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
					V3 (WEEK 12)	126	0.58	H	NO	0.35 - 0.45
					V4 (WEEK 24)	168	0.46	H	NO	0.35 - 0.45
					V5 (WEEK 36)	252	0.53	H	NO	0.35 - 0.45
					V6 (WEEK 52)	364	0.48	H	NO	0.35 - 0.45
					V7 (WEEK 56)	391	0.46	H	NO	0.35 - 0.45
		044	Female	Placebo	V4 (WEEK 24)	176	0.47	H	NO	0.35 - 0.45
					V5 (WEEK 36)	260	0.47	H	NO	0.35 - 0.45
		046	Female	ACI-91	V4 (WEEK 24)	178	0.48	H	NO	0.35 - 0.45
					V5 (WEEK 36)	255	0.48	H	NO	0.35 - 0.45
		047	Male	Placebo	SCREENING	-21	0.52	H	NO	0.40 - 0.50
					V1 (WEEK 0)	1	0.53	H	NO	0.40 - 0.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMATOCRIT	L/L	048	Male	ACI-91	V1 (WEEK 0)	1	0.51	H	NO	0.40 - 0.50
					V5 (WEEK 36)	247	0.57	H	NO	0.40 - 0.50
		051	Female	Placebo	V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
					V3 (WEEK 12)	97	0.46	H	NO	0.35 - 0.45
					V5 (WEEK 36)	251	0.48	H	NO	0.35 - 0.45
					V6 (WEEK 52)	363	0.47	H	NO	0.35 - 0.45
					V7 (WEEK 56)	391	0.51	H	NO	0.35 - 0.45
		055	Female	ACI-91	V6 (WEEK 52)	30	0.49	H	NO	0.35 - 0.45
		057	Female	ACI-91	SCREENING	-21	0.47	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.49	H	NO	0.35 - 0.45
					V3 (WEEK 12)	82	0.46	H	NO	0.35 - 0.45
					V4 (WEEK 24)	170	0.51	H	NO	0.35 - 0.45
		059	Male	Placebo	V4 (WEEK 24)	161	0.53	H	NO	0.40 - 0.50
		068	Male	Placebo	V6 (WEEK 52)	372	0.39	L	NO	0.40 - 0.50
		069	Male	Placebo	SCREENING	-13	0.52	H	NO	0.40 - 0.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMATOCRIT	L/L	069	Male	Placebo	V3 (WEEK 12)	93	0.54	H	NO	0.40 - 0.50
					V5 (WEEK 36)	261	0.54	H	NO	0.40 - 0.50
		071	Female	ACI-91	SCREENING	-20	0.46	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.47	H	NO	0.35 - 0.45
					V3 (WEEK 12)	87	0.46	H	NO	0.35 - 0.45
					V4 (WEEK 24)	177	0.49	H	NO	0.35 - 0.45
					V5 (WEEK 36)	253	0.48	H	NO	0.35 - 0.45
					V7 (WEEK 56)	392	0.47	H	NO	0.35 - 0.45
		072	Female	Placebo	SCREENING	-20	0.47	H	NO	0.35 - 0.45
		079	Female	Placebo	V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
		080	Female	ACI-91	SCREENING	-10	0.48	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
					V3 (WEEK 12)	84	0.47	H	NO	0.35 - 0.45
					V6 (WEEK 52)	196	0.51	H	NO	0.35 - 0.45
		082	Male	Placebo	V4 (WEEK 24)	175	0.56	H	NO	0.40 - 0.50

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
HEMATOCRIT	L/L	083	Female	ACI-91	V1 (WEEK 0)	1	0.46	H	NO	0.35 - 0.45
		086	Female	Placebo	SCREENING	-24	0.47	H	NO	0.35 - 0.45
					V7 (WEEK 56)	391	0.46	H	NO	0.35 - 0.45
		089	Female	ACI-91	V1 (WEEK 0)	1	0.47	H	NO	0.35 - 0.45
		093	Female	ACI-91	SCREENING	-3	0.46	H	NO	0.35 - 0.45
					V1 (WEEK 0)	1	0.47	H	NO	0.35 - 0.45
					V3 (WEEK 12)	86	0.48	H	NO	0.35 - 0.45
					V5 (WEEK 36)	258	0.46	H	NO	0.35 - 0.45
MCH (HbE)	fmol	001	Female	Placebo	V3 (WEEK 12)	90	1.72	L	NO	1.74 - 1.99
		006	Male	ACI-91	SCREENING	-32	2.10	H	NO	1.59 - 2.00
					V1 (WEEK 0)	1	2.11	H	NO	1.59 - 2.00
					V3 (WEEK 12)	85	2.04	H	NO	1.59 - 2.00
					V4 (WEEK 24)	169	2.03	H	NO	1.59 - 2.00
					V5 (WEEK 36)	252	2.11	H	NO	1.59 - 2.00
					V6 (WEEK 52)	364	2.06	H	NO	1.59 - 2.00
					V7 (WEEK 56)	390	2.03	H	NO	1.59 - 2.00

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCH (HbE)	fmol	009	Female	Placebo	V1 (WEEK 0)	1	1.73	L	NO	1.74 - 1.99
		013	Female	Placebo	SCREENING	-30	2.02	H	NO	1.74 - 1.99
					V6 (WEEK 52)	366	2.05	H	NO	1.59 - 2.00
					V7 (WEEK 56)	400	2.02	H	NO	1.59 - 2.00
		017	Male	ACI-91	SCREENING	-22	2.00	H	NO	1.74 - 1.99
					V1 (WEEK 0)	1	2.04	H	NO	1.74 - 1.99
					V4 (WEEK 24)	169	2.00	H	NO	1.59 - 2.00
					V6 (WEEK 52)	364	2.01	H	NO	1.59 - 2.00
					V7 (WEEK 56)	392	2.05	H	NO	1.59 - 2.00
		019	Male	ACI-91	SCREENING	-21	2.00	H	NO	1.74 - 1.99
					V3 (WEEK 12)	85	2.03	H	NO	1.59 - 2.00
					V4 (WEEK 24)	168	2.06	H	NO	1.59 - 2.00
					V7 (WEEK 56)	399	2.03	H	NO	1.59 - 2.00
		023	Male	ACI-91	SCREENING	-19	2.03	H	NO	1.59 - 2.00
					V1 (WEEK 0)	1	2.04	H	NO	1.59 - 2.00
					V3 (WEEK 12)	86	2.03	H	NO	1.59 - 2.00
					V4 (WEEK 24)	177	2.03	H	NO	1.59 - 2.00

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCH (HbE)	fmol	027	Female	ACI-91	SCREENING	-21	2.06	H	NO	1.59 - 2.00
					V1 (WEEK 0)	1	2.07	H	NO	1.59 - 2.00
					V3 (WEEK 12)	92	2.03	H	NO	1.59 - 2.00
					V4 (WEEK 24)	174	2.12	H	NO	1.59 - 2.00
					V5 (WEEK 36)	259	2.05	H	NO	1.59 - 2.00
					V6 (WEEK 52)	370	2.06	H	NO	1.59 - 2.00
					V7 (WEEK 56)	407	2.03	H	NO	1.59 - 2.00
		044	Female	Placebo	SCREENING	-28	1.66	L	NO	1.74 - 1.99
					V1 (WEEK 0)	1	1.67	L	NO	1.74 - 1.99
		046	Female	ACI-91	SCREENING	-28	2.00	H	NO	1.74 - 1.99
					V1 (WEEK 0)	1	2.03	H	NO	1.59 - 1.99
		047	Male	Placebo	SCREENING	-21	2.06	H	NO	1.59 - 2.00
					V1 (WEEK 0)	1	2.06	H	NO	1.59 - 2.00
					V3 (WEEK 12)	80	2.11	H	NO	1.59 - 2.00
					V4 (WEEK 24)	162	2.06	H	NO	1.59 - 2.00
					V5 (WEEK 36)	254	2.10	H	NO	1.59 - 2.00
					V6 (WEEK 52)	360	2.07	H	NO	1.59 - 2.00
					V7 (WEEK 56)	393	2.05	H	NO	1.59 - 2.00

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCH (HbE)	fmol	052	Female	ACI-91	V3 (WEEK 12)	82	1.56	L	NO	1.59 - 2.00
					V4 (WEEK 24)	166	1.50	L	NO	1.59 - 2.00
					V5 (WEEK 36)	250	1.46	L	NO	1.59 - 2.00
					V6 (WEEK 52)	362	1.50	L	NO	1.59 - 2.00
					V7 (WEEK 56)	390	1.48	L	NO	1.59 - 2.00
		065	Male	Placebo	SCREENING	-20	2.06	H	NO	1.59 - 2.00
					V1 (WEEK 0)	1	2.08	H	NO	1.59 - 2.00
					V3 (WEEK 12)	85	2.05	H	NO	1.59 - 2.00
					V4 (WEEK 24)	141	2.12	H	NO	1.59 - 2.00
		081	Male	ACI-91	V4 (WEEK 24)	175	2.05	H	NO	1.59 - 2.00
		083	Female	ACI-91	V4 (WEEK 24)	168	1.53	L	NO	1.59 - 2.00
		084	Female	Placebo	SCREENING	-9	1.54	L	NO	1.59 - 2.00
					V1 (WEEK 0)	1	1.53	L	NO	1.59 - 2.00
					V3 (WEEK 12)	84	1.57	L	NO	1.59 - 2.00
					V4 (WEEK 24)	175	1.54	L	NO	1.59 - 2.00
		093	Female	ACI-91	V3 (WEEK 12)	86	2.03	H	NO	1.59 - 2.00

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	001	Female	Placebo	SCREENING	-7	19.5	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	19.5	L	NO	19.9 - 22.9
					V3 (WEEK 12)	90	18.5	L	NO	19.9 - 22.9
					V4 (WEEK 24)	162	19.7	L	NO	19.9 - 22.9
					V6 (WEEK 52)	365	19.3	L	NO	19.8 - 22.3
		002	Female	ACI-91	SCREENING	-7	19.8	L	NO	19.9 - 22.9
					V3 (WEEK 12)	85	18.9	L	NO	19.9 - 22.9
		003	Female	Placebo	SCREENING	-21	19.5	L	NO	19.9 - 22.9
					V3 (WEEK 12)	90	19.0	L	NO	19.9 - 22.9
		004	Male	ACI-91	SCREENING	-29	19.7	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	18.7	L	NO	19.9 - 22.9
		005	Female	Placebo	SCREENING	-16	19.7	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	19.4	L	NO	19.9 - 22.9
					V3 (WEEK 12)	83	18.7	L	NO	19.9 - 22.9
					V4 (WEEK 24)	168	19.6	L	NO	19.9 - 22.9
					V5 (WEEK 36)	258	19.7	L	NO	19.8 - 22.3
					V6 (WEEK 52)	364	18.2	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	005	Female	Placebo	V7 (WEEK 56)	400	17.6	L	NO	19.8 - 22.3
		009	Female	Placebo	SCREENING	-33	18.7	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	17.7	L	NO	19.9 - 22.9
					V4 (WEEK 24)	178	19.8	L	NO	19.8 - 22.3
					V5 (WEEK 36)	246	19.7	L	NO	19.8 - 22.3
					V6 (WEEK 52)	361	17.7	L	NO	19.8 - 22.3
					V7 (WEEK 56)	389	17.7	L	NO	19.8 - 22.3
		010	Male	ACI-91	SCREENING	-26	19.7	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	19.3	L	NO	19.9 - 22.9
					V3 (WEEK 12)	85	19.8	L	NO	19.9 - 22.9
		012	Male	ACI-91	V1 (WEEK 0)	1	18.9	L	NO	19.8 - 22.3
					V5 (WEEK 36)	257	19.3	L	NO	19.8 - 22.3
					V7 (WEEK 56)	396	18.8	L	NO	19.8 - 22.3
		013	Female	Placebo	SCREENING	-30	18.4	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	19.2	L	NO	19.9 - 22.9
					V3 (WEEK 12)	85	19.7	L	NO	19.9 - 22.9
					V5 (WEEK 36)	247	19.6	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	014	Male	ACI-91	SCREENING	-26	19.7	L	NO	19.9 - 22.9
					V5 (WEEK 36)	256	16.8	L	NO	19.8 - 22.3
		016	Male	Placebo	V6 (WEEK 52)	365	19.0	L	NO	19.8 - 22.3
		017	Male	ACI-91	SCREENING	-22	19.7	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	19.2	L	NO	19.9 - 22.9
					V6 (WEEK 52)	364	19.7	L	NO	19.8 - 22.3
		018	Female	Placebo	SCREENING	-20	19.7	L	NO	19.9 - 22.9
					V5 (WEEK 36)	247	19.3	L	NO	19.8 - 22.3
		019	Male	ACI-91	V1 (WEEK 0)	1	19.7	L	NO	19.9 - 22.9
		023	Male	ACI-91	V1 (WEEK 0)	1	19.2	L	NO	19.8 - 22.3
		024	Male	Placebo	SCREENING	-31	16.3	L	NO	19.8 - 22.3
					V1 (WEEK 0)	1	19.6	L	NO	19.8 - 22.3
					V6 (WEEK 52)	358	19.5	L		19.8 - 22.3
		027	Female	ACI-91	V5 (WEEK 36)	259	19.3	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	028	Female	Placebo	V3 (WEEK 12)	89	19.7	L	NO	19.8 - 22.3
					V4 (WEEK 24)	180	18.9	L	NO	19.8 - 22.3
					V5 (WEEK 36)	273	18.3	L	NO	19.8 - 22.3
		029	Female	Placebo	V1 (WEEK 0)	1	19.0	L	NO	19.8 - 22.3
					V4 (WEEK 24)	158	18.8	L	NO	19.8 - 22.3
					V5 (WEEK 36)	245	19.7	L	NO	19.8 - 22.3
		030	Female	ACI-91	V7 (WEEK 56)	383	19.5	L	NO	19.8 - 22.3
		031	Male	Placebo	V3 (WEEK 12)	90	19.5	L	NO	19.8 - 22.3
					V7 (WEEK 56)	391	19.7	L	NO	19.8 - 22.3
		032	Female	ACI-91	V1 (WEEK 0)	1	18.9	L	NO	19.8 - 22.3
		033	Female	ACI-91	V1 (WEEK 0)	1	19.5	L	NO	19.9 - 22.9
					V5 (WEEK 36)	261	18.8	L	NO	19.8 - 22.3
		034	Female	Placebo	V3 (WEEK 12)	83	19.3	L	NO	19.8 - 22.3
		041	Male	Placebo	SCREENING	-16	19.0	L	NO	19.9 - 22.9

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	041	Male	Placebo	V5 (WEEK 36)	251	19.5	L	NO	19.8 - 22.3
					V6 (WEEK 52)	363	19.7	L	NO	19.8 - 22.3
		042	Female	ACI-91	V3 (WEEK 12)	126	16.4	L	NO	19.8 - 22.3
					V4 (WEEK 24)	168	18.5	L	NO	19.8 - 22.3
					V5 (WEEK 36)	252	19.5	L	NO	19.8 - 22.3
		044	Female	Placebo	SCREENING	-28	19.3	L	NO	19.9 - 22.9
					V1 (WEEK 0)	1	19.8	L	NO	19.9 - 22.9
					V5 (WEEK 36)	260	19.5	L	NO	19.8 - 22.3
					V7 (WEEK 56)	400	19.5	L	NO	19.8 - 22.3
		046	Female	ACI-91	V4 (WEEK 24)	178	18.5	L	NO	19.8 - 22.3
					V7 (WEEK 56)	393	19.6	L	NO	19.8 - 22.3
		047	Male	Placebo	SCREENING	-21	18.2	L	NO	19.8 - 22.3
					V1 (WEEK 0)	1	18.2	L	NO	19.8 - 22.3
		048	Male	ACI-91	V5 (WEEK 36)	247	17.6	L	NO	19.8 - 22.3
		049	Female	Placebo	V5 (WEEK 36)	252	19.2	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	050	Female	ACI-91	V3 (WEEK 12)	83	19.3	L	NO	19.8 - 22.3
					V4 (WEEK 24)	167	18.8	L	NO	19.8 - 22.3
					V5 (WEEK 36)	251	18.8	L	NO	19.8 - 22.3
					V6 (WEEK 52)	363	19.5	L	NO	19.8 - 22.3
					V7 (WEEK 56)	391	19.6	L	NO	19.8 - 22.3
		051	Female	Placebo	V5 (WEEK 36)	251	18.5	L	NO	19.8 - 22.3
					V7 (WEEK 56)	391	18.2	L	NO	19.8 - 22.3
		052	Female	ACI-91	V1 (WEEK 0)	1	19.3	L	NO	19.8 - 22.3
					V3 (WEEK 12)	82	19.1	L	NO	19.8 - 22.3
					V4 (WEEK 24)	166	18.4	L	NO	19.8 - 22.3
					V5 (WEEK 36)	250	17.7	L	NO	19.8 - 22.3
					V6 (WEEK 52)	362	19.0	L	NO	19.8 - 22.3
					V7 (WEEK 56)	390	19.0	L	NO	19.8 - 22.3
		055	Female	ACI-91	V6 (WEEK 52)	30	17.1	L	NO	19.8 - 22.3
		056	Female	Placebo	V3 (WEEK 12)	84	18.8	L	NO	19.8 - 22.3
		057	Female	ACI-91	SCREENING	-21	19.5	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	057	Female	ACI-91	V1 (WEEK 0)	1	19.4	L	NO	19.8 - 22.3
					V4 (WEEK 24)	170	19.0	L	NO	19.8 - 22.3
		058	Male	Placebo	V4 (WEEK 24)	166	17.5	L	NO	19.8 - 22.3
		059	Male	Placebo	V4 (WEEK 24)	161	18.6	L	NO	19.8 - 22.3
		066	Male	ACI-91	V3 (WEEK 12)	83	19.0	L	NO	19.8 - 22.3
		068	Male	Placebo	V5 (WEEK 36)	262	19.7	L	NO	19.8 - 22.3
		069	Male	Placebo	SCREENING	-13	19.0	L	NO	19.8 - 22.3
					V3 (WEEK 12)	93	19.2	L	NO	19.8 - 22.3
					V5 (WEEK 36)	261	18.7	L	NO	19.8 - 22.3
		072	Female	Placebo	SCREENING	-20	19.2	L	NO	19.8 - 22.3
					V1 (WEEK 0)	1	19.5	L	NO	19.8 - 22.3
					V3 (WEEK 12)	85	19.4	L	NO	19.8 - 22.3
					V4 (WEEK 24)	169	18.4	L	NO	19.8 - 22.3
					V5 (WEEK 36)	262	18.8	L	NO	19.8 - 22.3
					V6 (WEEK 52)	360	19.3	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	079	Female	Placebo	SCREENING	-18	19.0	L	NO	19.8 - 22.3
					V1 (WEEK 0)	1	18.9	L	NO	19.8 - 22.3
					V5 (WEEK 36)	249	19.2	L	NO	19.8 - 22.3
					V6 (WEEK 52)	320	19.3	L	NO	19.8 - 22.3
					V7 (WEEK 56)	348	19.7	L	NO	19.8 - 22.3
		080	Female	ACI-91	V1 (WEEK 0)	1	19.7	L	NO	19.8 - 22.3
					V6 (WEEK 52)	196	18.0	L	NO	19.8 - 22.3
		081	Male	ACI-91	SCREENING	-10	19.5	L	NO	19.8 - 22.3
					V3 (WEEK 12)	89	19.5	L	NO	19.8 - 22.3
					V5 (WEEK 36)	250	19.2	L	NO	19.8 - 22.3
		082	Male	Placebo	SCREENING	-8	19.6	L	NO	19.8 - 22.3
					V3 (WEEK 12)	84	19.5	L	NO	19.8 - 22.3
					V4 (WEEK 24)	175	19.7	L	NO	19.8 - 22.3
					V5 (WEEK 36)	252	18.8	L	NO	19.8 - 22.3
					V6 (WEEK 52)	364	19.6	L	NO	19.8 - 22.3
		083	Female	ACI-91	V4 (WEEK 24)	168	18.7	L	NO	19.8 - 22.3

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCHC	mmol/L	084	Female	Placebo	SCREENING	-9	18.7	L	NO	19.8 - 22.3
					V1 (WEEK 0)	1	19.5	L	NO	19.8 - 22.3
					V3 (WEEK 12)	84	18.9	L	NO	19.8 - 22.3
					V4 (WEEK 24)	175	18.9	L	NO	19.8 - 22.3
					V5 (WEEK 36)	259	19.0	L	NO	19.8 - 22.3
		086	Female	Placebo	SCREENING	-24	19.5	L	NO	19.8 - 22.3
					V5 (WEEK 36)	251	19.5	L	NO	19.8 - 22.3
		087	Female	ACI-91	V4 (WEEK 24)	169	19.7	L	NO	19.8 - 22.3
		088	Female	Placebo	V1 (WEEK 0)	1	19.5	L	NO	19.8 - 22.3
					V3 (WEEK 12)	83	19.6	L	NO	19.8 - 22.3
					V4 (WEEK 24)	162	18.8	L	NO	19.8 - 22.3
					V5 (WEEK 36)	264	19.0	L	NO	19.8 - 22.3
		093	Female	ACI-91	V4 (WEEK 24)	173	19.7	L	NO	19.8 - 22.3
MCV	fL	002	Female	ACI-91	SCREENING	-7	98.5	H	NO	82.0 - 96.0
					V3 (WEEK 12)	85	101.1	H	NO	82.0 - 96.0
					V4 (WEEK 24)	169	96.6	H	NO	82.0 - 96.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	002	Female	ACI-91	V6 (WEEK 52)	365	95.8	H	NO	79.4 - 94.8
		004	Male	ACI-91	SCREENING	-29	98.0	H	NO	82.0 - 96.0
					V1 (WEEK 0)	1	104.4	H	NO	82.0 - 96.0
		005	Female	Placebo	V6 (WEEK 52)	364	98.8	H	NO	79.4 - 94.8
					V7 (WEEK 56)	400	100.5	H	NO	79.4 - 94.8
		006	Male	ACI-91	SCREENING	-32	100.2	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	105.1	H	NO	79.0 - 92.2
					V3 (WEEK 12)	85	102.0	H	NO	79.0 - 92.2
					V4 (WEEK 24)	169	102.0	H	NO	79.0 - 92.2
					V5 (WEEK 36)	252	102.0	H	NO	79.0 - 92.2
					V6 (WEEK 52)	364	98.5	H	NO	79.0 - 92.2
					V7 (WEEK 56)	390	102.8	H	NO	79.0 - 92.2
		009	Female	Placebo	V1 (WEEK 0)	1	98.0	H	NO	82.0 - 96.0
					V6 (WEEK 52)	361	100.2	H	NO	79.4 - 94.8
					V7 (WEEK 56)	389	100.2	H	NO	79.4 - 94.8
		010	Male	ACI-91	SCREENING	-26	99.0	H	NO	82.0 - 96.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	010	Male	ACI-91	V1 (WEEK 0)	1	102.0	H	NO	82.0 - 96.0
					V3 (WEEK 12)	85	99.2	H	NO	82.0 - 96.0
		012	Male	ACI-91	SCREENING	-32	97.1	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	101.5	H	NO	79.0 - 92.2
					V3 (WEEK 12)	88	96.9	H	NO	79.0 - 92.2
					V5 (WEEK 36)	257	100.4	H	NO	79.0 - 92.2
					V6 (WEEK 52)	361	97.0	H	NO	79.0 - 92.2
					V7 (WEEK 56)	396	102.8	H	NO	79.0 - 92.2
		013	Female	Placebo	SCREENING	-30	109.5	H	NO	82.0 - 96.0
					V1 (WEEK 0)	1	103.9	H	NO	82.0 - 96.0
					V3 (WEEK 12)	85	100.5	H	NO	82.0 - 96.0
					V4 (WEEK 24)	170	100.0	H	NO	79.4 - 94.8
					V5 (WEEK 36)	247	101.8	H	NO	79.4 - 94.8
					V6 (WEEK 52)	366	101.0	H	NO	79.4 - 94.8
					V7 (WEEK 56)	400	100.5	H	NO	79.4 - 94.8
		014	Male	ACI-91	SCREENING	-26	96.6	H	NO	82.0 - 96.0
					V4 (WEEK 24)	172	94.7	H	NO	79.0 - 92.2
					V5 (WEEK 36)	256	114.9	H	NO	79.0 - 92.2

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	015	Female	ACI-91	SCREENING	-32	96.4	H	NO	79.4 - 94.8
					V3 (WEEK 12)	85	95.1	H	NO	79.4 - 94.8
					V4 (WEEK 24)	162	96.6	H	NO	79.4 - 94.8
					V5 (WEEK 36)	248	96.8	H	NO	79.4 - 94.8
					V7 (WEEK 56)	394	98.3	H	NO	79.4 - 94.8
		016	Male	Placebo	V4 (WEEK 24)	162	92.4	H	NO	79.0 - 92.2
					V6 (WEEK 52)	365	96.9	H	NO	79.0 - 92.2
		017	Male	ACI-91	SCREENING	-22	102.1	H	NO	82.0 - 96.0
					V1 (WEEK 0)	1	106.4	H	NO	82.0 - 96.0
					V3 (WEEK 12)	85	98.6	H	NO	82.0 - 96.0
					V4 (WEEK 24)	169	99.3	H	NO	79.0 - 92.2
					V5 (WEEK 36)	252	97.2	H	NO	79.0 - 92.2
					V6 (WEEK 52)	364	101.9	H	NO	79.0 - 92.2
					V7 (WEEK 56)	392	99.1	H	NO	79.0 - 92.2
		019	Male	ACI-91	SCREENING	-21	98.4	H	NO	82.0 - 96.0
					V1 (WEEK 0)	1	101.1	H	NO	82.0 - 96.0
					V3 (WEEK 12)	85	97.4	H	NO	79.0 - 92.2
					V4 (WEEK 24)	168	98.7	H	NO	79.0 - 92.2

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	019	Male	ACI-91	V5 (WEEK 36)	259	99.1	H	NO	79.0 - 92.2
					V6 (WEEK 52)	364	96.8	H	NO	79.0 - 92.2
					V7 (WEEK 56)	399	96.5	H	NO	79.0 - 92.2
		023	Male	ACI-91	SCREENING	-19	102.3	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	106.0	H	NO	79.0 - 92.2
					V3 (WEEK 12)	86	95.4	H	NO	79.0 - 92.2
					V4 (WEEK 24)	177	95.3	H	NO	79.0 - 92.2
					V5 (WEEK 36)	245	94.6	H	NO	79.0 - 92.2
					V6 (WEEK 52)	364	95.5	H	NO	79.0 - 92.2
					V7 (WEEK 56)	388	100.6	H		79.0 - 92.2
		024	Male	Placebo	SCREENING	-31	110.1	H	NO	79.0 - 92.2
		027	Female	ACI-91	SCREENING	-21	100.9	H	NO	79.4 - 94.8
					V1 (WEEK 0)	1	100.7	H	NO	79.4 - 94.8
					V3 (WEEK 12)	92	101.0	H	NO	79.4 - 94.8
					V4 (WEEK 24)	174	102.3	H	NO	79.4 - 94.8
					V5 (WEEK 36)	259	106.0	H	NO	79.4 - 94.8
					V6 (WEEK 52)	370	100.9	H	NO	79.4 - 94.8
					V7 (WEEK 56)	407	99.5	H	NO	79.4 - 94.8

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	028	Female	Placebo	V4 (WEEK 24)	180	95.7	H	NO	79.4 - 94.8
					V5 (WEEK 36)	273	100.2	H	NO	79.4 - 94.8
		029	Female	Placebo	V1 (WEEK 0)	1	95.6	H	NO	79.4 - 94.8
					V4 (WEEK 24)	158	97.9	H	NO	79.4 - 94.8
		030	Female	ACI-91	SCREENING	-7	95.6	H	NO	79.4 - 94.8
					V1 (WEEK 0)	1	96.8	H	NO	79.4 - 94.8
					V3 (WEEK 12)	85	97.1	H	NO	79.4 - 94.8
					V4 (WEEK 24)	163	95.7	H	NO	79.4 - 94.8
					V6 (WEEK 52)	355	96.7	H	NO	79.4 - 94.8
					V7 (WEEK 56)	383	100.0	H	NO	79.4 - 94.8
		031	Male	Placebo	SCREENING	-14	92.5	H	NO	79.0 - 92.2
					V7 (WEEK 56)	391	92.5	H	NO	79.0 - 92.2
		032	Female	ACI-91	V1 (WEEK 0)	1	97.7	H	NO	79.4 - 94.8
		034	Female	Placebo	V3 (WEEK 12)	83	97.1	H	NO	79.4 - 94.8
		041	Male	Placebo	SCREENING	-16	97.2	H	NO	82.0 - 96.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	041	Male	Placebo	V3 (WEEK 12)	89	93.2	H	NO	79.0 - 92.2
					V4 (WEEK 24)	167	95.1	H	NO	79.0 - 92.2
					V5 (WEEK 36)	251	98.4	H	NO	79.0 - 92.2
					V6 (WEEK 52)	363	97.3	H	NO	79.0 - 92.2
					V7 (WEEK 56)	392	94.7	H	NO	79.0 - 92.2
		042	Female	ACI-91	V3 (WEEK 12)	126	112.8	H	NO	79.4 - 94.8
					V4 (WEEK 24)	168	95.2	H	NO	79.4 - 94.8
		043	Male	ACI-91	V3 (WEEK 12)	85	94.2	H	NO	79.0 - 92.2
		045	Male	Placebo	V4 (WEEK 24)	169	93.1	H	NO	79.0 - 92.2
		046	Female	ACI-91	SCREENING	-28	98.2	H	NO	82.0 - 96.0
					V4 (WEEK 24)	178	98.1	H	NO	79.4 - 94.8
		047	Male	Placebo	SCREENING	-21	113.6	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	113.2	H	NO	79.0 - 92.2
					V3 (WEEK 12)	80	99.8	H	NO	79.0 - 92.2
					V4 (WEEK 24)	162	99.6	H	NO	79.0 - 92.2
					V5 (WEEK 36)	254	100.0	H	NO	79.0 - 92.2

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	047	Male	Placebo	V6 (WEEK 52)	360	104.5	H	NO	79.0 - 92.2
					V7 (WEEK 56)	393	101.8	H	NO	79.0 - 92.2
		048	Male	ACI-91	V1 (WEEK 0)	1	92.3	H	NO	79.0 - 92.2
					V3 (WEEK 12)	86	94.4	H	NO	79.0 - 92.2
					V4 (WEEK 24)	176	96.1	H	NO	79.0 - 92.2
					V5 (WEEK 36)	247	109.8	H	NO	79.0 - 92.2
					V6 (WEEK 52)	360	93.4	H	NO	79.0 - 92.2
		050	Female	ACI-91	V4 (WEEK 24)	167	95.1	H	NO	79.4 - 94.8
					V5 (WEEK 36)	251	95.5	H	NO	79.4 - 94.8
		051	Female	Placebo	V7 (WEEK 56)	391	97.5	H	NO	79.4 - 94.8
		052	Female	ACI-91	V1 (WEEK 0)	1	95.9	H	NO	79.4 - 94.8
					V6 (WEEK 52)	362	79.0	L	NO	79.4 - 94.8
					V7 (WEEK 56)	390	77.9	L	NO	79.4 - 94.8
		055	Female	ACI-91	V6 (WEEK 52)	30	105.4	H	NO	79.4 - 94.8
		056	Female	Placebo	V3 (WEEK 12)	84	104.2	H	NO	79.4 - 94.8

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	057	Female	ACI-91	SCREENING	-21	95.3	H	NO	79.4 - 94.8
					V4 (WEEK 24)	170	100.6	H	NO	79.4 - 94.8
		058	Male	Placebo	V3 (WEEK 12)	93	92.9	H	NO	79.0 - 92.2
					V4 (WEEK 24)	166	108.7	H	NO	79.0 - 92.2
					V5 (WEEK 36)	260	96.0	H	NO	79.0 - 92.2
					V6 (WEEK 52)	345	93.1	H	NO	79.0 - 92.2
					V7 (WEEK 56)	380	92.7	H	NO	79.0 - 92.2
		059	Male	Placebo	SCREENING	-2	93.3	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	94.7	H	NO	79.0 - 92.2
					V3 (WEEK 12)	93	96.9	H	NO	79.0 - 92.2
					V4 (WEEK 24)	161	101.9	H	NO	79.0 - 92.2
					V5 (WEEK 36)	254	96.8	H	NO	79.0 - 92.2
					V6 (WEEK 52)	345	93.5	H	NO	79.0 - 92.2
					V7 (WEEK 56)	380	93.4	H	NO	79.0 - 92.2
		065	Male	Placebo	SCREENING	-20	102.8	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	98.8	H	NO	79.0 - 92.2
					V3 (WEEK 12)	85	97.8	H	NO	79.0 - 92.2
					V4 (WEEK 24)	141	102.6	H	NO	79.0 - 92.2

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	066	Male	ACI-91	SCREENING	-31	97.6	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	96.4	H	NO	79.0 - 92.2
					V3 (WEEK 12)	83	102.1	H	NO	79.0 - 92.2
		079	Female	Placebo	SCREENING	-18	97.0	H	NO	79.4 - 94.8
					V1 (WEEK 0)	1	98.7	H	NO	79.4 - 94.8
					V5 (WEEK 36)	249	95.3	H	NO	79.4 - 94.8
					V6 (WEEK 52)	320	95.9	H	NO	79.4 - 94.8
		080	Female	ACI-91	V6 (WEEK 52)	196	100.6	H	NO	79.4 - 94.8
		081	Male	ACI-91	V4 (WEEK 24)	175	101.9	H	NO	79.0 - 92.2
					V5 (WEEK 36)	250	93.5	H	NO	79.0 - 92.2
		082	Male	Placebo	SCREENING	-8	92.3	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	93.1	H	NO	79.0 - 92.2
					V3 (WEEK 12)	84	93.1	H	NO	79.0 - 92.2
					V4 (WEEK 24)	175	94.4	H	NO	79.0 - 92.2
					V5 (WEEK 36)	252	103.0	H	NO	79.0 - 92.2
					V6 (WEEK 52)	364	94.5	H	NO	79.0 - 92.2
					V7 (WEEK 56)	407	94.0	H	NO	79.0 - 92.2

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MCV	fL	084	Female	Placebo	V1 (WEEK 0)	1	78.5	L	NO	79.4 - 94.8
		087	Female	ACI-91	V5 (WEEK 36)	255	94.9	H	NO	79.4 - 94.8
		093	Female	ACI-91	V1 (WEEK 0)	1	95.9	H	NO	79.4 - 94.8
					V3 (WEEK 12)	86	98.2	H	NO	79.4 - 94.8
					V5 (WEEK 36)	258	96.8	H	NO	79.4 - 94.8
		097	Male	ACI-91	SCREENING	-21	96.3	H	NO	79.0 - 92.2
					V1 (WEEK 0)	1	94.6	H	NO	79.0 - 92.2
					V3 (WEEK 12)	85	95.7	H	NO	79.0 - 92.2
THROMBOCYTES	/nL	014	Male	ACI-91	V5 (WEEK 36)	256	146	L	NO	163 - 337
		017	Male	ACI-91	V6 (WEEK 52)	364	342	H	NO	163 - 337
		018	Female	Placebo	V3 (WEEK 12)	86	174	L	NO	182 - 369
					V4 (WEEK 24)	170	175	L	NO	182 - 369
					V5 (WEEK 36)	247	160	L	NO	182 - 369
					V6 (WEEK 52)	366	177	L	NO	182 - 369
					V7 (WEEK 56)	387	150	L	NO	182 - 369

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
THROMBOCYTES	/nL	027	Female	ACI-91	V7 (WEEK 56)	407	399	H	NO	182 - 369
		028	Female	Placebo	V1 (WEEK 0)	1	170	L	NO	182 - 369
					V3 (WEEK 12)	89	175	L	NO	182 - 369
					V4 (WEEK 24)	180	176	L	NO	182 - 369
					V5 (WEEK 36)	273	136	L	NO	182 - 369
					V6 (WEEK 52)	364	171	L	NO	182 - 369
					V7 (WEEK 56)	390	181	L	NO	182 - 369
		031	Male	Placebo	V3 (WEEK 12)	90	338	H	NO	163 - 337
					V4 (WEEK 24)	174	389	H	NO	163 - 337
					V6 (WEEK 52)	363	351	H	NO	163 - 337
		034	Female	Placebo	V3 (WEEK 12)	83	93	L	NO	182 - 369
		041	Male	Placebo	V3 (WEEK 12)	89	151	L	NO	163 - 337
		042	Female	ACI-91	V4 (WEEK 24)	168	178	L	NO	182 - 369
		043	Male	ACI-91	V3 (WEEK 12)	85	359	H	NO	163 - 337

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
THROMBOCYTES	/nL	044	Female	Placebo	SCREENING	-28	132	L	NO	150 - 400
					V1 (WEEK 0)	1	115	L	NO	150 - 400
					V3 (WEEK 12)	85	120	L	NO	182 - 369
					V4 (WEEK 24)	176	124	L	NO	182 - 369
					V5 (WEEK 36)	260	122	L	NO	182 - 369
					V6 (WEEK 52)	365	98	L	NO	182 - 369
					V7 (WEEK 56)	400	85	L	NO	182 - 369
		045	Male	Placebo	V3 (WEEK 12)	85	156	L	NO	163 - 337
					V5 (WEEK 36)	260	152	L	NO	163 - 337
					V7 (WEEK 56)	393	154	L	NO	163 - 337
		048	Male	ACI-91	V5 (WEEK 36)	247	141	L	NO	163 - 337
		051	Female	Placebo	V7 (WEEK 56)	391	378	H	NO	182 - 369
		052	Female	ACI-91	V1 (WEEK 0)	1	385	H	NO	182 - 369
					V3 (WEEK 12)	82	430	H	NO	182 - 369
					V4 (WEEK 24)	166	413	H	NO	182 - 369
					V6 (WEEK 52)	362	400	H	NO	182 - 369
					V7 (WEEK 56)	390	395	H	NO	182 - 369

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
THROMBOCYTES	/nL	058	Male	Placebo	V1 (WEEK 0)	1	372	H	NO	163 - 337
					V7 (WEEK 56)	380	341	H	NO	163 - 337
		066	Male	ACI-91	V3 (WEEK 12)	83	156	L	NO	163 - 337
		069	Male	Placebo	V4 (WEEK 24)	164	356	H	NO	163 - 337
		071	Female	ACI-91	V1 (WEEK 0)	1	382	H	NO	182 - 369
					V3 (WEEK 12)	87	412	H	NO	182 - 369
					V4 (WEEK 24)	177	388	H	NO	182 - 369
					V6 (WEEK 52)	374	386	H	NO	182 - 369
					V7 (WEEK 56)	392	421	H	NO	182 - 369
		081	Male	ACI-91	V6 (WEEK 52)	376	348	H	NO	163 - 337
		082	Male	Placebo	V3 (WEEK 12)	84	155	L	NO	163 - 337
					V4 (WEEK 24)	175	145	L	NO	163 - 337
					V5 (WEEK 36)	252	157	L	NO	163 - 337
					V6 (WEEK 52)	364	156	L	NO	163 - 337
					V7 (WEEK 56)	407	153	L	NO	163 - 337

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
THROMBOCYTES	/nL	089	Female	ACI-91	V6 (WEEK 52)	364	168	L	NO	182 - 369
		093	Female	ACI-91	V5 (WEEK 36)	258	181	L	NO	182 - 369
LEUKOCYTES	/nL	013	Female	Placebo	V1 (WEEK 0)	1	3.8	L	NO	4.0 - 9.0
					V3 (WEEK 12)	85	3.9	L	NO	4.0 - 9.0
					V4 (WEEK 24)	170	3.7	L	NO	4.0 - 10.0
					V5 (WEEK 36)	247	3.5	L	NO	4.0 - 10.0
					V7 (WEEK 56)	400	3.9	L	NO	4.0 - 10.0
		023	Male	ACI-91	V1 (WEEK 0)	1	4.1	L	NO	4.2 - 9.1
		027	Female	ACI-91	SCREENING	-21	17.2	H	YES	4.0 - 10.0
					V1 (WEEK 0)	1	15.9	H	YES	4.0 - 10.0
					V3 (WEEK 12)	92	13.8	H	NO	4.0 - 10.0
					V4 (WEEK 24)	174	12.3	H	NO	4.0 - 10.0
					V5 (WEEK 36)	259	13.3	H	NO	4.0 - 10.0
					V6 (WEEK 52)	370	18.2	H	NO	4.0 - 10.0
					V7 (WEEK 56)	407	16.4	H	NO	4.0 - 10.0
		028	Female	Placebo	SCREENING	-8	3.7	L	NO	4.0 - 10.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/nL	028	Female	Placebo	V1 (WEEK 0)	1	3.0	L	NO	4.0 - 10.0
					V3 (WEEK 12)	89	3.9	L	NO	4.0 - 10.0
					V4 (WEEK 24)	180	3.5	L	NO	4.0 - 10.0
					V5 (WEEK 36)	273	3.9	L	NO	4.0 - 10.0
					V6 (WEEK 52)	364	3.4	L	NO	4.0 - 10.0
		034	Female	Placebo	V4 (WEEK 24)	175	10.4	H	NO	4.0 - 10.0
		051	Female	Placebo	SCREENING	-52	10.1	H	NO	4.0 - 10.0
					V1 (WEEK 0)	1	10.3	H	NO	4.0 - 10.0
					V3 (WEEK 12)	97	10.5	H	NO	4.0 - 10.0
					V4 (WEEK 24)	167	11.4	H	NO	4.0 - 10.0
					V6 (WEEK 52)	363	10.9	H	NO	4.0 - 10.0
					V7 (WEEK 56)	391	12.1	H	NO	4.0 - 10.0
		065	Male	Placebo	V1 (WEEK 0)	1	12.1	H	NO	4.2 - 9.1
		068	Male	Placebo	SCREENING	-27	3.5	L	NO	4.2 - 9.1
					V1 (WEEK 0)	1	4.1	L	NO	4.2 - 9.1
					V3 (WEEK 12)	81	3.1	L	NO	4.2 - 9.1
					V4 (WEEK 24)	163	3.4	L	NO	4.2 - 9.1

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/nL	068	Male	Placebo	V6 (WEEK 52)	372	3.1	L	NO	4.2 - 9.1
					V7 (WEEK 56)	414	4.1	L	NO	4.2 - 9.1
		069	Male	Placebo	V1 (WEEK 0)	1	1.7	L	NO	4.2 - 9.1
		072	Female	Placebo	SCREENING	-20	3.2	L	NO	4.0 - 10.0
		088	Female	Placebo	V7 (WEEK 56)	404	3.3	L	NO	4.0 - 10.0
		093	Female	ACI-91	V1 (WEEK 0)	1	10.4	H	NO	4.0 - 10.0
NEUTROPHILS	%	001	Female	Placebo	SCREENING	-7	71.6	H	NO	50.0 - 70.0
					V1 (WEEK 0)	1	76.7	H	NO	50.0 - 70.0
					V4 (WEEK 24)	162	70.5	H	NO	50.0 - 70.0
		003	Female	Placebo	V3 (WEEK 12)	90	72.2	H	NO	50.0 - 70.0
		005	Female	Placebo	V6 (WEEK 52)	364	75.1	H	NO	34.0 - 71.0
		009	Female	Placebo	V5 (WEEK 36)	246	73.4	H	NO	34.0 - 71.0
					V6 (WEEK 52)	361	72.3	H	NO	34.0 - 71.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
NEUTROPHILS	%	015	Female	ACI-91	V1 (WEEK 0)	1	71.7	H	NO	34.0 - 71.0
					V7 (WEEK 56)	394	74.3	H	NO	34.0 - 71.0
		016	Male	Placebo	V6 (WEEK 52)	365	83.3	H	NO	34.0 - 68.0
		018	Female	Placebo	SCREENING	-20	46.4	L	NO	50.0 - 70.0
		023	Male	ACI-91	V5 (WEEK 36)	245	70.4	H	NO	34.0 - 68.0
		024	Male	Placebo	SCREENING	-31	70.2	H	NO	34.0 - 68.0
					V1 (WEEK 0)	1	69.9	H	NO	34.0 - 68.0
					V5 (WEEK 36)	246	69.3	H	NO	34.0 - 68.0
		027	Female	ACI-91	SCREENING	-21	78.0	H	NO	34.0 - 71.0
					V1 (WEEK 0)	1	73.5	H	NO	34.0 - 71.0
					V3 (WEEK 12)	92	78.8	H	NO	34.0 - 71.0
					V5 (WEEK 36)	259	71.9	H	NO	34.0 - 71.0
					V6 (WEEK 52)	370	78.3	H	NO	34.0 - 71.0
					V7 (WEEK 56)	407	80.8	H	NO	34.0 - 71.0
		028	Female	Placebo	V1 (WEEK 0)	1	5.0	L	NO	34 - 71

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
NEUTROPHILS	%	028	Female	Placebo	V7 (WEEK 56)	390	33.6	L	NO	34.0 - 71.0
		029	Female	Placebo	V7 (WEEK 56)	391	75.0	H	YES	34.0 - 71.0
		031	Male	Placebo	V3 (WEEK 12)	90	68.7	H	NO	34.0 - 68.0
					V4 (WEEK 24)	174	71.1	H	NO	34.0 - 68.0
					V5 (WEEK 36)	251	72.6	H	NO	34.0 - 68.0
					V6 (WEEK 52)	363	73.7	H	NO	34.0 - 68.0
					V7 (WEEK 56)	391	70.5	H	NO	34.0 - 68.0
		034	Female	Placebo	V4 (WEEK 24)	175	76.4	H	NO	34.0 - 71.0
		041	Male	Placebo	SCREENING	-16	74.4	H	NO	50.0 - 70.0
					V3 (WEEK 12)	89	73.4	H	NO	34.0 - 68.0
					V5 (WEEK 36)	251	70.0	H	NO	34.0 - 68.0
					V7 (WEEK 56)	392	69.9	H	NO	34.0 - 68.0
		042	Female	ACI-91	V7 (WEEK 56)	391	72.0	H	NO	34.0 - 71.0
		043	Male	ACI-91	V1 (WEEK 0)	1	70.1	H	NO	50.0 - 70.0
					V3 (WEEK 12)	85	79.8	H	NO	34.0 - 68.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
NEUTROPHILS	%	044	Female	Placebo	SCREENING	-28	73.5	H	NO	50.0 - 70.0
					V3 (WEEK 12)	85	72.9	H	NO	34.0 - 71.0
		045	Male	Placebo	SCREENING	-14	44.4	L	NO	50.0 - 70.0
					V1 (WEEK 0)	1	39.2	L	NO	50.0 - 70.0
		046	Female	ACI-91	SCREENING	-28	72.8	H	NO	50.0 - 70.0
					V1 (WEEK 0)	1	76.8	H	NO	34.0 - 71.0
					V3 (WEEK 12)	87	75.8	H	NO	34.0 - 71.0
					V4 (WEEK 24)	178	75.0	H	NO	34.0 - 71.0
					V5 (WEEK 36)	255	78.4	H	NO	34.0 - 71.0
					V6 (WEEK 52)	367	75.3	H	NO	34.0 - 71.0
					V7 (WEEK 56)	393	77.0	H	NO	34.0 - 71.0
		048	Male	ACI-91	SCREENING	-5	69.3	H	NO	34.0 - 68.0
					V3 (WEEK 12)	86	69.0	H	NO	34.0 - 68.0
					V6 (WEEK 52)	360	70.1	H	NO	34.0 - 68.0
		049	Female	Placebo	V5 (WEEK 36)	252	85.8	H	NO	34.0 - 71.0
		057	Female	ACI-91	SCREENING	-21	81.3	H	NO	34.0 - 71.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
NEUTROPHILS	%	057	Female	ACI-91	V1 (WEEK 0)	1	76.4	H	NO	34.0 - 71.0
					V3 (WEEK 12)	82	73.0	H	NO	34.0 - 71.0
					V4 (WEEK 24)	170	76.0	H	NO	34.0 - 71.0
		058	Male	Placebo	V4 (WEEK 24)	166	69.0	H	NO	34.0 - 68.0
					V5 (WEEK 36)	260	69.2	H	NO	34.0 - 68.0
					V6 (WEEK 52)	345	68.1	H	NO	34.0 - 68.0
					V7 (WEEK 56)	380	69.1	H	NO	34.0 - 68.0
		065	Male	Placebo	SCREENING	-20	71.8	H	NO	34.0 - 68.0
					V1 (WEEK 0)	1	85.4	H	NO	34.0 - 68.0
					V3 (WEEK 12)	85	73.7	H	NO	34.0 - 68.0
					V4 (WEEK 24)	141	78.2	H	NO	34.0 - 68.0
		069	Male	Placebo	V4 (WEEK 24)	164	69.5	H	NO	34.0 - 68.0
		071	Female	ACI-91	SCREENING	-20	82.0	H	NO	34.0 - 71.0
					V3 (WEEK 12)	87	71.5	H	NO	34.0 - 71.0
					V5 (WEEK 36)	253	77.2	H	NO	34.0 - 71.0
					V6 (WEEK 52)	374	72.3	H	NO	34.0 - 71.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
NEUTROPHILS	%	072	Female	Placebo	V1 (WEEK 0)	1	79.9	H	NO	34.0 - 71.0
					V3 (WEEK 12)	85	77.2	H	NO	34.0 - 71.0
					V4 (WEEK 24)	169	81.0	H	NO	34.0 - 71.0
					V5 (WEEK 36)	262	81.1	H	NO	34.0 - 71.0
					V6 (WEEK 52)	360	76.1	H	NO	34.0 - 71.0
					V7 (WEEK 56)	393	78.7	H	NO	34.0 - 71.0
		080	Female	ACI-91	SCREENING	-10	74.1	H	NO	34.0 - 71.0
					V3 (WEEK 12)	84	72.6	H	NO	34.0 - 71.0
		081	Male	ACI-91	V4 (WEEK 24)	175	69.2	H	NO	34.0 - 68.0
		083	Female	ACI-91	V7 (WEEK 56)	392	77.7	H	NO	34.0 - 71.0
		086	Female	Placebo	V5 (WEEK 36)	251	74.9	H	NO	34.0 - 71.0
					V6 (WEEK 52)	363	73.8	H	NO	34.0 - 71.0
		088	Female	Placebo	V7 (WEEK 56)	404	25.5	L	NO	34.0 - 71.0
		093	Female	ACI-91	V1 (WEEK 0)	1	79.6	H	NO	34.0 - 71.0
					V6 (WEEK 52)	370	77.7	H	NO	34.0 - 71.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	001	Female	Placebo	SCREENING	-7	21.3	L	NO	25.0 - 40.0
					V1 (WEEK 0)	1	17.2	L	NO	25.0 - 40.0
					V4 (WEEK 24)	162	23.1	L	NO	25.0 - 40.0
		002	Female	ACI-91	V4 (WEEK 24)	169	21.8	L	NO	25.0 - 40.0
		003	Female	Placebo	SCREENING	-21	22.3	L	NO	25.0 - 40.0
					V1 (WEEK 0)	1	22.7	L	NO	25.0 - 40.0
					V3 (WEEK 12)	90	18.4	L	NO	25.0 - 40.0
		004	Male	ACI-91	SCREENING	-29	23.5	L	NO	25.0 - 40.0
					V1 (WEEK 0)	1	24.7	L	NO	25.0 - 40.0
					V3 (WEEK 12)	92	24.4	L	NO	25.0 - 40.0
		005	Female	Placebo	V6 (WEEK 52)	364	18.5	L	NO	19.0 - 52.0
		009	Female	Placebo	V4 (WEEK 24)	178	23.0	L	NO	25 - 40
					V5 (WEEK 36)	246	17.4	L	NO	19.0 - 52.0
		012	Male	ACI-91	V3 (WEEK 12)	88	18.7	L	NO	22.0 - 53.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	013	Female	Placebo	SCREENING	-30	20.8	L	NO	25.0 - 40.0
		015	Female	ACI-91	V1 (WEEK 0)	1	18.9	L	NO	19.0 - 52.0
					V7 (WEEK 56)	394	17.6	L	NO	19.0 - 52.0
		016	Male	Placebo	V6 (WEEK 52)	365	12.0	L	NO	22.0 - 53.0
		017	Male	ACI-91	SCREENING	-22	22.5	L	NO	25.0 - 40.0
					V1 (WEEK 0)	1	21.9	L	NO	25.0 - 40.0
					V3 (WEEK 12)	85	23.8	L	NO	25.0 - 40.0
		019	Male	ACI-91	V5 (WEEK 36)	259	21.4	L	NO	22.0 - 53.0
		023	Male	ACI-91	V5 (WEEK 36)	245	21.5	L	NO	22.0 - 53.0
		024	Male	Placebo	V1 (WEEK 0)	1	20.8	L	NO	22.0 - 53.0
					V5 (WEEK 36)	246	20.7	L	NO	22.0 - 53.0
		027	Female	ACI-91	SCREENING	-21	13.0	L	NO	19.0 - 52.0
					V1 (WEEK 0)	1	14.2	L	NO	19.0 - 52.0
					V3 (WEEK 12)	92	12.6	L	NO	19.0 - 52.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	027	Female	ACI-91	V5 (WEEK 36)	259	16.3	L	NO	19.0 - 52.0
					V6 (WEEK 52)	370	12.7	L	NO	19.0 - 52.0
					V7 (WEEK 56)	407	12.3	L	NO	19.0 - 52.0
		028	Female	Placebo	V1 (WEEK 0)	1	75.0	H	NO	25 - 40
		029	Female	Placebo	SCREENING	-3	18.8	L	NO	19.0 - 52.0
					V7 (WEEK 56)	391	16.1	L	NO	19.0 - 52.0
		031	Male	Placebo	V4 (WEEK 24)	174	21.5	L	NO	22.0 - 53.0
					V5 (WEEK 36)	251	21.1	L	NO	22.0 - 53.0
					V6 (WEEK 52)	363	18.7	L	NO	22.0 - 53.0
					V7 (WEEK 56)	391	21.3	L	NO	22.0 - 53.0
		033	Female	ACI-91	SCREENING	-7	24.2	L	NO	25.0 - 40.0
		034	Female	Placebo	V4 (WEEK 24)	175	16.5	L	NO	19.0 - 52.0
		041	Male	Placebo	SCREENING	-16	19.0	L	NO	25.0 - 40.0
					V3 (WEEK 12)	89	20.7	L	NO	22.0 - 53.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	042	Female	ACI-91	SCREENING	-29	22.3	L	NO	25.0 - 40.0
					V7 (WEEK 56)	391	17.4	L	NO	19.0 - 52.0
		043	Male	ACI-91	SCREENING	-28	22.8	L	NO	25.0 - 40.0
					V1 (WEEK 0)	1	21.4	L	NO	25.0 - 40.0
					V3 (WEEK 12)	85	12.2	L	NO	22.0 - 53.0
		044	Female	Placebo	SCREENING	-28	20.3	L	NO	25.0 - 40.0
		045	Male	Placebo	SCREENING	-14	41.6	H	NO	25.0 - 40.0
					V1 (WEEK 0)	1	46.9	H	NO	25.0 - 40.0
		046	Female	ACI-91	SCREENING	-28	15.3	L	NO	25.0 - 40.0
					V1 (WEEK 0)	1	11.1	L	NO	19.0 - 52.0
					V3 (WEEK 12)	87	13.9	L	NO	19.0 - 52.0
					V4 (WEEK 24)	178	13.8	L	NO	19.0 - 52.0
					V5 (WEEK 36)	255	11.4	L	NO	19.0 - 52.0
					V6 (WEEK 52)	367	10.1	L	NO	19.0 - 52.0
					V7 (WEEK 56)	393	12.4	L	NO	19.0 - 52.0
		048	Male	ACI-91	V6 (WEEK 52)	360	21.3	L	NO	22.0 - 53.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	049	Female	Placebo	V5 (WEEK 36)	252	8.1	L	NO	19.0 - 52.0
		057	Female	ACI-91	SCREENING	-21	11.1	L	NO	19.0 - 52.0
					V1 (WEEK 0)	1	12.5	L	NO	19.0 - 52.0
					V3 (WEEK 12)	82	17.1	L	NO	19.0 - 52.0
					V4 (WEEK 24)	170	15.5	L	NO	19.0 - 52.0
		058	Male	Placebo	V1 (WEEK 0)	1	21.1	L	NO	22.0 - 53.0
					V3 (WEEK 12)	93	21.2	L	NO	22.0 - 53.0
					V4 (WEEK 24)	166	21.4	L	NO	22.0 - 53.0
					V5 (WEEK 36)	260	21.1	L	NO	22.0 - 53.0
					V6 (WEEK 52)	345	17.8	L	NO	22.0 - 53.0
					V7 (WEEK 56)	380	15.4	L	NO	22.0 - 53.0
		065	Male	Placebo	SCREENING	-20	20.4	L	NO	22.0 - 53.0
					V1 (WEEK 0)	1	10.3	L	NO	22.0 - 53.0
					V3 (WEEK 12)	85	15.8	L	NO	22.0 - 53.0
					V4 (WEEK 24)	141	10.7	L	NO	22.0 - 53.0
		071	Female	ACI-91	SCREENING	-20	12.6	L	NO	19.0 - 52.0
					V5 (WEEK 36)	253	17.9	L	NO	19.0 - 52.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	072	Female	Placebo	V1 (WEEK 0)	1	14.7	L	NO	19.0 - 52.0
					V3 (WEEK 12)	85	16.6	L	NO	19.0 - 52.0
					V4 (WEEK 24)	169	13.1	L	NO	19.0 - 52.0
					V5 (WEEK 36)	262	14.7	L	NO	19.0 - 52.0
					V6 (WEEK 52)	360	17.1	L	NO	19.0 - 52.0
					V7 (WEEK 56)	393	14.6	L	NO	19.0 - 52.0
		080	Female	ACI-91	SCREENING	-10	18.2	L	NO	19.0 - 52.0
					V3 (WEEK 12)	84	18.6	L	NO	19.0 - 52.0
		081	Male	ACI-91	V4 (WEEK 24)	175	20.9	L	NO	22.0 - 53.0
					V6 (WEEK 52)	376	19.1	L	NO	22.0 - 53.0
		083	Female	ACI-91	V7 (WEEK 56)	392	15.1	L	NO	19.0 - 52.0
		086	Female	Placebo	V5 (WEEK 36)	251	15.5	L	NO	19.0 - 52.0
					V6 (WEEK 52)	363	17.4	L	NO	19.0 - 52.0
		088	Female	Placebo	V7 (WEEK 56)	404	55.9	H	NO	19.0 - 52.0
		093	Female	ACI-91	V1 (WEEK 0)	1	13.9	L	NO	19.0 - 52.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LYMPHOCYTES	%	093	Female	ACI-91	V6 (WEEK 52)	370	14.3	L	NO	19.0 - 52.0
MONOCYTES	%	009	Female	Placebo	V4 (WEEK 24)	178	22.0	H	NO	4 - 11
		012	Male	ACI-91	V3 (WEEK 12)	88	14.1	H	NO	5.0 - 12.0
		016	Male	Placebo	V6 (WEEK 52)	365	3.7	L	NO	5.0 - 12.0
		017	Male	ACI-91	V4 (WEEK 24)	169	17.1	H	NO	5.0 - 12.0
					V7 (WEEK 56)	392	12.2	H	NO	5.0 - 12.0
		018	Female	Placebo	V7 (WEEK 56)	387	13.3	H	NO	5.0 - 13.0
		028	Female	Placebo	SCREENING	-8	21.1	H	NO	5.0 - 13.0
					V1 (WEEK 0)	1	16.0	H	NO	4 - 11
					V3 (WEEK 12)	89	17.5	H	YES	5.0 - 13.0
					V4 (WEEK 24)	180	25.1	H	NO	5.0 - 13.0
					V5 (WEEK 36)	273	17.6	H	NO	5.0 - 13.0
					V6 (WEEK 52)	364	20.5	H	NO	5.0 - 13.0
					V7 (WEEK 56)	390	23.0	H	NO	5.0 - 13.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MONOCYTES	%	033	Female	ACI-91	V5 (WEEK 36)	261	4.7	L	NO	5.0 - 13.0
		034	Female	Placebo	V3 (WEEK 12)	83	4.7	L	NO	5.0 - 13.0
					V7 (WEEK 56)	399	4.8	L	NO	5.0 - 13.0
		041	Male	Placebo	V5 (WEEK 36)	251	4.5	L	NO	5.0 - 12.0
					V7 (WEEK 56)	392	4.4	L	NO	5.0 - 12.0
		044	Female	Placebo	V5 (WEEK 36)	260	4.4	L	NO	5.0 - 13.0
		047	Male	Placebo	V3 (WEEK 12)	80	15.7	H	NO	5.0 - 12.0
					V4 (WEEK 24)	162	13.5	H	NO	5.0 - 12.0
					V7 (WEEK 56)	393	12.3	H	NO	5.0 - 12.0
		056	Female	Placebo	SCREENING	-21	13.1	H	NO	5.0 - 13.0
					V1 (WEEK 0)	1	13.7	H	NO	5.0 - 13.0
					V4 (WEEK 24)	168	14.9	H	NO	5.0 - 13.0
					V5 (WEEK 36)	259	14.9	H	NO	5.0 - 13.0
		058	Male	Placebo	V1 (WEEK 0)	1	12.6	H	NO	5.0 - 12.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
MONOCYTES	%	065	Male	Placebo	V1 (WEEK 0)	1	4.0	L	NO	5.0 - 12.0
		066	Male	ACI-91	SCREENING	-31	12.6	H	NO	5.0 - 12.0
					V1 (WEEK 0)	1	12.7	H	NO	5.0 - 12.0
					V3 (WEEK 12)	83	13.2	H	NO	5.0 - 12.0
		069	Male	Placebo	V4 (WEEK 24)	164	4.9	L	NO	5.0 - 12.0
		071	Female	ACI-91	V5 (WEEK 36)	253	4.5	L	NO	5.0 - 13.0
		072	Female	Placebo	V1 (WEEK 0)	1	4.7	L	NO	5.0 - 13.0
					V4 (WEEK 24)	169	4.7	L	NO	5.0 - 13.0
					V5 (WEEK 36)	262	3.8	L	NO	5.0 - 13.0
		081	Male	ACI-91	V6 (WEEK 52)	376	13.1	H	NO	5.0 - 12.0
EOSINOPHILS	%	002	Female	ACI-91	SCREENING	-7	4.4	H	NO	< 4.0
					V1 (WEEK 0)	1	4.3	H	NO	< 4.0
					V3 (WEEK 12)	85	5.2	H	NO	< 4.0
		003	Female	Placebo	SCREENING	-21	4.8	H	NO	< 4.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
EOSINOPHILS	%	003	Female	Placebo	V1 (WEEK 0)	1	4.4	H	NO	< 4.0
		005	Female	Placebo	V6 (WEEK 52)	364	0.5	L	NO	1.0 - 6.0
		006	Male	ACI-91	SCREENING	-32	0.8	L	NO	1.0 - 7.0
					V1 (WEEK 0)	1	0.3	L	NO	1.0 - 7.0
					V3 (WEEK 12)	85	0.6	L	NO	1.0 - 7.0
					V4 (WEEK 24)	169	0.8	L	NO	1.0 - 7.0
					V5 (WEEK 36)	252	0.6	L	NO	1.0 - 7.0
					V6 (WEEK 52)	364	0.5	L	NO	1.0 - 7.0
					V7 (WEEK 56)	390	0.8	L	NO	1.0 - 7.0
		009	Female	Placebo	V5 (WEEK 36)	246	0.4	L	NO	1.0 - 6.0
					V6 (WEEK 52)	361	0.9	L	NO	1.0 - 6.0
		012	Male	ACI-91	SCREENING	-32	0.9	L	NO	1.0 - 7.0
		016	Male	Placebo	V6 (WEEK 52)	365	0.7	L	NO	1.0 - 7.0
		018	Female	Placebo	SCREENING	-20	4.3	H	NO	< 4.0
					V4 (WEEK 24)	170	6.2	H	NO	1.0 - 6.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
EOSINOPHILS	%	023	Male	ACI-91	V5 (WEEK 36)	245	0.5	L	NO	1.0 - 7.0
		028	Female	Placebo	SCREENING	-8	0.8	L	NO	1.0 - 6.0
					V3 (WEEK 12)	89	0.8	L	NO	1.0 - 6.0
					V5 (WEEK 36)	273	0.8	L	NO	1.0 - 6.0
					V6 (WEEK 52)	364	0.9	L	NO	1.0 - 6.0
					V7 (WEEK 56)	390	0.7	L	NO	1.0 - 6.0
		029	Female	Placebo	SCREENING	-3	15.1	H	NO	1.0 - 6.0
					V3 (WEEK 12)	82	7.1	H	NO	1.0 - 6.0
		030	Female	ACI-91	V4 (WEEK 24)	163	0.9	L	NO	1.0 - 6.0
		031	Male	Placebo	V4 (WEEK 24)	174	0.8	L	NO	1.0 - 7.0
					V5 (WEEK 36)	251	0.6	L	NO	1.0 - 7.0
					V6 (WEEK 52)	363	0.8	L	NO	1.0 - 7.0
		032	Female	ACI-91	SCREENING	-10	0.4	L	YES	1.0 - 6.0
					V1 (WEEK 0)	1	0.6	L	YES	1.0 - 6.0
					V3 (WEEK 12)	82	0.7	L	YES	1.0 - 6.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
EOSINOPHILS	%	034	Female	Placebo	V1 (WEEK 0)	1	0.5	L	NO	1.0 - 6.0
		041	Male	Placebo	V3 (WEEK 12)	89	0.6	L	NO	1.0 - 7.0
					V4 (WEEK 24)	167	0.9	L	NO	1.0 - 7.0
					V5 (WEEK 36)	251	0.7	L	NO	1.0 - 7.0
		043	Male	ACI-91	V3 (WEEK 12)	85	0.5	L	NO	1.0 - 7.0
		044	Female	Placebo	V3 (WEEK 12)	85	0.4	L	NO	1.0 - 6.0
					V4 (WEEK 24)	176	0.9	L	NO	1.0 - 6.0
					V5 (WEEK 36)	260	0.9	L	NO	1.0 - 6.0
					V7 (WEEK 56)	400	0.8	L	NO	1.0 - 6.0
		046	Female	ACI-91	V5 (WEEK 36)	255	0.8	L	NO	1.0 - 6.0
		048	Male	ACI-91	V4 (WEEK 24)	176	0.8	L	NO	1.0 - 7.0
		049	Female	Placebo	V4 (WEEK 24)	168	0.6	L	NO	1.0 - 6.0
					V5 (WEEK 36)	252	0.6	L	NO	1.0 - 6.0
		050	Female	ACI-91	SCREENING	-51	0.3	L	NO	1.0 - 6.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
EOSINOPHILS	%	050	Female	ACI-91	V1 (WEEK 0)	1	0.6	L	NO	1.0 - 6.0
					V3 (WEEK 12)	83	0.4	L	NO	1.0 - 6.0
					V4 (WEEK 24)	167	0.7	L	NO	1.0 - 6.0
					V6 (WEEK 52)	363	0.7	L	NO	1.0 - 6.0
		051	Female	Placebo	V3 (WEEK 12)	97	0.9	L	NO	1.0 - 6.0
		055	Female	ACI-91	V1 (WEEK 0)	1	7.0	H	NO	1.0 - 6.0
					V6 (WEEK 52)	30	6.2	H	NO	1.0 - 6.0
		057	Female	ACI-91	SCREENING	-21	0.7	L	NO	1.0 - 6.0
					V1 (WEEK 0)	1	0.8	L	NO	1.0 - 6.0
		065	Male	Placebo	SCREENING	-20	0.9	L	NO	1.0 - 7.0
					V1 (WEEK 0)	1	0.1	L	NO	1.0 - 7.0
					V3 (WEEK 12)	85	0.8	L	NO	1.0 - 7.0
					V4 (WEEK 24)	141	0.3	L	NO	1.0 - 7.0
		071	Female	ACI-91	SCREENING	-20	0.1	L	NO	1.0 - 6.0
					V3 (WEEK 12)	87	0.1	L	NO	1.0 - 6.0
					V5 (WEEK 36)	253	0.2	L	NO	1.0 - 6.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
EOSINOPHILS	%	071	Female	ACI-91	V6 (WEEK 52)	374	0.3	L	NO	1.0 - 6.0
		072	Female	Placebo	V1 (WEEK 0)	1	0.4	L	NO	1.0 - 6.0
					V3 (WEEK 12)	85	0.6	L	NO	1.0 - 6.0
					V4 (WEEK 24)	169	0.9	L	NO	1.0 - 6.0
					V5 (WEEK 36)	262	0.3	L	NO	1.0 - 6.0
					V7 (WEEK 56)	393	0.7	L	NO	1.0 - 6.0
		079	Female	Placebo	V3 (WEEK 12)	96	0.8	L	NO	1.0 - 6.0
					V4 (WEEK 24)	175	0.5	L	NO	1.0 - 6.0
					V5 (WEEK 36)	249	0.7	L	NO	1.0 - 6.0
					V6 (WEEK 52)	320	0.8	L	NO	1.0 - 6.0
		080	Female	ACI-91	SCREENING	-10	0.4	L	NO	1.0 - 6.0
					V1 (WEEK 0)	1	0.5	L	NO	1.0 - 6.0
					V3 (WEEK 12)	84	0.6	L	NO	1.0 - 6.0
					V6 (WEEK 52)	196	0.6	L	NO	1.0 - 6.0
		083	Female	ACI-91	SCREENING	-15	7.7	H	NO	1.0 - 6.0
					V7 (WEEK 56)	392	0.2	L	NO	1.0 - 6.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
EOSINOPHILS	%	084	Female	Placebo	V1 (WEEK 0)	1	0.7	L	NO	1.0 - 6.0
		086	Female	Placebo	V3 (WEEK 12)	83	0.7	L	NO	1.0 - 6.0
					V6 (WEEK 52)	363	0.8	L	NO	1.0 - 6.0
		087	Female	ACI-91	SCREENING	-20	9.9	H	NO	1.0 - 6.0
					V1 (WEEK 0)	1	6.8	H	NO	1.0 - 6.0
					V3 (WEEK 12)	81	12.5	H	NO	1.0 - 6.0
					V4 (WEEK 24)	169	9.7	H	NO	1.0 - 6.0
					V5 (WEEK 36)	255	16.8	H	NO	1.0 - 6.0
					V6 (WEEK 52)	365	10.3	H	NO	1.0 - 6.0
					V7 (WEEK 56)	395	6.1	H	NO	1.0 - 6.0
		093	Female	ACI-91	SCREENING	-3	0.5	L	NO	1.0 - 6.0
					V1 (WEEK 0)	1	0.7	L	NO	1.0 - 6.0
					V3 (WEEK 12)	86	0.8	L	NO	1.0 - 6.0
					V6 (WEEK 52)	370	0.3	L	NO	1.0 - 6.0
					V7 (WEEK 56)	392	10.6	H	NO	1.0 - 6.0
BASOPHILS	%	009	Female	Placebo	V1 (WEEK 0)	1	1.0	H	NO	< 1.0
					V4 (WEEK 24)	178	4.0	H	NO	< 1

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BASOPHILS	%	013	Female	Placebo	V3 (WEEK 12)	85	1.0	H	NO	< 1.0
		028	Female	Placebo	V1 (WEEK 0)	1	4.0	H	NO	< 1
		029	Female	Placebo	SCREENING	-3	1.0	H	NO	< 1.0
		030	Female	ACI-91	V5 (WEEK 36)	253	1.1	H	NO	< 1.0
		042	Female	ACI-91	V4 (WEEK 24)	168	1.1	H	NO	< 1.0
					V5 (WEEK 36)	252	1.4	H	NO	< 1.0
					V6 (WEEK 52)	364	1.1	H	NO	< 1.0
					V7 (WEEK 56)	391	1.0	H	NO	< 1.0
		045	Male	Placebo	V3 (WEEK 12)	85	1.2	H	NO	< 1.0
					V4 (WEEK 24)	169	1.0	H	NO	< 1.0
		047	Male	Placebo	V4 (WEEK 24)	162	1.0	H	NO	< 1.0
		056	Female	Placebo	V1 (WEEK 0)	1	1.0	H	NO	< 1.0
		066	Male	ACI-91	V3 (WEEK 12)	83	1.0	H	NO	< 1.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.2: Hematology, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BASOPHILS	%	067	Female	ACI-91	V1 (WEEK 0)	1	1.2	H	NO	< 1.0
					V6 (WEEK 52)	69	1.3	H	NO	< 1.0
					V7 (WEEK 56)	111	1.0	H	NO	< 1.0
		068	Male	Placebo	V3 (WEEK 12)	81	1.0	H	NO	< 1.0
		072	Female	Placebo	SCREENING	-20	1.2	H	NO	< 1.0
		083	Female	ACI-91	V5 (WEEK 36)	258	1.4	H	NO	< 1.0
		087	Female	ACI-91	SCREENING	-20	1.6	H	NO	< 1.0
					V3 (WEEK 12)	81	1.2	H	NO	< 1.0
					V4 (WEEK 24)	169	1.0	H	NO	< 1.0
					V5 (WEEK 36)	255	1.7	H	NO	< 1.0
		088	Female	Placebo	V7 (WEEK 56)	404	1.5	H	NO	< 1.0
		093	Female	ACI-91	V7 (WEEK 56)	392	1.8	H	NO	< 1.0

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.2.3: Hematology, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
ERYTHROCYTES	ACI-91	LOW	0	0	1	3.1	0	0	2	6.3
		NORMAL	1	3.1	21	65.6	1	3.1	5	15.6
		HIGH	0	0	1	3.1	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	1	3.2	0	0	0	0
		NORMAL	2	6.5	24	77.4	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
HEMOGLOBIN	ACI-91	LOW	0	0	0	0	0	0	2	6.3
		NORMAL	1	3.1	23	71.9	0	0	5	15.6
		HIGH	0	0	1	3.1	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	1	3.2	0	0	0	0
		NORMAL	1	3.2	25	80.6	0	0	4	12.9
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.3: Hematology, shift tables

14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
HEMATOCRIT	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	13	40.6	2	6.3	6	18.8
		HIGH	0	0	7	21.9	3	9.4	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.2	19	61.3	2	6.5	4	12.9
		HIGH	0	0	2	6.5	3	9.7	0	0
		MISSING	0	0	0	0	0	0	0	0
MCH (HbE)	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.1	19	59.4	0	0	7	21.9
		HIGH	0	0	2	6.3	3	9.4	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	3	9.7	0	0	0	0
		NORMAL	0	0	22	71.0	1	3.2	3	9.7
		HIGH	0	0	0	0	1	3.2	1	3.2
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.3: Hematology, shift tables

14FEB2013

Safety Population

Parameter	Treat-ment	V1 (Week 0)	V6 (WEEK 52) Low N	Low %	Normal N	Normal %	High N	High %	Missing N	Missing %
MCHC	ACI-91	LOW	3	9.4	4	12.5	0	0	4	12.5
		NORMAL	2	6.3	16	50.0	0	0	3	9.4
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	6	19.4	5	16.1	0	0	1	3.2
		NORMAL	3	9.7	13	41.9	0	0	3	9.7
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
MCV	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	12	37.5	3	9.4	2	6.3
		HIGH	1	3.1	1	3.1	8	25.0	5	15.6
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	1	3.2	0	0	0	0
		NORMAL	0	0	15	48.4	4	12.9	3	9.7
		HIGH	0	0	1	3.2	6	19.4	1	3.2
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.3: Hematology, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
THROMBOCYTES	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	1	3.1	20	62.5	2	6.3	7	21.9
		HIGH	0	0	0	0	2	6.3	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	2	6.5	0	0	0	0	0	0
		NORMAL	2	6.5	21	67.7	1	3.2	4	12.9
		HIGH	0	0	1	3.2	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
LEUKOCYTES	ACI-91	LOW	0	0	1	3.1	0	0	0	0
		NORMAL	0	0	22	68.8	0	0	7	21.9
		HIGH	0	0	1	3.1	1	3.1	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	2	6.5	2	6.5	0	0	0	0
		NORMAL	0	0	22	71.0	0	0	3	9.7
		HIGH	0	0	0	0	1	3.2	1	3.2
		MISSING	0	0	0	0	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.3: Hematology, shift tables

 14FEB2013

Safety Population

Parameter	Treat-ment	V1 (Week 0)	V6 (WEEK 52) Low N	Low %	Normal N	Normal %	High N	High %	Missing N	Missing %
NEUTROPHILS	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	19	59.4	2	6.3	5	15.6
		HIGH	0	0	1	3.1	3	9.4	2	6.3
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	2	6.5	0	0	0	0
		NORMAL	0	0	16	51.6	6	19.4	3	9.7
		HIGH	0	0	2	6.5	1	3.2	1	3.2
		MISSING	0	0	0	0	0	0	0	0
LYMPHOCYTES	ACI-91	LOW	3	9.4	2	6.3	0	0	3	9.4
		NORMAL	2	6.3	18	56.3	0	0	4	12.5
		HIGH	0	0	0	0	0	0	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	2	6.5	2	6.5	0	0	2	6.5
		NORMAL	4	12.9	15	48.4	0	0	2	6.5
		HIGH	0	0	2	6.5	0	0	0	0
		MISSING	0	0	2	6.5	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.3: Hematology, shift tables

14FEB2013

Safety Population

Parameter	Treat-ment	V1 (Week 0)	V6 (WEEK 52) Low N	Low %	Normal N	Normal %	High N	High %	Missing N	Missing %
MONOCYTES	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	24	75.0	1	3.1	6	18.8
		HIGH	0	0	0	0	0	0	1	3.1
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	1	3.2	0	0	1	3.2
		NORMAL	1	3.2	20	64.5	0	0	3	9.7
		HIGH	0	0	2	6.5	1	3.2	0	0
		MISSING	0	0	2	6.5	0	0	0	0
EOSINOPHILS	ACI-91	LOW	4	12.5	0	0	0	0	2	6.3
		NORMAL	1	3.1	17	53.1	0	0	5	15.6
		HIGH	0	0	1	3.1	2	6.3	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	3	9.7	0	0	1	3.2
		NORMAL	7	22.6	15	48.4	0	0	2	6.5
		HIGH	0	0	0	0	0	0	1	3.2
		MISSING	0	0	2	6.5	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.3: Hematology, shift tables

 14FEB2013

Safety Population

			V6 (WEEK 52)							
			Low		Normal		High		Missing	
Parameter	Treat-ment	V1 (Week 0)	N	%	N	%	N	%	N	%
BASOPHILS	ACI-91	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	23	71.9	1	3.1	7	21.9
		HIGH	0	0	0	0	1	3.1	0	0
		MISSING	0	0	0	0	0	0	0	0
	Placebo	LOW	0	0	0	0	0	0	0	0
		NORMAL	0	0	22	71.0	0	0	4	12.9
		HIGH	0	0	3	9.7	0	0	0	0
		MISSING	0	0	2	6.5	0	0	0	0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
ERYTHROCYTES	ACI-91	SCREENING			6	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			5	100.0
	Placebo	SCREENING			2	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			5	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
HEMOGLOBIN	ACI-91	SCREENING			3	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			1	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			5	100.0
	Placebo	SCREENING			2	100.0
		V1 (WEEK 0)			1	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
HEMATOCRIT	ACI-91	SCREENING			6	100.0
		V1 (WEEK 0)			11	100.0
		V3 (WEEK 12)			7	100.0
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			8	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			5	100.0
	Placebo	SCREENING			6	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			6	100.0
		V5 (WEEK 36)			6	100.0
		V6 (WEEK 52)			7	100.0
		V7 (WEEK 56)			5	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
MCH (HbE)	ACI-91	SCREENING			7	100.0
		V1 (WEEK 0)			6	100.0
		V3 (WEEK 12)			7	100.0
		V4 (WEEK 24)			9	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			5	100.0
		V7 (WEEK 56)			7	100.0
	Placebo	SCREENING			5	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			3	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
MCHC	ACI-91	SCREENING			8	100.0
		V1 (WEEK 0)			12	100.0
		V3 (WEEK 12)			8	100.0
		V4 (WEEK 24)			9	100.0
		V5 (WEEK 36)			10	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			7	100.0
	Placebo	SCREENING			16	100.0
		V1 (WEEK 0)			12	100.0
		V3 (WEEK 12)			13	100.0
		V4 (WEEK 24)			11	100.0
		V5 (WEEK 36)			18	100.0
		V6 (WEEK 52)			8	100.0
		V7 (WEEK 56)			7	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
MCV	ACI-91	SCREENING			17	100.0
		V1 (WEEK 0)			16	100.0
		V3 (WEEK 12)			17	100.0
		V4 (WEEK 24)			16	100.0
		V5 (WEEK 36)			14	100.0
		V6 (WEEK 52)			13	100.0
		V7 (WEEK 56)			10	100.0
	Placebo	SCREENING			9	100.0
		V1 (WEEK 0)			9	100.0
		V3 (WEEK 12)			10	100.0
		V4 (WEEK 24)			12	100.0
		V5 (WEEK 36)			9	100.0
		V6 (WEEK 52)			11	100.0
		V7 (WEEK 56)			11	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
THROMBOCYTES	ACI-91	SCREENING			1	100.0
		V1 (WEEK 0)			2	100.0
		V3 (WEEK 12)			4	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			5	100.0
		V7 (WEEK 56)			4	100.0
	Placebo	SCREENING			1	100.0
		V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)			9	100.0
		V4 (WEEK 24)			7	100.0
		V5 (WEEK 36)			6	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
LEUKOCYTES	ACI-91	SCREENING	1	50.0	1	50.0
		V1 (WEEK 0)	1	25.0	3	75.0
		V3 (WEEK 12)			2	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			3	100.0
	Placebo	SCREENING			4	100.0
		V1 (WEEK 0)			6	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			6	100.0
		V5 (WEEK 36)			3	100.0
		V6 (WEEK 52)			4	100.0
		V7 (WEEK 56)			5	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
NEUTROPHILS	ACI-91	SCREENING			6	100.0
		V1 (WEEK 0)			7	100.0
		V3 (WEEK 12)			7	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			4	100.0
		V6 (WEEK 52)			5	100.0
		V7 (WEEK 56)			7	100.0
	Placebo	SCREENING			7	100.0
		V1 (WEEK 0)			6	100.0
		V3 (WEEK 12)			6	100.0
		V4 (WEEK 24)			7	100.0
		V5 (WEEK 36)			8	100.0
		V6 (WEEK 52)			7	100.0
		V7 (WEEK 56)	1	14.3	6	85.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
LYMPHOCYTES	ACI-91	SCREENING			10	100.0
		V1 (WEEK 0)			9	100.0
		V3 (WEEK 12)			9	100.0
		V4 (WEEK 24)			5	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			7	100.0
	Placebo	SCREENING			8	100.0
		V1 (WEEK 0)			8	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			7	100.0
		V5 (WEEK 36)			7	100.0
		V6 (WEEK 52)			6	100.0
		V7 (WEEK 56)			5	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
MONOCYTES	ACI-91	SCREENING			2	100.0
		V1 (WEEK 0)			2	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			2	100.0
		V5 (WEEK 36)			2	100.0
		V6 (WEEK 52)			2	100.0
		V7 (WEEK 56)			3	100.0
	Placebo	SCREENING			2	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)	1	25.0	3	75.0
		V4 (WEEK 24)			6	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			6	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
EOSINOPHILS	ACI-91	SCREENING	1	9.1	10	90.9
		V1 (WEEK 0)	1	10.0	9	90.0
		V3 (WEEK 12)	1	11.1	8	88.9
		V4 (WEEK 24)			6	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			7	100.0
		V7 (WEEK 56)			6	100.0
	Placebo	SCREENING			5	100.0
		V1 (WEEK 0)			5	100.0
		V3 (WEEK 12)			9	100.0
		V4 (WEEK 24)			8	100.0
		V5 (WEEK 36)			8	100.0
		V6 (WEEK 52)			8	100.0
		V7 (WEEK 56)			3	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.2.4: Hematology, frequency of abnormal values by clinical significance

 14FEB2013

Safety Population

Parameter	Treatment	Visit	Clinically significant N	Clinically significant %	Not clinically significant N	Not clinically significant %
BASOPHILS	ACI-91	SCREENING			2	100.0
		V1 (WEEK 0)			2	100.0
		V3 (WEEK 12)			3	100.0
		V4 (WEEK 24)			3	100.0
		V5 (WEEK 36)			5	100.0
		V6 (WEEK 52)			3	100.0
		V7 (WEEK 56)			5	100.0
	Placebo	SCREENING			2	100.0
		V1 (WEEK 0)			3	100.0
		V3 (WEEK 12)			5	100.0
		V4 (WEEK 24)			4	100.0
		V5 (WEEK 36)			1	100.0
		V6 (WEEK 52)			1	100.0
		V7 (WEEK 56)			2	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.1: Urinalysis, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
pH-VALUE	ACI-91	SCREENING			32	100.0		
		V1 (WEEK 0)			29	96.7	1	3.3
		V3 (WEEK 12)			27	93.1	2	6.9
		V4 (WEEK 24)			22	100.0		
		V5 (WEEK 36)			13	100.0		
		V6 (WEEK 52)			22	91.7	2	8.3
		V7 (WEEK 56)			21	100.0		
	Placebo	SCREENING			31	100.0		
		V1 (WEEK 0)			29	96.7	1	3.3
		V3 (WEEK 12)			30	96.8	1	3.2
		V4 (WEEK 24)			31	100.0		
		V5 (WEEK 36)			18	100.0		
		V6 (WEEK 52)			23	92.0	2	8.0
		V7 (WEEK 56)			25	100.0		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.1: Urinalysis, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
PROTEIN	ACI-91	SCREENING			25	80.6	6	19.4
		V1 (WEEK 0)			25	86.2	4	13.8
		V3 (WEEK 12)			27	93.1	2	6.9
		V4 (WEEK 24)			18	81.8	4	18.2
		V5 (WEEK 36)			12	92.3	1	7.7
		V6 (WEEK 52)			22	91.7	2	8.3
		V7 (WEEK 56)			19	90.5	2	9.5
	Placebo	SCREENING			28	90.3	3	9.7
		V1 (WEEK 0)			27	90.0	3	10.0
		V3 (WEEK 12)			25	80.6	6	19.4
		V4 (WEEK 24)			22	73.3	8	26.7
		V5 (WEEK 36)			16	88.9	2	11.1
		V6 (WEEK 52)			20	80.0	5	20.0
		V7 (WEEK 56)			18	72.0	7	28.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.1: Urinalysis, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
GLUCOSE	ACI-91	SCREENING			29	93.5	2	6.5
		V1 (WEEK 0)			29	100.0		
		V3 (WEEK 12)			28	96.6	1	3.4
		V4 (WEEK 24)			22	100.0		
		V5 (WEEK 36)			13	100.0		
		V6 (WEEK 52)			23	95.8	1	4.2
		V7 (WEEK 56)			21	100.0		
	Placebo	SCREENING			30	96.8	1	3.2
		V1 (WEEK 0)			28	93.3	2	6.7
		V3 (WEEK 12)			31	100.0		
		V4 (WEEK 24)			28	93.3	2	6.7
		V5 (WEEK 36)			17	94.4	1	5.6
		V6 (WEEK 52)			23	92.0	2	8.0
		V7 (WEEK 56)			24	96.0	1	4.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.1: Urinalysis, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
KETONES	ACI-91	SCREENING			28	87.5	4	12.5
		V1 (WEEK 0)			28	93.3	2	6.7
		V3 (WEEK 12)			28	96.6	1	3.4
		V4 (WEEK 24)			21	95.5	1	4.5
		V5 (WEEK 36)			13	100.0		
		V6 (WEEK 52)			22	91.7	2	8.3
		V7 (WEEK 56)			19	90.5	2	9.5
	Placebo	SCREENING			28	90.3	3	9.7
		V1 (WEEK 0)			26	86.7	4	13.3
		V3 (WEEK 12)			29	93.5	2	6.5
		V4 (WEEK 24)			25	80.6	6	19.4
		V5 (WEEK 36)			14	77.8	4	22.2
		V6 (WEEK 52)			21	84.0	4	16.0
		V7 (WEEK 56)			22	88.0	3	12.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.1: Urinalysis, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
BLOOD	ACI-91	SCREENING			26	81.3	6	18.8
		V1 (WEEK 0)			26	86.7	4	13.3
		V3 (WEEK 12)			24	82.8	5	17.2
		V4 (WEEK 24)			18	81.8	4	18.2
		V5 (WEEK 36)			10	76.9	3	23.1
		V6 (WEEK 52)			17	70.8	7	29.2
		V7 (WEEK 56)			17	81.0	4	19.0
	Placebo	SCREENING			22	71.0	9	29.0
		V1 (WEEK 0)			24	80.0	6	20.0
		V3 (WEEK 12)			26	83.9	5	16.1
		V4 (WEEK 24)			23	74.2	8	25.8
		V5 (WEEK 36)			13	72.2	5	27.8
		V6 (WEEK 52)			20	80.0	5	20.0
		V7 (WEEK 56)			16	64.0	9	36.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.1: Urinalysis, number of values out of reference range

 14FEB2013

Safety Population

Parameter	Treat-ment	Visit	Low N	Low %	Normal N	Normal %	High N	High %
LEUKOCYTES	ACI-91	SCREENING			22	71.0	9	29.0
		V1 (WEEK 0)			22	75.9	7	24.1
		V3 (WEEK 12)			18	62.1	11	37.9
		V4 (WEEK 24)			11	50.0	11	50.0
		V5 (WEEK 36)			6	46.2	7	53.8
		V6 (WEEK 52)			11	45.8	13	54.2
		V7 (WEEK 56)			11	52.4	10	47.6
	Placebo	SCREENING			21	67.7	10	32.3
		V1 (WEEK 0)			21	70.0	9	30.0
		V3 (WEEK 12)			22	71.0	9	29.0
		V4 (WEEK 24)			21	70.0	9	30.0
		V5 (WEEK 36)			10	55.6	8	44.4
		V6 (WEEK 52)			17	68.0	8	32.0
		V7 (WEEK 56)			15	60.0	10	40.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.4.3.2: Urinalysis, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
pH-VALUE		006	Male	ACI-91	V3 (WEEK 12)	85	8.0	H	NO	5.0 - 7.0
		013	Female	Placebo	V6 (WEEK 52)	366	8.0	H	NO	5.0 - 7.0
		032	Female	ACI-91	V3 (WEEK 12)	82	8.0	H	NO	5.0 - 7.0
		044	Female	Placebo	V1 (WEEK 0)	1	8.0	H	NO	5.0 - 7.0
		056	Female	Placebo	V3 (WEEK 12)	84	9.0	H	NO	5.0 - 7.0
		071	Female	ACI-91	V1 (WEEK 0)	1	8.0	H	NO	5.0 - 7.0
					V6 (WEEK 52)	374	8.0	H	NO	5.0 - 7.0
		072	Female	Placebo	V6 (WEEK 52)	360	8.0	H	NO	5.0 - 7.0
		080	Female	ACI-91	V6 (WEEK 52)	196	8.0	H	NO	5.0 - 7.0
PROTEIN	mg/L	010	Male	ACI-91	V1 (WEEK 0)	1	250	H	NO	< 150
		011	Female	Placebo	V6 (WEEK 52)	366	250	H	NO	< 150
					V7 (WEEK 56)	397	750	H	YES	< 150

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
PROTEIN	mg/L	012	Male	ACI-91	SCREENING	-32	250	H	NO	< 150
					V1 (WEEK 0)	1	250	H	NO	< 150
		014	Male	ACI-91	V4 (WEEK 24)	172	250	H	NO	< 150
					V6 (WEEK 52)	361	250	H	NO	< 150
		015	Female	ACI-91	V5 (WEEK 36)	248	250	H	NO	< 150
		016	Male	Placebo	V3 (WEEK 12)	80	250	H	NO	< 150
					V4 (WEEK 24)	162	250	H	NO	< 150
					V6 (WEEK 52)	365	250	H	NO	< 150
					V7 (WEEK 56)	403	250	H	NO	< 150
		024	Male	Placebo	V3 (WEEK 12)	87	250	H	NO	< 150
					V4 (WEEK 24)	171	250	H	NO	< 150
					V6 (WEEK 52)	358	250	H		< 150
					V7 (WEEK 56)	393	250	H	NO	< 150
		027	Female	ACI-91	V4 (WEEK 24)	174	250	H	NO	< 150
		028	Female	Placebo	SCREENING	-8	250	H	NO	< 150

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
PROTEIN	mg/L	028	Female	Placebo	V1 (WEEK 0)	1	250	H	NO	< 150
					V3 (WEEK 12)	89	250	H	YES	< 150
					V4 (WEEK 24)	180	250	H	NO	< 150
					V5 (WEEK 36)	273	250	H	NO	< 150
					V6 (WEEK 52)	364	250	H	NO	< 150
					V7 (WEEK 56)	390	250	H	NO	< 150
		034	Female	Placebo	SCREENING	-22	250	H	NO	< 150
					V7 (WEEK 56)	399	250	H	NO	< 150
		041	Male	Placebo	V4 (WEEK 24)	167	250	H	NO	< 150
					V7 (WEEK 56)	392	250	H	NO	< 150
		046	Female	ACI-91	SCREENING	-28	750	H	YES	< 150
					V7 (WEEK 56)	393	250	H	YES	< 150
		049	Female	Placebo	V4 (WEEK 24)	168	250	H	NO	< 150
					V5 (WEEK 36)	252	750	H	NO	< 150
		050	Female	ACI-91	V4 (WEEK 24)	167	250	H	NO	< 150

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
PROTEIN	mg/L	051	Female	Placebo	V1 (WEEK 0)	1	250	H	NO	< 150
					V3 (WEEK 12)	97	250	H	NO	< 150
					V6 (WEEK 52)	363	250	H	NO	< 150
					V7 (WEEK 56)	391	750	H	NO	< 150
		052	Female	ACI-91	SCREENING	-52	250	H	NO	< 150
					V1 (WEEK 0)	1	250	H	NO	< 150
					V7 (WEEK 56)	390	250	H	NO	< 150
		058	Male	Placebo	SCREENING	-21	250	H	NO	< 150
					V3 (WEEK 12)	93	250	H	NO	< 150
					V4 (WEEK 24)	166	250	H	NO	< 150
		065	Male	Placebo	V1 (WEEK 0)	1	250	H	NO	< 150
		068	Male	Placebo	V4 (WEEK 24)	163	250	H	NO	< 150
		069	Male	Placebo	V3 (WEEK 12)	93	250	H	NO	< 150
		071	Female	ACI-91	SCREENING	-20	250	H	NO	< 150

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

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Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
PROTEIN	mg/L	081	Male	ACI-91	V6 (WEEK 52)	376	250	H	NO	< 150
		083	Female	ACI-91	V4 (WEEK 24)	168	250	H	NO	< 150
		084	Female	Placebo	V4 (WEEK 24)	175	250	H	NO	< 150
		089	Female	ACI-91	SCREENING	-28	250	H	NO	< 150
		093	Female	ACI-91	V3 (WEEK 12)	86	250	H	NO	< 150
		097	Male	ACI-91	SCREENING	-21	250	H	NO	< 150
					V1 (WEEK 0)	1	250	H	NO	< 150
					V3 (WEEK 12)	85	250	H	NO	< 150
GLUCOSE	mmol/L	009	Female	Placebo	SCREENING	-33	56.7	H	NO	< 0.8
					V1 (WEEK 0)	1	5.7	H	NO	< 0.8
					V4 (WEEK 24)	178	56.7	H	NO	< 0.8
					V5 (WEEK 36)	246	2.8	H	NO	< 0.8
					V6 (WEEK 52)	361	56.7	H	NO	< 0.8
					V7 (WEEK 56)	389	56.7	H	NO	< 0.8

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
GLUCOSE	mmol/L	043	Male	ACI-91	SCREENING	-28	2.8	H	NO	< 0.8
		046	Female	ACI-91	V6 (WEEK 52)	367	2.8	H	NO	< 0.8
		059	Male	Placebo	V1 (WEEK 0)	1	17.0	H	NO	< 0.8
					V4 (WEEK 24)	161	17.0	H	NO	< 0.8
					V6 (WEEK 52)	345	5.7	H	NO	< 0.8
		066	Male	ACI-91	V3 (WEEK 12)	83	2.8	H	NO	< 0.8
		071	Female	ACI-91	SCREENING	-20	17.0	H	NO	< 0.8
KETONES	mmol/L	009	Female	Placebo	V4 (WEEK 24)	178	1.5	H	NO	< 0.5
					V6 (WEEK 52)	361	0.5	H	NO	< 0.5
					V7 (WEEK 56)	389	0.5	H	NO	< 0.5
		010	Male	ACI-91	V1 (WEEK 0)	1	0.5	H	NO	< 0.5
		011	Female	Placebo	V1 (WEEK 0)	1	0.5	H	NO	< 0.5
					V4 (WEEK 24)	162	5.0	H	NO	< 0.5
					V5 (WEEK 36)	253	0.5	H	NO	< 0.5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
KETONES	mmol/L	011	Female	Placebo	V6 (WEEK 52)	366	1.5	H	NO	< 0.5
					V7 (WEEK 56)	397	0.5	H	NO	< 0.5
		013	Female	Placebo	V5 (WEEK 36)	247	0.5	H	NO	< 0.5
		014	Male	ACI-91	V6 (WEEK 52)	361	0.5	H	NO	< 0.5
		016	Male	Placebo	V6 (WEEK 52)	365	0.5	H	NO	< 0.5
		027	Female	ACI-91	V4 (WEEK 24)	174	0.5	H	YES	< 0.5
		028	Female	Placebo	SCREENING	-8	0.5	H	NO	< 0.5
					V1 (WEEK 0)	1	0.5	H	NO	< 0.5
					V3 (WEEK 12)	89	0.5	H	YES	< 0.5
					V5 (WEEK 36)	273	0.5	H	NO	< 0.5
		031	Male	Placebo	V1 (WEEK 0)	1	0.5	H	NO	< 0.5
		033	Female	ACI-91	V6 (WEEK 52)	372	0.5	H	NO	< 0.5
		046	Female	ACI-91	SCREENING	-28	0.5	H	NO	< 0.5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
KETONES	mmol/L	046	Female	ACI-91	V7 (WEEK 56)	393	0.5	H	NO	< 0.5
		049	Female	Placebo	V4 (WEEK 24)	168	0.5	H	NO	< 0.5
					V5 (WEEK 36)	252	0.5	H	NO	< 0.5
		051	Female	Placebo	V1 (WEEK 0)	1	0.5	H	NO	< 0.5
					V3 (WEEK 12)	97	0.5	H	NO	< 0.5
					V6 (WEEK 52)	363	0.5	H	NO	< 0.5
					V7 (WEEK 56)	391	0.5	H	NO	< 0.5
		052	Female	ACI-91	SCREENING	-52	0.5	H	NO	< 0.5
					V7 (WEEK 56)	390	0.5	H	NO	< 0.5
		059	Male	Placebo	SCREENING	-2	0.5	H	NO	< 0.5
		065	Male	Placebo	V4 (WEEK 24)	141	1.5	H	NO	< 0.5
		071	Female	ACI-91	SCREENING	-20	0.5	H	NO	< 0.5
		072	Female	Placebo	V4 (WEEK 24)	169	0.5	H	NO	< 0.5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
KETONES	mmol/L	080	Female	ACI-91	SCREENING	-10	0.5	H	NO	< 0.5
					V1 (WEEK 0)	1	1.5	H	NO	< 0.5
					V3 (WEEK 12)	84	1.5	H	NO	< 0.5
		084	Female	Placebo	SCREENING	-9	0.5	H	NO	< 0.5
					V4 (WEEK 24)	175	0.5	H	NO	< 0.5
BLOOD	/µL	001	Female	Placebo	SCREENING	-7	10	H	NO	< 5
					V5 (WEEK 36)	246	10	H	NO	< 5
					V6 (WEEK 52)	365	10	H	NO	< 5
					V7 (WEEK 56)	393	10	H	NO	< 5
		005	Female	Placebo	V6 (WEEK 52)	364	10	H	NO	< 5
					V7 (WEEK 56)	400	10	H	NO	< 5
		011	Female	Placebo	V6 (WEEK 52)	366	10	H	NO	< 5
					V7 (WEEK 56)	397	10	H	NO	< 5
		013	Female	Placebo	V4 (WEEK 24)	170	10	H	NO	< 5
					V5 (WEEK 36)	247	10	H	NO	< 5
					V7 (WEEK 56)	400	10	H	NO	< 5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BLOOD	/µL	015	Female	ACI-91	SCREENING	-32	10	H	NO	< 5
					V5 (WEEK 36)	248	10	H	NO	< 5
					V6 (WEEK 52)	365	10	H	NO	< 5
					V7 (WEEK 56)	394	10	H	NO	< 5
		017	Male	ACI-91	V1 (WEEK 0)	1	10	H	NO	< 5
					V4 (WEEK 24)	169	25	H	NO	< 5
					V5 (WEEK 36)	252	10	H	NO	< 5
					V7 (WEEK 56)	392	25	H	NO	< 5
		024	Male	Placebo	SCREENING	-31	10	H	NO	< 5
		027	Female	ACI-91	V4 (WEEK 24)	174	10	H	YES	< 5
		028	Female	Placebo	SCREENING	-8	10	H	NO	< 5
					V3 (WEEK 12)	89	10	H	YES	< 5
		029	Female	Placebo	V7 (WEEK 56)	391	10	H	YES	< 5
		033	Female	ACI-91	V3 (WEEK 12)	78	10	H	NO	< 5
					V6 (WEEK 52)	372	10	H	NO	< 5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BLOOD	/µL	033	Female	ACI-91	V7 (WEEK 56)	398	10	H	NO	< 5
		034	Female	Placebo	SCREENING	-22	10	H	NO	< 5
					V1 (WEEK 0)	1	10	H	NO	< 5
					V3 (WEEK 12)	83	10	H	NO	< 5
					V7 (WEEK 56)	399	10	H	NO	< 5
		042	Female	ACI-91	V3 (WEEK 12)	126	10	H	NO	< 5
					V6 (WEEK 52)	364	10	H	NO	< 5
		044	Female	Placebo	V4 (WEEK 24)	176	10	H	NO	< 5
					V5 (WEEK 36)	260	10	H	NO	< 5
					V7 (WEEK 56)	400	10	H	NO	< 5
		046	Female	ACI-91	SCREENING	-28	10	H	NO	< 5
		049	Female	Placebo	V3 (WEEK 12)	84	10	H	NO	< 5
					V4 (WEEK 24)	168	10	H	NO	< 5
					V5 (WEEK 36)	252	10	H	NO	< 5
		050	Female	ACI-91	V6 (WEEK 52)	363	10	H	NO	< 5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BLOOD	/µL	051	Female	Placebo	SCREENING	-52	10	H	NO	< 5
					V1 (WEEK 0)	1	10	H	NO	< 5
					V3 (WEEK 12)	97	10	H	NO	< 5
					V4 (WEEK 24)	167	10	H	NO	< 5
					V6 (WEEK 52)	363	10	H	NO	< 5
					V7 (WEEK 56)	391	10	H	NO	< 5
		052	Female	ACI-91	SCREENING	-52	10	H	NO	< 5
					V7 (WEEK 56)	390	10	H	NO	< 5
		055	Female	ACI-91	SCREENING	-21	10	H	NO	< 5
					V6 (WEEK 52)	30	10	H	NO	< 5
		057	Female	ACI-91	V1 (WEEK 0)	1	10	H	NO	< 5
					V3 (WEEK 12)	82	10	H	NO	< 5
		058	Male	Placebo	SCREENING	-21	10	H	NO	< 5
					V1 (WEEK 0)	1	10	H	NO	< 5
					V6 (WEEK 52)	345	10	H	YES	< 5
		065	Male	Placebo	V1 (WEEK 0)	1	10	H	NO	< 5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BLOOD	/µL	065	Male	Placebo	V4 (WEEK 24)	141	10	H	NO	< 5
		068	Male	Placebo	SCREENING	-27	10	H	NO	< 5
					V1 (WEEK 0)	1	10	H	NO	< 5
					V3 (WEEK 12)	81	10	H	YES	< 5
		069	Male	Placebo	SCREENING	-13	10	H	NO	< 5
					V1 (WEEK 0)	1	10	H	NO	< 5
					V4 (WEEK 24)	164	25	H	NO	< 5
		071	Female	ACI-91	SCREENING	-20	50	H	NO	< 5
					V1 (WEEK 0)	1	10	H	NO	< 5
					V3 (WEEK 12)	87	25	H	NO	< 5
					V4 (WEEK 24)	177	10	H	NO	< 5
					V5 (WEEK 36)	253	10	H	NO	< 5
					V6 (WEEK 52)	374	25	H	NO	< 5
		072	Female	Placebo	V4 (WEEK 24)	169	10	H	NO	< 5
					V5 (WEEK 36)	262	10	H	NO	< 5
		079	Female	Placebo	SCREENING	-18	10	H	NO	< 5

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
BLOOD	/µL	079	Female	Placebo	V4 (WEEK 24)	175	10	H	NO	< 5
		081	Male	ACI-91	V3 (WEEK 12)	89	10	H	NO	< 5
		083	Female	ACI-91	SCREENING	-15	10	H	NO	< 5
					V4 (WEEK 24)	168	10	H	NO	< 5
		084	Female	Placebo	V7 (WEEK 56)	394	10	H	NO	< 5
		089	Female	ACI-91	V1 (WEEK 0)	1	10	H	NO	< 5
					V6 (WEEK 52)	364	10	H	NO	< 5
LEUKOCYTES	/µL	002	Female	ACI-91	V6 (WEEK 52)	365	25	H	NO	< 20
		005	Female	Placebo	V7 (WEEK 56)	400	25	H	NO	< 20
		006	Male	ACI-91	V6 (WEEK 52)	364	25	H	NO	< 20
		009	Female	Placebo	V5 (WEEK 36)	246	25	H	NO	< 20
		010	Male	ACI-91	V1 (WEEK 0)	1	25	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	011	Female	Placebo	SCREENING	-21	25	H	NO	< 20
					V3 (WEEK 12)	85	25	H	NO	< 20
					V6 (WEEK 52)	366	500	H	NO	< 20
					V7 (WEEK 56)	397	500	H	YES	< 20
		013	Female	Placebo	V5 (WEEK 36)	247	25	H	NO	< 20
		015	Female	ACI-91	SCREENING	-32	25	H	NO	< 20
					V1 (WEEK 0)	1	100	H	NO	< 20
					V3 (WEEK 12)	85	100	H	NO	< 20
					V4 (WEEK 24)	162	25	H	NO	< 20
					V5 (WEEK 36)	248	500	H	NO	< 20
					V6 (WEEK 52)	365	500	H	NO	< 20
					V7 (WEEK 56)	394	25	H	NO	< 20
		016	Male	Placebo	V6 (WEEK 52)	365	25	H	NO	< 20
		019	Male	ACI-91	V6 (WEEK 52)	364	25	H	NO	< 20
		024	Male	Placebo	SCREENING	-31	25	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	027	Female	ACI-91	SCREENING	-21	25	H	NO	< 20
					V3 (WEEK 12)	92	25	H	NO	< 20
					V4 (WEEK 24)	174	100	H	YES	< 20
					V5 (WEEK 36)	259	25	H	NO	< 20
					V6 (WEEK 52)	370	100	H	YES	< 20
					V7 (WEEK 56)	407	25	H	NO	< 20
		028	Female	Placebo	SCREENING	-8	25	H	NO	< 20
					V1 (WEEK 0)	1	25	H	NO	< 20
					V3 (WEEK 12)	89	25	H	YES	< 20
					V5 (WEEK 36)	273	25	H	NO	< 20
		029	Female	Placebo	V1 (WEEK 0)	1	25	H	YES	< 20
					V4 (WEEK 24)	158	100	H	YES	< 20
					V6 (WEEK 52)	369	25	H	YES	< 20
					V7 (WEEK 56)	391	25	H	YES	< 20
		030	Female	ACI-91	V3 (WEEK 12)	85	25	H	YES	< 20
					V4 (WEEK 24)	163	25	H	NO	< 20
					V6 (WEEK 52)	355	100	H	YES	< 20
					V7 (WEEK 56)	383	25	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

 14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	033	Female	ACI-91	V5 (WEEK 36)	261	25	H	NO	< 20
					V7 (WEEK 56)	398	25	H	NO	< 20
		034	Female	Placebo	SCREENING	-22	100	H	NO	< 20
					V1 (WEEK 0)	1	100	H	NO	< 20
					V3 (WEEK 12)	83	25	H	NO	< 20
					V4 (WEEK 24)	175	100	H	NO	< 20
					V5 (WEEK 36)	258	25	H	NO	< 20
					V7 (WEEK 56)	399	25	H	NO	< 20
		041	Male	Placebo	V7 (WEEK 56)	392	25	H	NO	< 20
		042	Female	ACI-91	V4 (WEEK 24)	168	25	H	NO	< 20
					V5 (WEEK 36)	252	25	H	NO	< 20
					V6 (WEEK 52)	364	500	H	NO	< 20
					V7 (WEEK 56)	391	500	H	NO	< 20
		044	Female	Placebo	V1 (WEEK 0)	1	25	H	NO	< 20
					V3 (WEEK 12)	85	25	H	NO	< 20
					V4 (WEEK 24)	176	100	H	NO	< 20
					V5 (WEEK 36)	260	500	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	044	Female	Placebo	V6 (WEEK 52)	365	100	H	NO	< 20
					V7 (WEEK 56)	400	25	H	NO	< 20
		045	Male	Placebo	V7 (WEEK 56)	393	25	H	NO	< 20
		046	Female	ACI-91	V7 (WEEK 56)	393	25	H	NO	< 20
		048	Male	ACI-91	V3 (WEEK 12)	86	25	H	NO	< 20
					V7 (WEEK 56)	395	25	H	NO	< 20
		049	Female	Placebo	SCREENING	-51	25	H	NO	< 20
					V1 (WEEK 0)	1	100	H	NO	< 20
					V3 (WEEK 12)	84	25	H	NO	< 20
					V4 (WEEK 24)	168	500	H	NO	< 20
					V5 (WEEK 36)	252	25	H	NO	< 20
		050	Female	ACI-91	V1 (WEEK 0)	1	500	H	NO	< 20
					V3 (WEEK 12)	83	100	H	NO	< 20
					V4 (WEEK 24)	167	25	H	NO	< 20
					V5 (WEEK 36)	251	25	H	NO	< 20
					V6 (WEEK 52)	363	500	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	050	Female	ACI-91	V7 (WEEK 56)	391	25	H	NO	< 20
		051	Female	Placebo	SCREENING	-52	100	H	NO	< 20
					V1 (WEEK 0)	1	500	H	NO	< 20
					V3 (WEEK 12)	97	500	H	NO	< 20
					V4 (WEEK 24)	167	500	H	NO	< 20
					V5 (WEEK 36)	251	500	H	NO	< 20
					V6 (WEEK 52)	363	500	H	NO	< 20
					V7 (WEEK 56)	391	500	H	NO	< 20
		052	Female	ACI-91	SCREENING	-52	100	H	NO	< 20
					V1 (WEEK 0)	1	25	H	NO	< 20
					V3 (WEEK 12)	82	100	H	NO	< 20
					V4 (WEEK 24)	166	25	H	NO	< 20
					V5 (WEEK 36)	250	500	H	NO	< 20
					V6 (WEEK 52)	362	100	H	NO	< 20
					V7 (WEEK 56)	390	25	H	NO	< 20
		056	Female	Placebo	V6 (WEEK 52)	364	25	H	NO	< 20
		057	Female	ACI-91	SCREENING	-21	25	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	057	Female	ACI-91	V1 (WEEK 0)	1	100	H	NO	< 20
					V3 (WEEK 12)	82	100	H	NO	< 20
					V4 (WEEK 24)	170	25	H	NO	< 20
		067	Female	ACI-91	SCREENING	-16	25	H	NO	< 20
					V1 (WEEK 0)	1	25	H	NO	< 20
		068	Male	Placebo	SCREENING	-27	25	H	NO	< 20
					V1 (WEEK 0)	1	25	H	NO	< 20
					V3 (WEEK 12)	81	100	H	YES	< 20
		069	Male	Placebo	V4 (WEEK 24)	164	25	H	NO	< 20
		071	Female	ACI-91	SCREENING	-20	25	H	NO	< 20
					V4 (WEEK 24)	177	25	H	NO	< 20
		072	Female	Placebo	V5 (WEEK 36)	262	25	H	NO	< 20
		079	Female	Placebo	SCREENING	-18	500	H	NO	< 20
					V1 (WEEK 0)	1	25	H	NO	< 20
					V3 (WEEK 12)	96	25	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	079	Female	Placebo	V4 (WEEK 24)	175	100	H	NO	< 20
		081	Male	ACI-91	SCREENING	-10	25	H	NO	< 20
					V3 (WEEK 12)	89	25	H	NO	< 20
					V6 (WEEK 52)	376	25	H	NO	< 20
		082	Male	Placebo	SCREENING	-8	25	H	NO	< 20
					V6 (WEEK 52)	364	25	H	NO	< 20
					V7 (WEEK 56)	407	25	H	NO	< 20
		083	Female	ACI-91	SCREENING	-15	500	H	NO	< 20
					V4 (WEEK 24)	168	500	H	NO	< 20
					V5 (WEEK 36)	258	100	H	NO	< 20
					V6 (WEEK 52)	365	25	H	NO	< 20
		084	Female	Placebo	SCREENING	-9	100	H	NO	< 20
					V4 (WEEK 24)	175	25	H	NO	< 20
					V6 (WEEK 52)	371	25	H	NO	< 20
					V7 (WEEK 56)	394	25	H	NO	< 20
		086	Female	Placebo	V1 (WEEK 0)	1	100	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.4.3.2: Urinalysis, values out of reference range

14FEB2013

Safety Population

Parameter	Unit	Random No.	Gender	Treatment	Visit	Actual day	Value	L/H	Clinically significant	Reference range
LEUKOCYTES	/µL	087	Female	ACI-91	V3 (WEEK 12)	81	25	H	NO	< 20
					V4 (WEEK 24)	169	25	H	NO	< 20
					V6 (WEEK 52)	365	25	H	NO	< 20
		088	Female	Placebo	V3 (WEEK 12)	83	25	H	NO	< 20
					V4 (WEEK 24)	162	25	H	NO	< 20
		089	Female	ACI-91	V1 (WEEK 0)	1	500	H	NO	< 20
					V3 (WEEK 12)	84	25	H	NO	< 20
					V6 (WEEK 52)	364	100	H	NO	< 20
		093	Female	ACI-91	SCREENING	-3	100	H	NO	< 20
					V3 (WEEK 12)	86	100	H	NO	< 20
					V4 (WEEK 24)	173	25	H	NO	< 20
					V7 (WEEK 56)	392	25	H	NO	< 20

V6 (WEEK 52) does also include assessments performed due to early termination
L/H = Below lower/above upper limit

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SODIUM [mmol/L]
Reference Range: 135 - 150 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	142.3	2.56	1.8	139	142.0	148
		V1 (WEEK 0)	13	142.6	2.06	1.4	139	143.0	147
		V3 (WEEK 12)	13	142.5	2.03	1.4	139	143.0	145
		V4 (WEEK 24)	8	142.0	2.00	1.4	138	143.0	144
		V5 (WEEK 36)	8	141.1	1.96	1.4	137	141.5	143
		V6 (WEEK 52)	8	140.3	3.20	2.3	133	140.5	143
		V7 (WEEK 56)	8	141.0	2.07	1.5	137	141.5	144
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.1	2.53		-4	-1.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.3	2.55		-4	0.0	4
		V5 (WEEK 36) - V1 (WEEK 0)	8	-1.4	2.07		-6	-1.0	1
		V6 (WEEK 52) - V1 (WEEK 0)	8	-2.3	3.85		-11	-1.0	1
		V7 (WEEK 56) - V1 (WEEK 0)	8	-1.5	2.45		-7	-1.0	1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SODIUM [mmol/L]
Reference Range: 135 - 150 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	141.6	3.20	2.3	135	141.0	146
		V1 (WEEK 0)	19	141.2	3.44	2.4	130	142.0	145
		V3 (WEEK 12)	16	140.9	3.53	2.5	131	141.5	147
		V4 (WEEK 24)	15	141.2	3.00	2.1	133	141.0	146
		V5 (WEEK 36)	14	141.0	3.11	2.2	135	141.0	146
		V6 (WEEK 52)	17	142.2	2.38	1.7	139	142.0	149
		V7 (WEEK 56)	15	141.7	2.64	1.9	139	142.0	148
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.3	2.72		-6	-0.5	3
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.1	2.80		-4	1.0	5
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.1	4.68		-9	-1.0	11
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.9	3.74		-4	0.0	9
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.4	3.92		-5	0.0	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SODIUM [mmol/L]
Reference Range: 135 - 150 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	141.9	2.93	2.1	135	142.0	148
		V1 (WEEK 0)	32	141.8	3.00	2.1	130	142.0	147
		V3 (WEEK 12)	29	141.7	3.02	2.1	131	142.0	147
		V4 (WEEK 24)	23	141.5	2.68	1.9	133	142.0	146
		V5 (WEEK 36)	22	141.0	2.70	1.9	135	141.0	146
		V6 (WEEK 52)	25	141.6	2.75	1.9	133	141.0	149
		V7 (WEEK 56)	23	141.4	2.43	1.7	137	142.0	148
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.2	2.59		-6	-1.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.0	2.66		-4	1.0	5
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.5	3.92		-9	-1.0	11
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.1	3.98		-11	-1.0	9
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.3	3.54		-7	-1.0	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SODIUM [mmol/L]
Reference Range: 135 - 150 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	141.0	2.34	1.7	137	141.0	145
		V1 (WEEK 0)	12	141.3	2.10	1.5	138	141.0	145
		V3 (WEEK 12)	12	141.8	1.27	0.9	140	142.0	144
		V4 (WEEK 24)	12	142.3	2.38	1.7	139	142.0	146
		V5 (WEEK 36)	11	141.6	2.01	1.4	139	141.0	145
		V6 (WEEK 52)	11	142.3	2.37	1.7	138	142.0	146
		V7 (WEEK 56)	11	141.5	1.92	1.4	139	141.0	145
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.5	2.78		-5	1.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.9	2.39		-3	0.5	5
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.2	3.60		-6	0.0	4
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.8	2.93		-4	0.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	11	0.0	3.77		-6	0.0	5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SODIUM [mmol/L]
Reference Range: 135 - 150 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	143.0	3.37	2.4	134	143.0	149
		V1 (WEEK 0)	19	142.7	3.23	2.3	133	144.0	146
		V3 (WEEK 12)	19	142.8	3.18	2.2	133	143.0	147
		V4 (WEEK 24)	19	142.5	2.41	1.7	137	143.0	147
		V5 (WEEK 36)	18	141.6	3.26	2.3	135	142.0	147
		V6 (WEEK 52)	16	141.7	3.16	2.2	134	141.5	147
		V7 (WEEK 56)	16	142.8	1.91	1.3	139	143.0	146
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.2	2.43		-5	0.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.2	3.93		-5	-1.0	9
		V5 (WEEK 36) - V1 (WEEK 0)	18	-1.1	4.02		-9	-1.0	8
		V6 (WEEK 52) - V1 (WEEK 0)	16	-1.0	3.18		-7	-1.5	6
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.4	3.44		-4	-1.0	6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

14FEB2013

Safety Population

Parameter: SODIUM [mmol/L]
Reference Range: 135 - 150 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	142.2	3.13	2.2	134	142.0	149
		V1 (WEEK 0)	31	142.2	2.89	2.0	133	142.0	146
		V3 (WEEK 12)	31	142.5	2.63	1.8	133	143.0	147
		V4 (WEEK 24)	31	142.4	2.36	1.7	137	143.0	147
		V5 (WEEK 36)	29	141.6	2.81	2.0	135	141.0	147
		V6 (WEEK 52)	27	141.9	2.83	2.0	134	142.0	147
		V7 (WEEK 56)	27	142.2	1.99	1.4	139	142.0	146
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.3	2.53		-5	1.0	4
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.3	3.42		-5	0.0	9
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.6	3.85		-9	-1.0	8
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.3	3.16		-7	-1.0	6
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.2	3.51		-6	-1.0	6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: POTASSIUM [mmol/L]
Reference Range: 3.5 - 5.4 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	4.51	0.452	10.02	4.0	4.40	5.3
		V1 (WEEK 0)	13	4.49	0.425	9.46	3.9	4.40	5.1
		V3 (WEEK 12)	13	4.35	0.355	8.17	3.9	4.20	5.1
		V4 (WEEK 24)	8	4.39	0.247	5.64	4.1	4.40	4.8
		V5 (WEEK 36)	8	4.34	0.389	8.97	4.1	4.15	5.2
		V6 (WEEK 52)	8	4.39	0.439	10.00	3.6	4.35	4.9
		V7 (WEEK 56)	8	4.34	0.302	6.96	3.7	4.35	4.6
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.15	0.285		-0.6	-0.20	0.3
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.04	0.350		-0.6	0.00	0.5
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.03	0.354		-0.5	-0.05	0.6
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.03	0.381		-0.4	0.05	0.4
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.03	0.396		-0.8	0.10	0.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: POTASSIUM [mmol/L]
Reference Range: 3.5 - 5.4 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	4.38	0.484	11.05	3.7	4.30	5.4
		V1 (WEEK 0)	19	4.40	0.387	8.80	3.8	4.30	5.1
		V3 (WEEK 12)	16	4.42	0.572	12.94	3.2	4.45	5.2
		V4 (WEEK 24)	15	4.39	0.538	12.27	3.1	4.40	5.3
		V5 (WEEK 36)	14	4.49	0.696	15.52	3.8	4.40	5.9
		V6 (WEEK 52)	17	4.33	0.434	10.03	3.6	4.20	5.0
		V7 (WEEK 56)	15	4.55	0.424	9.33	3.9	4.60	5.5
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.03	0.446		-0.9	0.00	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.05	0.449		-1.0	0.10	0.7
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.14	0.518		-0.4	-0.05	1.5
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.07	0.302		-0.6	0.00	0.4
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.16	0.348		-0.4	0.20	0.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: POTASSIUM [mmol/L]
Reference Range: 3.5 - 5.4 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	4.43	0.468	10.56	3.7	4.35	5.4
		V1 (WEEK 0)	32	4.44	0.399	8.99	3.8	4.40	5.1
		V3 (WEEK 12)	29	4.39	0.480	10.95	3.2	4.40	5.2
		V4 (WEEK 24)	23	4.39	0.452	10.29	3.1	4.40	5.3
		V5 (WEEK 36)	22	4.43	0.596	13.46	3.8	4.20	5.9
		V6 (WEEK 52)	25	4.35	0.427	9.83	3.6	4.30	5.0
		V7 (WEEK 56)	23	4.47	0.392	8.77	3.7	4.50	5.5
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.05	0.386		-0.9	-0.10	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.02	0.411		-1.0	0.10	0.7
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.08	0.463		-0.5	-0.05	1.5
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.04	0.324		-0.6	0.00	0.4
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.10	0.367		-0.8	0.20	0.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: POTASSIUM [mmol/L]
Reference Range: 3.5 - 5.4 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	4.18	0.262	6.27	3.8	4.10	4.7
		V1 (WEEK 0)	12	4.37	0.350	8.01	3.9	4.30	4.9
		V3 (WEEK 12)	12	4.45	0.412	9.27	3.9	4.40	5.2
		V4 (WEEK 24)	12	4.47	0.362	8.09	3.9	4.45	5.1
		V5 (WEEK 36)	11	4.43	0.424	9.59	3.9	4.40	5.3
		V6 (WEEK 52)	11	4.46	0.411	9.20	3.8	4.40	5.1
		V7 (WEEK 56)	11	4.36	0.474	10.86	3.8	4.30	5.5
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.08	0.349		-0.5	0.20	0.5
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.11	0.337		-0.4	0.10	0.7
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.05	0.537		-0.8	-0.10	1.0
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.08	0.306		-0.5	0.20	0.6
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.02	0.407		-0.7	0.00	0.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: POTASSIUM [mmol/L]
Reference Range: 3.5 - 5.4 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	4.41	0.327	7.43	4.0	4.30	5.1
		V1 (WEEK 0)	19	4.51	0.400	8.86	3.8	4.50	5.5
		V3 (WEEK 12)	19	4.42	0.371	8.38	3.7	4.40	5.1
		V4 (WEEK 24)	19	4.35	0.381	8.75	3.5	4.40	4.9
		V5 (WEEK 36)	18	4.27	0.358	8.39	3.5	4.30	4.9
		V6 (WEEK 52)	16	4.16	0.350	8.41	3.5	4.20	5.1
		V7 (WEEK 56)	16	4.24	0.350	8.25	3.7	4.25	5.1
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.09	0.596		-1.2	-0.10	1.1
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.16	0.541		-1.0	-0.20	0.9
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.24	0.518		-1.1	-0.15	0.8
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.39	0.543		-1.4	-0.30	0.7
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.29	0.545		-1.3	-0.20	1.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: POTASSIUM [mmol/L]
Reference Range: 3.5 - 5.4 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	4.32	0.319	7.38	3.8	4.20	5.1
		V1 (WEEK 0)	31	4.45	0.382	8.57	3.8	4.40	5.5
		V3 (WEEK 12)	31	4.43	0.381	8.59	3.7	4.40	5.2
		V4 (WEEK 24)	31	4.40	0.373	8.48	3.5	4.40	5.1
		V5 (WEEK 36)	29	4.33	0.385	8.90	3.5	4.30	5.3
		V6 (WEEK 52)	27	4.29	0.398	9.28	3.5	4.20	5.1
		V7 (WEEK 56)	27	4.29	0.401	9.34	3.7	4.30	5.5
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.02	0.515		-1.2	0.10	1.1
		V4 (WEEK 24) - V1 (WEEK 0)	31	-0.06	0.485		-1.0	-0.10	0.9
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.13	0.535		-1.1	-0.10	1.0
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.20	0.511		-1.4	-0.20	0.7
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.18	0.504		-1.3	-0.20	1.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHLORIDE [mmol/L]
Reference Range: 95 - 107 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	99.3	3.79	3.8	95	100.0	106
		V1 (WEEK 0)	13	100.8	2.68	2.7	96	101.0	107
		V3 (WEEK 12)	13	101.1	3.38	3.3	95	102.0	107
		V4 (WEEK 24)	8	101.1	3.18	3.1	97	101.5	107
		V5 (WEEK 36)	8	99.6	3.78	3.8	93	99.5	105
		V6 (WEEK 52)	8	100.6	3.85	3.8	94	99.5	106
		V7 (WEEK 56)	8	101.8	2.96	2.9	98	101.5	106
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.3	3.61		-5	0.0	6
		V4 (WEEK 24) - V1 (WEEK 0)	8	0.8	2.49		-3	0.5	4
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.9	4.05		-9	-0.5	4
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.1	3.40		-5	0.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	8	1.3	1.67		-1	1.5	4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHLORIDE [mmol/L]
Reference Range: 95 - 107 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	99.3	3.51	3.5	93	99.0	106
		V1 (WEEK 0)	19	99.5	2.80	2.8	90	100.0	104
		V3 (WEEK 12)	16	100.3	3.50	3.5	95	100.0	106
		V4 (WEEK 24)	15	99.8	3.30	3.3	93	100.0	106
		V5 (WEEK 36)	14	100.4	3.08	3.1	93	101.0	104
		V6 (WEEK 52)	17	102.6	2.87	2.8	97	103.0	106
		V7 (WEEK 56)	15	102.0	2.56	2.5	96	102.0	106
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.9	2.89		-4	1.0	5
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.5	3.07		-6	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	14	1.0	2.45		-4	1.5	4
		V6 (WEEK 52) - V1 (WEEK 0)	17	3.1	3.27		-3	3.0	8
		V7 (WEEK 56) - V1 (WEEK 0)	15	2.5	2.85		-1	2.0	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHLORIDE [mmol/L]
Reference Range: 95 - 107 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	99.3	3.57	3.6	93	99.0	106
		V1 (WEEK 0)	32	100.0	2.78	2.8	90	100.0	107
		V3 (WEEK 12)	29	100.7	3.40	3.4	95	101.0	107
		V4 (WEEK 24)	23	100.3	3.25	3.2	93	101.0	107
		V5 (WEEK 36)	22	100.1	3.28	3.3	93	101.0	105
		V6 (WEEK 52)	25	102.0	3.27	3.2	94	102.0	106
		V7 (WEEK 56)	23	101.9	2.64	2.6	96	102.0	106
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.7	3.19		-5	1.0	6
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.6	2.83		-6	0.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.3	3.17		-9	0.5	4
		V6 (WEEK 52) - V1 (WEEK 0)	25	2.1	3.53		-5	2.0	8
		V7 (WEEK 56) - V1 (WEEK 0)	23	2.1	2.54		-1	2.0	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHLORIDE [mmol/L]
Reference Range: 95 - 107 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	99.8	2.09	2.1	96	100.0	103
		V1 (WEEK 0)	12	100.8	3.17	3.1	95	101.5	106
		V3 (WEEK 12)	12	99.8	2.83	2.8	93	100.5	103
		V4 (WEEK 24)	12	103.3	2.50	2.4	97	104.0	107
		V5 (WEEK 36)	11	102.2	1.94	1.9	99	102.0	105
		V6 (WEEK 52)	11	103.4	2.11	2.0	100	103.0	108
		V7 (WEEK 56)	11	103.5	1.92	1.9	100	103.0	107
		V3 (WEEK 12) - V1 (WEEK 0)	12	-1.0	4.20		-8	-0.5	6
		V4 (WEEK 24) - V1 (WEEK 0)	12	2.6	2.64		-2	2.5	7
		V5 (WEEK 36) - V1 (WEEK 0)	11	1.1	2.77		-3	0.0	7
		V6 (WEEK 52) - V1 (WEEK 0)	11	2.3	2.65		-3	2.0	6
		V7 (WEEK 56) - V1 (WEEK 0)	11	2.4	2.87		-2	2.0	7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHLORIDE [mmol/L]
Reference Range: 95 - 107 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	99.8	2.95	3.0	94	100.0	104
		V1 (WEEK 0)	19	100.3	3.80	3.8	92	100.0	107
		V3 (WEEK 12)	18	100.9	3.07	3.0	94	101.0	107
		V4 (WEEK 24)	19	100.6	3.89	3.9	95	101.0	107
		V5 (WEEK 36)	18	101.3	3.83	3.8	93	101.5	108
		V6 (WEEK 52)	16	101.8	2.93	2.9	97	101.0	107
		V7 (WEEK 56)	16	102.0	3.14	3.1	97	102.0	109
		V3 (WEEK 12) - V1 (WEEK 0)	18	0.5	4.05		-9	0.0	7
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.3	5.02		-8	1.0	6
		V5 (WEEK 36) - V1 (WEEK 0)	18	1.1	4.86		-8	1.0	8
		V6 (WEEK 52) - V1 (WEEK 0)	16	1.8	4.04		-6	2.0	10
		V7 (WEEK 56) - V1 (WEEK 0)	16	1.3	5.51		-7	2.5	10

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHLORIDE [mmol/L]
Reference Range: 95 - 107 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	99.8	2.61	2.6	94	100.0	104
		V1 (WEEK 0)	31	100.5	3.52	3.5	92	101.0	107
		V3 (WEEK 12)	30	100.4	2.98	3.0	93	101.0	107
		V4 (WEEK 24)	31	101.6	3.64	3.6	95	103.0	107
		V5 (WEEK 36)	29	101.6	3.23	3.2	93	102.0	108
		V6 (WEEK 52)	27	102.4	2.71	2.6	97	103.0	108
		V7 (WEEK 56)	27	102.6	2.76	2.7	97	103.0	109
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.1	4.11		-9	0.0	7
		V4 (WEEK 24) - V1 (WEEK 0)	31	1.2	4.35		-8	2.0	7
		V5 (WEEK 36) - V1 (WEEK 0)	29	1.1	4.13		-8	1.0	8
		V6 (WEEK 52) - V1 (WEEK 0)	27	2.0	3.49		-6	2.0	10
		V7 (WEEK 56) - V1 (WEEK 0)	27	1.7	4.58		-7	2.0	10

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: BICARBONATE [mmol/L]
Reference Range: 22.0 - 29.0 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	24.69	3.895	15.77	18.2	24.90	30.3
		V1 (WEEK 0)	13	24.96	2.899	11.61	19.6	25.10	29.8
		V3 (WEEK 12)	13	25.42	1.959	7.71	21.8	25.30	28.4
		V4 (WEEK 24)	8	24.13	1.323	5.48	22.3	23.55	25.9
		V5 (WEEK 36)	8	25.38	2.938	11.58	21.1	25.30	29.2
		V6 (WEEK 52)	8	26.21	1.862	7.10	23.7	26.25	28.9
		V7 (WEEK 56)	8	25.79	1.421	5.51	23.0	26.10	27.9
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.46	3.773		-6.6	1.20	8.8
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.88	2.195		-3.8	-0.80	1.6
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.13	2.275		-3.0	-0.35	3.8
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.71	1.460		-0.9	0.30	2.6
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.29	1.942		-3.3	0.95	2.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: BICARBONATE [mmol/L]
Reference Range: 22.0 - 29.0 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	24.63	2.393	9.71	20.9	24.50	29.7
		V1 (WEEK 0)	19	25.06	2.354	9.39	20.6	25.20	29.7
		V3 (WEEK 12)	16	24.94	3.585	14.37	18.4	25.30	31.5
		V4 (WEEK 24)	15	24.72	2.395	9.69	20.4	24.90	29.2
		V5 (WEEK 36)	14	24.79	2.106	8.50	21.3	24.80	28.7
		V6 (WEEK 52)	17	26.04	1.979	7.60	22.9	26.00	31.0
		V7 (WEEK 56)	15	25.56	2.439	9.54	21.6	25.10	33.1
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.13	2.661		-5.0	-0.05	5.9
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.10	2.540		-3.8	-0.90	3.6
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.16	2.768		-5.1	-0.50	3.8
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.88	2.321		-3.9	0.50	4.8
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.37	2.538		-3.5	0.00	5.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: BICARBONATE [mmol/L]
Reference Range: 22.0 - 29.0 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	24.66	3.033	12.30	18.2	24.50	30.3
		V1 (WEEK 0)	32	25.02	2.544	10.17	19.6	25.15	29.8
		V3 (WEEK 12)	29	25.16	2.930	11.65	18.4	25.30	31.5
		V4 (WEEK 24)	23	24.51	2.072	8.45	20.4	24.20	29.2
		V5 (WEEK 36)	22	25.00	2.389	9.56	21.1	25.05	29.2
		V6 (WEEK 52)	25	26.10	1.905	7.30	22.9	26.00	31.0
		V7 (WEEK 56)	23	25.64	2.108	8.22	21.6	25.50	33.1
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.28	3.150		-6.6	0.10	8.8
		V4 (WEEK 24) - V1 (WEEK 0)	23	-0.37	2.404		-3.8	-0.90	3.6
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.15	2.543		-5.1	-0.40	3.8
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.82	2.054		-3.9	0.50	4.8
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.34	2.302		-3.5	0.30	5.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: BICARBONATE [mmol/L]
Reference Range: 22.0 - 29.0 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	24.15	2.502	10.36	19.8	25.25	27.7
		V1 (WEEK 0)	12	23.86	2.362	9.90	17.6	24.10	26.6
		V3 (WEEK 12)	12	25.18	2.570	10.21	21.3	24.50	30.0
		V4 (WEEK 24)	12	25.28	2.603	10.30	19.5	25.20	28.8
		V5 (WEEK 36)	11	25.09	1.052	4.19	23.4	25.30	26.7
		V6 (WEEK 52)	11	26.59	1.597	6.01	24.7	26.80	29.3
		V7 (WEEK 56)	11	25.50	1.550	6.08	23.3	26.00	27.5
		V3 (WEEK 12) - V1 (WEEK 0)	12	1.32	3.995		-2.9	1.05	10.5
		V4 (WEEK 24) - V1 (WEEK 0)	12	1.42	4.466		-7.1	1.70	11.2
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.66	0.700		-0.8	0.60	1.6
		V6 (WEEK 52) - V1 (WEEK 0)	11	2.16	2.156		-1.5	1.90	5.6
		V7 (WEEK 56) - V1 (WEEK 0)	11	1.07	2.385		-3.3	0.50	3.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: BICARBONATE [mmol/L]
Reference Range: 22.0 - 29.0 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	24.78	2.071	8.36	22.0	24.10	29.1
		V1 (WEEK 0)	19	25.44	2.505	9.85	20.0	25.70	29.1
		V3 (WEEK 12)	19	25.57	2.268	8.87	20.7	25.10	31.1
		V4 (WEEK 24)	19	25.12	2.642	10.52	20.2	24.60	29.8
		V5 (WEEK 36)	18	24.57	2.862	11.65	19.7	24.15	29.3
		V6 (WEEK 52)	16	25.46	2.388	9.38	20.8	25.85	29.0
		V7 (WEEK 56)	16	26.10	2.267	8.69	22.0	25.70	29.8
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.13	3.513		-8.4	-0.50	6.7
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.33	3.895		-7.6	0.00	8.4
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.77	3.987		-7.4	-1.15	7.1
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.33	2.254		-3.6	0.20	5.6
		V7 (WEEK 56) - V1 (WEEK 0)	16	0.87	2.822		-4.5	1.60	5.1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: BICARBONATE [mmol/L]
Reference Range: 22.0 - 29.0 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	24.54	2.228	9.08	19.8	24.60	29.1
		V1 (WEEK 0)	31	24.83	2.535	10.21	17.6	25.00	29.1
		V3 (WEEK 12)	31	25.42	2.355	9.26	20.7	24.80	31.1
		V4 (WEEK 24)	31	25.18	2.584	10.26	19.5	25.00	29.8
		V5 (WEEK 36)	29	24.77	2.331	9.41	19.7	24.80	29.3
		V6 (WEEK 52)	27	25.92	2.144	8.27	20.8	25.90	29.3
		V7 (WEEK 56)	27	25.86	1.995	7.72	22.0	25.70	29.8
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.59	3.689		-8.4	-0.10	10.5
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.35	4.144		-7.6	1.10	11.2
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.23	3.214		-7.4	0.60	7.1
		V6 (WEEK 52) - V1 (WEEK 0)	27	1.07	2.359		-3.6	1.20	5.6
		V7 (WEEK 56) - V1 (WEEK 0)	27	0.96	2.606		-4.5	1.60	5.1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: UREA [mmol/L]
Reference Range: 2.77 - 8.40 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	6.025	1.5070	25.014	3.84	6.010	9.02
		V1 (WEEK 0)	13	5.961	2.1060	35.331	3.51	5.850	11.36
		V3 (WEEK 12)	13	5.615	1.2448	22.168	3.67	5.340	8.52
		V4 (WEEK 24)	8	6.325	1.8690	29.550	3.67	6.015	9.69
		V5 (WEEK 36)	8	5.615	1.7075	30.409	3.51	5.425	9.02
		V6 (WEEK 52)	8	5.785	1.7787	30.747	4.01	5.260	8.52
		V7 (WEEK 56)	8	6.285	2.1595	34.359	3.51	6.180	9.85
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.345	1.4631		-2.84	-0.660	2.01
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.146	0.9334		-1.67	-0.250	1.33
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.585	1.4033		-2.84	-0.420	1.50
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.415	1.4625		-2.84	-0.410	2.17
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.085	1.4359		-1.51	-0.080	3.01

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: UREA [mmol/L]
Reference Range: 2.77 - 8.40 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	5.749	2.1441	37.292	3.34	5.340	13.69
		V1 (WEEK 0)	19	5.626	1.0511	18.683	4.01	5.680	7.35
		V3 (WEEK 12)	16	5.698	2.4374	42.775	3.01	5.425	12.02
		V4 (WEEK 24)	15	5.209	1.4493	27.821	3.67	4.840	9.35
		V5 (WEEK 36)	14	5.584	1.6343	29.269	3.84	5.180	9.69
		V6 (WEEK 52)	17	5.020	1.5446	30.768	2.67	5.180	9.35
		V7 (WEEK 56)	15	5.667	2.2505	39.710	2.34	5.340	12.36
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.064	1.9356		-3.00	-0.420	4.67
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.469	1.2107		-2.34	-0.670	2.00
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.024	1.5276		-2.17	-0.415	2.51
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.492	1.2081		-2.67	-0.510	2.00
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.089	1.7099		-1.67	-0.160	5.01

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: UREA [mmol/L]
Reference Range: 2.77 - 8.40 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	5.861	1.8887	32.223	3.34	5.765	13.69
		V1 (WEEK 0)	32	5.762	1.5448	26.810	3.51	5.765	11.36
		V3 (WEEK 12)	29	5.661	1.9617	34.653	3.01	5.340	12.02
		V4 (WEEK 24)	23	5.597	1.6563	29.590	3.67	5.510	9.69
		V5 (WEEK 36)	22	5.595	1.6203	28.960	3.51	5.260	9.69
		V6 (WEEK 52)	25	5.265	1.6266	30.896	2.67	5.180	9.35
		V7 (WEEK 56)	23	5.882	2.1903	37.236	2.34	5.680	12.36
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.190	1.7160		-3.00	-0.660	4.67
		V4 (WEEK 24) - V1 (WEEK 0)	23	-0.357	1.1112		-2.34	-0.510	2.00
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.228	1.4756		-2.84	-0.420	2.51
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.467	1.2642		-2.84	-0.510	2.17
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.087	1.5864		-1.67	-0.160	5.01

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: UREA [mmol/L]
Reference Range: 2.77 - 8.40 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	5.108	1.0356	20.273	3.01	5.260	6.68
		V1 (WEEK 0)	12	5.399	1.0105	18.716	4.01	5.175	7.35
		V3 (WEEK 12)	12	5.442	0.8508	15.634	3.67	5.425	6.51
		V4 (WEEK 24)	12	5.525	1.1486	20.789	3.01	5.930	6.51
		V5 (WEEK 36)	11	5.588	1.0065	18.012	3.34	5.680	6.85
		V6 (WEEK 52)	11	5.937	0.9126	15.370	4.18	5.850	7.35
		V7 (WEEK 56)	11	5.753	1.0293	17.893	3.67	5.510	7.35
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.042	0.7862		-1.50	0.250	1.00
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.126	1.2291		-2.17	0.165	2.17
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.108	0.9545		-1.00	0.170	2.01
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.457	1.2347		-2.01	0.670	2.34
		V7 (WEEK 56) - V1 (WEEK 0)	11	0.273	0.9997		-1.34	0.000	2.34

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: UREA [mmol/L]
Reference Range: 2.77 - 8.40 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	5.512	1.0394	18.858	3.84	5.180	7.01
		V1 (WEEK 0)	19	5.662	1.0173	17.969	3.67	5.680	7.52
		V3 (WEEK 12)	19	5.335	1.1302	21.184	3.67	5.180	7.52
		V4 (WEEK 24)	19	5.196	1.2747	24.533	3.17	5.340	7.18
		V5 (WEEK 36)	18	5.373	1.3880	25.833	3.34	5.180	8.68
		V6 (WEEK 52)	16	5.418	1.0988	20.282	3.51	5.340	7.01
		V7 (WEEK 56)	16	5.137	1.3615	26.504	2.67	5.260	7.35
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.326	0.7666		-1.84	-0.340	1.51
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.466	1.3063		-2.67	-0.500	2.17
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.223	0.8936		-1.84	-0.170	1.17
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.168	1.1651		-2.18	-0.245	2.00
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.406	1.1587		-2.84	-0.080	1.17

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

14FEB2013

Safety Population

Parameter: UREA [mmol/L]
Reference Range: 2.77 - 8.40 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	5.355	1.0398	19.416	3.01	5.180	7.01
		V1 (WEEK 0)	31	5.560	1.0061	18.095	3.67	5.510	7.52
		V3 (WEEK 12)	31	5.376	1.0171	18.919	3.67	5.340	7.52
		V4 (WEEK 24)	31	5.323	1.2187	22.894	3.01	5.680	7.18
		V5 (WEEK 36)	29	5.454	1.2421	22.772	3.34	5.340	8.68
		V6 (WEEK 52)	27	5.629	1.0414	18.500	3.51	5.340	7.35
		V7 (WEEK 56)	27	5.388	1.2538	23.271	2.67	5.510	7.35
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.184	0.7827		-1.84	-0.170	1.51
		V4 (WEEK 24) - V1 (WEEK 0)	31	-0.237	1.2898		-2.67	-0.330	2.17
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.097	0.9148		-1.84	0.000	2.01
		V6 (WEEK 52) - V1 (WEEK 0)	27	0.087	1.2114		-2.18	0.340	2.34
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.130	1.1289		-2.84	0.000	2.34

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CREATININE [µmol/L]
Reference Range: 59 - 106 (MALE), 44 - 97 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	83.5	14.03	16.8	65	75.0	111
		V1 (WEEK 0)	13	86.9	14.91	17.2	67	88.0	114
		V3 (WEEK 12)	13	89.8	14.63	16.3	69	95.0	111
		V4 (WEEK 24)	8	90.7	17.57	19.4	61	90.3	113
		V5 (WEEK 36)	8	93.5	11.68	12.5	79	91.8	112
		V6 (WEEK 52)	8	86.1	17.36	20.2	56	88.8	107
		V7 (WEEK 56)	8	88.2	20.26	23.0	55	88.0	115
		V3 (WEEK 12) - V1 (WEEK 0)	13	3.0	9.05		-12	5.0	21
		V4 (WEEK 24) - V1 (WEEK 0)	8	2.3	12.92		-20	4.7	24
		V5 (WEEK 36) - V1 (WEEK 0)	8	4.9	9.90		-4	1.4	24
		V6 (WEEK 52) - V1 (WEEK 0)	8	-2.4	10.63		-27	0.4	6
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.4	12.94		-28	1.0	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CREATININE [µmol/L]
Reference Range: 59 - 106 (MALE), 44 - 97 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	79.0	20.75	26.3	48	80.0	146
		V1 (WEEK 0)	19	77.3	14.67	19.0	50	80.4	103
		V3 (WEEK 12)	16	76.0	15.22	20.0	55	74.7	117
		V4 (WEEK 24)	15	77.4	13.16	17.0	61	75.1	111
		V5 (WEEK 36)	14	81.6	18.71	22.9	63	75.6	132
		V6 (WEEK 52)	17	79.2	13.69	17.3	60	76.9	119
		V7 (WEEK 56)	15	84.8	22.76	26.8	61	81.3	157
		V3 (WEEK 12) - V1 (WEEK 0)	16	1.0	7.28		-11	-1.4	21
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.6	8.10		-15	2.7	11
		V5 (WEEK 36) - V1 (WEEK 0)	14	5.8	11.21		-16	4.9	29
		V6 (WEEK 52) - V1 (WEEK 0)	17	1.7	9.41		-12	3.6	17
		V7 (WEEK 56) - V1 (WEEK 0)	15	8.4	14.23		-7	3.5	54

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CREATININE [µmol/L]
Reference Range: 59 - 106 (MALE), 44 - 97 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	80.8	18.20	22.5	48	79.8	146
		V1 (WEEK 0)	32	81.2	15.29	18.8	50	84.0	114
		V3 (WEEK 12)	29	82.2	16.27	19.8	55	78.7	117
		V4 (WEEK 24)	23	82.0	15.83	19.3	61	76.0	113
		V5 (WEEK 36)	22	85.9	17.21	20.0	63	85.3	132
		V6 (WEEK 52)	25	81.4	14.96	18.4	56	78.7	119
		V7 (WEEK 56)	23	86.0	21.51	25.0	55	83.1	157
		V3 (WEEK 12) - V1 (WEEK 0)	29	1.9	8.03		-12	0.0	21
		V4 (WEEK 24) - V1 (WEEK 0)	23	1.2	9.78		-20	4.4	24
		V5 (WEEK 36) - V1 (WEEK 0)	22	5.5	10.52		-16	4.5	29
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.4	9.79		-27	2.7	17
		V7 (WEEK 56) - V1 (WEEK 0)	23	5.4	14.16		-28	3.2	54

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CREATININE [µmol/L]
Reference Range: 59 - 106 (MALE), 44 - 97 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	80.7	13.87	17.2	55	78.3	99
		V1 (WEEK 0)	12	84.3	12.95	15.4	58	89.3	100
		V3 (WEEK 12)	12	87.2	15.49	17.8	66	90.6	111
		V4 (WEEK 24)	12	87.0	11.74	13.5	68	87.1	103
		V5 (WEEK 36)	11	88.4	10.66	12.1	75	87.5	107
		V6 (WEEK 52)	11	88.4	13.22	15.0	57	91.9	103
		V7 (WEEK 56)	11	86.3	15.74	18.2	50	89.3	103
		V3 (WEEK 12) - V1 (WEEK 0)	12	2.9	12.27		-9	-0.5	35
		V4 (WEEK 24) - V1 (WEEK 0)	12	2.7	7.05		-5	0.9	19
		V5 (WEEK 36) - V1 (WEEK 0)	11	3.1	8.67		-8	4.4	17
		V6 (WEEK 52) - V1 (WEEK 0)	11	3.0	11.95		-25	7.1	17
		V7 (WEEK 56) - V1 (WEEK 0)	11	0.9	12.78		-32	5.8	14

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: CREATININE [µmol/L]
Reference Range: 59 - 106 (MALE), 44 - 97 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	66.5	11.08	16.7	48	66.0	88
		V1 (WEEK 0)	19	67.8	14.00	20.7	47	67.0	90
		V3 (WEEK 12)	19	68.7	10.37	15.1	53	69.8	92
		V4 (WEEK 24)	19	70.6	13.34	18.9	52	69.8	111
		V5 (WEEK 36)	18	71.1	9.83	13.8	56	69.4	91
		V6 (WEEK 52)	16	72.0	11.98	16.6	54	72.1	97
		V7 (WEEK 56)	16	74.8	12.64	16.9	52	72.7	101
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.9	7.94		-15	1.0	13
		V4 (WEEK 24) - V1 (WEEK 0)	19	2.8	9.48		-14	1.0	23
		V5 (WEEK 36) - V1 (WEEK 0)	18	2.1	10.71		-23	2.0	19
		V6 (WEEK 52) - V1 (WEEK 0)	16	4.6	9.34		-14	5.5	23
		V7 (WEEK 56) - V1 (WEEK 0)	16	6.8	7.42		-17	9.0	14

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CREATININE [µmol/L]
Reference Range: 59 - 106 (MALE), 44 - 97 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	72.0	13.92	19.3	48	72.5	99
		V1 (WEEK 0)	31	74.1	15.68	21.1	47	73.0	100
		V3 (WEEK 12)	31	75.8	15.38	20.3	53	72.5	111
		V4 (WEEK 24)	31	76.9	14.95	19.4	52	74.3	111
		V5 (WEEK 36)	29	77.6	13.15	16.9	56	76.0	107
		V6 (WEEK 52)	27	78.7	14.74	18.7	54	75.1	103
		V7 (WEEK 56)	27	79.5	14.85	18.7	50	79.6	103
		V3 (WEEK 12) - V1 (WEEK 0)	31	1.7	9.70		-15	0.0	35
		V4 (WEEK 24) - V1 (WEEK 0)	31	2.8	8.49		-14	0.9	23
		V5 (WEEK 36) - V1 (WEEK 0)	29	2.5	9.84		-23	2.1	19
		V6 (WEEK 52) - V1 (WEEK 0)	27	3.9	10.29		-25	5.6	23
		V7 (WEEK 56) - V1 (WEEK 0)	27	4.4	10.16		-32	7.1	14

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CALCIUM [mmol/L]
Reference Range: 2.1 - 2.7 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	2.43	0.125	5.15	2.2	2.50	2.6
		V1 (WEEK 0)	13	2.42	0.101	4.18	2.3	2.40	2.6
		V3 (WEEK 12)	13	2.39	0.126	5.25	2.2	2.40	2.7
		V4 (WEEK 24)	8	2.38	0.116	4.91	2.2	2.40	2.5
		V5 (WEEK 36)	8	2.39	0.113	4.72	2.2	2.40	2.5
		V6 (WEEK 52)	8	2.39	0.113	4.72	2.3	2.35	2.6
		V7 (WEEK 56)	8	2.40	0.141	5.89	2.2	2.40	2.6
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.03	0.111		-0.2	-0.10	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.09	0.083		-0.2	-0.10	0.0
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.05	0.093		-0.2	-0.05	0.1
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.05	0.076		-0.2	0.00	0.0
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.04	0.106		-0.2	-0.05	0.1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CALCIUM [mmol/L]
Reference Range: 2.1 - 2.7 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	2.45	0.126	5.15	2.2	2.50	2.7
		V1 (WEEK 0)	19	2.40	0.137	5.73	2.1	2.40	2.7
		V3 (WEEK 12)	16	2.47	0.154	6.23	2.1	2.50	2.7
		V4 (WEEK 24)	15	2.46	0.124	5.05	2.3	2.40	2.7
		V5 (WEEK 36)	14	2.44	0.139	5.72	2.2	2.40	2.7
		V6 (WEEK 52)	17	2.36	0.137	5.78	2.1	2.40	2.6
		V7 (WEEK 56)	15	2.36	0.164	6.94	2.1	2.30	2.7
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.06	0.096		-0.2	0.10	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.04	0.140		-0.2	0.00	0.3
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.01	0.135		-0.3	0.00	0.3
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.04	0.206		-0.6	0.00	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.05	0.177		-0.3	-0.10	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CALCIUM [mmol/L]
Reference Range: 2.1 - 2.7 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	2.44	0.124	5.09	2.2	2.50	2.7
		V1 (WEEK 0)	32	2.41	0.123	5.10	2.1	2.40	2.7
		V3 (WEEK 12)	29	2.43	0.145	5.94	2.1	2.40	2.7
		V4 (WEEK 24)	23	2.43	0.126	5.18	2.2	2.40	2.7
		V5 (WEEK 36)	22	2.42	0.130	5.36	2.2	2.40	2.7
		V6 (WEEK 52)	25	2.37	0.128	5.38	2.1	2.40	2.6
		V7 (WEEK 56)	23	2.37	0.154	6.50	2.1	2.30	2.7
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.02	0.110		-0.2	0.00	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	23	-0.00	0.136		-0.2	0.00	0.3
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.01	0.123		-0.3	0.00	0.3
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.04	0.173		-0.6	0.00	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.05	0.153		-0.3	-0.10	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CALCIUM [mmol/L]
Reference Range: 2.1 - 2.7 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	2.35	0.100	4.26	2.2	2.30	2.6
		V1 (WEEK 0)	12	2.39	0.144	6.04	2.2	2.40	2.7
		V3 (WEEK 12)	12	2.37	0.075	3.17	2.2	2.40	2.5
		V4 (WEEK 24)	12	2.42	0.153	6.32	2.2	2.40	2.8
		V5 (WEEK 36)	11	2.41	0.122	5.07	2.1	2.40	2.5
		V6 (WEEK 52)	11	2.36	0.103	4.34	2.2	2.40	2.5
		V7 (WEEK 56)	11	2.36	0.100	4.22	2.2	2.40	2.5
		V3 (WEEK 12) - V1 (WEEK 0)	12	-0.02	0.153		-0.3	0.00	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.02	0.205		-0.3	0.10	0.4
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.01	0.170		-0.3	0.10	0.2
		V6 (WEEK 52) - V1 (WEEK 0)	11	-0.04	0.150		-0.2	0.00	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.04	0.156		-0.2	-0.06	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CALCIUM [mmol/L]
Reference Range: 2.1 - 2.7 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	2.42	0.103	4.26	2.3	2.40	2.6
		V1 (WEEK 0)	19	2.42	0.117	4.83	2.2	2.40	2.6
		V3 (WEEK 12)	19	2.42	0.113	4.68	2.3	2.40	2.6
		V4 (WEEK 24)	19	2.46	0.135	5.48	2.3	2.40	2.9
		V5 (WEEK 36)	18	2.33	0.114	4.88	2.1	2.30	2.5
		V6 (WEEK 52)	16	2.32	0.111	4.78	2.1	2.35	2.5
		V7 (WEEK 56)	16	2.33	0.131	5.64	2.2	2.30	2.6
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.01	0.131		-0.3	0.00	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.04	0.135		-0.2	0.00	0.4
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.08	0.111		-0.4	-0.10	0.1
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.10	0.110		-0.3	-0.10	0.1
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.07	0.134		-0.4	-0.04	0.1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CALCIUM [mmol/L]
Reference Range: 2.1 - 2.7 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	2.39	0.106	4.44	2.2	2.40	2.6
		V1 (WEEK 0)	31	2.41	0.126	5.25	2.2	2.40	2.7
		V3 (WEEK 12)	31	2.40	0.102	4.23	2.2	2.40	2.6
		V4 (WEEK 24)	31	2.44	0.141	5.77	2.2	2.40	2.9
		V5 (WEEK 36)	29	2.36	0.121	5.11	2.1	2.40	2.5
		V6 (WEEK 52)	27	2.34	0.108	4.62	2.1	2.40	2.5
		V7 (WEEK 56)	27	2.34	0.118	5.05	2.2	2.34	2.6
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.00	0.138		-0.3	0.00	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.04	0.162		-0.3	0.10	0.4
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.04	0.140		-0.4	-0.10	0.2
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.07	0.129		-0.3	-0.10	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.06	0.142		-0.4	-0.06	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: PHOSPHATE [mmol/L]
Reference Range: 0.8 - 1.6 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	1.05	0.190	18.01	0.7	1.00	1.5
		V1 (WEEK 0)	13	1.06	0.171	16.11	0.8	1.00	1.3
		V3 (WEEK 12)	13	1.07	0.206	19.24	0.8	1.00	1.4
		V4 (WEEK 24)	8	1.13	0.167	14.84	0.9	1.15	1.4
		V5 (WEEK 36)	8	1.04	0.213	20.57	0.8	0.95	1.4
		V6 (WEEK 52)	8	1.08	0.205	19.10	0.8	1.00	1.4
		V7 (WEEK 56)	8	1.08	0.219	20.35	0.7	1.10	1.3
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.01	0.185		-0.4	0.10	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	8	0.02	0.128		-0.2	0.05	0.2
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.04	0.130		-0.2	-0.10	0.2
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.00	0.177		-0.3	0.10	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.00	0.151		-0.3	0.00	0.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: PHOSPHATE [mmol/L]
Reference Range: 0.8 - 1.6 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	1.14	0.150	13.18	0.9	1.10	1.4
		V1 (WEEK 0)	19	1.12	0.157	14.10	0.9	1.10	1.4
		V3 (WEEK 12)	16	1.14	0.155	13.53	0.9	1.10	1.4
		V4 (WEEK 24)	15	1.15	0.164	14.32	0.8	1.10	1.4
		V5 (WEEK 36)	14	1.12	0.233	20.74	0.5	1.20	1.4
		V6 (WEEK 52)	17	1.06	0.197	18.61	0.5	1.10	1.3
		V7 (WEEK 56)	15	1.19	0.234	19.64	0.8	1.20	1.6
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.01	0.173		-0.3	0.05	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.01	0.185		-0.4	0.10	0.2
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.00	0.251		-0.7	0.00	0.3
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.04	0.150		-0.4	0.00	0.1
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.09	0.196		-0.4	0.10	0.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: PHOSPHATE [mmol/L]
Reference Range: 0.8 - 1.6 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	1.10	0.169	15.36	0.7	1.10	1.5
		V1 (WEEK 0)	32	1.09	0.163	14.86	0.8	1.10	1.4
		V3 (WEEK 12)	29	1.11	0.180	16.21	0.8	1.10	1.4
		V4 (WEEK 24)	23	1.14	0.162	14.19	0.8	1.10	1.4
		V5 (WEEK 36)	22	1.09	0.224	20.58	0.5	1.10	1.4
		V6 (WEEK 52)	25	1.06	0.196	18.38	0.5	1.10	1.4
		V7 (WEEK 56)	23	1.15	0.231	20.08	0.7	1.20	1.6
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.00	0.175		-0.4	0.10	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.02	0.164		-0.4	0.10	0.2
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.01	0.212		-0.7	-0.05	0.3
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.03	0.157		-0.4	0.00	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.06	0.183		-0.4	0.10	0.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: PHOSPHATE [mmol/L]
Reference Range: 0.8 - 1.6 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	0.99	0.168	16.91	0.7	1.00	1.3
		V1 (WEEK 0)	12	1.03	0.106	10.30	0.8	1.00	1.2
		V3 (WEEK 12)	12	1.00	0.154	15.37	0.7	1.00	1.2
		V4 (WEEK 24)	12	0.98	0.180	18.31	0.8	0.95	1.4
		V5 (WEEK 36)	11	0.97	0.127	13.08	0.8	1.00	1.1
		V6 (WEEK 52)	11	0.97	0.168	17.26	0.7	1.00	1.2
		V7 (WEEK 56)	11	0.99	0.111	11.21	0.9	0.99	1.3
		V3 (WEEK 12) - V1 (WEEK 0)	12	-0.03	0.106		-0.2	-0.05	0.1
		V4 (WEEK 24) - V1 (WEEK 0)	12	-0.04	0.162		-0.3	-0.05	0.3
		V5 (WEEK 36) - V1 (WEEK 0)	11	-0.05	0.082		-0.2	0.00	0.1
		V6 (WEEK 52) - V1 (WEEK 0)	11	-0.05	0.121		-0.2	0.00	0.1
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.03	0.129		-0.3	-0.01	0.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: PHOSPHATE [mmol/L]
Reference Range: 0.8 - 1.6 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	1.21	0.139	11.56	0.9	1.20	1.5
		V1 (WEEK 0)	19	1.18	0.199	16.86	0.6	1.10	1.5
		V3 (WEEK 12)	18	1.16	0.150	12.92	0.9	1.20	1.4
		V4 (WEEK 24)	19	1.17	0.179	15.25	0.9	1.20	1.6
		V5 (WEEK 36)	18	1.17	0.145	12.35	0.8	1.20	1.3
		V6 (WEEK 52)	16	1.11	0.150	13.48	0.8	1.10	1.3
		V7 (WEEK 56)	16	1.14	0.122	10.71	1.0	1.10	1.4
		V3 (WEEK 12) - V1 (WEEK 0)	18	-0.01	0.163		-0.2	0.00	0.3
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.01	0.184		-0.4	0.00	0.3
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.01	0.211		-0.4	0.00	0.4
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.07	0.148		-0.4	0.00	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.04	0.191		-0.4	-0.03	0.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: PHOSPHATE [mmol/L]
Reference Range: 0.8 - 1.6 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	1.12	0.182	16.22	0.7	1.10	1.5
		V1 (WEEK 0)	31	1.12	0.183	16.38	0.6	1.10	1.5
		V3 (WEEK 12)	30	1.10	0.169	15.42	0.7	1.10	1.4
		V4 (WEEK 24)	31	1.10	0.200	18.18	0.8	1.10	1.6
		V5 (WEEK 36)	29	1.10	0.168	15.31	0.8	1.10	1.3
		V6 (WEEK 52)	27	1.06	0.169	16.05	0.7	1.10	1.3
		V7 (WEEK 56)	27	1.08	0.137	12.68	0.9	1.01	1.4
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.01	0.141		-0.2	0.00	0.3
		V4 (WEEK 24) - V1 (WEEK 0)	31	-0.02	0.174		-0.4	0.00	0.3
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.02	0.172		-0.4	0.00	0.4
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.06	0.136		-0.4	0.00	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.04	0.166		-0.4	-0.01	0.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: 2.78 - 5.55 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	5.653	1.4735	26.066	3.78	5.390	7.95
		V1 (WEEK 0)	13	6.137	1.2083	19.689	4.61	6.120	9.23
		V3 (WEEK 12)	13	6.002	1.3340	22.228	4.06	5.840	8.73
		V4 (WEEK 24)	8	5.798	1.2011	20.717	3.95	5.895	7.01
		V5 (WEEK 36)	8	6.443	1.0618	16.482	4.56	6.725	7.90
		V6 (WEEK 52)	8	5.908	1.3825	23.402	3.67	5.475	7.84
		V7 (WEEK 56)	8	6.186	1.3728	22.192	4.06	6.365	8.01
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.135	1.3110		-2.06	-0.500	3.12
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.367	0.9910		-2.17	-0.195	0.89
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.056	1.3105		-1.56	0.000	2.28
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.591	1.2804		-2.45	-0.610	1.61
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.313	1.3683		-2.22	-0.165	1.78

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: 2.78 - 5.55 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	5.511	1.3640	24.752	4.11	5.170	9.06
		V1 (WEEK 0)	19	4.885	0.7897	16.166	3.84	4.730	6.89
		V3 (WEEK 12)	16	5.533	0.7416	13.403	4.45	5.560	7.28
		V4 (WEEK 24)	15	5.153	0.6608	12.825	3.89	5.060	6.67
		V5 (WEEK 36)	14	5.600	1.2966	23.154	3.84	5.365	7.90
		V6 (WEEK 52)	17	5.662	1.5792	27.890	4.17	5.390	10.95
		V7 (WEEK 56)	15	5.186	1.2292	23.703	3.95	4.730	8.23
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.713	0.6943		-0.28	0.670	2.34
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.404	0.6504		-0.55	0.120	1.61
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.806	1.3203		-0.45	0.475	3.73
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.706	1.7077		-0.56	0.220	6.67
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.296	0.8540		-1.28	0.220	1.95

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: 2.78 - 5.55 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	5.568	1.3877	24.921	3.78	5.255	9.06
		V1 (WEEK 0)	32	5.393	1.1479	21.283	3.84	5.145	9.23
		V3 (WEEK 12)	29	5.743	1.0552	18.374	4.06	5.620	8.73
		V4 (WEEK 24)	23	5.377	0.9141	17.000	3.89	5.120	7.01
		V5 (WEEK 36)	22	5.906	1.2604	21.340	3.84	5.975	7.90
		V6 (WEEK 52)	25	5.741	1.4946	26.034	3.67	5.450	10.95
		V7 (WEEK 56)	23	5.534	1.3411	24.234	3.95	5.230	8.23
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.332	1.0858		-2.06	0.450	3.12
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.136	0.8502		-2.17	0.110	1.61
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.492	1.3534		-1.56	0.335	3.73
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.291	1.6745		-2.45	-0.110	6.67
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.084	1.0713		-2.22	0.160	1.95

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: 2.78 - 5.55 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	5.504	0.8593	15.611	4.73	5.225	7.67
		V1 (WEEK 0)	12	5.703	1.5143	26.552	4.17	4.980	8.28
		V3 (WEEK 12)	12	5.268	0.8563	16.256	3.67	5.060	6.84
		V4 (WEEK 24)	12	5.606	0.9954	17.756	4.50	5.310	7.73
		V5 (WEEK 36)	11	5.480	1.0079	18.393	4.17	5.060	7.73
		V6 (WEEK 52)	11	5.323	0.9007	16.921	3.39	5.280	6.62
		V7 (WEEK 56)	11	5.675	0.7732	13.623	4.67	5.500	6.84
		V3 (WEEK 12) - V1 (WEEK 0)	12	-0.436	1.1885		-2.89	0.025	0.78
		V4 (WEEK 24) - V1 (WEEK 0)	12	-0.098	1.1860		-2.33	0.055	1.61
		V5 (WEEK 36) - V1 (WEEK 0)	11	-0.226	1.7774		-3.11	0.110	3.06
		V6 (WEEK 52) - V1 (WEEK 0)	11	-0.384	1.0963		-2.33	-0.110	1.11
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.031	1.4171		-2.56	0.220	1.66

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: 2.78 - 5.55 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	5.311	0.9439	17.772	3.89	5.170	7.84
		V1 (WEEK 0)	19	5.407	1.1186	20.686	3.28	5.560	7.84
		V3 (WEEK 12)	18	5.109	1.2057	23.600	2.00	5.115	7.34
		V4 (WEEK 24)	19	6.466	3.2419	50.135	4.50	5.500	19.24
		V5 (WEEK 36)	18	5.143	0.6650	12.930	4.17	5.090	6.23
		V6 (WEEK 52)	16	6.164	2.3086	37.454	3.78	5.700	13.73
		V7 (WEEK 56)	16	5.574	1.3561	24.328	3.45	5.310	9.34
		V3 (WEEK 12) - V1 (WEEK 0)	18	-0.287	0.8568		-1.44	-0.360	1.39
		V4 (WEEK 24) - V1 (WEEK 0)	19	1.059	3.7705		-1.78	0.000	15.96
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.266	0.9370		-1.83	-0.285	1.33
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.622	2.8665		-2.22	0.055	10.45
		V7 (WEEK 56) - V1 (WEEK 0)	16	0.084	1.8692		-2.11	-0.245	6.06

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: 2.78 - 5.55 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	5.386	0.9024	16.756	3.89	5.170	7.84
		V1 (WEEK 0)	31	5.522	1.2701	23.000	3.28	5.390	8.28
		V3 (WEEK 12)	30	5.172	1.0661	20.611	2.00	5.115	7.34
		V4 (WEEK 24)	31	6.133	2.6174	42.675	4.50	5.450	19.24
		V5 (WEEK 36)	29	5.271	0.8118	15.402	4.17	5.060	7.73
		V6 (WEEK 52)	27	5.821	1.8879	32.432	3.39	5.670	13.73
		V7 (WEEK 56)	27	5.616	1.1373	20.253	3.45	5.340	9.34
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.346	0.9857		-2.89	-0.275	1.39
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.611	3.0616		-2.33	0.000	15.96
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.251	1.2890		-3.11	-0.230	3.06
		V6 (WEEK 52) - V1 (WEEK 0)	27	0.212	2.3358		-2.33	0.000	10.45
		V7 (WEEK 56) - V1 (WEEK 0)	27	0.037	1.6708		-2.56	0.110	6.06

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: TOTAL BILIRUBIN [µmol/L]
Reference Range: < 20.5 µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	8.82	3.829	43.43	5.1	8.60	17.1
		V1 (WEEK 0)	13	9.48	5.387	56.84	3.4	8.60	23.9
		V3 (WEEK 12)	13	10.01	3.951	39.48	5.1	10.30	17.1
		V4 (WEEK 24)	8	9.84	4.274	43.44	5.1	9.45	18.8
		V5 (WEEK 36)	8	10.04	5.059	50.40	3.4	8.55	17.1
		V6 (WEEK 52)	8	10.05	3.728	37.09	5.1	10.30	15.4
		V7 (WEEK 56)	8	10.29	2.589	25.17	6.8	10.30	15.4
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.53	3.368		-6.8	1.70	6.8
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.64	3.163		-5.1	0.00	3.5
		V5 (WEEK 36) - V1 (WEEK 0)	8	0.00	3.662		-6.8	0.00	5.2
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.01	5.193		-8.5	0.00	6.9
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.25	4.702		-8.5	1.75	5.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL BILIRUBIN [µmol/L]
Reference Range: < 20.5 µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	7.93	3.497	44.12	1.7	8.60	15.4
		V1 (WEEK 0)	19	7.20	2.965	41.18	3.4	6.80	13.7
		V3 (WEEK 12)	16	7.49	2.515	33.59	3.4	7.70	13.7
		V4 (WEEK 24)	15	7.75	3.492	45.04	3.4	6.80	15.4
		V5 (WEEK 36)	14	8.17	4.267	52.22	5.1	6.80	18.8
		V6 (WEEK 52)	17	7.65	3.338	43.65	3.4	6.80	15.4
		V7 (WEEK 56)	15	6.95	1.676	24.13	5.1	6.80	10.3
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.22	3.204		-5.2	0.85	5.2
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.34	3.569		-6.9	0.00	6.8
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.47	3.638		-5.2	0.00	10.2
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.20	3.694		-6.9	0.00	6.8
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.58	2.213		-5.1	0.00	1.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL BILIRUBIN [µmol/L]
Reference Range: < 20.5 µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	8.29	3.602	43.46	1.7	8.60	17.1
		V1 (WEEK 0)	32	8.13	4.199	51.67	3.4	7.70	23.9
		V3 (WEEK 12)	29	8.62	3.421	39.70	3.4	8.60	17.1
		V4 (WEEK 24)	23	8.48	3.821	45.07	3.4	8.60	18.8
		V5 (WEEK 36)	22	8.85	4.544	51.35	3.4	6.80	18.8
		V6 (WEEK 52)	25	8.42	3.576	42.50	3.4	8.60	15.4
		V7 (WEEK 56)	23	8.11	2.563	31.61	5.1	8.60	15.4
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.36	3.223		-6.8	1.70	6.8
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.00	3.394		-6.9	0.00	6.8
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.30	3.566		-6.8	0.00	10.2
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.14	4.119		-8.5	0.00	6.9
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.29	3.212		-8.5	0.00	5.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL BILIRUBIN [µmol/L]
Reference Range: < 20.5 µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	10.42	4.157	39.91	5.1	9.45	20.5
		V1 (WEEK 0)	12	7.99	3.836	48.00	1.7	8.60	12.0
		V3 (WEEK 12)	12	7.83	3.404	43.46	3.4	6.80	13.7
		V4 (WEEK 24)	12	7.99	2.590	32.41	3.4	8.60	12.0
		V5 (WEEK 36)	11	9.34	3.868	41.43	3.4	8.60	15.4
		V6 (WEEK 52)	11	10.44	3.547	33.98	5.1	10.30	17.1
		V7 (WEEK 56)	11	10.27	3.757	36.57	5.1	8.60	15.4
		V3 (WEEK 12) - V1 (WEEK 0)	12	-0.16	2.249		-3.5	0.00	3.4
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.00	3.967		-5.2	-1.70	5.2
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.93	2.230		-3.5	1.70	3.5
		V6 (WEEK 52) - V1 (WEEK 0)	11	2.03	2.948		-3.4	3.40	5.2
		V7 (WEEK 56) - V1 (WEEK 0)	11	1.86	3.122		-3.5	3.40	5.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL BILIRUBIN [µmol/L]
Reference Range: < 20.5 µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	8.73	4.201	48.11	3.4	8.60	17.1
		V1 (WEEK 0)	19	7.82	3.359	42.95	3.4	6.80	17.1
		V3 (WEEK 12)	19	8.92	3.686	41.32	3.4	8.60	20.5
		V4 (WEEK 24)	19	8.63	4.030	46.72	3.4	6.80	15.4
		V5 (WEEK 36)	18	9.03	5.115	56.66	3.4	8.60	23.9
		V6 (WEEK 52)	16	8.13	5.578	68.65	1.7	6.85	22.2
		V7 (WEEK 56)	16	8.56	3.607	42.13	1.7	8.60	15.4
		V3 (WEEK 12) - V1 (WEEK 0)	19	1.10	3.093		-5.1	0.00	8.5
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.81	2.565		-5.1	0.00	5.1
		V5 (WEEK 36) - V1 (WEEK 0)	18	1.44	4.434		-5.1	1.70	13.6
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.44	4.422		-5.1	0.00	11.9
		V7 (WEEK 56) - V1 (WEEK 0)	16	0.99	3.426		-5.1	0.00	6.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: TOTAL BILIRUBIN [µmol/L]
Reference Range: < 20.5 µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	9.38	4.198	44.73	3.4	8.60	20.5
		V1 (WEEK 0)	31	7.89	3.489	44.24	1.7	6.80	17.1
		V3 (WEEK 12)	31	8.50	3.563	41.91	3.4	8.60	20.5
		V4 (WEEK 24)	31	8.38	3.508	41.85	3.4	6.80	15.4
		V5 (WEEK 36)	29	9.14	4.610	50.41	3.4	8.60	23.9
		V6 (WEEK 52)	27	9.07	4.912	54.18	1.7	8.60	22.2
		V7 (WEEK 56)	27	9.26	3.697	39.93	1.7	8.60	15.4
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.61	2.826		-5.1	0.00	8.5
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.49	3.143		-5.2	0.00	5.2
		V5 (WEEK 36) - V1 (WEEK 0)	29	1.24	3.712		-5.1	1.70	13.6
		V6 (WEEK 52) - V1 (WEEK 0)	27	1.09	3.906		-5.1	0.00	11.9
		V7 (WEEK 56) - V1 (WEEK 0)	27	1.34	3.273		-5.1	1.70	6.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: TOTAL PROTEIN [g/L]
Reference Range: 61 - 87 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	71.5	4.70	6.6	62	72.0	78
		V1 (WEEK 0)	13	72.0	4.22	5.9	64	72.0	78
		V3 (WEEK 12)	13	70.9	3.97	5.6	65	71.0	80
		V4 (WEEK 24)	8	70.1	3.94	5.6	63	71.0	75
		V5 (WEEK 36)	8	70.0	3.55	5.1	64	71.5	73
		V6 (WEEK 52)	8	69.8	4.46	6.4	64	68.5	76
		V7 (WEEK 56)	8	70.5	4.34	6.2	65	69.5	77
		V3 (WEEK 12) - V1 (WEEK 0)	13	-1.1	2.99		-8	-1.0	3
		V4 (WEEK 24) - V1 (WEEK 0)	8	-2.4	3.42		-8	-2.5	4
		V5 (WEEK 36) - V1 (WEEK 0)	8	-2.3	3.62		-7	-3.5	4
		V6 (WEEK 52) - V1 (WEEK 0)	8	-2.5	4.69		-11	-1.5	3
		V7 (WEEK 56) - V1 (WEEK 0)	8	-1.8	3.28		-8	-1.0	3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL PROTEIN [g/L]
Reference Range: 61 - 87 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	72.9	5.07	7.0	62	74.0	83
		V1 (WEEK 0)	19	70.7	4.01	5.7	63	70.0	77
		V3 (WEEK 12)	16	70.7	5.99	8.5	59	71.5	81
		V4 (WEEK 24)	15	70.5	5.71	8.1	61	71.0	80
		V5 (WEEK 36)	14	72.6	4.54	6.2	65	73.0	81
		V6 (WEEK 52)	17	70.1	4.99	7.1	62	70.0	80
		V7 (WEEK 56)	15	69.4	6.14	8.8	61	70.0	81
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.1	4.36		-8	1.0	7
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.6	4.52		-7	0.0	8
		V5 (WEEK 36) - V1 (WEEK 0)	14	1.3	3.99		-5	2.0	7
		V6 (WEEK 52) - V1 (WEEK 0)	17	-1.1	3.93		-9	0.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	15	-2.0	4.96		-11	-3.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL PROTEIN [g/L]
Reference Range: 61 - 87 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	72.3	4.90	6.8	62	72.5	83
		V1 (WEEK 0)	32	71.2	4.09	5.7	63	71.5	78
		V3 (WEEK 12)	29	70.8	5.09	7.2	59	71.0	81
		V4 (WEEK 24)	23	70.3	5.07	7.2	61	71.0	80
		V5 (WEEK 36)	22	71.6	4.30	6.0	64	72.0	81
		V6 (WEEK 52)	25	70.0	4.74	6.8	62	70.0	80
		V7 (WEEK 56)	23	69.8	5.50	7.9	61	70.0	81
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.5	3.78		-8	0.0	7
		V4 (WEEK 24) - V1 (WEEK 0)	23	-1.2	4.18		-8	-1.0	8
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.0	4.15		-7	1.0	7
		V6 (WEEK 52) - V1 (WEEK 0)	25	-1.5	4.14		-11	-1.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	23	-1.9	4.37		-11	-3.0	8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL PROTEIN [g/L]
Reference Range: 61 - 87 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	70.0	3.77	5.4	60	71.0	74
		V1 (WEEK 0)	12	70.3	3.63	5.2	63	70.5	76
		V3 (WEEK 12)	12	70.3	3.68	5.2	64	70.0	75
		V4 (WEEK 24)	12	69.8	5.11	7.3	63	70.0	81
		V5 (WEEK 36)	11	71.1	3.88	5.5	64	71.0	78
		V6 (WEEK 52)	11	70.5	3.91	5.5	62	71.0	75
		V7 (WEEK 56)	11	69.7	2.72	3.9	64	71.0	73
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.0	3.74		-6	-0.5	6
		V4 (WEEK 24) - V1 (WEEK 0)	12	-0.5	5.92		-8	-2.5	11
		V5 (WEEK 36) - V1 (WEEK 0)	11	1.3	2.97		-4	1.0	5
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.6	4.18		-8	0.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.1	4.37		-6	-2.0	10

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL PROTEIN [g/L]
Reference Range: 61 - 87 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	72.0	4.88	6.8	64	71.0	83
		V1 (WEEK 0)	19	70.3	5.11	7.3	63	70.0	80
		V3 (WEEK 12)	18	70.3	3.64	5.2	62	71.0	75
		V4 (WEEK 24)	19	68.7	3.77	5.5	60	69.0	75
		V5 (WEEK 36)	18	68.3	3.56	5.2	63	67.5	75
		V6 (WEEK 52)	16	68.3	3.55	5.2	62	68.0	77
		V7 (WEEK 56)	16	69.3	4.28	6.2	62	70.5	75
		V3 (WEEK 12) - V1 (WEEK 0)	18	0.5	4.38		-11	0.5	7
		V4 (WEEK 24) - V1 (WEEK 0)	19	-1.5	3.75		-9	-1.0	5
		V5 (WEEK 36) - V1 (WEEK 0)	18	-1.9	3.81		-7	-2.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	16	-1.9	4.65		-9	-1.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	16	-1.5	5.47		-9	-3.0	9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TOTAL PROTEIN [g/L]
Reference Range: 61 - 87 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	71.2	4.52	6.3	60	71.0	83
		V1 (WEEK 0)	31	70.3	4.53	6.4	63	70.0	80
		V3 (WEEK 12)	30	70.3	3.59	5.1	62	71.0	75
		V4 (WEEK 24)	31	69.2	4.29	6.2	60	69.0	81
		V5 (WEEK 36)	29	69.4	3.87	5.6	63	70.0	78
		V6 (WEEK 52)	27	69.1	3.79	5.5	62	70.0	77
		V7 (WEEK 56)	27	69.4	3.67	5.3	62	71.0	75
		V3 (WEEK 12) - V1 (WEEK 0)	30	0.3	4.08		-11	0.0	7
		V4 (WEEK 24) - V1 (WEEK 0)	31	-1.1	4.64		-9	-1.0	11
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.7	3.81		-7	0.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.9	4.57		-9	0.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.9	5.01		-9	-2.0	10

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALBUMIN [g/L]
Reference Range: 35.0 - 55.0 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	45.12	3.427	7.60	38.0	45.00	51.0
		V1 (WEEK 0)	13	45.22	2.903	6.42	40.9	44.00	50.0
		V3 (WEEK 12)	13	45.08	3.048	6.76	37.3	45.00	50.0
		V4 (WEEK 24)	8	44.84	2.518	5.62	41.5	44.35	49.0
		V5 (WEEK 36)	8	45.15	2.836	6.28	42.0	44.50	49.9
		V6 (WEEK 52)	8	44.70	2.173	4.86	42.6	44.00	49.0
		V7 (WEEK 56)	8	45.04	2.141	4.75	42.0	45.00	48.0
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.14	2.191		-5.0	0.00	3.0
		V4 (WEEK 24) - V1 (WEEK 0)	8	-1.41	2.614		-6.5	-1.50	2.0
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.60	1.898		-5.0	-0.10	1.0
		V6 (WEEK 52) - V1 (WEEK 0)	8	-1.05	3.367		-7.0	-0.20	3.0
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.71	2.036		-4.7	-0.50	2.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALBUMIN [g/L]
Reference Range: 35.0 - 55.0 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	46.64	3.065	6.57	40.0	47.00	52.0
		V1 (WEEK 0)	19	45.10	2.700	5.99	38.0	45.00	50.0
		V3 (WEEK 12)	16	45.49	3.539	7.78	39.7	46.60	50.0
		V4 (WEEK 24)	15	44.43	3.134	7.05	39.0	44.40	50.0
		V5 (WEEK 36)	14	45.55	2.892	6.35	40.6	45.50	50.0
		V6 (WEEK 52)	17	44.72	2.769	6.19	39.2	44.00	49.0
		V7 (WEEK 56)	15	44.23	3.285	7.43	40.9	43.00	50.0
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.13	2.338		-4.0	1.10	3.0
		V4 (WEEK 24) - V1 (WEEK 0)	15	-1.09	2.845		-5.0	-1.90	3.0
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.08	3.068		-4.2	-1.00	6.0
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.45	2.314		-5.0	0.30	3.0
		V7 (WEEK 56) - V1 (WEEK 0)	15	-1.22	3.019		-7.1	-1.00	3.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALBUMIN [g/L]
Reference Range: 35.0 - 55.0 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	46.02	3.253	7.07	38.0	45.50	52.0
		V1 (WEEK 0)	32	45.15	2.739	6.07	38.0	44.90	50.0
		V3 (WEEK 12)	29	45.31	3.277	7.23	37.3	46.00	50.0
		V4 (WEEK 24)	23	44.57	2.882	6.47	39.0	44.40	50.0
		V5 (WEEK 36)	22	45.40	2.810	6.19	40.6	45.00	50.0
		V6 (WEEK 52)	25	44.71	2.547	5.70	39.2	44.00	49.0
		V7 (WEEK 56)	23	44.51	2.912	6.54	40.9	44.00	50.0
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.01	2.237		-5.0	0.00	3.0
		V4 (WEEK 24) - V1 (WEEK 0)	23	-1.20	2.711		-6.5	-1.90	3.0
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.27	2.663		-5.0	-0.70	6.0
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.64	2.637		-7.0	0.00	3.0
		V7 (WEEK 56) - V1 (WEEK 0)	23	-1.04	2.680		-7.1	-1.00	3.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALBUMIN [g/L]
Reference Range: 35.0 - 55.0 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	45.74	2.905	6.35	39.0	46.00	51.0
		V1 (WEEK 0)	12	46.02	2.502	5.44	42.0	46.00	50.0
		V3 (WEEK 12)	12	45.38	2.320	5.11	42.0	45.00	49.1
		V4 (WEEK 24)	12	45.88	4.379	9.54	39.0	45.50	57.0
		V5 (WEEK 36)	11	45.93	1.979	4.31	43.0	45.70	48.0
		V6 (WEEK 52)	11	46.46	2.055	4.42	43.0	46.60	50.5
		V7 (WEEK 56)	11	45.25	1.184	2.62	44.0	45.00	48.0
		V3 (WEEK 12) - V1 (WEEK 0)	12	-0.64	2.048		-4.0	-0.50	3.0
		V4 (WEEK 24) - V1 (WEEK 0)	12	-0.13	4.144		-6.0	-0.50	8.8
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.27	1.124		-2.0	0.70	2.0
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.81	2.688		-5.0	1.00	4.5
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.40	2.010		-4.8	-0.20	2.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALBUMIN [g/L]
Reference Range: 35.0 - 55.0 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	46.66	2.548	5.46	42.0	46.70	52.0
		V1 (WEEK 0)	19	45.52	3.102	6.81	39.0	46.00	50.0
		V3 (WEEK 12)	19	45.57	2.106	4.62	41.0	46.00	50.0
		V4 (WEEK 24)	19	44.83	3.210	7.16	39.6	45.90	49.8
		V5 (WEEK 36)	18	44.33	3.020	6.81	38.0	45.00	48.0
		V6 (WEEK 52)	16	44.97	2.199	4.89	41.0	44.65	49.0
		V7 (WEEK 56)	16	45.41	2.625	5.78	39.3	45.45	49.0
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.05	2.767		-5.7	0.10	4.1
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.69	2.803		-5.0	-1.40	4.3
		V5 (WEEK 36) - V1 (WEEK 0)	18	-1.29	2.645		-8.0	-0.70	4.0
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.80	2.366		-5.7	-0.60	2.0
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.16	2.998		-3.0	-0.75	8.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALBUMIN [g/L]
Reference Range: 35.0 - 55.0 g/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	46.30	2.682	5.79	39.0	46.00	52.0
		V1 (WEEK 0)	31	45.71	2.851	6.24	39.0	46.00	50.0
		V3 (WEEK 12)	31	45.50	2.155	4.74	41.0	45.00	50.0
		V4 (WEEK 24)	31	45.24	3.672	8.12	39.0	45.90	57.0
		V5 (WEEK 36)	29	44.94	2.749	6.12	38.0	45.00	48.0
		V6 (WEEK 52)	27	45.58	2.230	4.89	41.0	45.70	50.5
		V7 (WEEK 56)	27	45.35	2.127	4.69	39.3	45.00	49.0
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.22	2.500		-5.7	0.00	4.1
		V4 (WEEK 24) - V1 (WEEK 0)	31	-0.47	3.330		-6.0	-1.00	8.8
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.70	2.302		-8.0	0.00	4.0
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.14	2.580		-5.7	-0.30	4.5
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.26	2.599		-4.8	-0.50	8.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGOT (AST) [U/L]
Reference Range: 10 - 50 (MALE), 10 - 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	28.8	6.08	21.1	18	28.0	39
		V1 (WEEK 0)	13	29.6	7.04	23.8	21	29.0	48
		V3 (WEEK 12)	13	33.5	15.10	45.0	17	27.0	73
		V4 (WEEK 24)	8	29.8	4.71	15.8	22	29.0	36
		V5 (WEEK 36)	8	27.6	6.97	25.2	17	26.0	40
		V6 (WEEK 52)	8	25.3	4.68	18.5	18	26.0	32
		V7 (WEEK 56)	8	26.5	6.48	24.5	15	27.5	34
		V3 (WEEK 12) - V1 (WEEK 0)	13	3.9	14.93		-9	0.0	51
		V4 (WEEK 24) - V1 (WEEK 0)	8	-1.4	7.44		-12	-1.5	9
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.3	5.47		-7	1.0	6
		V6 (WEEK 52) - V1 (WEEK 0)	8	-2.6	6.02		-15	-2.5	4
		V7 (WEEK 56) - V1 (WEEK 0)	8	-1.4	4.07		-9	0.5	2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGOT (AST) [U/L]
Reference Range: 10 - 50 (MALE), 10 - 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	28.3	4.90	17.3	19	28.0	35
		V1 (WEEK 0)	19	27.7	6.05	21.8	18	28.0	40
		V3 (WEEK 12)	16	31.3	8.54	27.3	17	30.0	49
		V4 (WEEK 24)	15	29.5	7.49	25.4	20	30.0	40
		V5 (WEEK 36)	14	28.9	7.76	26.9	17	29.0	45
		V6 (WEEK 52)	17	24.6	5.68	23.1	16	26.0	39
		V7 (WEEK 56)	15	24.3	5.34	21.9	16	23.0	33
		V3 (WEEK 12) - V1 (WEEK 0)	16	3.6	8.16		-7	2.5	24
		V4 (WEEK 24) - V1 (WEEK 0)	15	1.9	6.94		-11	3.0	13
		V5 (WEEK 36) - V1 (WEEK 0)	14	1.9	5.75		-11	4.0	10
		V6 (WEEK 52) - V1 (WEEK 0)	17	-2.7	4.38		-12	-3.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	15	-2.9	5.88		-12	-2.0	11

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGOT (AST) [U/L]
Reference Range: 10 - 50 (MALE), 10 - 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	28.5	5.32	18.7	18	28.0	39
		V1 (WEEK 0)	32	28.5	6.43	22.6	18	28.0	48
		V3 (WEEK 12)	29	32.3	11.76	36.4	17	28.0	73
		V4 (WEEK 24)	23	29.6	6.54	22.1	20	29.0	40
		V5 (WEEK 36)	22	28.4	7.34	25.8	17	26.5	45
		V6 (WEEK 52)	25	24.8	5.29	21.3	16	26.0	39
		V7 (WEEK 56)	23	25.1	5.71	22.8	15	24.0	34
		V3 (WEEK 12) - V1 (WEEK 0)	29	3.7	11.46		-9	2.0	51
		V4 (WEEK 24) - V1 (WEEK 0)	23	0.8	7.13		-12	1.0	13
		V5 (WEEK 36) - V1 (WEEK 0)	22	1.1	5.61		-11	3.5	10
		V6 (WEEK 52) - V1 (WEEK 0)	25	-2.7	4.84		-15	-3.0	4
		V7 (WEEK 56) - V1 (WEEK 0)	23	-2.3	5.27		-12	-2.0	11

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGOT (AST) [U/L]
Reference Range: 10 - 50 (MALE), 10 - 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	27.5	5.55	20.2	21	26.5	38
		V1 (WEEK 0)	12	28.1	6.01	21.4	20	28.5	38
		V3 (WEEK 12)	12	27.2	3.43	12.6	21	27.5	33
		V4 (WEEK 24)	12	33.3	12.62	37.9	21	31.5	71
		V5 (WEEK 36)	11	28.0	6.08	21.7	19	30.0	36
		V6 (WEEK 52)	11	25.7	4.58	17.8	16	27.0	33
		V7 (WEEK 56)	11	27.0	6.05	22.4	18	28.0	37
		V3 (WEEK 12) - V1 (WEEK 0)	12	-0.9	5.87		-8	-0.5	12
		V4 (WEEK 24) - V1 (WEEK 0)	12	5.3	12.39		-4	2.5	42
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.0	5.33		-9	0.0	9
		V6 (WEEK 52) - V1 (WEEK 0)	11	-2.3	6.72		-12	-4.0	8
		V7 (WEEK 56) - V1 (WEEK 0)	11	-1.0	8.56		-14	-1.0	16

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGOT (AST) [U/L]
Reference Range: 10 - 50 (MALE), 10 - 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	25.5	5.62	22.1	19	23.0	42
		V1 (WEEK 0)	19	25.1	5.32	21.2	18	24.0	38
		V3 (WEEK 12)	19	24.9	6.04	24.2	18	23.0	42
		V4 (WEEK 24)	19	22.9	3.84	16.7	17	22.0	30
		V5 (WEEK 36)	18	22.7	3.36	14.8	16	21.5	29
		V6 (WEEK 52)	16	22.9	6.08	26.6	14	23.0	36
		V7 (WEEK 56)	16	21.3	5.85	27.5	15	19.0	36
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.1	6.85		-10	-2.0	21
		V4 (WEEK 24) - V1 (WEEK 0)	19	-2.1	4.47		-12	-1.0	5
		V5 (WEEK 36) - V1 (WEEK 0)	18	-2.4	4.53		-12	-1.0	3
		V6 (WEEK 52) - V1 (WEEK 0)	16	-2.1	4.51		-8	-3.0	9
		V7 (WEEK 56) - V1 (WEEK 0)	16	-3.8	4.37		-15	-3.0	5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGOT (AST) [U/L]
Reference Range: 10 - 50 (MALE), 10 - 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	26.3	5.59	21.3	19	25.0	42
		V1 (WEEK 0)	31	26.2	5.70	21.7	18	24.0	38
		V3 (WEEK 12)	31	25.8	5.24	20.3	18	24.0	42
		V4 (WEEK 24)	31	27.0	9.68	35.9	17	25.0	71
		V5 (WEEK 36)	29	24.7	5.20	21.0	16	24.0	36
		V6 (WEEK 52)	27	24.0	5.61	23.3	14	23.0	36
		V7 (WEEK 56)	27	23.6	6.49	27.5	15	22.0	37
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.4	6.40		-10	-2.0	21
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.7	9.03		-12	0.0	42
		V5 (WEEK 36) - V1 (WEEK 0)	29	-1.5	4.90		-12	-1.0	9
		V6 (WEEK 52) - V1 (WEEK 0)	27	-2.2	5.40		-12	-4.0	9
		V7 (WEEK 56) - V1 (WEEK 0)	27	-2.7	6.42		-15	-3.0	16

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGPT (ALT) [U/L]
Reference Range: < 50 (MALE), < 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	24.8	8.26	33.3	14	23.0	42
		V1 (WEEK 0)	13	24.8	9.49	38.2	14	20.0	45
		V3 (WEEK 12)	13	36.9	35.83	97.0	10	24.0	150
		V4 (WEEK 24)	8	27.5	7.21	26.2	18	26.5	38
		V5 (WEEK 36)	8	25.1	10.58	42.1	17	20.0	45
		V6 (WEEK 52)	8	23.5	10.61	45.1	8	23.0	45
		V7 (WEEK 56)	8	26.3	10.44	39.8	10	26.5	42
		V3 (WEEK 12) - V1 (WEEK 0)	13	12.1	37.76		-10	3.0	135
		V4 (WEEK 24) - V1 (WEEK 0)	8	3.0	6.39		-11	5.0	9
		V5 (WEEK 36) - V1 (WEEK 0)	8	2.5	8.23		-13	3.0	17
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.9	8.51		-15	3.5	11
		V7 (WEEK 56) - V1 (WEEK 0)	8	3.6	5.07		-4	5.0	10

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGPT (ALT) [U/L]
Reference Range: < 50 (MALE), < 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	21.7	6.57	30.3	13	21.0	41
		V1 (WEEK 0)	19	21.2	7.60	35.9	10	20.0	41
		V3 (WEEK 12)	16	32.4	19.54	60.2	10	27.0	86
		V4 (WEEK 24)	15	28.4	13.99	49.3	11	25.0	55
		V5 (WEEK 36)	14	24.3	13.18	54.3	11	21.5	61
		V6 (WEEK 52)	17	20.5	7.05	34.4	12	18.0	40
		V7 (WEEK 56)	15	21.3	9.48	44.5	11	18.0	48
		V3 (WEEK 12) - V1 (WEEK 0)	16	10.9	19.08		-6	3.5	65
		V4 (WEEK 24) - V1 (WEEK 0)	15	6.7	11.32		-8	3.0	29
		V5 (WEEK 36) - V1 (WEEK 0)	14	3.8	8.29		-6	1.0	23
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.4	4.42		-7	0.0	8
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.8	9.93		-11	0.0	31

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGPT (ALT) [U/L]
Reference Range: < 50 (MALE), < 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	23.0	7.35	32.0	13	21.5	42
		V1 (WEEK 0)	32	22.7	8.48	37.4	10	20.0	45
		V3 (WEEK 12)	29	34.4	27.56	80.0	10	26.0	150
		V4 (WEEK 24)	23	28.1	11.89	42.3	11	25.0	55
		V5 (WEEK 36)	22	24.6	12.04	49.0	11	21.0	61
		V6 (WEEK 52)	25	21.4	8.25	38.5	8	19.0	45
		V7 (WEEK 56)	23	23.0	9.88	42.9	10	24.0	48
		V3 (WEEK 12) - V1 (WEEK 0)	29	11.4	28.40		-10	3.0	135
		V4 (WEEK 24) - V1 (WEEK 0)	23	5.4	9.89		-11	3.0	29
		V5 (WEEK 36) - V1 (WEEK 0)	22	3.3	8.10		-13	2.0	23
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.6	5.85		-15	1.0	11
		V7 (WEEK 56) - V1 (WEEK 0)	23	1.8	8.53		-11	0.0	31

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGPT (ALT) [U/L]
Reference Range: < 50 (MALE), < 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	23.7	5.99	25.3	15	24.0	36
		V1 (WEEK 0)	12	24.3	6.33	26.0	15	24.5	32
		V3 (WEEK 12)	12	26.0	4.59	17.7	20	27.0	33
		V4 (WEEK 24)	12	37.4	21.11	56.4	20	29.5	93
		V5 (WEEK 36)	11	26.0	7.86	30.2	15	24.0	41
		V6 (WEEK 52)	11	24.9	7.52	30.2	14	27.0	39
		V7 (WEEK 56)	11	23.3	6.18	26.6	12	25.0	33
		V3 (WEEK 12) - V1 (WEEK 0)	12	1.7	6.44		-9	1.5	13
		V4 (WEEK 24) - V1 (WEEK 0)	12	13.1	19.56		-2	6.0	61
		V5 (WEEK 36) - V1 (WEEK 0)	11	2.4	6.76		-9	3.0	12
		V6 (WEEK 52) - V1 (WEEK 0)	11	1.3	6.29		-9	-2.0	11
		V7 (WEEK 56) - V1 (WEEK 0)	11	-0.4	7.07		-12	-1.0	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGPT (ALT) [U/L]
Reference Range: < 50 (MALE), < 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	20.3	9.35	46.0	11	19.0	53
		V1 (WEEK 0)	19	19.7	9.64	48.9	9	18.0	55
		V3 (WEEK 12)	19	20.1	10.68	53.1	10	17.0	56
		V4 (WEEK 24)	19	18.0	5.89	32.7	10	18.0	37
		V5 (WEEK 36)	18	17.9	6.60	36.8	10	16.5	38
		V6 (WEEK 52)	16	17.4	10.22	58.6	6	15.0	50
		V7 (WEEK 56)	16	19.6	8.57	43.8	9	18.0	43
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.4	11.75		-24	-2.0	38
		V4 (WEEK 24) - V1 (WEEK 0)	19	-1.7	6.14		-18	-1.0	7
		V5 (WEEK 36) - V1 (WEEK 0)	18	-1.7	6.22		-17	-0.5	7
		V6 (WEEK 52) - V1 (WEEK 0)	16	-2.1	4.45		-12	-2.0	9
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.4	6.14		-12	-0.5	12

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: SGPT (ALT) [U/L]
Reference Range: < 50 (MALE), < 35 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	21.6	8.27	38.3	11	20.0	53
		V1 (WEEK 0)	31	21.5	8.70	40.4	9	20.0	55
		V3 (WEEK 12)	31	22.4	9.20	41.1	10	21.0	56
		V4 (WEEK 24)	31	25.5	16.63	65.2	10	20.0	93
		V5 (WEEK 36)	29	21.0	8.02	38.2	10	18.0	41
		V6 (WEEK 52)	27	20.5	9.80	47.8	6	19.0	50
		V7 (WEEK 56)	27	21.1	7.78	36.9	9	20.0	43
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.9	9.92		-24	1.0	38
		V4 (WEEK 24) - V1 (WEEK 0)	31	4.0	14.72		-18	1.0	61
		V5 (WEEK 36) - V1 (WEEK 0)	29	-0.2	6.62		-17	0.0	12
		V6 (WEEK 52) - V1 (WEEK 0)	27	-0.7	5.43		-12	-2.0	11
		V7 (WEEK 56) - V1 (WEEK 0)	27	-0.4	6.40		-12	-1.0	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: ALKALINE PHOSPHATASE [U/L]
Reference Range: 40 - 130 (MALE), 35 - 105 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	65.4	21.40	32.7	24	65.0	104
		V1 (WEEK 0)	13	67.2	24.02	35.8	22	64.0	110
		V3 (WEEK 12)	13	61.6	22.25	36.1	20	61.0	96
		V4 (WEEK 24)	8	56.6	20.69	36.5	23	61.0	80
		V5 (WEEK 36)	8	55.0	21.80	39.6	20	58.0	86
		V6 (WEEK 52)	8	55.8	20.00	35.9	23	59.5	80
		V7 (WEEK 56)	8	57.5	24.38	42.4	22	51.5	92
		V3 (WEEK 12) - V1 (WEEK 0)	13	-5.5	7.96		-14	-6.0	15
		V4 (WEEK 24) - V1 (WEEK 0)	8	-5.5	6.41		-16	-5.0	2
		V5 (WEEK 36) - V1 (WEEK 0)	8	-7.4	4.00		-12	-8.5	-1
		V6 (WEEK 52) - V1 (WEEK 0)	8	-6.6	9.84		-25	-9.0	5
		V7 (WEEK 56) - V1 (WEEK 0)	8	-4.9	13.45		-23	-5.5	23

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALKALINE PHOSPHATASE [U/L]
Reference Range: 40 - 130 (MALE), 35 - 105 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	83.5	26.85	32.2	50	76.0	152
		V1 (WEEK 0)	19	83.6	31.72	38.0	51	76.0	158
		V3 (WEEK 12)	16	82.1	26.03	31.7	56	76.0	148
		V4 (WEEK 24)	15	81.1	26.22	32.3	56	73.0	156
		V5 (WEEK 36)	14	77.8	26.32	33.8	54	72.5	152
		V6 (WEEK 52)	17	80.4	20.78	25.8	56	75.0	135
		V7 (WEEK 56)	15	80.7	25.54	31.7	47	74.0	150
		V3 (WEEK 12) - V1 (WEEK 0)	16	-1.4	27.29		-78	1.0	56
		V4 (WEEK 24) - V1 (WEEK 0)	15	-3.5	23.81		-80	2.0	19
		V5 (WEEK 36) - V1 (WEEK 0)	14	-6.1	24.26		-79	0.5	21
		V6 (WEEK 52) - V1 (WEEK 0)	17	-4.1	21.29		-70	2.0	20
		V7 (WEEK 56) - V1 (WEEK 0)	15	-4.3	23.98		-75	1.0	23

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: ALKALINE PHOSPHATASE [U/L]
Reference Range: 40 - 130 (MALE), 35 - 105 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	76.2	26.04	34.2	24	69.5	152
		V1 (WEEK 0)	32	76.9	29.58	38.5	22	69.0	158
		V3 (WEEK 12)	29	72.9	26.12	35.8	20	74.0	148
		V4 (WEEK 24)	23	72.6	26.76	36.9	23	68.0	156
		V5 (WEEK 36)	22	69.5	26.70	38.4	20	62.0	152
		V6 (WEEK 52)	25	72.5	23.29	32.1	23	71.0	135
		V7 (WEEK 56)	23	72.6	27.05	37.3	22	70.0	150
		V3 (WEEK 12) - V1 (WEEK 0)	29	-3.2	20.75		-78	-5.0	56
		V4 (WEEK 24) - V1 (WEEK 0)	23	-4.2	19.36		-80	-1.0	19
		V5 (WEEK 36) - V1 (WEEK 0)	22	-6.5	19.23		-79	-4.0	21
		V6 (WEEK 52) - V1 (WEEK 0)	25	-4.9	18.22		-70	1.0	20
		V7 (WEEK 56) - V1 (WEEK 0)	23	-4.5	20.58		-75	-3.0	23

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALKALINE PHOSPHATASE [U/L]
Reference Range: 40 - 130 (MALE), 35 - 105 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	70.1	22.22	31.7	38	67.5	114
		V1 (WEEK 0)	12	72.3	16.36	22.6	48	69.5	105
		V3 (WEEK 12)	12	73.3	21.71	29.6	47	68.5	120
		V4 (WEEK 24)	12	74.3	26.89	36.2	45	63.5	129
		V5 (WEEK 36)	11	73.9	17.77	24.0	51	71.0	102
		V6 (WEEK 52)	11	80.9	27.52	34.0	44	74.0	134
		V7 (WEEK 56)	11	75.3	21.29	28.3	46	71.0	119
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.9	12.06		-20	-1.5	23
		V4 (WEEK 24) - V1 (WEEK 0)	12	2.0	19.78		-28	-2.5	48
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.2	12.41		-27	-2.0	23
		V6 (WEEK 52) - V1 (WEEK 0)	11	7.2	15.39		-24	5.0	29
		V7 (WEEK 56) - V1 (WEEK 0)	11	1.5	8.87		-18	1.0	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALKALINE PHOSPHATASE [U/L]
Reference Range: 40 - 130 (MALE), 35 - 105 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	82.3	19.03	23.1	47	77.0	132
		V1 (WEEK 0)	19	80.6	21.74	27.0	45	83.0	146
		V3 (WEEK 12)	19	78.5	14.35	18.3	53	75.0	113
		V4 (WEEK 24)	19	77.2	14.37	18.6	51	76.0	109
		V5 (WEEK 36)	18	75.3	19.58	26.0	48	72.5	126
		V6 (WEEK 52)	16	73.5	18.41	25.1	39	70.0	110
		V7 (WEEK 56)	16	75.7	16.77	22.2	55	71.0	105
		V3 (WEEK 12) - V1 (WEEK 0)	19	-2.1	17.76		-44	-3.0	32
		V4 (WEEK 24) - V1 (WEEK 0)	19	-3.5	16.59		-60	-1.0	17
		V5 (WEEK 36) - V1 (WEEK 0)	18	-5.1	10.60		-21	-6.0	13
		V6 (WEEK 52) - V1 (WEEK 0)	16	-2.4	11.94		-21	-4.0	21
		V7 (WEEK 56) - V1 (WEEK 0)	16	-6.5	17.71		-54	-1.0	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: ALKALINE PHOSPHATASE [U/L]
Reference Range: 40 - 130 (MALE), 35 - 105 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	77.5	20.85	26.9	38	74.0	132
		V1 (WEEK 0)	31	77.4	19.96	25.8	45	76.0	146
		V3 (WEEK 12)	31	76.5	17.41	22.8	47	74.0	120
		V4 (WEEK 24)	31	76.1	19.78	26.0	45	72.0	129
		V5 (WEEK 36)	29	74.8	18.61	24.9	48	71.0	126
		V6 (WEEK 52)	27	76.5	22.37	29.2	39	72.0	134
		V7 (WEEK 56)	27	75.5	18.35	24.3	46	71.0	119
		V3 (WEEK 12) - V1 (WEEK 0)	31	-0.9	15.65		-44	-2.0	32
		V4 (WEEK 24) - V1 (WEEK 0)	31	-1.4	17.78		-60	-2.0	48
		V5 (WEEK 36) - V1 (WEEK 0)	29	-3.1	11.40		-27	-3.0	23
		V6 (WEEK 52) - V1 (WEEK 0)	27	1.5	14.01		-24	3.0	29
		V7 (WEEK 56) - V1 (WEEK 0)	27	-3.2	15.08		-54	0.0	15

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: GAMMA-GT [U/L]
Reference Range: < 60 (MALE), < 40 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	40.5	48.57	119.8	10	29.0	199
		V1 (WEEK 0)	13	39.2	50.16	127.9	9	25.0	203
		V3 (WEEK 12)	13	35.5	39.77	111.9	10	24.0	164
		V4 (WEEK 24)	8	25.8	8.53	33.1	16	24.5	38
		V5 (WEEK 36)	8	25.5	6.89	27.0	16	24.0	37
		V6 (WEEK 52)	8	26.3	9.68	36.9	13	26.0	40
		V7 (WEEK 56)	8	27.0	8.68	32.2	13	27.5	42
		V3 (WEEK 12) - V1 (WEEK 0)	13	-3.7	11.61		-39	-1.0	11
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.8	5.04		-6	-2.5	7
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.1	7.32		-8	-4.0	12
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.6	5.88		-6	0.0	11
		V7 (WEEK 56) - V1 (WEEK 0)	8	1.4	7.60		-9	2.0	12

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GAMMA-GT [U/L]
Reference Range: < 60 (MALE), < 40 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	30.0	32.42	108.1	13	19.0	153
		V1 (WEEK 0)	19	28.9	36.93	127.6	12	17.0	175
		V3 (WEEK 12)	16	44.9	66.72	148.7	10	22.0	262
		V4 (WEEK 24)	15	35.3	39.86	112.8	11	21.0	168
		V5 (WEEK 36)	14	35.5	38.22	107.7	11	23.5	160
		V6 (WEEK 52)	17	30.0	34.66	115.5	10	22.0	160
		V7 (WEEK 56)	15	30.5	32.51	106.7	9	23.0	143
		V3 (WEEK 12) - V1 (WEEK 0)	16	13.2	62.39		-27	0.0	244
		V4 (WEEK 24) - V1 (WEEK 0)	15	2.4	15.86		-27	1.0	44
		V5 (WEEK 36) - V1 (WEEK 0)	14	1.1	12.93		-25	0.5	32
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.8	11.25		-25	-1.0	18
		V7 (WEEK 56) - V1 (WEEK 0)	15	-2.5	13.05		-32	0.0	22

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GAMMA-GT [U/L]
Reference Range: < 60 (MALE), < 40 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	34.3	39.39	114.9	10	25.5	199
		V1 (WEEK 0)	32	33.1	42.33	127.8	9	20.0	203
		V3 (WEEK 12)	29	40.7	55.54	136.5	10	23.0	262
		V4 (WEEK 24)	23	32.0	32.49	101.5	11	22.0	168
		V5 (WEEK 36)	22	31.9	30.73	96.4	11	24.0	160
		V6 (WEEK 52)	25	28.8	28.84	100.1	10	23.0	160
		V7 (WEEK 56)	23	29.3	26.44	90.4	9	23.0	143
		V3 (WEEK 12) - V1 (WEEK 0)	29	5.6	47.08		-39	0.0	244
		V4 (WEEK 24) - V1 (WEEK 0)	23	1.3	13.06		-27	0.0	44
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.7	11.03		-25	0.0	32
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.4	9.74		-25	-1.0	18
		V7 (WEEK 56) - V1 (WEEK 0)	23	-1.1	11.41		-32	0.0	22

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GAMMA-GT [U/L]
Reference Range: < 60 (MALE), < 40 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	25.3	6.18	24.4	17	25.5	36
		V1 (WEEK 0)	12	26.0	10.52	40.5	18	23.0	53
		V3 (WEEK 12)	12	36.4	26.41	72.5	14	29.5	102
		V4 (WEEK 24)	12	38.1	29.27	76.9	16	26.5	116
		V5 (WEEK 36)	11	29.4	8.81	30.0	18	27.0	46
		V6 (WEEK 52)	11	26.5	9.02	34.1	11	26.0	39
		V7 (WEEK 56)	11	27.5	9.27	33.6	16	26.0	46
		V3 (WEEK 12) - V1 (WEEK 0)	12	10.4	27.90		-15	2.0	79
		V4 (WEEK 24) - V1 (WEEK 0)	12	12.1	26.93		-6	3.5	93
		V5 (WEEK 36) - V1 (WEEK 0)	11	5.8	8.13		-7	4.0	23
		V6 (WEEK 52) - V1 (WEEK 0)	11	2.9	8.38		-7	-1.0	17
		V7 (WEEK 56) - V1 (WEEK 0)	11	4.0	7.69		-4	4.0	23

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

14FEB2013

Safety Population

Parameter: GAMMA-GT [U/L]
Reference Range: < 60 (MALE), < 40 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	20.6	15.21	73.9	9	14.0	75
		V1 (WEEK 0)	19	18.2	8.80	48.3	8	16.0	38
		V3 (WEEK 12)	19	18.6	12.69	68.3	7	14.0	55
		V4 (WEEK 24)	19	16.9	7.88	46.5	8	15.0	35
		V5 (WEEK 36)	18	15.3	7.62	49.7	9	13.5	44
		V6 (WEEK 52)	16	16.3	8.90	54.5	9	15.5	46
		V7 (WEEK 56)	16	16.9	11.55	68.2	8	14.5	58
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.4	5.41		-4	-2.0	18
		V4 (WEEK 24) - V1 (WEEK 0)	19	-1.3	6.26		-19	-1.0	8
		V5 (WEEK 36) - V1 (WEEK 0)	18	-1.8	7.99		-23	-2.5	17
		V6 (WEEK 52) - V1 (WEEK 0)	16	-1.8	8.23		-22	-1.0	19
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.6	10.65		-24	-1.5	31

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: GAMMA-GT [U/L]
Reference Range: < 60 (MALE), < 40 (FEMALE) U/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	22.4	12.59	56.1	9	19.0	75
		V1 (WEEK 0)	31	21.2	10.10	47.6	8	20.0	53
		V3 (WEEK 12)	31	25.5	20.74	81.4	7	19.0	102
		V4 (WEEK 24)	31	25.1	21.47	85.4	8	18.0	116
		V5 (WEEK 36)	29	20.7	10.54	51.0	9	15.0	46
		V6 (WEEK 52)	27	20.4	10.13	49.6	9	17.0	46
		V7 (WEEK 56)	27	21.3	11.76	55.3	8	17.0	58
		V3 (WEEK 12) - V1 (WEEK 0)	31	4.3	18.10		-15	-2.0	79
		V4 (WEEK 24) - V1 (WEEK 0)	31	3.9	18.25		-19	0.0	93
		V5 (WEEK 36) - V1 (WEEK 0)	29	1.1	8.75		-23	1.0	23
		V6 (WEEK 52) - V1 (WEEK 0)	27	0.1	8.46		-22	-1.0	19
		V7 (WEEK 56) - V1 (WEEK 0)	27	1.3	9.66		-24	-1.0	31

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

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Safety Population

Parameter: CHOLESTEROL [mmol/L]
Reference Range: < 6.50 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	5.482	1.0959	19.992	3.65	5.460	7.30
		V1 (WEEK 0)	13	5.524	1.0356	18.748	4.22	5.230	7.43
		V3 (WEEK 12)	13	5.452	1.0847	19.894	4.53	4.970	7.90
		V4 (WEEK 24)	8	5.298	0.8769	16.553	4.33	5.000	6.73
		V5 (WEEK 36)	8	5.384	1.0133	18.822	4.25	5.050	6.97
		V6 (WEEK 52)	8	5.370	0.7865	14.646	4.53	5.100	6.89
		V7 (WEEK 56)	8	5.550	0.7160	12.901	4.71	5.440	6.97
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.072	0.6258		-1.60	-0.110	0.70
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.227	0.7732		-1.40	0.045	0.91
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.265	0.8084		-1.37	-0.405	0.96
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.279	1.0941		-1.63	-0.300	1.71
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.099	1.0443		-1.30	-0.115	1.82

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

14FEB2013

Safety Population

Parameter: CHOLESTEROL [mmol/L]
Reference Range: < 6.50 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	6.088	1.3209	21.695	4.12	5.700	9.14
		V1 (WEEK 0)	19	6.072	1.0000	16.471	3.96	6.140	8.73
		V3 (WEEK 12)	16	6.300	1.0666	16.930	4.64	6.435	8.29
		V4 (WEEK 24)	15	5.987	0.8168	13.642	4.71	6.090	7.20
		V5 (WEEK 36)	14	6.239	0.8901	14.266	4.79	6.370	7.72
		V6 (WEEK 52)	17	6.132	1.1587	18.896	3.94	6.110	8.21
		V7 (WEEK 56)	15	6.231	1.0472	16.805	4.53	6.290	7.72
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.057	0.6166		-1.04	-0.080	1.09
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.086	1.0659		-2.46	-0.130	1.74
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.208	1.5311		-3.94	0.155	2.54
		V6 (WEEK 52) - V1 (WEEK 0)	17	0.112	1.0599		-1.17	-0.020	2.98
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.215	1.3908		-1.97	-0.130	3.76

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHOLESTEROL [mmol/L]
Reference Range: < 6.50 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	5.842	1.2529	21.446	3.65	5.530	9.14
		V1 (WEEK 0)	32	5.849	1.0347	17.690	3.96	5.905	8.73
		V3 (WEEK 12)	29	5.920	1.1392	19.243	4.53	5.670	8.29
		V4 (WEEK 24)	23	5.747	0.8843	15.387	4.33	5.700	7.20
		V5 (WEEK 36)	22	5.928	1.0051	16.954	4.25	5.855	7.72
		V6 (WEEK 52)	25	5.888	1.0986	18.659	3.94	5.750	8.21
		V7 (WEEK 56)	23	5.994	0.9854	16.439	4.53	5.960	7.72
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.000	0.6130		-1.60	-0.110	1.09
		V4 (WEEK 24) - V1 (WEEK 0)	23	-0.135	0.9581		-2.46	-0.020	1.74
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.036	1.3127		-3.94	0.120	2.54
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.013	1.0643		-1.63	-0.060	2.98
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.106	1.2654		-1.97	-0.130	3.76

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHOLESTEROL [mmol/L]
Reference Range: < 6.50 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	5.672	1.2204	21.517	3.65	5.760	7.54
		V1 (WEEK 0)	12	5.833	1.3861	23.765	3.19	6.135	7.49
		V3 (WEEK 12)	12	5.931	1.1610	19.575	3.42	6.370	6.89
		V4 (WEEK 24)	12	5.890	1.0739	18.233	3.83	6.050	7.20
		V5 (WEEK 36)	11	6.165	1.2066	19.573	3.76	6.140	8.00
		V6 (WEEK 52)	11	5.849	1.4476	24.749	3.57	6.220	8.16
		V7 (WEEK 56)	11	6.043	1.5141	25.057	3.76	5.720	8.73
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.098	1.0072		-1.71	0.055	2.23
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.057	1.0509		-1.79	0.155	1.48
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.480	0.9177		-0.65	0.160	2.51
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.165	0.6917		-0.90	0.150	1.19
		V7 (WEEK 56) - V1 (WEEK 0)	11	0.358	0.8316		-0.96	0.210	1.76

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

Safety Population

Parameter: CHOLESTEROL [mmol/L]
Reference Range: < 6.50 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	6.061	1.1474	18.931	4.45	5.830	8.00
		V1 (WEEK 0)	19	5.811	0.9541	16.419	4.33	5.800	7.54
		V3 (WEEK 12)	19	5.937	1.0401	17.519	4.22	5.830	7.82
		V4 (WEEK 24)	19	5.761	0.9341	16.214	4.30	5.830	7.51
		V5 (WEEK 36)	18	5.763	0.8081	14.022	4.45	5.855	7.17
		V6 (WEEK 52)	16	5.755	0.9166	15.928	4.45	5.710	7.80
		V7 (WEEK 56)	16	5.611	0.9492	16.919	4.35	5.810	7.43
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.126	0.4548		-0.57	0.000	1.27
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.050	0.6038		-0.96	-0.050	1.12
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.014	0.7350		-2.02	0.070	1.19
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.080	0.5937		-1.01	0.120	1.12
		V7 (WEEK 56) - V1 (WEEK 0)	16	-0.064	0.6471		-1.45	-0.035	1.09

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: CHOLESTEROL [mmol/L]
Reference Range: < 6.50 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	5.910	1.1718	19.827	3.65	5.800	8.00
		V1 (WEEK 0)	31	5.819	1.1184	19.219	3.19	5.830	7.54
		V3 (WEEK 12)	31	5.935	1.0692	18.017	3.42	5.880	7.82
		V4 (WEEK 24)	31	5.811	0.9749	16.778	3.83	5.880	7.51
		V5 (WEEK 36)	29	5.915	0.9776	16.527	3.76	5.980	8.00
		V6 (WEEK 52)	27	5.793	1.1371	19.627	3.57	5.850	8.16
		V7 (WEEK 56)	27	5.787	1.2035	20.798	3.76	5.720	8.73
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.115	0.7044		-1.71	0.000	2.23
		V4 (WEEK 24) - V1 (WEEK 0)	31	-0.008	0.7915		-1.79	-0.030	1.48
		V5 (WEEK 36) - V1 (WEEK 0)	29	0.173	0.8296		-2.02	0.100	2.51
		V6 (WEEK 52) - V1 (WEEK 0)	27	0.114	0.6238		-1.01	0.150	1.19
		V7 (WEEK 56) - V1 (WEEK 0)	27	0.108	0.7432		-1.45	0.050	1.76

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TRIGLYCERIDES [mmol/L]
Reference Range: 0.57 - 2.28 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	1.652	0.6503	39.374	0.55	1.700	2.59
		V1 (WEEK 0)	13	1.631	0.5897	36.163	0.72	1.710	2.46
		V3 (WEEK 12)	13	1.688	0.7807	46.236	0.48	1.620	2.71
		V4 (WEEK 24)	8	1.618	0.5149	31.830	0.66	1.600	2.29
		V5 (WEEK 36)	8	1.580	0.7266	45.988	0.50	1.620	2.49
		V6 (WEEK 52)	8	1.510	0.7412	49.088	0.63	1.630	2.85
		V7 (WEEK 56)	8	1.674	0.9930	59.331	0.60	1.590	3.55
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.058	0.4898		-0.84	-0.030	0.91
		V4 (WEEK 24) - V1 (WEEK 0)	8	-0.157	0.3314		-0.72	-0.135	0.22
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.071	0.1980		-0.38	-0.045	0.17
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.141	0.5209		-0.69	-0.200	0.70
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.023	0.5998		-0.70	-0.090	1.19

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TRIGLYCERIDES [mmol/L]
Reference Range: 0.57 - 2.28 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	1.667	1.0997	65.951	0.76	1.220	4.90
		V1 (WEEK 0)	19	1.638	0.7276	44.408	0.88	1.370	3.15
		V3 (WEEK 12)	16	1.529	0.9126	59.668	0.71	1.260	4.39
		V4 (WEEK 24)	15	1.473	0.7842	53.228	0.71	1.410	3.92
		V5 (WEEK 36)	14	1.505	0.4376	29.075	0.89	1.540	2.49
		V6 (WEEK 52)	17	1.534	0.6185	40.315	0.88	1.370	2.87
		V7 (WEEK 56)	15	1.657	0.7670	46.280	0.78	1.500	3.73
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.159	0.7600		-1.60	-0.260	1.38
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.259	0.7580		-2.30	-0.070	0.77
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.248	0.7033		-1.91	0.015	0.61
		V6 (WEEK 52) - V1 (WEEK 0)	17	-0.151	0.8261		-1.87	0.000	0.98
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.037	0.9009		-2.13	-0.130	1.30

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TRIGLYCERIDES [mmol/L]
Reference Range: 0.57 - 2.28 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	1.661	0.9305	56.024	0.55	1.400	4.90
		V1 (WEEK 0)	32	1.635	0.6649	40.656	0.72	1.445	3.15
		V3 (WEEK 12)	29	1.601	0.8449	52.781	0.48	1.440	4.39
		V4 (WEEK 24)	23	1.523	0.6933	45.507	0.66	1.430	3.92
		V5 (WEEK 36)	22	1.532	0.5440	35.500	0.50	1.540	2.49
		V6 (WEEK 52)	25	1.526	0.6445	42.224	0.63	1.480	2.87
		V7 (WEEK 56)	23	1.663	0.8296	49.884	0.60	1.500	3.73
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.062	0.6513		-1.60	-0.050	1.38
		V4 (WEEK 24) - V1 (WEEK 0)	23	-0.224	0.6349		-2.30	-0.120	0.77
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.184	0.5717		-1.91	-0.030	0.61
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.148	0.7308		-1.87	-0.050	0.98
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.017	0.7949		-2.13	-0.130	1.30

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TRIGLYCERIDES [mmol/L]
Reference Range: 0.57 - 2.28 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	1.588	0.7192	45.280	0.73	1.605	2.93
		V1 (WEEK 0)	12	1.618	0.7339	45.370	0.71	1.575	3.42
		V3 (WEEK 12)	12	1.809	0.9649	53.334	0.63	1.655	3.39
		V4 (WEEK 24)	12	1.618	0.9193	56.806	0.68	1.355	3.48
		V5 (WEEK 36)	11	1.907	0.8333	43.692	0.70	1.580	3.21
		V6 (WEEK 52)	11	1.776	1.0916	61.451	0.72	1.370	4.02
		V7 (WEEK 56)	11	1.785	1.0405	58.305	0.71	1.300	3.73
		V3 (WEEK 12) - V1 (WEEK 0)	12	0.192	0.6346		-0.71	0.035	1.25
		V4 (WEEK 24) - V1 (WEEK 0)	12	0.001	0.7570		-1.27	-0.080	1.64
		V5 (WEEK 36) - V1 (WEEK 0)	11	0.252	0.6217		-0.73	0.380	1.15
		V6 (WEEK 52) - V1 (WEEK 0)	11	0.121	0.5428		-0.42	0.010	1.18
		V7 (WEEK 56) - V1 (WEEK 0)	11	0.129	0.6413		-0.76	-0.040	1.81

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TRIGLYCERIDES [mmol/L]
Reference Range: 0.57 - 2.28 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	1.608	0.6956	43.247	0.82	1.520	3.44
		V1 (WEEK 0)	19	1.465	0.7150	48.815	0.63	1.230	3.31
		V3 (WEEK 12)	18	1.533	0.9416	61.433	0.58	1.290	4.07
		V4 (WEEK 24)	19	1.581	0.8320	52.622	0.75	1.130	3.52
		V5 (WEEK 36)	18	1.580	0.6493	41.097	0.70	1.415	2.75
		V6 (WEEK 52)	16	1.949	1.1744	60.242	0.73	1.515	4.71
		V7 (WEEK 56)	16	1.754	0.8113	46.243	0.82	1.595	3.72
		V3 (WEEK 12) - V1 (WEEK 0)	18	0.038	0.5733		-0.71	0.000	1.69
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.116	0.5919		-0.94	0.090	1.19
		V5 (WEEK 36) - V1 (WEEK 0)	18	0.114	0.4795		-0.56	0.075	1.45
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.415	0.7381		-0.43	0.125	2.02
		V7 (WEEK 56) - V1 (WEEK 0)	16	0.210	0.5767		-0.49	0.130	1.87

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: TRIGLYCERIDES [mmol/L]
Reference Range: 0.57 - 2.28 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	1.601	0.6929	43.287	0.73	1.520	3.44
		V1 (WEEK 0)	31	1.524	0.7141	46.861	0.63	1.410	3.42
		V3 (WEEK 12)	30	1.643	0.9444	57.468	0.58	1.455	4.07
		V4 (WEEK 24)	31	1.595	0.8518	53.388	0.68	1.130	3.52
		V5 (WEEK 36)	29	1.704	0.7281	42.725	0.70	1.430	3.21
		V6 (WEEK 52)	27	1.879	1.1231	59.777	0.72	1.370	4.71
		V7 (WEEK 56)	27	1.767	0.8924	50.511	0.71	1.540	3.73
		V3 (WEEK 12) - V1 (WEEK 0)	30	0.100	0.5926		-0.71	0.000	1.69
		V4 (WEEK 24) - V1 (WEEK 0)	31	0.072	0.6509		-1.27	-0.010	1.64
		V5 (WEEK 36) - V1 (WEEK 0)	29	0.167	0.5313		-0.73	0.080	1.45
		V6 (WEEK 52) - V1 (WEEK 0)	27	0.295	0.6703		-0.43	0.100	2.02
		V7 (WEEK 56) - V1 (WEEK 0)	27	0.177	0.5931		-0.76	0.110	1.87

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: URIC ACID [µmol/L]
Reference Range: 202 - 416 (MALE), 143 - 357 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	327.7	58.96	18.0	232	327.0	416
		V1 (WEEK 0)	13	334.9	73.26	21.9	238	333.0	446
		V3 (WEEK 12)	13	339.5	63.14	18.6	256	333.0	440
		V4 (WEEK 24)	8	368.0	68.52	18.6	280	345.0	458
		V5 (WEEK 36)	8	360.8	71.77	19.9	244	366.0	458
		V6 (WEEK 52)	8	344.9	83.32	24.2	190	360.0	428
		V7 (WEEK 56)	8	341.3	84.50	24.8	208	351.0	440
		V3 (WEEK 12) - V1 (WEEK 0)	13	4.6	44.21		-113	12.0	83
		V4 (WEEK 24) - V1 (WEEK 0)	8	14.1	63.96		-113	23.5	107
		V5 (WEEK 36) - V1 (WEEK 0)	8	11.4	56.71		-95	21.0	89
		V6 (WEEK 52) - V1 (WEEK 0)	8	-4.5	38.14		-54	6.0	36
		V7 (WEEK 56) - V1 (WEEK 0)	8	-8.1	38.60		-83	3.0	36

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: URIC ACID [µmol/L]
Reference Range: 202 - 416 (MALE), 143 - 357 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	321.5	78.42	24.4	202	315.0	488
		V1 (WEEK 0)	19	325.0	70.19	21.6	214	321.0	470
		V3 (WEEK 12)	16	305.9	74.83	24.5	190	300.0	416
		V4 (WEEK 24)	15	318.5	71.57	22.5	238	303.0	446
		V5 (WEEK 36)	14	326.6	88.98	27.2	202	324.0	470
		V6 (WEEK 52)	17	323.6	74.83	23.1	208	327.0	470
		V7 (WEEK 56)	15	315.3	78.21	24.8	208	303.0	458
		V3 (WEEK 12) - V1 (WEEK 0)	16	-9.0	30.03		-54	-12.0	48
		V4 (WEEK 24) - V1 (WEEK 0)	15	-14.3	61.79		-172	-12.0	59
		V5 (WEEK 36) - V1 (WEEK 0)	14	-7.4	81.19		-244	6.0	83
		V6 (WEEK 52) - V1 (WEEK 0)	17	-8.5	72.59		-185	-6.0	89
		V7 (WEEK 56) - V1 (WEEK 0)	15	-17.5	74.49		-238	0.0	78

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: URIC ACID [µmol/L]
Reference Range: 202 - 416 (MALE), 143 - 357 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	324.0	70.19	21.7	202	318.0	488
		V1 (WEEK 0)	32	329.0	70.45	21.4	214	327.0	470
		V3 (WEEK 12)	29	321.0	70.69	22.0	190	321.0	440
		V4 (WEEK 24)	23	335.7	73.04	21.8	238	309.0	458
		V5 (WEEK 36)	22	339.0	83.07	24.5	202	345.0	470
		V6 (WEEK 52)	25	330.4	76.55	23.2	190	327.0	470
		V7 (WEEK 56)	23	324.3	79.52	24.5	208	339.0	458
		V3 (WEEK 12) - V1 (WEEK 0)	29	-2.9	36.99		-113	-6.0	83
		V4 (WEEK 24) - V1 (WEEK 0)	23	-4.4	62.63		-172	6.0	107
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.5	72.37		-244	12.0	89
		V6 (WEEK 52) - V1 (WEEK 0)	25	-7.2	62.78		-185	-6.0	89
		V7 (WEEK 56) - V1 (WEEK 0)	23	-14.2	63.45		-238	0.0	78

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: URIC ACID [µmol/L]
Reference Range: 202 - 416 (MALE), 143 - 357 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	351.9	65.80	18.7	250	336.0	470
		V1 (WEEK 0)	12	361.4	51.74	14.3	274	351.0	470
		V3 (WEEK 12)	12	358.4	63.17	17.6	256	360.0	470
		V4 (WEEK 24)	12	358.4	56.39	15.7	262	354.0	464
		V5 (WEEK 36)	11	358.0	58.61	16.4	268	351.0	482
		V6 (WEEK 52)	11	370.4	65.27	17.6	286	351.0	470
		V7 (WEEK 56)	11	359.0	70.75	19.7	244	345.0	452
		V3 (WEEK 12) - V1 (WEEK 0)	12	-3.0	54.95		-119	0.0	101
		V4 (WEEK 24) - V1 (WEEK 0)	12	-3.0	52.68		-131	3.0	65
		V5 (WEEK 36) - V1 (WEEK 0)	11	6.5	25.87		-24	0.0	60
		V6 (WEEK 52) - V1 (WEEK 0)	11	18.8	43.81		-54	18.0	83
		V7 (WEEK 56) - V1 (WEEK 0)	11	7.5	53.00		-89	12.0	101

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: URIC ACID [µmol/L]
Reference Range: 202 - 416 (MALE), 143 - 357 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	267.7	65.09	24.3	167	244.0	410
		V1 (WEEK 0)	19	269.3	69.36	25.8	190	244.0	458
		V3 (WEEK 12)	19	272.2	85.61	31.5	143	262.0	488
		V4 (WEEK 24)	19	263.7	71.95	27.3	155	256.0	482
		V5 (WEEK 36)	18	279.3	67.89	24.3	172	271.0	458
		V6 (WEEK 52)	16	263.6	65.98	25.0	172	265.0	458
		V7 (WEEK 56)	16	257.6	65.97	25.6	196	235.0	440
		V3 (WEEK 12) - V1 (WEEK 0)	19	2.9	53.23		-160	11.0	72
		V4 (WEEK 24) - V1 (WEEK 0)	19	-5.6	36.28		-65	-6.0	72
		V5 (WEEK 36) - V1 (WEEK 0)	18	7.7	36.61		-77	0.0	66
		V6 (WEEK 52) - V1 (WEEK 0)	16	-2.9	39.88		-65	-15.0	89
		V7 (WEEK 56) - V1 (WEEK 0)	16	-9.4	52.39		-107	-18.0	78

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.1: Blood chemistry, descriptive statistics

 14FEB2013

Safety Population

Parameter: URIC ACID [µmol/L]
Reference Range: 202 - 416 (MALE), 143 - 357 (FEMALE) µmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	300.3	76.61	25.5	167	297.0	470
		V1 (WEEK 0)	31	304.9	77.14	25.3	190	303.0	470
		V3 (WEEK 12)	31	305.5	87.66	28.7	143	297.0	488
		V4 (WEEK 24)	31	300.4	80.45	26.8	155	280.0	482
		V5 (WEEK 36)	29	309.2	74.39	24.1	172	291.0	482
		V6 (WEEK 52)	27	307.1	83.70	27.3	172	286.0	470
		V7 (WEEK 56)	27	298.9	83.76	28.0	196	286.0	452
		V3 (WEEK 12) - V1 (WEEK 0)	31	0.6	53.07		-160	6.0	101
		V4 (WEEK 24) - V1 (WEEK 0)	31	-4.6	42.54		-131	-6.0	72
		V5 (WEEK 36) - V1 (WEEK 0)	29	7.2	32.45		-77	0.0	66
		V6 (WEEK 52) - V1 (WEEK 0)	27	5.9	42.12		-65	0.0	89
		V7 (WEEK 56) - V1 (WEEK 0)	27	-2.5	52.29		-107	-12.0	101

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: ERYTHROCYTES [/pL]
Reference Range: 4.2 - 6.1 (MALE), 3.8 - 5.3 (FEMALE) /pL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	4.65	0.386	8.30	4.0	4.60	5.3
		V1 (WEEK 0)	13	4.67	0.442	9.47	4.0	4.60	5.5
		V3 (WEEK 12)	13	4.64	0.333	7.18	4.0	4.60	5.2
		V4 (WEEK 24)	7	4.56	0.305	6.69	4.2	4.50	5.1
		V5 (WEEK 36)	8	4.75	0.302	6.37	4.4	4.60	5.2
		V6 (WEEK 52)	8	4.73	0.287	6.07	4.3	4.70	5.3
		V7 (WEEK 56)	8	4.64	0.320	6.91	4.2	4.60	5.2
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.03	0.138		-0.3	0.00	0.2
		V4 (WEEK 24) - V1 (WEEK 0)	7	-0.21	0.302		-0.8	-0.10	0.1
		V5 (WEEK 36) - V1 (WEEK 0)	8	0.00	0.239		-0.3	0.00	0.4
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.03	0.183		-0.3	0.05	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.11	0.290		-0.5	-0.10	0.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: ERYTHROCYTES [/pL]
Reference Range: 4.2 - 6.1 (MALE), 3.8 - 5.3 (FEMALE) /pL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	4.69	0.403	8.59	3.9	4.80	5.4
		V1 (WEEK 0)	19	4.75	0.388	8.17	4.0	4.80	5.3
		V3 (WEEK 12)	16	4.77	0.311	6.53	4.1	4.80	5.2
		V4 (WEEK 24)	15	4.79	0.323	6.74	4.0	4.80	5.2
		V5 (WEEK 36)	14	4.81	0.423	8.81	4.2	4.75	5.8
		V6 (WEEK 52)	16	4.75	0.253	5.33	4.3	4.80	5.3
		V7 (WEEK 56)	15	4.70	0.344	7.33	4.1	4.80	5.2
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.03	0.257		-0.3	0.00	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.04	0.261		-0.3	0.00	0.8
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.09	0.410		-0.5	0.00	0.8
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.02	0.315		-0.5	0.10	0.7
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.01	0.322		-0.6	0.00	0.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: ERYTHROCYTES [/pL]
Reference Range: 4.2 - 6.1 (MALE), 3.8 - 5.3 (FEMALE) /pL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	4.68	0.390	8.35	3.9	4.75	5.4
		V1 (WEEK 0)	32	4.72	0.406	8.60	4.0	4.75	5.5
		V3 (WEEK 12)	29	4.71	0.322	6.84	4.0	4.80	5.2
		V4 (WEEK 24)	22	4.71	0.328	6.97	4.0	4.75	5.2
		V5 (WEEK 36)	22	4.79	0.377	7.88	4.2	4.70	5.8
		V6 (WEEK 52)	24	4.74	0.259	5.45	4.3	4.70	5.3
		V7 (WEEK 56)	23	4.68	0.330	7.06	4.1	4.70	5.2
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.00	0.211		-0.3	0.00	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.04	0.294		-0.8	0.00	0.8
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.06	0.354		-0.5	0.00	0.8
		V6 (WEEK 52) - V1 (WEEK 0)	24	0.01	0.275		-0.5	0.10	0.7
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.03	0.310		-0.6	0.00	0.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: ERYTHROCYTES [/pL]
Reference Range: 4.2 - 6.1 (MALE), 3.8 - 5.3 (FEMALE) /pL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	4.94	0.370	7.50	4.5	4.80	5.8
		V1 (WEEK 0)	11	4.94	0.301	6.10	4.7	4.80	5.7
		V3 (WEEK 12)	12	4.96	0.390	7.86	4.5	5.00	5.9
		V4 (WEEK 24)	12	4.99	0.452	9.06	4.2	5.00	5.9
		V5 (WEEK 36)	11	5.01	0.375	7.49	4.6	5.00	6.0
		V6 (WEEK 52)	11	4.96	0.411	8.27	4.4	4.90	5.9
		V7 (WEEK 56)	11	4.87	0.382	7.85	4.5	4.80	5.8
		V3 (WEEK 12) - V1 (WEEK 0)	11	0.02	0.209		-0.3	0.00	0.4
		V4 (WEEK 24) - V1 (WEEK 0)	11	0.06	0.441		-0.6	0.00	1.1
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.06	0.171		-0.2	0.05	0.3
		V6 (WEEK 52) - V1 (WEEK 0)	10	0.03	0.200		-0.3	0.05	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	10	-0.06	0.190		-0.4	0.00	0.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: ERYTHROCYTES [/pL]
Reference Range: 4.2 - 6.1 (MALE), 3.8 - 5.3 (FEMALE) /pL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	4.74	0.370	7.81	3.9	4.70	5.3
		V1 (WEEK 0)	19	4.66	0.352	7.54	3.6	4.70	5.1
		V3 (WEEK 12)	19	4.70	0.448	9.54	3.6	4.80	5.4
		V4 (WEEK 24)	19	4.72	0.391	8.28	3.9	4.80	5.6
		V5 (WEEK 36)	18	4.66	0.385	8.28	3.9	4.80	5.4
		V6 (WEEK 52)	15	4.70	0.380	8.08	3.9	4.80	5.1
		V7 (WEEK 56)	15	4.70	0.442	9.41	3.8	4.80	5.3
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.04	0.248		-0.6	0.00	0.5
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.06	0.232		-0.3	0.00	0.7
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.01	0.215		-0.3	0.05	0.5
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.05	0.173		-0.3	0.10	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.02	0.218		-0.4	0.00	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: ERYTHROCYTES [/pL]
Reference Range: 4.2 - 6.1 (MALE), 3.8 - 5.3 (FEMALE) /pL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	4.82	0.378	7.84	3.9	4.80	5.8
		V1 (WEEK 0)	30	4.76	0.355	7.45	3.6	4.80	5.7
		V3 (WEEK 12)	31	4.80	0.439	9.14	3.6	4.80	5.9
		V4 (WEEK 24)	31	4.83	0.430	8.90	3.9	4.90	5.9
		V5 (WEEK 36)	29	4.79	0.413	8.63	3.9	4.80	6.0
		V6 (WEEK 52)	26	4.81	0.407	8.46	3.9	4.85	5.9
		V7 (WEEK 56)	26	4.77	0.419	8.78	3.8	4.80	5.8
		V3 (WEEK 12) - V1 (WEEK 0)	30	0.03	0.231		-0.6	0.00	0.5
		V4 (WEEK 24) - V1 (WEEK 0)	30	0.06	0.317		-0.6	0.00	1.1
		V5 (WEEK 36) - V1 (WEEK 0)	28	0.02	0.200		-0.3	0.05	0.5
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.04	0.180		-0.3	0.10	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	25	-0.01	0.207		-0.4	0.00	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMOGLOBIN [mmol/L]
Reference Range: 8.4 - 11.2 (MALE), 6.8 - 10.2 (FEMALE) mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	9.08	0.685	7.54	7.8	8.90	10.0
		V1 (WEEK 0)	13	9.13	0.805	8.81	7.8	9.00	10.7
		V3 (WEEK 12)	13	9.06	0.686	7.57	7.8	9.20	10.3
		V4 (WEEK 24)	7	9.17	0.544	5.93	8.6	9.00	10.2
		V5 (WEEK 36)	8	9.30	0.521	5.60	8.7	9.15	10.1
		V6 (WEEK 52)	8	9.23	0.587	6.37	8.4	9.30	10.2
		V7 (WEEK 56)	8	9.13	0.696	7.63	8.1	9.20	10.0
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.07	0.259		-0.5	0.00	0.3
		V4 (WEEK 24) - V1 (WEEK 0)	7	-0.27	0.304		-0.6	-0.40	0.2
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.05	0.404		-0.6	0.00	0.6
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.13	0.333		-0.6	-0.15	0.4
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.22	0.468		-0.9	-0.25	0.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMOGLOBIN [mmol/L]
Reference Range: 8.4 - 11.2 (MALE), 6.8 - 10.2 (FEMALE) mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	8.84	0.741	8.38	7.5	9.00	10.2
		V1 (WEEK 0)	19	8.88	0.702	7.90	7.6	9.20	9.8
		V3 (WEEK 12)	16	8.84	0.662	7.49	7.4	8.95	9.9
		V4 (WEEK 24)	15	8.70	0.779	8.96	7.3	8.90	9.7
		V5 (WEEK 36)	14	8.89	0.857	9.64	7.1	9.00	10.3
		V6 (WEEK 52)	16	8.76	0.635	7.25	7.1	8.95	9.5
		V7 (WEEK 56)	15	8.62	0.763	8.85	6.9	8.60	9.9
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.06	0.400		-0.9	-0.05	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.28	0.527		-1.6	-0.30	0.4
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.06	0.527		-0.7	0.00	1.1
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.10	0.486		-1.0	0.05	0.8
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.28	0.576		-1.8	-0.20	0.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMOGLOBIN [mmol/L]
Reference Range: 8.4 - 11.2 (MALE), 6.8 - 10.2 (FEMALE) mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	8.94	0.717	8.02	7.5	8.95	10.2
		V1 (WEEK 0)	32	8.98	0.743	8.27	7.6	9.15	10.7
		V3 (WEEK 12)	29	8.94	0.670	7.49	7.4	9.00	10.3
		V4 (WEEK 24)	22	8.85	0.735	8.30	7.3	9.00	10.2
		V5 (WEEK 36)	22	9.04	0.766	8.47	7.1	9.15	10.3
		V6 (WEEK 52)	24	8.91	0.647	7.26	7.1	9.05	10.2
		V7 (WEEK 56)	23	8.80	0.765	8.70	6.9	8.90	10.0
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.07	0.338		-0.9	0.00	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.28	0.460		-1.6	-0.30	0.4
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.06	0.476		-0.7	0.00	1.1
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.11	0.433		-1.0	-0.05	0.8
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.26	0.531		-1.8	-0.20	0.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: HEMOGLOBIN [mmol/L]
Reference Range: 8.4 - 11.2 (MALE), 6.8 - 10.2 (FEMALE) mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	9.24	0.540	5.84	8.4	9.25	10.2
		V1 (WEEK 0)	11	9.30	0.531	5.71	8.4	9.40	10.0
		V3 (WEEK 12)	12	9.31	0.573	6.15	8.4	9.35	10.4
		V4 (WEEK 24)	12	9.33	0.647	6.93	8.4	9.20	10.9
		V5 (WEEK 36)	11	9.35	0.396	4.23	8.8	9.50	10.0
		V6 (WEEK 52)	11	9.25	0.548	5.93	8.1	9.40	9.9
		V7 (WEEK 56)	11	9.18	0.421	4.59	8.6	9.10	9.9
		V3 (WEEK 12) - V1 (WEEK 0)	11	0.00	0.452		-0.8	0.10	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	11	0.03	0.822		-1.0	-0.20	2.0
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.11	0.166		-0.1	0.10	0.5
		V6 (WEEK 52) - V1 (WEEK 0)	10	0.03	0.221		-0.5	0.05	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	10	-0.04	0.313		-0.5	-0.05	0.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMOGLOBIN [mmol/L]
Reference Range: 8.4 - 11.2 (MALE), 6.8 - 10.2 (FEMALE) mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	8.54	0.594	6.95	7.6	8.60	9.9
		V1 (WEEK 0)	19	8.41	0.632	7.52	7.1	8.60	9.5
		V3 (WEEK 12)	19	8.42	0.680	8.08	6.9	8.60	9.8
		V4 (WEEK 24)	19	8.50	0.645	7.58	7.5	8.70	9.3
		V5 (WEEK 36)	18	8.39	0.682	8.14	7.4	8.50	10.0
		V6 (WEEK 52)	15	8.61	0.606	7.05	7.4	8.50	9.6
		V7 (WEEK 56)	15	8.53	0.772	9.06	7.4	8.60	10.4
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.02	0.441		-1.3	0.00	0.6
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.09	0.384		-0.4	0.00	1.1
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.01	0.427		-0.9	-0.05	0.9
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.11	0.336		-0.5	0.00	0.9
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.07	0.392		-0.5	0.00	0.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: HEMOGLOBIN [mmol/L]
Reference Range: 8.4 - 11.2 (MALE), 6.8 - 10.2 (FEMALE) mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	8.81	0.664	7.53	7.6	8.70	10.2
		V1 (WEEK 0)	30	8.73	0.733	8.39	7.1	8.70	10.0
		V3 (WEEK 12)	31	8.76	0.769	8.77	6.9	8.80	10.4
		V4 (WEEK 24)	31	8.82	0.757	8.58	7.5	9.00	10.9
		V5 (WEEK 36)	29	8.76	0.752	8.59	7.4	8.90	10.0
		V6 (WEEK 52)	26	8.88	0.658	7.41	7.4	9.10	9.9
		V7 (WEEK 56)	26	8.80	0.717	8.14	7.4	8.90	10.4
		V3 (WEEK 12) - V1 (WEEK 0)	30	0.01	0.437		-1.3	0.05	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	30	0.07	0.571		-1.0	0.00	2.0
		V5 (WEEK 36) - V1 (WEEK 0)	28	0.03	0.357		-0.9	0.00	0.9
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.08	0.293		-0.5	0.00	0.9
		V7 (WEEK 56) - V1 (WEEK 0)	25	0.03	0.360		-0.5	0.00	0.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMATOCRIT [L/L]
Reference Range: 0.39 - 0.55 (MALE), 0.35 - 0.55 (FEMALE) L/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	0.452	0.0279	6.188	0.40	0.450	0.50
		V1 (WEEK 0)	13	0.462	0.0326	7.068	0.40	0.460	0.51
		V3 (WEEK 12)	13	0.445	0.0267	5.984	0.40	0.440	0.49
		V4 (WEEK 24)	7	0.449	0.0204	4.538	0.43	0.450	0.49
		V5 (WEEK 36)	8	0.483	0.0446	9.252	0.44	0.465	0.57
		V6 (WEEK 52)	8	0.450	0.0245	5.443	0.41	0.450	0.49
		V7 (WEEK 56)	8	0.449	0.0344	7.668	0.40	0.440	0.50
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.016	0.0222		-0.05	-0.020	0.04
		V4 (WEEK 24) - V1 (WEEK 0)	7	-0.026	0.0162		-0.06	-0.020	-0.01
		V5 (WEEK 36) - V1 (WEEK 0)	8	0.010	0.0396		-0.04	0.000	0.07
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.023	0.0149		-0.04	-0.025	0.00
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.024	0.0160		-0.05	-0.020	0.00

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMATOCRIT [L/L]
Reference Range: 0.39 - 0.55 (MALE), 0.35 - 0.55 (FEMALE) L/L

Treatment	Sex	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	0.435	0.0405	9.308	0.35	0.440	0.50
		V1 (WEEK 0)	19	0.442	0.0308	6.975	0.38	0.460	0.49
		V3 (WEEK 12)	16	0.450	0.0446	9.905	0.39	0.455	0.58
		V4 (WEEK 24)	15	0.447	0.0337	7.553	0.38	0.450	0.51
		V5 (WEEK 36)	14	0.451	0.0328	7.262	0.40	0.450	0.53
		V6 (WEEK 52)	16	0.442	0.0347	7.849	0.38	0.435	0.51
		V7 (WEEK 56)	15	0.430	0.0370	8.612	0.36	0.430	0.51
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.006	0.0356		-0.03	0.000	0.12
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.001	0.0217		-0.04	0.000	0.05
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.009	0.0276		-0.03	0.005	0.07
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.004	0.0294		-0.05	0.005	0.06
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.009	0.0294		-0.07	0.000	0.05

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMATOCRIT [L/L]
Reference Range: 0.39 - 0.55 (MALE), 0.35 - 0.55 (FEMALE) L/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	0.442	0.0364	8.238	0.35	0.450	0.50
		V1 (WEEK 0)	32	0.450	0.0325	7.228	0.38	0.460	0.51
		V3 (WEEK 12)	29	0.448	0.0371	8.276	0.39	0.450	0.58
		V4 (WEEK 24)	22	0.447	0.0296	6.625	0.38	0.450	0.51
		V5 (WEEK 36)	22	0.463	0.0395	8.546	0.40	0.460	0.57
		V6 (WEEK 52)	24	0.445	0.0313	7.050	0.38	0.445	0.51
		V7 (WEEK 56)	23	0.437	0.0365	8.363	0.36	0.430	0.51
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.004	0.0318		-0.05	-0.010	0.12
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.007	0.0235		-0.06	-0.005	0.05
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.010	0.0315		-0.04	0.000	0.07
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.005	0.0281		-0.05	-0.005	0.06
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.014	0.0261		-0.07	-0.020	0.05

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: HEMATOCRIT [L/L]
Reference Range: 0.39 - 0.55 (MALE), 0.35 - 0.55 (FEMALE) L/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	0.470	0.0379	8.064	0.41	0.470	0.52
		V1 (WEEK 0)	11	0.461	0.0295	6.396	0.42	0.450	0.53
		V3 (WEEK 12)	12	0.457	0.0358	7.831	0.40	0.455	0.54
		V4 (WEEK 24)	12	0.471	0.0412	8.755	0.42	0.455	0.56
		V5 (WEEK 36)	11	0.470	0.0286	6.093	0.44	0.460	0.54
		V6 (WEEK 52)	11	0.459	0.0327	7.122	0.39	0.470	0.51
		V7 (WEEK 56)	11	0.445	0.0202	4.540	0.40	0.450	0.47
		V3 (WEEK 12) - V1 (WEEK 0)	11	-0.005	0.0330		-0.07	0.000	0.06
		V4 (WEEK 24) - V1 (WEEK 0)	11	0.011	0.0505		-0.08	0.010	0.11
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.008	0.0343		-0.07	0.010	0.06
		V6 (WEEK 52) - V1 (WEEK 0)	10	-0.002	0.0274		-0.04	0.000	0.05
		V7 (WEEK 56) - V1 (WEEK 0)	10	-0.016	0.0259		-0.07	-0.015	0.01

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: HEMATOCRIT [L/L]
Reference Range: 0.39 - 0.55 (MALE), 0.35 - 0.55 (FEMALE) L/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	0.434	0.0263	6.062	0.38	0.430	0.47
		V1 (WEEK 0)	19	0.425	0.0324	7.624	0.37	0.430	0.48
		V3 (WEEK 12)	19	0.429	0.0331	7.702	0.37	0.430	0.51
		V4 (WEEK 24)	19	0.429	0.0285	6.635	0.37	0.440	0.47
		V5 (WEEK 36)	18	0.429	0.0302	7.030	0.39	0.430	0.48
		V6 (WEEK 52)	15	0.437	0.0279	6.378	0.38	0.440	0.48
		V7 (WEEK 56)	15	0.437	0.0377	8.641	0.37	0.430	0.51
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.005	0.0274		-0.05	0.000	0.05
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.004	0.0239		-0.05	0.010	0.06
		V5 (WEEK 36) - V1 (WEEK 0)	18	0.005	0.0257		-0.05	0.005	0.06
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.007	0.0144		-0.02	0.010	0.03
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.007	0.0235		-0.02	0.000	0.05

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: HEMATOCRIT [L/L]
Reference Range: 0.39 - 0.55 (MALE), 0.35 - 0.55 (FEMALE) L/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	0.448	0.0356	7.943	0.38	0.440	0.52
		V1 (WEEK 0)	30	0.438	0.0356	8.120	0.37	0.445	0.53
		V3 (WEEK 12)	31	0.440	0.0361	8.215	0.37	0.440	0.54
		V4 (WEEK 24)	31	0.445	0.0392	8.813	0.37	0.450	0.56
		V5 (WEEK 36)	29	0.445	0.0353	7.939	0.39	0.440	0.54
		V6 (WEEK 52)	26	0.447	0.0314	7.023	0.38	0.450	0.51
		V7 (WEEK 56)	26	0.440	0.0312	7.100	0.37	0.440	0.51
		V3 (WEEK 12) - V1 (WEEK 0)	30	0.001	0.0294		-0.07	0.000	0.06
		V4 (WEEK 24) - V1 (WEEK 0)	30	0.007	0.0353		-0.08	0.010	0.11
		V5 (WEEK 36) - V1 (WEEK 0)	28	0.006	0.0285		-0.07	0.010	0.06
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.004	0.0206		-0.04	0.010	0.05
		V7 (WEEK 56) - V1 (WEEK 0)	25	-0.002	0.0265		-0.07	-0.010	0.05

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCH (HbE) [fmol]
Reference Range: 1.59 - 2.00 fmol

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	1.952	0.0797	4.083	1.77	1.950	2.10
		V1 (WEEK 0)	13	1.963	0.0728	3.711	1.82	1.950	2.11
		V3 (WEEK 12)	13	1.959	0.0712	3.636	1.77	1.970	2.04
		V4 (WEEK 24)	7	2.007	0.0547	2.725	1.90	2.030	2.06
		V5 (WEEK 36)	8	1.960	0.0896	4.572	1.79	1.965	2.11
		V6 (WEEK 52)	8	1.960	0.0769	3.924	1.80	1.970	2.06
		V7 (WEEK 56)	8	1.959	0.0919	4.691	1.77	1.975	2.05
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.004	0.0423		-0.07	0.000	0.07
		V4 (WEEK 24) - V1 (WEEK 0)	7	0.024	0.1041		-0.08	-0.010	0.23
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.015	0.0251		-0.05	-0.010	0.03
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.015	0.0245		-0.05	-0.015	0.02
		V7 (WEEK 56) - V1 (WEEK 0)	8	-0.016	0.0400		-0.08	-0.010	0.04

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCH (HbE) [fmol]
Reference Range: 1.59 - 2.00 fmol

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	1.893	0.0847	4.475	1.75	1.880	2.06
		V1 (WEEK 0)	19	1.874	0.0956	5.104	1.72	1.850	2.07
		V3 (WEEK 12)	16	1.863	0.1116	5.990	1.56	1.865	2.03
		V4 (WEEK 24)	15	1.826	0.1584	8.673	1.50	1.820	2.12
		V5 (WEEK 36)	14	1.853	0.1432	7.727	1.46	1.880	2.05
		V6 (WEEK 52)	16	1.844	0.1209	6.557	1.50	1.850	2.06
		V7 (WEEK 56)	15	1.837	0.1262	6.874	1.48	1.850	2.03
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.021	0.0901		-0.29	0.010	0.08
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.068	0.1371		-0.35	-0.020	0.10
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.047	0.1277		-0.39	-0.015	0.08
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.032	0.1207		-0.35	0.000	0.10
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.061	0.1207		-0.37	-0.030	0.03

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCH (HbE) [fmol]
Reference Range: 1.59 - 2.00 fmol

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	1.917	0.0866	4.517	1.75	1.925	2.10
		V1 (WEEK 0)	32	1.910	0.0967	5.064	1.72	1.915	2.11
		V3 (WEEK 12)	29	1.906	0.1060	5.563	1.56	1.930	2.04
		V4 (WEEK 24)	22	1.884	0.1582	8.400	1.50	1.905	2.12
		V5 (WEEK 36)	22	1.892	0.1347	7.121	1.46	1.930	2.11
		V6 (WEEK 52)	24	1.883	0.1202	6.382	1.50	1.890	2.06
		V7 (WEEK 56)	23	1.879	0.1279	6.807	1.48	1.880	2.05
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.013	0.0720		-0.29	0.000	0.08
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.039	0.1325		-0.35	-0.015	0.23
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.035	0.1028		-0.39	-0.010	0.08
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.026	0.0987		-0.35	-0.005	0.10
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.045	0.1013		-0.37	-0.030	0.04

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCH (HbE) [fmol]
Reference Range: 1.59 - 2.00 fmol

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	1.878	0.0997	5.312	1.71	1.865	2.06
		V1 (WEEK 0)	11	1.886	0.0990	5.249	1.77	1.850	2.08
		V3 (WEEK 12)	12	1.887	0.1099	5.825	1.76	1.865	2.11
		V4 (WEEK 24)	12	1.881	0.1205	6.406	1.69	1.885	2.12
		V5 (WEEK 36)	11	1.885	0.1081	5.737	1.67	1.900	2.10
		V6 (WEEK 52)	11	1.869	0.1070	5.725	1.67	1.850	2.07
		V7 (WEEK 56)	11	1.885	0.0873	4.632	1.71	1.880	2.05
		V3 (WEEK 12) - V1 (WEEK 0)	11	0.002	0.0442		-0.07	-0.010	0.07
		V4 (WEEK 24) - V1 (WEEK 0)	11	-0.010	0.0363		-0.08	0.000	0.04
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.014	0.0530		-0.10	0.020	0.08
		V6 (WEEK 52) - V1 (WEEK 0)	10	-0.003	0.0581		-0.10	0.000	0.12
		V7 (WEEK 56) - V1 (WEEK 0)	10	0.014	0.0392		-0.06	0.025	0.07

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCH (HbE) [fmol]
Reference Range: 1.59 - 2.00 fmol

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	1.806	0.1093	6.051	1.54	1.840	2.02
		V1 (WEEK 0)	19	1.805	0.1109	6.142	1.53	1.820	1.99
		V3 (WEEK 12)	19	1.803	0.1013	5.619	1.57	1.820	1.98
		V4 (WEEK 24)	19	1.806	0.0979	5.422	1.54	1.830	1.99
		V5 (WEEK 36)	18	1.809	0.1044	5.773	1.59	1.805	2.00
		V6 (WEEK 52)	15	1.835	0.0940	5.123	1.66	1.840	2.05
		V7 (WEEK 56)	15	1.813	0.0947	5.223	1.62	1.810	2.02
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.002	0.0377		-0.06	-0.010	0.09
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.001	0.0335		-0.07	0.000	0.06
		V5 (WEEK 36) - V1 (WEEK 0)	18	0.004	0.0509		-0.13	0.015	0.06
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.007	0.0347		-0.08	0.010	0.06
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.004	0.0498		-0.10	-0.010	0.09

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCH (HbE) [fmol]
Reference Range: 1.59 - 2.00 fmol

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	1.834	0.1098	5.988	1.54	1.840	2.06
		V1 (WEEK 0)	30	1.835	0.1122	6.115	1.53	1.850	2.08
		V3 (WEEK 12)	31	1.835	0.1109	6.042	1.57	1.840	2.11
		V4 (WEEK 24)	31	1.835	0.1115	6.077	1.54	1.850	2.12
		V5 (WEEK 36)	29	1.838	0.1104	6.008	1.59	1.820	2.10
		V6 (WEEK 52)	26	1.850	0.0991	5.358	1.66	1.850	2.07
		V7 (WEEK 56)	26	1.843	0.0970	5.264	1.62	1.840	2.05
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.001	0.0395		-0.07	-0.010	0.09
		V4 (WEEK 24) - V1 (WEEK 0)	30	-0.003	0.0344		-0.08	0.000	0.06
		V5 (WEEK 36) - V1 (WEEK 0)	28	0.008	0.0509		-0.13	0.015	0.08
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.003	0.0447		-0.10	0.000	0.12
		V7 (WEEK 56) - V1 (WEEK 0)	25	0.008	0.0453		-0.10	0.010	0.09

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCHC [mmol/L]
Reference Range: 19.8 - 22.9 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	20.05	0.454	2.26	19.5	19.90	21.0
		V1 (WEEK 0)	13	19.85	0.722	3.64	18.7	20.20	21.0
		V3 (WEEK 12)	13	20.39	0.753	3.69	19.0	20.20	21.5
		V4 (WEEK 24)	7	20.44	0.509	2.49	19.9	20.20	21.3
		V5 (WEEK 36)	8	19.41	1.538	7.92	16.8	19.65	21.2
		V6 (WEEK 52)	8	20.59	0.544	2.64	19.7	20.65	21.3
		V7 (WEEK 56)	8	20.34	0.825	4.05	18.8	20.50	21.4
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.55	1.137		-1.6	0.60	2.5
		V4 (WEEK 24) - V1 (WEEK 0)	7	0.46	0.978		-0.4	-0.10	2.1
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.44	2.076		-3.6	0.35	2.0
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.74	0.600		-0.2	0.80	1.8
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.49	0.732		-0.4	0.40	1.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCHC [mmol/L]
Reference Range: 19.8 - 22.9 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	20.39	0.548	2.69	19.5	20.30	21.6
		V1 (WEEK 0)	19	20.14	0.608	3.02	18.9	20.20	21.4
		V3 (WEEK 12)	16	19.77	1.035	5.23	16.4	20.00	20.7
		V4 (WEEK 24)	15	19.53	0.807	4.13	18.4	19.70	20.7
		V5 (WEEK 36)	14	19.77	0.932	4.71	17.7	19.90	21.5
		V6 (WEEK 52)	16	19.91	1.048	5.27	17.1	20.30	20.8
		V7 (WEEK 56)	15	20.06	0.504	2.51	19.0	20.10	20.7
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.32	1.123		-3.6	-0.25	1.3
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.69	0.911		-2.9	-0.40	0.7
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.51	0.712		-1.6	-0.50	1.0
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.33	0.977		-2.9	-0.10	1.2
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.25	0.660		-1.8	-0.20	0.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCHC [mmol/L]
Reference Range: 19.8 - 22.9 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	20.26	0.532	2.63	19.5	20.25	21.6
		V1 (WEEK 0)	32	20.02	0.662	3.30	18.7	20.20	21.4
		V3 (WEEK 12)	29	20.05	0.957	4.77	16.4	20.10	21.5
		V4 (WEEK 24)	22	19.82	0.834	4.21	18.4	20.05	21.3
		V5 (WEEK 36)	22	19.64	1.165	5.93	16.8	19.90	21.5
		V6 (WEEK 52)	24	20.13	0.956	4.75	17.1	20.40	21.3
		V7 (WEEK 56)	23	20.16	0.629	3.12	18.8	20.20	21.4
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.07	1.192		-3.6	-0.10	2.5
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.33	1.062		-2.9	-0.30	2.1
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.49	1.324		-3.6	-0.50	2.0
		V6 (WEEK 52) - V1 (WEEK 0)	24	0.03	0.998		-2.9	0.10	1.8
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.01	0.759		-1.8	-0.10	1.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCHC [mmol/L]
Reference Range: 19.8 - 22.9 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	19.72	1.473	7.47	16.3	19.95	21.9
		V1 (WEEK 0)	11	20.25	0.850	4.20	18.2	20.50	21.1
		V3 (WEEK 12)	12	20.42	0.741	3.63	19.2	20.65	21.5
		V4 (WEEK 24)	12	19.88	0.920	4.63	17.5	20.25	20.6
		V5 (WEEK 36)	11	20.11	0.927	4.61	18.7	20.00	21.6
		V6 (WEEK 52)	11	20.23	0.780	3.86	19.0	20.20	21.5
		V7 (WEEK 56)	11	20.67	0.666	3.22	19.7	20.80	21.6
		V3 (WEEK 12) - V1 (WEEK 0)	11	0.21	1.128		-1.6	0.30	2.9
		V4 (WEEK 24) - V1 (WEEK 0)	11	-0.41	1.284		-3.0	-0.50	2.4
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.01	1.288		-2.1	0.10	2.8
		V6 (WEEK 52) - V1 (WEEK 0)	10	0.12	0.986		-2.0	0.10	1.6
		V7 (WEEK 56) - V1 (WEEK 0)	10	0.54	0.677		-0.6	0.40	1.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCHC [mmol/L]
Reference Range: 19.8 - 22.9 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	19.72	0.774	3.93	18.4	19.70	21.1
		V1 (WEEK 0)	19	19.78	0.797	4.03	17.7	19.80	20.8
		V3 (WEEK 12)	19	19.64	0.619	3.15	18.5	19.70	20.6
		V4 (WEEK 24)	19	19.85	0.752	3.79	18.4	19.90	20.9
		V5 (WEEK 36)	18	19.58	0.832	4.25	18.3	19.50	21.3
		V6 (WEEK 52)	15	19.73	0.855	4.33	17.7	20.00	20.8
		V7 (WEEK 56)	15	19.59	0.980	5.00	17.6	19.80	20.8
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.14	0.975		-2.0	-0.20	2.3
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.07	0.792		-1.1	0.10	2.1
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.19	0.960		-2.0	-0.05	2.0
		V6 (WEEK 52) - V1 (WEEK 0)	15	-0.02	0.648		-1.2	-0.10	1.2
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.07	0.929		-2.3	0.00	1.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCHC [mmol/L]
Reference Range: 19.8 - 22.9 mmol/L

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	19.72	1.075	5.45	16.3	19.70	21.9
		V1 (WEEK 0)	30	19.95	0.834	4.18	17.7	19.95	21.1
		V3 (WEEK 12)	31	19.94	0.761	3.81	18.5	20.00	21.5
		V4 (WEEK 24)	31	19.86	0.806	4.06	17.5	20.20	20.9
		V5 (WEEK 36)	29	19.78	0.892	4.51	18.3	19.70	21.6
		V6 (WEEK 52)	26	19.94	0.846	4.24	17.7	20.00	21.5
		V7 (WEEK 56)	26	20.05	1.006	5.02	17.6	20.00	21.6
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.01	1.028		-2.0	-0.10	2.9
		V4 (WEEK 24) - V1 (WEEK 0)	30	-0.11	1.007		-3.0	-0.20	2.4
		V5 (WEEK 36) - V1 (WEEK 0)	28	-0.12	1.069		-2.1	0.10	2.8
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.04	0.784		-2.0	-0.10	1.6
		V7 (WEEK 56) - V1 (WEEK 0)	25	0.18	0.876		-2.3	0.30	1.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCV [fL]
Reference Range: 79.0 - 96.0 (MALE), 79.4 - 110.0 (FEMALE) fL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	97.35	3.424	3.52	90.6	97.60	102.3
		V1 (WEEK 0)	13	99.15	5.650	5.70	89.9	101.10	106.4
		V3 (WEEK 12)	13	96.15	3.702	3.85	90.5	95.70	102.1
		V4 (WEEK 24)	7	98.29	3.017	3.07	94.7	98.70	102.0
		V5 (WEEK 36)	8	101.44	7.423	7.32	93.5	99.75	114.9
		V6 (WEEK 52)	8	95.41	4.193	4.39	88.3	96.15	101.9
		V7 (WEEK 56)	8	96.59	5.716	5.92	87.7	97.80	102.8
		V3 (WEEK 12) - V1 (WEEK 0)	13	-2.99	5.139		-12.5	-3.10	5.7
		V4 (WEEK 24) - V1 (WEEK 0)	7	-1.16	7.413		-10.7	-2.40	12.0
		V5 (WEEK 36) - V1 (WEEK 0)	8	1.74	11.393		-11.4	-1.55	19.6
		V6 (WEEK 52) - V1 (WEEK 0)	8	-4.29	3.403		-10.5	-4.40	1.1
		V7 (WEEK 56) - V1 (WEEK 0)	8	-3.11	2.799		-7.3	-3.20	1.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCV [fL]
Reference Range: 79.0 - 96.0 (MALE), 79.4 - 110.0 (FEMALE) fL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	92.90	3.939	4.24	86.5	92.40	100.9
		V1 (WEEK 0)	19	92.97	3.533	3.80	87.4	93.30	100.7
		V3 (WEEK 12)	16	94.44	6.921	7.33	81.4	93.10	112.8
		V4 (WEEK 24)	15	93.46	5.958	6.37	81.5	95.10	102.3
		V5 (WEEK 36)	14	93.61	5.244	5.60	82.4	94.50	106.0
		V6 (WEEK 52)	16	92.80	6.328	6.82	79.0	92.50	105.4
		V7 (WEEK 56)	15	91.51	5.457	5.96	77.9	92.10	100.0
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.78	7.409		-14.5	0.30	22.9
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.09	5.519		-14.4	1.40	7.3
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.04	5.263		-13.5	1.25	5.3
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.18	7.556		-16.9	-0.15	17.4
		V7 (WEEK 56) - V1 (WEEK 0)	15	-1.83	5.390		-18.0	-1.20	4.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCV [fL]
Reference Range: 79.0 - 96.0 (MALE), 79.4 - 110.0 (FEMALE) fL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	94.71	4.300	4.54	86.5	95.45	102.3
		V1 (WEEK 0)	32	95.48	5.394	5.65	87.4	94.65	106.4
		V3 (WEEK 12)	29	95.21	5.682	5.97	81.4	94.40	112.8
		V4 (WEEK 24)	22	95.00	5.617	5.91	81.5	95.50	102.3
		V5 (WEEK 36)	22	96.45	7.089	7.35	82.4	94.85	114.9
		V6 (WEEK 52)	24	93.67	5.749	6.14	79.0	93.30	105.4
		V7 (WEEK 56)	23	93.28	5.954	6.38	77.9	92.20	102.8
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.91	6.661		-14.5	-1.10	22.9
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.43	6.022		-14.4	-0.05	12.0
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.65	7.818		-13.5	0.90	19.6
		V6 (WEEK 52) - V1 (WEEK 0)	24	-1.31	6.737		-16.9	-1.20	17.4
		V7 (WEEK 56) - V1 (WEEK 0)	23	-2.27	4.623		-18.0	-2.30	4.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCV [fL]
Reference Range: 79.0 - 96.0 (MALE), 79.4 - 110.0 (FEMALE) fL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	95.73	8.634	9.02	86.4	92.40	113.6
		V1 (WEEK 0)	11	93.36	7.461	7.99	85.2	91.40	113.2
		V3 (WEEK 12)	12	92.35	4.195	4.54	86.5	92.30	99.8
		V4 (WEEK 24)	12	94.76	7.206	7.60	84.5	93.75	108.7
		V5 (WEEK 36)	11	93.85	5.206	5.55	87.4	91.60	103.0
		V6 (WEEK 52)	11	92.54	6.387	6.90	79.3	93.10	104.5
		V7 (WEEK 56)	11	91.25	5.626	6.17	79.3	92.50	101.8
		V3 (WEEK 12) - V1 (WEEK 0)	11	-1.09	4.894		-13.4	-0.90	6.5
		V4 (WEEK 24) - V1 (WEEK 0)	11	1.36	7.488		-13.6	1.30	16.8
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.58	5.991		-13.2	0.95	9.9
		V6 (WEEK 52) - V1 (WEEK 0)	10	-0.76	4.689		-8.7	-0.50	9.0
		V7 (WEEK 56) - V1 (WEEK 0)	10	-1.91	4.003		-11.4	-0.60	2.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCV [fL]
Reference Range: 79.0 - 96.0 (MALE), 79.4 - 110.0 (FEMALE) fL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	91.63	5.534	6.04	82.3	91.50	109.5
		V1 (WEEK 0)	19	91.35	5.663	6.20	78.5	91.00	103.9
		V3 (WEEK 12)	19	91.86	5.499	5.99	81.7	91.20	104.2
		V4 (WEEK 24)	19	91.05	4.251	4.67	81.2	90.90	100.0
		V5 (WEEK 36)	18	92.36	4.249	4.60	83.5	91.70	101.8
		V6 (WEEK 52)	15	93.16	4.661	5.00	82.7	92.30	101.0
		V7 (WEEK 56)	15	92.67	5.305	5.72	83.3	91.60	100.5
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.51	4.231		-7.4	-0.10	10.4
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.31	3.554		-8.1	-0.20	6.0
		V5 (WEEK 36) - V1 (WEEK 0)	18	0.98	3.757		-7.9	1.85	6.4
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.49	2.811		-4.8	0.80	5.6
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.57	3.697		-6.2	0.30	7.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MCV [fL]
Reference Range: 79.0 - 96.0 (MALE), 79.4 - 110.0 (FEMALE) fL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	93.21	7.059	7.57	82.3	91.60	113.6
		V1 (WEEK 0)	30	92.09	6.330	6.87	78.5	91.00	113.2
		V3 (WEEK 12)	31	92.05	4.965	5.39	81.7	91.70	104.2
		V4 (WEEK 24)	31	92.48	5.767	6.24	81.2	91.30	108.7
		V5 (WEEK 36)	29	92.92	4.603	4.95	83.5	91.60	103.0
		V6 (WEEK 52)	26	92.90	5.347	5.76	79.3	92.65	104.5
		V7 (WEEK 56)	26	92.07	5.378	5.84	79.3	92.05	101.8
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.08	4.470		-13.4	-0.15	10.4
		V4 (WEEK 24) - V1 (WEEK 0)	30	0.31	5.277		-13.6	0.25	16.8
		V5 (WEEK 36) - V1 (WEEK 0)	28	0.84	4.570		-13.2	1.60	9.9
		V6 (WEEK 52) - V1 (WEEK 0)	25	-0.01	3.639		-8.7	0.20	9.0
		V7 (WEEK 56) - V1 (WEEK 0)	25	-0.42	3.939		-11.4	-0.30	7.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: THROMBOCYTES [/nL]
Reference Range: 150 - 400 /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	207.8	42.58	20.5	164	198.0	305
		V1 (WEEK 0)	13	221.6	37.50	16.9	182	206.0	308
		V3 (WEEK 12)	13	225.2	52.84	23.5	156	220.0	359
		V4 (WEEK 24)	7	199.4	20.83	10.4	166	202.0	221
		V5 (WEEK 36)	8	211.9	44.59	21.0	141	225.0	259
		V6 (WEEK 52)	8	239.0	70.94	29.7	163	220.5	348
		V7 (WEEK 56)	8	222.5	40.90	18.4	179	222.0	279
		V3 (WEEK 12) - V1 (WEEK 0)	13	3.6	21.61		-30	1.0	51
		V4 (WEEK 24) - V1 (WEEK 0)	7	-15.1	19.42		-41	-15.0	15
		V5 (WEEK 36) - V1 (WEEK 0)	8	-6.0	27.48		-50	-2.5	26
		V6 (WEEK 52) - V1 (WEEK 0)	8	21.1	49.96		-19	-5.0	111
		V7 (WEEK 56) - V1 (WEEK 0)	8	4.6	25.00		-29	3.0	45

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: THROMBOCYTES [/nL]
Reference Range: 150 - 400 /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	250.9	42.36	16.9	189	251.0	351
		V1 (WEEK 0)	19	267.8	59.88	22.4	196	257.0	385
		V3 (WEEK 12)	16	261.0	69.76	26.7	184	237.0	430
		V4 (WEEK 24)	15	266.4	67.05	25.2	178	261.0	413
		V5 (WEEK 36)	14	258.2	53.45	20.7	181	247.0	366
		V6 (WEEK 52)	16	264.0	63.76	24.2	168	267.5	400
		V7 (WEEK 56)	15	297.3	64.17	21.6	196	281.0	421
		V3 (WEEK 12) - V1 (WEEK 0)	16	-2.3	36.10		-91	3.0	45
		V4 (WEEK 24) - V1 (WEEK 0)	15	-8.8	47.46		-114	-1.0	60
		V5 (WEEK 36) - V1 (WEEK 0)	14	-14.6	48.46		-112	-15.5	83
		V6 (WEEK 52) - V1 (WEEK 0)	16	-8.0	56.48		-136	-12.0	107
		V7 (WEEK 56) - V1 (WEEK 0)	15	25.2	38.52		-51	21.0	78

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: THROMBOCYTES [/nL]
Reference Range: 150 - 400 /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	233.4	46.98	20.1	164	234.0	351
		V1 (WEEK 0)	32	249.1	56.20	22.6	182	234.0	385
		V3 (WEEK 12)	29	245.0	64.27	26.2	156	236.0	430
		V4 (WEEK 24)	22	245.1	64.35	26.3	166	224.5	413
		V5 (WEEK 36)	22	241.4	54.33	22.5	141	243.5	366
		V6 (WEEK 52)	24	255.7	65.79	25.7	163	249.0	400
		V7 (WEEK 56)	23	271.3	66.94	24.7	179	259.0	421
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.4	30.12		-91	1.0	51
		V4 (WEEK 24) - V1 (WEEK 0)	22	-10.8	40.23		-114	-8.0	60
		V5 (WEEK 36) - V1 (WEEK 0)	22	-11.5	41.52		-112	-14.0	83
		V6 (WEEK 52) - V1 (WEEK 0)	24	1.7	55.11		-136	-11.0	111
		V7 (WEEK 56) - V1 (WEEK 0)	23	18.0	35.26		-51	17.0	78

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: THROMBOCYTES [/nL]
Reference Range: 150 - 400 /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	211.9	51.10	24.1	159	205.5	322
		V1 (WEEK 0)	11	221.3	71.89	32.5	159	202.0	372
		V3 (WEEK 12)	12	220.3	69.58	31.6	151	196.5	338
		V4 (WEEK 24)	12	230.7	78.51	34.0	145	202.0	389
		V5 (WEEK 36)	11	212.3	59.20	27.9	152	199.0	335
		V6 (WEEK 52)	11	224.4	64.12	28.6	156	190.0	351
		V7 (WEEK 56)	11	211.1	63.78	30.2	153	193.0	341
		V3 (WEEK 12) - V1 (WEEK 0)	11	5.3	44.61		-41	-3.0	119
		V4 (WEEK 24) - V1 (WEEK 0)	11	15.4	64.93		-66	6.0	184
		V5 (WEEK 36) - V1 (WEEK 0)	10	-4.3	36.04		-75	1.0	36
		V6 (WEEK 52) - V1 (WEEK 0)	10	7.3	31.84		-54	8.0	61
		V7 (WEEK 56) - V1 (WEEK 0)	10	-8.3	26.87		-34	-9.0	59

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: THROMBOCYTES [/nL]
Reference Range: 150 - 400 /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	244.3	46.50	19.0	132	253.0	311
		V1 (WEEK 0)	19	244.1	51.92	21.3	115	260.0	350
		V3 (WEEK 12)	19	248.4	67.57	27.2	93	259.0	352
		V4 (WEEK 24)	19	244.3	54.76	22.4	124	250.0	349
		V5 (WEEK 36)	18	237.7	57.52	24.2	122	241.5	306
		V6 (WEEK 52)	15	242.1	71.30	29.4	98	240.0	365
		V7 (WEEK 56)	15	242.5	73.94	30.5	85	242.0	378
		V3 (WEEK 12) - V1 (WEEK 0)	19	4.3	52.40		-132	5.0	151
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.2	34.11		-91	4.0	62
		V5 (WEEK 36) - V1 (WEEK 0)	18	-4.7	26.26		-55	4.0	26
		V6 (WEEK 52) - V1 (WEEK 0)	15	7.7	34.54		-29	-7.0	83
		V7 (WEEK 56) - V1 (WEEK 0)	15	-1.9	47.95		-108	-8.0	95

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: THROMBOCYTES [/nL]
Reference Range: 150 - 400 /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	231.8	50.12	21.6	132	231.0	322
		V1 (WEEK 0)	30	235.7	59.84	25.4	115	233.0	372
		V3 (WEEK 12)	31	237.5	68.63	28.9	93	248.0	352
		V4 (WEEK 24)	31	239.0	64.07	26.8	124	241.0	389
		V5 (WEEK 36)	29	228.1	58.47	25.6	122	221.0	335
		V6 (WEEK 52)	26	234.6	67.61	28.8	98	231.0	365
		V7 (WEEK 56)	26	229.2	70.29	30.7	85	225.5	378
		V3 (WEEK 12) - V1 (WEEK 0)	30	4.7	48.89		-132	0.5	151
		V4 (WEEK 24) - V1 (WEEK 0)	30	5.8	47.23		-91	5.0	184
		V5 (WEEK 36) - V1 (WEEK 0)	28	-4.5	29.45		-75	3.5	36
		V6 (WEEK 52) - V1 (WEEK 0)	25	7.5	32.80		-54	1.0	83
		V7 (WEEK 56) - V1 (WEEK 0)	25	-4.4	40.28		-108	-8.0	95

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/nL]
Reference Range: 4.0 - 9.1 (MALE), 4.0 - 10.0 (FEMALE) /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	6.15	0.917	14.92	4.8	6.30	7.7
		V1 (WEEK 0)	13	6.09	1.170	19.21	4.1	6.30	8.0
		V3 (WEEK 12)	13	6.08	0.862	14.19	4.9	6.00	7.7
		V4 (WEEK 24)	7	5.44	0.798	14.65	4.4	5.20	7.0
		V5 (WEEK 36)	8	6.06	1.265	20.86	4.5	6.10	8.4
		V6 (WEEK 52)	8	6.01	1.212	20.16	5.1	5.70	8.8
		V7 (WEEK 56)	8	6.20	1.200	19.35	5.1	5.80	8.1
		V3 (WEEK 12) - V1 (WEEK 0)	13	-0.02	0.964		-1.8	0.10	1.5
		V4 (WEEK 24) - V1 (WEEK 0)	7	-0.64	1.594		-3.6	0.00	1.0
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.02	1.168		-1.4	-0.15	2.3
		V6 (WEEK 52) - V1 (WEEK 0)	8	-0.07	1.430		-2.2	-0.05	2.0
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.11	1.163		-1.7	0.10	1.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LEUKOCYTES [/nL]
Reference Range: 4.0 - 9.1 (MALE), 4.0 - 10.0 (FEMALE) /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	7.36	2.660	36.16	4.7	7.00	17.2
		V1 (WEEK 0)	19	7.16	2.441	34.08	4.1	6.80	15.9
		V3 (WEEK 12)	16	6.96	1.989	28.57	5.4	6.30	13.8
		V4 (WEEK 24)	15	7.06	1.730	24.50	5.0	6.80	12.3
		V5 (WEEK 36)	14	7.43	1.931	26.00	5.8	6.65	13.3
		V6 (WEEK 52)	16	7.43	3.297	44.41	4.3	6.85	18.2
		V7 (WEEK 56)	15	7.49	2.879	38.45	5.1	6.60	16.4
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.47	1.368		-4.1	-0.20	1.2
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.55	1.261		-3.6	-0.20	1.0
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.21	1.136		-2.6	0.05	1.6
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.16	2.004		-4.6	0.05	3.4
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.08	1.746		-4.3	0.30	2.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/nL]
Reference Range: 4.0 - 9.1 (MALE), 4.0 - 10.0 (FEMALE) /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	6.87	2.191	31.91	4.7	6.45	17.2
		V1 (WEEK 0)	32	6.73	2.068	30.74	4.1	6.60	15.9
		V3 (WEEK 12)	29	6.57	1.625	24.75	4.9	6.20	13.8
		V4 (WEEK 24)	22	6.55	1.665	25.43	4.4	6.25	12.3
		V5 (WEEK 36)	22	6.93	1.815	26.19	4.5	6.55	13.3
		V6 (WEEK 52)	24	6.95	2.829	40.67	4.3	6.05	18.2
		V7 (WEEK 56)	23	7.04	2.475	35.16	5.1	6.10	16.4
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.27	1.206		-4.1	-0.20	1.5
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.58	1.337		-3.6	-0.15	1.0
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.15	1.124		-2.6	0.05	2.3
		V6 (WEEK 52) - V1 (WEEK 0)	24	0.08	1.804		-4.6	0.05	3.4
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.09	1.539		-4.3	0.10	2.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/nL]
Reference Range: 4.0 - 9.1 (MALE), 4.0 - 10.0 (FEMALE) /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	5.80	1.258	21.70	3.5	5.65	8.0
		V1 (WEEK 0)	11	6.05	2.619	43.26	1.7	5.70	12.1
		V3 (WEEK 12)	12	5.85	1.279	21.86	3.1	6.05	7.7
		V4 (WEEK 24)	12	5.95	1.308	21.98	3.4	5.95	8.6
		V5 (WEEK 36)	11	5.77	1.018	17.63	4.3	5.60	8.1
		V6 (WEEK 52)	11	6.08	1.428	23.48	3.1	5.80	8.9
		V7 (WEEK 56)	11	5.79	1.273	21.99	4.1	5.80	8.0
		V3 (WEEK 12) - V1 (WEEK 0)	11	-0.12	2.707		-6.0	0.00	5.7
		V4 (WEEK 24) - V1 (WEEK 0)	11	-0.16	2.409		-5.4	0.00	4.9
		V5 (WEEK 36) - V1 (WEEK 0)	10	0.34	0.956		-0.3	0.15	2.9
		V6 (WEEK 52) - V1 (WEEK 0)	10	0.66	1.508		-1.0	0.35	4.0
		V7 (WEEK 56) - V1 (WEEK 0)	10	0.26	1.466		-0.8	-0.25	4.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LEUKOCYTES [/nL]
Reference Range: 4.0 - 9.1 (MALE), 4.0 - 10.0 (FEMALE) /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	5.89	1.517	25.75	3.2	5.70	10.1
		V1 (WEEK 0)	19	6.04	1.968	32.61	3.0	5.70	10.3
		V3 (WEEK 12)	19	6.02	1.703	28.30	3.8	5.90	10.5
		V4 (WEEK 24)	19	6.40	2.097	32.76	3.5	6.30	11.4
		V5 (WEEK 36)	18	6.17	1.651	26.77	3.5	6.00	9.6
		V6 (WEEK 52)	15	6.14	1.904	31.01	3.4	5.80	10.9
		V7 (WEEK 56)	15	6.24	2.218	35.55	3.3	5.80	12.1
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.02	1.640		-4.0	0.10	3.4
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.36	1.508		-3.6	0.30	3.9
		V5 (WEEK 36) - V1 (WEEK 0)	18	0.13	1.708		-4.1	-0.30	4.2
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.09	1.257		-3.2	0.30	1.7
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.05	1.745		-3.2	0.10	3.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LEUKOCYTES [/nL]
Reference Range: 4.0 - 9.1 (MALE), 4.0 - 10.0 (FEMALE) /nL

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	5.85	1.401	23.93	3.2	5.70	10.1
		V1 (WEEK 0)	30	6.04	2.184	36.14	1.7	5.70	12.1
		V3 (WEEK 12)	31	5.95	1.532	25.73	3.1	6.00	10.5
		V4 (WEEK 24)	31	6.23	1.821	29.24	3.4	6.20	11.4
		V5 (WEEK 36)	29	6.02	1.436	23.87	3.5	5.80	9.6
		V6 (WEEK 52)	26	6.12	1.687	27.59	3.1	5.80	10.9
		V7 (WEEK 56)	26	6.05	1.859	30.73	3.3	5.80	12.1
		V3 (WEEK 12) - V1 (WEEK 0)	30	-0.06	2.049		-6.0	0.05	5.7
		V4 (WEEK 24) - V1 (WEEK 0)	30	0.17	1.865		-5.4	0.10	4.9
		V5 (WEEK 36) - V1 (WEEK 0)	28	0.21	1.467		-4.1	-0.10	4.2
		V6 (WEEK 52) - V1 (WEEK 0)	25	0.32	1.362		-3.2	0.30	4.0
		V7 (WEEK 56) - V1 (WEEK 0)	25	0.13	1.611		-3.2	0.00	4.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: NEUTROPHILS [%]
Reference Range: 34.0 - 70.0 (MALE), 34.0 - 71.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	59.37	7.662	12.91	44.9	59.60	69.3
		V1 (WEEK 0)	13	60.25	5.681	9.43	51.2	58.80	70.1
		V3 (WEEK 12)	13	61.53	8.033	13.06	51.0	61.80	79.8
		V4 (WEEK 24)	7	61.13	4.595	7.52	56.3	60.20	69.2
		V5 (WEEK 36)	8	59.39	7.677	12.93	50.6	59.35	70.4
		V6 (WEEK 52)	8	62.01	5.508	8.88	53.0	60.65	70.1
		V7 (WEEK 56)	8	60.51	4.710	7.78	53.5	60.50	66.8
		V3 (WEEK 12) - V1 (WEEK 0)	13	1.28	4.404		-6.1	0.50	9.7
		V4 (WEEK 24) - V1 (WEEK 0)	7	1.91	6.760		-7.9	0.70	12.6
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.61	7.635		-14.0	-0.10	9.0
		V6 (WEEK 52) - V1 (WEEK 0)	8	2.01	4.898		-6.1	3.70	7.7
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.51	5.608		-8.7	0.70	9.8

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: NEUTROPHILS [%]
Reference Range: 34.0 - 70.0 (MALE), 34.0 - 71.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	64.00	10.494	16.40	39.8	63.20	82.0
		V1 (WEEK 0)	19	63.53	9.589	15.10	44.2	63.70	79.6
		V3 (WEEK 12)	16	63.58	9.669	15.21	45.9	64.10	78.8
		V4 (WEEK 24)	15	62.71	9.595	15.30	40.5	64.90	76.0
		V5 (WEEK 36)	14	60.29	11.606	19.25	39.8	61.45	78.4
		V6 (WEEK 52)	16	63.46	10.394	16.38	42.8	63.95	78.3
		V7 (WEEK 56)	15	63.73	10.472	16.43	48.5	61.10	80.8
		V3 (WEEK 12) - V1 (WEEK 0)	16	-1.99	7.563		-13.2	-3.20	15.3
		V4 (WEEK 24) - V1 (WEEK 0)	15	-2.77	9.117		-23.6	-1.80	8.7
		V5 (WEEK 36) - V1 (WEEK 0)	14	-4.41	12.066		-30.9	-3.85	21.0
		V6 (WEEK 52) - V1 (WEEK 0)	16	1.16	5.879		-11.7	0.20	16.1
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.03	9.036		-23.4	1.10	13.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: NEUTROPHILS [%]
Reference Range: 34.0 - 70.0 (MALE), 34.0 - 71.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	62.12	9.592	15.44	39.8	62.70	82.0
		V1 (WEEK 0)	32	62.19	8.281	13.31	44.2	61.90	79.6
		V3 (WEEK 12)	29	62.66	8.878	14.17	45.9	63.70	79.8
		V4 (WEEK 24)	22	62.21	8.245	13.25	40.5	63.65	76.0
		V5 (WEEK 36)	22	59.96	10.160	16.94	39.8	59.35	78.4
		V6 (WEEK 52)	24	62.98	8.954	14.22	42.8	62.00	78.3
		V7 (WEEK 56)	23	62.61	8.905	14.22	48.5	61.10	80.8
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.52	6.457		-13.2	-0.50	15.3
		V4 (WEEK 24) - V1 (WEEK 0)	22	-1.28	8.571		-23.6	-0.70	12.6
		V5 (WEEK 36) - V1 (WEEK 0)	22	-3.03	10.633		-30.9	-2.25	21.0
		V6 (WEEK 52) - V1 (WEEK 0)	24	1.45	5.478		-11.7	0.95	16.1
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.20	7.875		-23.4	1.10	13.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: NEUTROPHILS [%]
Reference Range: 34.0 - 70.0 (MALE), 34.0 - 71.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	60.71	8.467	13.95	44.4	60.50	74.4
		V1 (WEEK 0)	10	59.85	12.737	21.28	39.2	60.05	85.4
		V3 (WEEK 12)	12	60.50	9.113	15.06	45.2	59.40	73.7
		V4 (WEEK 24)	12	61.57	9.738	15.82	45.4	61.40	78.2
		V5 (WEEK 36)	11	61.08	8.160	13.36	49.2	58.20	72.6
		V6 (WEEK 52)	11	62.41	10.546	16.90	44.2	62.80	83.3
		V7 (WEEK 56)	11	59.55	8.262	13.87	46.3	60.00	70.5
		V3 (WEEK 12) - V1 (WEEK 0)	10	-1.13	5.600		-11.7	-2.00	6.6
		V4 (WEEK 24) - V1 (WEEK 0)	10	0.71	5.791		-7.2	-0.60	9.3
		V5 (WEEK 36) - V1 (WEEK 0)	9	3.57	6.113		-4.9	2.90	11.8
		V6 (WEEK 52) - V1 (WEEK 0)	9	5.57	10.385		-7.0	5.00	29.5
		V7 (WEEK 56) - V1 (WEEK 0)	9	1.58	5.638		-7.9	1.40	9.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: NEUTROPHILS [%]
Reference Range: 34.0 - 70.0 (MALE), 34.0 - 71.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	59.68	9.252	15.50	36.5	58.80	73.5
		V1 (WEEK 0)	19	60.21	15.382	25.55	5.0	63.20	79.9
		V3 (WEEK 12)	19	60.16	10.642	17.69	35.7	62.30	77.2
		V4 (WEEK 24)	19	60.99	11.741	19.25	35.0	64.10	81.0
		V5 (WEEK 36)	18	61.17	13.807	22.57	34.4	62.15	85.8
		V6 (WEEK 52)	15	65.31	10.121	15.50	36.2	67.70	76.1
		V7 (WEEK 56)	15	60.81	14.436	23.74	25.5	62.70	78.7
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.05	10.152		-17.6	-0.60	30.7
		V4 (WEEK 24) - V1 (WEEK 0)	19	0.78	9.120		-12.5	0.80	30.0
		V5 (WEEK 36) - V1 (WEEK 0)	18	1.24	12.159		-13.6	-1.10	29.4
		V6 (WEEK 52) - V1 (WEEK 0)	15	4.93	10.276		-14.9	2.10	31.2
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.14	13.360		-34.3	0.70	28.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: NEUTROPHILS [%]
Reference Range: 34.0 - 70.0 (MALE), 34.0 - 71.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	60.08	8.827	14.69	36.5	60.10	74.4
		V1 (WEEK 0)	29	60.09	14.293	23.79	5.0	61.70	85.4
		V3 (WEEK 12)	31	60.29	9.921	16.45	35.7	62.10	77.2
		V4 (WEEK 24)	31	61.21	10.842	17.71	35.0	63.70	81.0
		V5 (WEEK 36)	29	61.13	11.812	19.32	34.4	61.20	85.8
		V6 (WEEK 52)	26	64.08	10.198	15.91	36.2	65.70	83.3
		V7 (WEEK 56)	26	60.28	12.017	19.93	25.5	61.55	78.7
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.42	8.753		-17.6	-1.60	30.7
		V4 (WEEK 24) - V1 (WEEK 0)	29	0.76	8.016		-12.5	0.40	30.0
		V5 (WEEK 36) - V1 (WEEK 0)	27	2.02	10.460		-13.6	1.20	29.4
		V6 (WEEK 52) - V1 (WEEK 0)	24	5.17	10.094		-14.9	4.65	31.2
		V7 (WEEK 56) - V1 (WEEK 0)	24	0.50	10.974		-34.3	1.05	28.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LYMPHOCYTES [%]
Reference Range: 22.0 - 53.0 (MALE), 19.0 - 52.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	29.10	5.989	20.58	22.5	27.80	38.4
		V1 (WEEK 0)	13	27.89	4.547	16.30	21.4	28.90	37.0
		V3 (WEEK 12)	13	26.14	6.559	25.09	12.2	24.40	35.5
		V4 (WEEK 24)	7	26.41	3.879	14.69	20.9	26.40	32.1
		V5 (WEEK 36)	8	29.13	7.415	25.46	21.4	26.10	38.8
		V6 (WEEK 52)	8	25.68	5.492	21.39	19.1	24.50	35.8
		V7 (WEEK 56)	8	26.94	3.821	14.19	22.1	26.95	33.7
		V3 (WEEK 12) - V1 (WEEK 0)	13	-1.75	4.022		-9.2	-1.20	5.9
		V4 (WEEK 24) - V1 (WEEK 0)	7	-2.46	4.046		-8.0	-1.00	2.1
		V5 (WEEK 36) - V1 (WEEK 0)	8	0.89	6.815		-7.9	1.00	13.4
		V6 (WEEK 52) - V1 (WEEK 0)	8	-2.56	4.766		-9.8	-2.90	4.0
		V7 (WEEK 56) - V1 (WEEK 0)	8	-1.30	5.406		-9.2	-2.35	8.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LYMPHOCYTES [%]
Reference Range: 22.0 - 53.0 (MALE), 19.0 - 52.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	25.06	8.091	32.29	11.1	27.00	35.8
		V1 (WEEK 0)	19	25.08	8.126	32.40	11.1	26.20	38.0
		V3 (WEEK 12)	16	25.57	7.755	30.33	12.6	25.65	36.8
		V4 (WEEK 24)	15	26.64	9.257	34.75	13.8	24.70	50.4
		V5 (WEEK 36)	14	28.04	8.791	31.36	11.4	28.30	41.4
		V6 (WEEK 52)	16	25.16	8.177	32.50	10.1	26.05	41.4
		V7 (WEEK 56)	15	24.83	8.595	34.61	12.3	26.40	40.4
		V3 (WEEK 12) - V1 (WEEK 0)	16	1.81	6.367		-12.3	3.35	12.2
		V4 (WEEK 24) - V1 (WEEK 0)	15	3.08	8.733		-8.0	3.00	26.2
		V5 (WEEK 36) - V1 (WEEK 0)	14	3.69	9.468		-16.4	3.00	25.7
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.84	4.721		-12.6	-0.40	5.6
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.17	4.777		-9.1	0.20	7.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LYMPHOCYTES [%]
Reference Range: 22.0 - 53.0 (MALE), 19.0 - 52.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	26.70	7.481	28.02	11.1	27.40	38.4
		V1 (WEEK 0)	32	26.22	6.951	26.51	11.1	27.65	38.0
		V3 (WEEK 12)	29	25.82	7.123	27.58	12.2	25.40	36.8
		V4 (WEEK 24)	22	26.57	7.839	29.50	13.8	24.70	50.4
		V5 (WEEK 36)	22	28.43	8.152	28.67	11.4	26.70	41.4
		V6 (WEEK 52)	24	25.33	7.270	28.70	10.1	25.25	41.4
		V7 (WEEK 56)	23	25.57	7.260	28.40	12.3	26.40	40.4
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.21	5.648		-12.3	-0.70	12.2
		V4 (WEEK 24) - V1 (WEEK 0)	22	1.32	7.905		-8.0	0.35	26.2
		V5 (WEEK 36) - V1 (WEEK 0)	22	2.67	8.537		-16.4	2.00	25.7
		V6 (WEEK 52) - V1 (WEEK 0)	24	-1.41	4.705		-12.6	-1.25	5.6
		V7 (WEEK 56) - V1 (WEEK 0)	23	-0.56	4.912		-9.2	-1.30	8.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LYMPHOCYTES [%]
Reference Range: 22.0 - 53.0 (MALE), 19.0 - 52.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	28.26	6.329	22.40	19.0	28.35	41.6
		V1 (WEEK 0)	10	28.07	10.249	36.51	10.3	27.25	46.9
		V3 (WEEK 12)	12	27.15	7.315	26.94	15.8	25.40	41.8
		V4 (WEEK 24)	12	27.05	8.183	30.25	10.7	26.80	40.1
		V5 (WEEK 36)	11	27.81	6.065	21.81	20.7	26.80	36.9
		V6 (WEEK 52)	11	26.25	8.184	31.17	12.0	26.20	42.1
		V7 (WEEK 56)	11	27.71	6.483	23.40	15.4	28.00	39.5
		V3 (WEEK 12) - V1 (WEEK 0)	10	-0.05	4.043		-5.2	-0.75	5.5
		V4 (WEEK 24) - V1 (WEEK 0)	10	-0.98	3.205		-7.1	0.35	2.4
		V5 (WEEK 36) - V1 (WEEK 0)	9	-2.43	5.108		-10.2	-2.50	3.8
		V6 (WEEK 52) - V1 (WEEK 0)	9	-4.53	7.700		-22.0	-4.80	5.4
		V7 (WEEK 56) - V1 (WEEK 0)	9	-2.19	4.232		-7.4	-2.70	6.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: LYMPHOCYTES [%]
Reference Range: 22.0 - 53.0 (MALE), 19.0 - 52.0 (FEMALE) %

Treatment	Sex	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	28.64	7.329	25.59	18.8	27.30	41.1
		V1 (WEEK 0)	19	29.46	12.886	43.74	14.7	26.40	75.0
		V3 (WEEK 12)	19	29.03	8.861	30.53	16.6	27.80	47.5
		V4 (WEEK 24)	19	27.21	7.995	29.38	13.1	26.80	43.8
		V5 (WEEK 36)	18	28.58	11.759	41.15	8.1	27.65	47.7
		V6 (WEEK 52)	15	24.60	6.802	27.65	17.1	23.90	42.1
		V7 (WEEK 56)	15	28.19	10.511	37.28	14.6	26.20	55.9
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.43	8.788		-29.5	-0.50	13.7
		V4 (WEEK 24) - V1 (WEEK 0)	19	-2.25	9.760		-37.7	-1.20	9.5
		V5 (WEEK 36) - V1 (WEEK 0)	18	-1.26	10.377		-27.8	0.90	12.8
		V6 (WEEK 52) - V1 (WEEK 0)	15	-4.77	9.744		-32.9	-3.60	12.9
		V7 (WEEK 56) - V1 (WEEK 0)	15	-1.17	12.615		-32.8	-2.20	26.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: LYMPHOCYTES [%]
Reference Range: 22.0 - 53.0 (MALE), 19.0 - 52.0 (FEMALE) %

Treatment	Sex	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	28.49	6.852	24.05	18.8	27.30	41.6
		V1 (WEEK 0)	29	28.98	11.873	40.97	10.3	26.40	75.0
		V3 (WEEK 12)	31	28.30	8.221	29.05	15.8	25.90	47.5
		V4 (WEEK 24)	31	27.15	7.932	29.22	10.7	26.80	43.8
		V5 (WEEK 36)	29	28.29	9.861	34.86	8.1	26.80	47.7
		V6 (WEEK 52)	26	25.30	7.307	28.88	12.0	24.30	42.1
		V7 (WEEK 56)	26	27.99	8.874	31.71	14.6	27.20	55.9
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.30	7.412		-29.5	-0.50	13.7
		V4 (WEEK 24) - V1 (WEEK 0)	29	-1.81	8.057		-37.7	-0.60	9.5
		V5 (WEEK 36) - V1 (WEEK 0)	27	-1.65	8.875		-27.8	0.00	12.8
		V6 (WEEK 52) - V1 (WEEK 0)	24	-4.68	8.856		-32.9	-4.20	12.9
		V7 (WEEK 56) - V1 (WEEK 0)	24	-1.55	10.166		-32.8	-2.45	26.7

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MONOCYTES [%]
Reference Range: 2.0 - 14.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	8.75	2.027	23.18	6.1	8.90	12.6
		V1 (WEEK 0)	13	9.12	1.948	21.35	5.4	8.70	12.7
		V3 (WEEK 12)	13	9.44	2.628	27.85	6.2	9.10	14.1
		V4 (WEEK 24)	7	10.11	3.414	33.76	7.1	9.10	17.1
		V5 (WEEK 36)	8	9.39	1.591	16.95	7.1	9.55	11.5
		V6 (WEEK 52)	8	9.50	1.838	19.34	7.1	9.25	13.1
		V7 (WEEK 56)	8	9.71	1.770	18.22	7.5	9.30	12.2
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.32	2.009		-3.1	0.20	5.4
		V4 (WEEK 24) - V1 (WEEK 0)	7	1.03	2.400		-1.3	-0.20	5.3
		V5 (WEEK 36) - V1 (WEEK 0)	8	0.35	1.124		-0.9	0.15	1.9
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.46	2.442		-3.0	0.55	4.7
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.67	1.463		-1.3	0.55	3.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MONOCYTES [%]
Reference Range: 2.0 - 14.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	8.05	1.846	22.94	5.0	7.90	12.9
		V1 (WEEK 0)	19	8.46	1.944	22.97	5.1	8.80	12.1
		V3 (WEEK 12)	16	7.98	1.204	15.09	6.1	7.75	10.5
		V4 (WEEK 24)	15	7.67	1.463	19.09	5.4	8.20	10.1
		V5 (WEEK 36)	14	7.74	1.847	23.85	4.5	8.50	9.7
		V6 (WEEK 52)	16	8.21	1.960	23.88	5.5	7.65	11.9
		V7 (WEEK 56)	15	7.96	1.517	19.06	5.3	7.60	10.2
		V3 (WEEK 12) - V1 (WEEK 0)	16	-0.09	1.470		-2.3	-0.20	2.2
		V4 (WEEK 24) - V1 (WEEK 0)	15	-0.50	1.908		-4.0	-0.50	4.5
		V5 (WEEK 36) - V1 (WEEK 0)	14	-0.29	1.424		-2.5	-0.40	2.8
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.40	2.105		-2.9	-1.15	4.7
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.35	2.093		-3.7	-0.50	4.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MONOCYTES [%]
Reference Range: 2.0 - 14.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	8.33	1.921	23.06	5.0	7.90	12.9
		V1 (WEEK 0)	32	8.73	1.942	22.25	5.1	8.75	12.7
		V3 (WEEK 12)	29	8.63	2.070	23.98	6.1	8.30	14.1
		V4 (WEEK 24)	22	8.45	2.474	29.29	5.4	8.30	17.1
		V5 (WEEK 36)	22	8.34	1.900	22.78	4.5	8.70	11.5
		V6 (WEEK 52)	24	8.64	1.980	22.92	5.5	8.30	13.1
		V7 (WEEK 56)	23	8.57	1.786	20.84	5.3	8.80	12.2
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.09	1.712		-3.1	0.20	5.4
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.01	2.145		-4.0	-0.40	5.3
		V5 (WEEK 36) - V1 (WEEK 0)	22	-0.06	1.333		-2.5	-0.35	2.8
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.11	2.208		-3.0	-0.30	4.7
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.01	1.928		-3.7	-0.30	4.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MONOCYTES [%]
Reference Range: 2.0 - 14.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	7.67	1.747	22.79	5.5	7.10	10.3
		V1 (WEEK 0)	10	8.49	2.375	27.98	4.0	8.35	12.6
		V3 (WEEK 12)	12	8.88	2.617	29.49	5.1	8.35	15.7
		V4 (WEEK 24)	12	8.35	2.449	29.33	4.9	8.80	13.5
		V5 (WEEK 36)	11	7.92	2.045	25.83	4.5	8.10	11.1
		V6 (WEEK 52)	11	7.99	2.355	29.47	3.7	8.50	11.1
		V7 (WEEK 56)	11	8.86	2.320	26.18	4.4	8.60	12.3
		V3 (WEEK 12) - V1 (WEEK 0)	10	0.91	2.620		-3.4	0.05	5.2
		V4 (WEEK 24) - V1 (WEEK 0)	10	0.54	3.214		-5.7	0.60	6.7
		V5 (WEEK 36) - V1 (WEEK 0)	9	-0.71	2.281		-5.8	0.00	1.9
		V6 (WEEK 52) - V1 (WEEK 0)	9	-0.76	2.389		-5.2	0.40	1.8
		V7 (WEEK 56) - V1 (WEEK 0)	9	0.26	2.027		-4.0	0.70	3.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MONOCYTES [%]
Reference Range: 2.0 - 14.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	8.43	3.590	42.60	5.0	7.30	21.1
		V1 (WEEK 0)	19	7.61	2.889	37.96	4.7	7.20	16.0
		V3 (WEEK 12)	19	8.44	3.081	36.52	4.7	7.60	17.5
		V4 (WEEK 24)	19	9.24	5.634	60.96	4.7	6.70	25.1
		V5 (WEEK 36)	18	8.04	3.566	44.32	3.8	7.05	17.6
		V6 (WEEK 52)	15	8.01	3.922	48.95	5.4	6.50	20.5
		V7 (WEEK 56)	15	8.75	4.701	53.71	4.8	6.60	23.0
		V3 (WEEK 12) - V1 (WEEK 0)	19	0.83	1.995		-4.2	0.70	4.6
		V4 (WEEK 24) - V1 (WEEK 0)	19	1.63	3.796		-2.9	0.50	13.7
		V5 (WEEK 36) - V1 (WEEK 0)	18	0.41	1.841		-4.0	0.55	4.5
		V6 (WEEK 52) - V1 (WEEK 0)	15	0.39	1.698		-1.8	0.60	4.5
		V7 (WEEK 56) - V1 (WEEK 0)	15	1.52	2.499		-1.5	1.00	7.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: MONOCYTES [%]
Reference Range: 2.0 - 14.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	8.13	2.999	36.87	5.0	7.30	21.1
		V1 (WEEK 0)	29	7.91	2.713	34.28	4.0	7.60	16.0
		V3 (WEEK 12)	31	8.61	2.873	33.38	4.7	8.20	17.5
		V4 (WEEK 24)	31	8.90	4.630	52.04	4.7	7.50	25.1
		V5 (WEEK 36)	29	8.00	3.036	37.97	3.8	7.40	17.6
		V6 (WEEK 52)	26	8.00	3.292	41.12	3.7	7.05	20.5
		V7 (WEEK 56)	26	8.80	3.813	43.32	4.4	8.00	23.0
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.86	2.183		-4.2	0.60	5.2
		V4 (WEEK 24) - V1 (WEEK 0)	29	1.26	3.587		-5.7	0.50	13.7
		V5 (WEEK 36) - V1 (WEEK 0)	27	0.04	2.026		-5.8	0.40	4.5
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.04	2.015		-5.2	0.40	4.5
		V7 (WEEK 56) - V1 (WEEK 0)	24	1.05	2.371		-4.0	0.80	7.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: EOSINOPHILS [%]
Reference Range: 1.0 - 7.0 (MALE), 1.0 - 6.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	2.35	1.431	60.99	0.8	2.10	5.1
		V1 (WEEK 0)	13	2.32	1.466	63.12	0.3	1.90	5.7
		V3 (WEEK 12)	13	2.43	1.788	73.54	0.5	1.90	6.8
		V4 (WEEK 24)	7	1.96	0.940	48.01	0.8	2.30	3.0
		V5 (WEEK 36)	8	1.76	1.406	79.78	0.5	1.30	4.9
		V6 (WEEK 52)	8	2.41	1.992	82.56	0.5	1.75	5.7
		V7 (WEEK 56)	8	2.40	1.415	58.97	0.8	2.15	5.0
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.11	1.000		-1.1	-0.10	2.8
		V4 (WEEK 24) - V1 (WEEK 0)	7	-0.47	1.406		-3.4	-0.20	0.9
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.58	0.848		-1.6	-0.65	0.9
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.08	1.183		-1.0	-0.15	2.8
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.06	1.203		-2.0	0.15	2.1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: EOSINOPHILS [%]
Reference Range: 1.0 - 7.0 (MALE), 1.0 - 6.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	2.37	2.582	109.03	0.1	1.70	9.9
		V1 (WEEK 0)	19	2.40	1.886	78.59	0.5	1.90	7.0
		V3 (WEEK 12)	16	2.37	2.968	125.28	0.1	1.65	12.5
		V4 (WEEK 24)	15	2.44	2.168	88.83	0.7	2.00	9.7
		V5 (WEEK 36)	14	3.21	4.129	128.74	0.2	2.35	16.8
		V6 (WEEK 52)	16	2.73	2.579	94.42	0.3	2.35	10.3
		V7 (WEEK 56)	15	2.83	2.748	97.00	0.2	1.70	10.6
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.24	1.668		-1.9	0.10	5.7
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.14	1.374		-1.4	0.10	3.0
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.80	2.826		-1.8	0.25	10.0
		V6 (WEEK 52) - V1 (WEEK 0)	16	0.18	1.245		-1.7	0.05	3.5
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.39	2.842		-1.7	-0.40	9.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: EOSINOPHILS [%]
Reference Range: 1.0 - 7.0 (MALE), 1.0 - 6.0 (FEMALE) %

Treatment	Sex	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	2.36	2.160	91.54	0.1	1.80	9.9
		V1 (WEEK 0)	32	2.37	1.703	71.89	0.3	1.90	7.0
		V3 (WEEK 12)	29	2.40	2.467	102.96	0.1	1.80	12.5
		V4 (WEEK 24)	22	2.29	1.854	81.09	0.7	2.00	9.7
		V5 (WEEK 36)	22	2.68	3.423	127.64	0.2	1.95	16.8
		V6 (WEEK 52)	24	2.63	2.360	89.89	0.3	1.90	10.3
		V7 (WEEK 56)	23	2.68	2.343	87.33	0.2	1.90	10.6
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.18	1.387		-1.9	0.00	5.7
		V4 (WEEK 24) - V1 (WEEK 0)	22	-0.05	1.381		-3.4	-0.05	3.0
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.30	2.375		-1.8	-0.05	10.0
		V6 (WEEK 52) - V1 (WEEK 0)	24	0.15	1.200		-1.7	-0.05	3.5
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.27	2.372		-2.0	-0.20	9.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: EOSINOPHILS [%]
Reference Range: 1.0 - 7.0 (MALE), 1.0 - 6.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	2.90	1.461	50.38	0.9	2.70	5.0
		V1 (WEEK 0)	10	3.07	2.021	65.83	0.1	2.75	6.5
		V3 (WEEK 12)	12	2.92	1.910	65.49	0.6	2.65	6.9
		V4 (WEEK 24)	12	2.56	1.543	60.31	0.3	2.50	5.4
		V5 (WEEK 36)	11	2.77	1.522	54.89	0.6	2.60	5.7
		V6 (WEEK 52)	11	2.89	1.897	65.60	0.7	2.30	6.5
		V7 (WEEK 56)	11	3.34	1.830	54.85	1.1	2.60	6.4
		V3 (WEEK 12) - V1 (WEEK 0)	10	0.18	0.915		-1.3	0.35	1.4
		V4 (WEEK 24) - V1 (WEEK 0)	10	-0.27	1.378		-3.5	-0.05	1.5
		V5 (WEEK 36) - V1 (WEEK 0)	9	-0.33	1.404		-3.4	-0.30	1.3
		V6 (WEEK 52) - V1 (WEEK 0)	9	-0.21	1.476		-2.0	-0.50	2.4
		V7 (WEEK 56) - V1 (WEEK 0)	9	0.33	0.798		-0.6	0.20	1.5

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: EOSINOPHILS [%]
Reference Range: 1.0 - 7.0 (MALE), 1.0 - 6.0 (FEMALE) %

Treatment	Sex	Visit / Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	2.72	3.244	119.20	0.5	1.60	15.1
		V1 (WEEK 0)	19	2.06	1.626	79.01	0.0	1.80	5.9
		V3 (WEEK 12)	19	1.94	1.571	80.89	0.4	1.50	7.1
		V4 (WEEK 24)	19	1.93	1.581	81.84	0.4	1.40	6.2
		V5 (WEEK 36)	18	1.87	1.395	74.73	0.3	1.45	4.9
		V6 (WEEK 52)	15	1.72	1.155	67.16	0.5	1.40	4.8
		V7 (WEEK 56)	15	1.80	1.099	61.04	0.7	1.40	4.8
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.12	1.162		-2.6	0.20	1.2
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.13	1.351		-2.2	-0.40	3.7
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.06	1.298		-2.2	-0.25	2.4
		V6 (WEEK 52) - V1 (WEEK 0)	15	-0.19	1.008		-1.9	-0.20	1.6
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.04	1.232		-3.2	0.10	2.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: EOSINOPHILS [%]
Reference Range: 1.0 - 7.0 (MALE), 1.0 - 6.0 (FEMALE) %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	2.79	2.665	95.51	0.5	1.90	15.1
		V1 (WEEK 0)	29	2.41	1.803	74.92	0.0	1.90	6.5
		V3 (WEEK 12)	31	2.32	1.747	75.32	0.4	1.90	7.1
		V4 (WEEK 24)	31	2.17	1.571	72.27	0.3	1.80	6.2
		V5 (WEEK 36)	29	2.21	1.486	67.24	0.3	1.90	5.7
		V6 (WEEK 52)	26	2.22	1.592	71.86	0.5	1.80	6.5
		V7 (WEEK 56)	26	2.45	1.617	66.00	0.7	2.00	6.4
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.01	1.076		-2.6	0.30	1.4
		V4 (WEEK 24) - V1 (WEEK 0)	29	-0.18	1.338		-3.5	-0.30	3.7
		V5 (WEEK 36) - V1 (WEEK 0)	27	-0.15	1.314		-3.4	-0.30	2.4
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.20	1.173		-2.0	-0.20	2.4
		V7 (WEEK 56) - V1 (WEEK 0)	24	0.15	1.080		-3.2	0.15	2.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: BASOPHILS [%]
Reference Range: < 1.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Male	SCREENING	13	0.44	0.210	47.97	0.2	0.40	0.9
		V1 (WEEK 0)	13	0.42	0.182	43.78	0.2	0.40	0.7
		V3 (WEEK 12)	13	0.46	0.210	45.57	0.2	0.40	1.0
		V4 (WEEK 24)	7	0.39	0.090	23.33	0.2	0.40	0.5
		V5 (WEEK 36)	8	0.34	0.160	47.35	0.2	0.30	0.6
		V6 (WEEK 52)	8	0.40	0.131	32.73	0.2	0.45	0.5
		V7 (WEEK 56)	8	0.44	0.160	36.53	0.3	0.40	0.8
		V3 (WEEK 12) - V1 (WEEK 0)	13	0.05	0.145		-0.2	0.00	0.3
		V4 (WEEK 24) - V1 (WEEK 0)	7	-0.01	0.146		-0.3	0.00	0.1
		V5 (WEEK 36) - V1 (WEEK 0)	8	-0.05	0.227		-0.5	-0.05	0.3
		V6 (WEEK 52) - V1 (WEEK 0)	8	0.01	0.223		-0.5	0.05	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	8	0.05	0.207		-0.4	0.10	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: BASOPHILS [%]
Reference Range: < 1.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Female	SCREENING	19	0.53	0.325	61.68	0.2	0.40	1.6
		V1 (WEEK 0)	19	0.53	0.269	50.58	0.1	0.50	1.2
		V3 (WEEK 12)	16	0.51	0.257	50.73	0.2	0.50	1.2
		V4 (WEEK 24)	15	0.54	0.264	48.90	0.2	0.50	1.1
		V5 (WEEK 36)	14	0.72	0.493	68.38	0.2	0.60	1.7
		V6 (WEEK 52)	16	0.44	0.356	81.30	0.0	0.30	1.3
		V7 (WEEK 56)	15	0.65	0.402	62.09	0.3	0.50	1.8
		V3 (WEEK 12) - V1 (WEEK 0)	16	0.03	0.265		-0.4	0.05	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	15	0.05	0.185		-0.2	0.00	0.5
		V5 (WEEK 36) - V1 (WEEK 0)	14	0.22	0.458		-0.3	0.20	1.2
		V6 (WEEK 52) - V1 (WEEK 0)	16	-0.11	0.262		-0.6	-0.10	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	15	0.10	0.507		-0.5	0.10	1.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

14FEB2013

Safety Population

Parameter: BASOPHILS [%]
Reference Range: < 1.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	Total	SCREENING	32	0.49	0.283	57.73	0.2	0.40	1.6
		V1 (WEEK 0)	32	0.48	0.241	49.78	0.1	0.40	1.2
		V3 (WEEK 12)	29	0.49	0.234	48.15	0.2	0.50	1.2
		V4 (WEEK 24)	22	0.49	0.233	47.42	0.2	0.40	1.1
		V5 (WEEK 36)	22	0.58	0.441	75.88	0.2	0.50	1.7
		V6 (WEEK 52)	24	0.43	0.297	69.82	0.0	0.40	1.3
		V7 (WEEK 56)	23	0.57	0.348	60.64	0.3	0.50	1.8
		V3 (WEEK 12) - V1 (WEEK 0)	29	0.04	0.216		-0.4	0.00	0.7
		V4 (WEEK 24) - V1 (WEEK 0)	22	0.03	0.173		-0.3	0.00	0.5
		V5 (WEEK 36) - V1 (WEEK 0)	22	0.12	0.406		-0.5	0.00	1.2
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.07	0.251		-0.6	0.00	0.3
		V7 (WEEK 56) - V1 (WEEK 0)	23	0.08	0.422		-0.5	0.10	1.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: BASOPHILS [%]
Reference Range: < 1.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Male	SCREENING	12	0.47	0.239	51.15	0.1	0.45	0.9
		V1 (WEEK 0)	10	0.52	0.199	38.25	0.2	0.60	0.8
		V3 (WEEK 12)	12	0.56	0.312	55.84	0.2	0.45	1.2
		V4 (WEEK 24)	12	0.47	0.325	68.44	0.1	0.40	1.0
		V5 (WEEK 36)	11	0.42	0.178	42.53	0.2	0.40	0.7
		V6 (WEEK 52)	11	0.45	0.238	52.40	0.2	0.40	0.8
		V7 (WEEK 56)	11	0.54	0.229	42.74	0.2	0.50	0.9
		V3 (WEEK 12) - V1 (WEEK 0)	10	0.09	0.223		-0.2	0.05	0.4
		V4 (WEEK 24) - V1 (WEEK 0)	10	0.00	0.240		-0.4	-0.05	0.4
		V5 (WEEK 36) - V1 (WEEK 0)	9	-0.09	0.117		-0.3	0.00	0.0
		V6 (WEEK 52) - V1 (WEEK 0)	9	-0.07	0.194		-0.4	0.00	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	9	0.02	0.130		-0.1	0.00	0.3

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: BASOPHILS [%]
Reference Range: < 1.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Female	SCREENING	19	0.53	0.271	50.96	0.2	0.50	1.2
		V1 (WEEK 0)	19	0.66	0.843	127.18	0.2	0.50	4.0
		V3 (WEEK 12)	19	0.43	0.186	43.04	0.1	0.40	1.0
		V4 (WEEK 24)	19	0.63	0.839	133.89	0.2	0.40	4.0
		V5 (WEEK 36)	18	0.34	0.212	61.56	0.0	0.30	0.8
		V6 (WEEK 52)	15	0.36	0.176	49.02	0.2	0.30	0.7
		V7 (WEEK 56)	15	0.44	0.331	75.28	0.1	0.40	1.5
		V3 (WEEK 12) - V1 (WEEK 0)	19	-0.23	0.822		-3.5	0.00	0.3
		V4 (WEEK 24) - V1 (WEEK 0)	19	-0.04	1.087		-3.4	0.00	3.0
		V5 (WEEK 36) - V1 (WEEK 0)	18	-0.34	0.929		-4.0	-0.05	0.1
		V6 (WEEK 52) - V1 (WEEK 0)	15	-0.36	0.950		-3.7	-0.10	0.1
		V7 (WEEK 56) - V1 (WEEK 0)	15	-0.25	0.943		-3.5	-0.10	0.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.2: Hematology, descriptive statistics

 14FEB2013

Safety Population

Parameter: BASOPHILS [%]
Reference Range: < 1.0 %

Treatment	Sex	Visit Difference	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	Total	SCREENING	31	0.51	0.257	50.71	0.1	0.50	1.2
		V1 (WEEK 0)	29	0.61	0.689	112.26	0.2	0.50	4.0
		V3 (WEEK 12)	31	0.48	0.246	51.08	0.1	0.40	1.2
		V4 (WEEK 24)	31	0.57	0.683	120.27	0.1	0.40	4.0
		V5 (WEEK 36)	29	0.37	0.200	53.65	0.0	0.40	0.8
		V6 (WEEK 52)	26	0.40	0.206	51.48	0.2	0.35	0.8
		V7 (WEEK 56)	26	0.48	0.291	60.58	0.1	0.45	1.5
		V3 (WEEK 12) - V1 (WEEK 0)	29	-0.12	0.689		-3.5	0.00	0.4
		V4 (WEEK 24) - V1 (WEEK 0)	29	-0.02	0.883		-3.4	0.00	3.0
		V5 (WEEK 36) - V1 (WEEK 0)	27	-0.26	0.763		-4.0	0.00	0.1
		V6 (WEEK 52) - V1 (WEEK 0)	24	-0.25	0.764		-3.7	-0.05	0.2
		V7 (WEEK 56) - V1 (WEEK 0)	24	-0.15	0.752		-3.5	-0.10	0.9

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: pH-VALUE
Reference Range: 5.0 - 7.0

Treat-ment	Sex	Visit	5.0 N	5.0 %	6.0 N	6.0 %	6.5 N	6.5 %	7.0 N	7.0 %	8.0 N	8.0 %	9.0 N	9.0 %	TOTAL N	TOTAL %
ACI-91	Male	SCREENING	7	53.8	1	7.7	3	23.1	2	15.4					13	100.0
		V1 (WEEK 0)	9	75.0	1	8.3	1	8.3	1	8.3					12	100.0
		V3 (WEEK 12)	9	69.2	2	15.4	1	7.7			1	7.7			13	100.0
		V4 (WEEK 24)	5	62.5	1	12.5	1	12.5	1	12.5					8	100.0
		V5 (WEEK 36)	2	66.7					1	33.3					3	100.0
		V6 (WEEK 52)	3	37.5			2	25.0	3	37.5					8	100.0
		V7 (WEEK 56)	5	62.5			1	12.5	2	25.0					8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: pH-VALUE
Reference Range: 5.0 - 7.0

Treat-ment	Sex	Visit	5.0 N	5.0 %	6.0 N	6.0 %	6.5 N	6.5 %	7.0 N	7.0 %	8.0 N	8.0 %	9.0 N	9.0 %	TOTAL N	TOTAL %
ACI-91	Female	SCREENING	13	68.4			2	10.5	4	21.1					19	100.0
		V1 (WEEK 0)	13	72.2	2	11.1			2	11.1	1	5.6			18	100.0
		V3 (WEEK 12)	11	68.8	1	6.3	1	6.3	2	12.5	1	6.3			16	100.0
		V4 (WEEK 24)	10	71.4	1	7.1	3	21.4							14	100.0
		V5 (WEEK 36)	6	60.0			1	10.0	3	30.0					10	100.0
		V6 (WEEK 52)	7	43.8	2	12.5	3	18.8	2	12.5	2	12.5			16	100.0
		V7 (WEEK 56)	10	76.9	1	7.7	1	7.7	1	7.7					13	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: pH-VALUE
Reference Range: 5.0 - 7.0

Treatment	Sex	Visit	5.0 N	5.0 %	6.0 N	6.0 %	6.5 N	6.5 %	7.0 N	7.0 %	8.0 N	8.0 %	9.0 N	9.0 %	TOTAL N	TOTAL %
ACI-91	Total	SCREENING	20	62.5	1	3.1	5	15.6	6	18.8					32	100.0
		V1 (WEEK 0)	22	73.3	3	10.0	1	3.3	3	10.0	1	3.3			30	100.0
		V3 (WEEK 12)	20	69.0	3	10.3	2	6.9	2	6.9	2	6.9			29	100.0
		V4 (WEEK 24)	15	68.2	2	9.1	4	18.2	1	4.5					22	100.0
		V5 (WEEK 36)	8	61.5			1	7.7	4	30.8					13	100.0
		V6 (WEEK 52)	10	41.7	2	8.3	5	20.8	5	20.8	2	8.3			24	100.0
		V7 (WEEK 56)	15	71.4	1	4.8	2	9.5	3	14.3					21	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: pH-VALUE
Reference Range: 5.0 - 7.0

Treatment	Sex	Visit	5.0 N	5.0 %	6.0 N	6.0 %	6.5 N	6.5 %	7.0 N	7.0 %	8.0 N	8.0 %	9.0 N	9.0 %	TOTAL N	TOTAL %
Placebo	Male	SCREENING	5	41.7	1	8.3	3	25.0	3	25.0					12	100.0
		V1 (WEEK 0)	7	63.6	1	9.1	1	9.1	2	18.2					11	100.0
		V3 (WEEK 12)	8	66.7			1	8.3	3	25.0					12	100.0
		V4 (WEEK 24)	7	58.3	2	16.7	2	16.7	1	8.3					12	100.0
		V5 (WEEK 36)	4	66.7			1	16.7	1	16.7					6	100.0
		V6 (WEEK 52)	6	60.0	2	20.0	1	10.0	1	10.0					10	100.0
		V7 (WEEK 56)	5	50.0	2	20.0	1	10.0	2	20.0					10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: pH-VALUE
Reference Range: 5.0 - 7.0

Treat-ment	Sex	Visit	5.0 N	5.0 %	6.0 N	6.0 %	6.5 N	6.5 %	7.0 N	7.0 %	8.0 N	8.0 %	9.0 N	9.0 %	TOTAL N	TOTAL %
Placebo	Female	SCREENING	13	68.4	2	10.5	2	10.5	2	10.5					19	100.0
		V1 (WEEK 0)	10	52.6	1	5.3	1	5.3	6	31.6	1	5.3			19	100.0
		V3 (WEEK 12)	9	47.4	2	10.5	3	15.8	4	21.1			1	5.3	19	100.0
		V4 (WEEK 24)	11	57.9	1	5.3	3	15.8	4	21.1					19	100.0
		V5 (WEEK 36)	7	58.3	2	16.7	1	8.3	2	16.7					12	100.0
		V6 (WEEK 52)	9	60.0	1	6.7	2	13.3	1	6.7	2	13.3			15	100.0
		V7 (WEEK 56)	8	53.3	2	13.3	4	26.7	1	6.7					15	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: pH-VALUE
Reference Range: 5.0 - 7.0

Treatment	Sex	Visit	5.0 N	5.0 %	6.0 N	6.0 %	6.5 N	6.5 %	7.0 N	7.0 %	8.0 N	8.0 %	9.0 N	9.0 %	TOTAL N	TOTAL %
Placebo	Total	SCREENING	18	58.1	3	9.7	5	16.1	5	16.1					31	100.0
		V1 (WEEK 0)	17	56.7	2	6.7	2	6.7	8	26.7	1	3.3			30	100.0
		V3 (WEEK 12)	17	54.8	2	6.5	4	12.9	7	22.6			1	3.2	31	100.0
		V4 (WEEK 24)	18	58.1	3	9.7	5	16.1	5	16.1					31	100.0
		V5 (WEEK 36)	11	61.1	2	11.1	2	11.1	3	16.7					18	100.0
		V6 (WEEK 52)	15	60.0	3	12.0	3	12.0	2	8.0	2	8.0			25	100.0
		V7 (WEEK 56)	13	52.0	4	16.0	5	20.0	3	12.0					25	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: PROTEIN [mg/L]
Reference Range: < 150 mg/L

Treat-ment	Sex	Visit	250 N	250 %	750 N	750 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Male	SCREENING	2	16.7			10	83.3	12	100.0
		V1 (WEEK 0)	3	27.3			8	72.7	11	100.0
		V3 (WEEK 12)	1	7.7			12	92.3	13	100.0
		V4 (WEEK 24)	1	12.5			7	87.5	8	100.0
		V5 (WEEK 36)					3	100.0	3	100.0
		V6 (WEEK 52)	2	25.0			6	75.0	8	100.0
		V7 (WEEK 56)					8	100.0	8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: PROTEIN [mg/L]
Reference Range: < 150 mg/L

Treatment	Sex	Visit	250 N	250 %	750 N	750 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Female	SCREENING	3	15.8	1	5.3	15	78.9	19	100.0
		V1 (WEEK 0)	1	5.6			17	94.4	18	100.0
		V3 (WEEK 12)	1	6.3			15	93.8	16	100.0
		V4 (WEEK 24)	3	21.4			11	78.6	14	100.0
		V5 (WEEK 36)	1	10.0			9	90.0	10	100.0
		V6 (WEEK 52)					16	100.0	16	100.0
		V7 (WEEK 56)	2	15.4			11	84.6	13	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: PROTEIN [mg/L]
Reference Range: < 150 mg/L

Treat-ment	Sex	Visit	250 N	250 %	750 N	750 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Total	SCREENING	5	16.1	1	3.2	25	80.6	31	100.0
		V1 (WEEK 0)	4	13.8			25	86.2	29	100.0
		V3 (WEEK 12)	2	6.9			27	93.1	29	100.0
		V4 (WEEK 24)	4	18.2			18	81.8	22	100.0
		V5 (WEEK 36)	1	7.7			12	92.3	13	100.0
		V6 (WEEK 52)	2	8.3			22	91.7	24	100.0
		V7 (WEEK 56)	2	9.5			19	90.5	21	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: PROTEIN [mg/L]
Reference Range: < 150 mg/L

Treatment	Sex	Visit	250 N	250 %	750 N	750 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Male	SCREENING	1	8.3			11	91.7	12	100.0
		V1 (WEEK 0)	1	9.1			10	90.9	11	100.0
		V3 (WEEK 12)	4	33.3			8	66.7	12	100.0
		V4 (WEEK 24)	5	41.7			7	58.3	12	100.0
		V5 (WEEK 36)					6	100.0	6	100.0
		V6 (WEEK 52)	2	20.0			8	80.0	10	100.0
		V7 (WEEK 56)	3	30.0			7	70.0	10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: PROTEIN [mg/L]
Reference Range: < 150 mg/L

Treatment	Sex	Visit	250 N	250 %	750 N	750 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Female	SCREENING	2	10.5			17	89.5	19	100.0
		V1 (WEEK 0)	2	10.5			17	89.5	19	100.0
		V3 (WEEK 12)	2	10.5			17	89.5	19	100.0
		V4 (WEEK 24)	3	16.7			15	83.3	18	100.0
		V5 (WEEK 36)	1	8.3	1	8.3	10	83.3	12	100.0
		V6 (WEEK 52)	3	20.0			12	80.0	15	100.0
		V7 (WEEK 56)	2	13.3	2	13.3	11	73.3	15	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: PROTEIN [mg/L]
Reference Range: < 150 mg/L

Treatment	Sex	Visit	250 N	250 %	750 N	750 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Total	SCREENING	3	9.7			28	90.3	31	100.0
		V1 (WEEK 0)	3	10.0			27	90.0	30	100.0
		V3 (WEEK 12)	6	19.4			25	80.6	31	100.0
		V4 (WEEK 24)	8	26.7			22	73.3	30	100.0
		V5 (WEEK 36)	1	5.6	1	5.6	16	88.9	18	100.0
		V6 (WEEK 52)	5	20.0			20	80.0	25	100.0
		V7 (WEEK 56)	5	20.0	2	8.0	18	72.0	25	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: < 0.8 mmol/L

Treat-ment	Sex	Visit	17.0 N	%	2.8 N	%	5.7 N	%	56.7 N	%	NEGATIVE N	%	TOTAL N	%
ACI-91	Male	SCREENING			1	8.3					11	91.7	12	100.0
		V1 (WEEK 0)									11	100.0	11	100.0
		V3 (WEEK 12)			1	7.7					12	92.3	13	100.0
		V4 (WEEK 24)									8	100.0	8	100.0
		V5 (WEEK 36)									3	100.0	3	100.0
		V6 (WEEK 52)									8	100.0	8	100.0
		V7 (WEEK 56)									8	100.0	8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: < 0.8 mmol/L

Treat-ment	Sex	Visit	17.0 N	17.0 %	2.8 N	2.8 %	5.7 N	5.7 %	56.7 N	56.7 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Female	SCREENING	1	5.3							18	94.7	19	100.0
		V1 (WEEK 0)									18	100.0	18	100.0
		V3 (WEEK 12)									16	100.0	16	100.0
		V4 (WEEK 24)									14	100.0	14	100.0
		V5 (WEEK 36)									10	100.0	10	100.0
		V6 (WEEK 52)			1	6.3					15	93.8	16	100.0
		V7 (WEEK 56)									13	100.0	13	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: < 0.8 mmol/L

Treat-ment	Sex	Visit	17.0 N	17.0 %	2.8 N	2.8 %	5.7 N	5.7 %	56.7 N	56.7 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Total	SCREENING	1	3.2	1	3.2					29	93.5	31	100.0
		V1 (WEEK 0)									29	100.0	29	100.0
		V3 (WEEK 12)			1	3.4					28	96.6	29	100.0
		V4 (WEEK 24)									22	100.0	22	100.0
		V5 (WEEK 36)									13	100.0	13	100.0
		V6 (WEEK 52)			1	4.2					23	95.8	24	100.0
		V7 (WEEK 56)									21	100.0	21	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: < 0.8 mmol/L

Treatment	Sex	Visit	17.0 N	17.0 %	2.8 N	2.8 %	5.7 N	5.7 %	56.7 N	56.7 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Male	SCREENING									12	100.0	12	100.0
		V1 (WEEK 0)	1	9.1							10	90.9	11	100.0
		V3 (WEEK 12)									12	100.0	12	100.0
		V4 (WEEK 24)	1	8.3							11	91.7	12	100.0
		V5 (WEEK 36)									6	100.0	6	100.0
		V6 (WEEK 52)					1	10.0			9	90.0	10	100.0
		V7 (WEEK 56)									10	100.0	10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: < 0.8 mmol/L

Treat-ment	Sex	Visit	17.0 N	17.0 %	2.8 N	2.8 %	5.7 N	5.7 %	56.7 N	56.7 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Female	SCREENING							1	5.3	18	94.7	19	100.0
		V1 (WEEK 0)					1	5.3			18	94.7	19	100.0
		V3 (WEEK 12)									19	100.0	19	100.0
		V4 (WEEK 24)							1	5.6	17	94.4	18	100.0
		V5 (WEEK 36)			1	8.3					11	91.7	12	100.0
		V6 (WEEK 52)							1	6.7	14	93.3	15	100.0
		V7 (WEEK 56)							1	6.7	14	93.3	15	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: GLUCOSE [mmol/L]
Reference Range: < 0.8 mmol/L

Treatment	Sex	Visit	17.0 N	17.0 %	2.8 N	2.8 %	5.7 N	5.7 %	56.7 N	56.7 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Total	SCREENING							1	3.2	30	96.8	31	100.0
		V1 (WEEK 0)	1	3.3			1	3.3			28	93.3	30	100.0
		V3 (WEEK 12)									31	100.0	31	100.0
		V4 (WEEK 24)	1	3.3					1	3.3	28	93.3	30	100.0
		V5 (WEEK 36)			1	5.6					17	94.4	18	100.0
		V6 (WEEK 52)					1	4.0	1	4.0	23	92.0	25	100.0
		V7 (WEEK 56)							1	4.0	24	96.0	25	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: KETONES [mmol/L]
Reference Range: < 0.5 mmol/L

Treat-ment	Sex	Visit	(+++) N	%	0.5 N	%	1.5 N	%	5.0 N	%	NEGATIVE N	%	TOTAL N	%
ACI-91	Male	SCREENING									13	100.0	13	100.0
		V1 (WEEK 0)			1	8.3					11	91.7	12	100.0
		V3 (WEEK 12)									13	100.0	13	100.0
		V4 (WEEK 24)									8	100.0	8	100.0
		V5 (WEEK 36)									3	100.0	3	100.0
		V6 (WEEK 52)			1	12.5					7	87.5	8	100.0
		V7 (WEEK 56)									8	100.0	8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: KETONES [mmol/L]
Reference Range: < 0.5 mmol/L

Treatment	Sex	Visit	(+++) N	(+++) %	0.5 N	0.5 %	1.5 N	1.5 %	5.0 N	5.0 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Female	SCREENING			4	21.1					15	78.9	19	100.0
		V1 (WEEK 0)					1	5.6			17	94.4	18	100.0
		V3 (WEEK 12)					1	6.3			15	93.8	16	100.0
		V4 (WEEK 24)			1	7.1					13	92.9	14	100.0
		V5 (WEEK 36)									10	100.0	10	100.0
		V6 (WEEK 52)			1	6.3					15	93.8	16	100.0
		V7 (WEEK 56)			2	15.4					11	84.6	13	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: KETONES [mmol/L]
Reference Range: < 0.5 mmol/L

Treatment	Sex	Visit	(+++) N	(+++) %	0.5 N	0.5 %	1.5 N	1.5 %	5.0 N	5.0 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Total	SCREENING			4	12.5					28	87.5	32	100.0
		V1 (WEEK 0)			1	3.3	1	3.3			28	93.3	30	100.0
		V3 (WEEK 12)					1	3.4			28	96.6	29	100.0
		V4 (WEEK 24)			1	4.5					21	95.5	22	100.0
		V5 (WEEK 36)									13	100.0	13	100.0
		V6 (WEEK 52)			2	8.3					22	91.7	24	100.0
		V7 (WEEK 56)			2	9.5					19	90.5	21	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: KETONES [mmol/L]
Reference Range: < 0.5 mmol/L

Treatment	Sex	Visit	(+++) N	(+++) %	0.5 N	0.5 %	1.5 N	1.5 %	5.0 N	5.0 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Male	SCREENING			1	8.3					11	91.7	12	100.0
		V1 (WEEK 0)	1	9.1	1	9.1					9	81.8	11	100.0
		V3 (WEEK 12)									12	100.0	12	100.0
		V4 (WEEK 24)					1	8.3			11	91.7	12	100.0
		V5 (WEEK 36)									6	100.0	6	100.0
		V6 (WEEK 52)			1	10.0					9	90.0	10	100.0
		V7 (WEEK 56)									10	100.0	10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: KETONES [mmol/L]
Reference Range: < 0.5 mmol/L

Treatment	Sex	Visit	(+++) N	(+++) %	0.5 N	0.5 %	1.5 N	1.5 %	5.0 N	5.0 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Female	SCREENING			2	10.5					17	89.5	19	100.0
		V1 (WEEK 0)			3	15.8					16	84.2	19	100.0
		V3 (WEEK 12)			2	10.5					17	89.5	19	100.0
		V4 (WEEK 24)			3	15.8	1	5.3	1	5.3	14	73.7	19	100.0
		V5 (WEEK 36)			4	33.3					8	66.7	12	100.0
		V6 (WEEK 52)			2	13.3	1	6.7			12	80.0	15	100.0
		V7 (WEEK 56)			3	20.0					12	80.0	15	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: KETONES [mmol/L]
Reference Range: < 0.5 mmol/L

Treatment	Sex	Visit	(+++) N	(+++) %	0.5 N	0.5 %	1.5 N	1.5 %	5.0 N	5.0 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Total	SCREENING			3	9.7					28	90.3	31	100.0
		V1 (WEEK 0)	1	3.3	4	13.3					25	83.3	30	100.0
		V3 (WEEK 12)			2	6.5					29	93.5	31	100.0
		V4 (WEEK 24)			3	9.7	2	6.5	1	3.2	25	80.6	31	100.0
		V5 (WEEK 36)			4	22.2					14	77.8	18	100.0
		V6 (WEEK 52)			3	12.0	1	4.0			21	84.0	25	100.0
		V7 (WEEK 56)			3	12.0					22	88.0	25	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: BLOOD [/µL]
Reference Range: < 5 /µL

Treatment	Sex	Visit	10 N	10 %	25 N	25 %	50 N	50 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Male	SCREENING							13	100.0	13	100.0
		V1 (WEEK 0)	1	8.3					11	91.7	12	100.0
		V3 (WEEK 12)	1	7.7					12	92.3	13	100.0
		V4 (WEEK 24)			1	12.5			7	87.5	8	100.0
		V5 (WEEK 36)	1	33.3					2	66.7	3	100.0
		V6 (WEEK 52)							8	100.0	8	100.0
		V7 (WEEK 56)			1	12.5			7	87.5	8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: BLOOD [/µL]
Reference Range: < 5 /µL

Treatment	Sex	Visit	10 N	10 %	25 N	25 %	50 N	50 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Female	SCREENING	5	26.3			1	5.3	13	68.4	19	100.0
		V1 (WEEK 0)	3	16.7					15	83.3	18	100.0
		V3 (WEEK 12)	3	18.8	1	6.3			12	75.0	16	100.0
		V4 (WEEK 24)	3	21.4					11	78.6	14	100.0
		V5 (WEEK 36)	2	20.0					8	80.0	10	100.0
		V6 (WEEK 52)	6	37.5	1	6.3			9	56.3	16	100.0
		V7 (WEEK 56)	3	23.1					10	76.9	13	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: BLOOD [/µL]
Reference Range: < 5 /µL

Treatment	Sex	Visit	10 N	10 %	25 N	25 %	50 N	50 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Total	SCREENING	5	15.6			1	3.1	26	81.3	32	100.0
		V1 (WEEK 0)	4	13.3					26	86.7	30	100.0
		V3 (WEEK 12)	4	13.8	1	3.4			24	82.8	29	100.0
		V4 (WEEK 24)	3	13.6	1	4.5			18	81.8	22	100.0
		V5 (WEEK 36)	3	23.1					10	76.9	13	100.0
		V6 (WEEK 52)	6	25.0	1	4.2			17	70.8	24	100.0
		V7 (WEEK 56)	3	14.3	1	4.8			17	81.0	21	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: BLOOD [/µL]
Reference Range: < 5 /µL

Treatment	Sex	Visit	10 N	10 %	25 N	25 %	50 N	50 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Male	SCREENING	4	33.3					8	66.7	12	100.0
		V1 (WEEK 0)	4	36.4					7	63.6	11	100.0
		V3 (WEEK 12)	1	8.3					11	91.7	12	100.0
		V4 (WEEK 24)	1	8.3	1	8.3			10	83.3	12	100.0
		V5 (WEEK 36)							6	100.0	6	100.0
		V6 (WEEK 52)	1	10.0					9	90.0	10	100.0
		V7 (WEEK 56)							10	100.0	10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: BLOOD [/µL]
Reference Range: < 5 /µL

Treatment	Sex	Visit	10 N	10 %	25 N	25 %	50 N	50 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Female	SCREENING	5	26.3					14	73.7	19	100.0
		V1 (WEEK 0)	2	10.5					17	89.5	19	100.0
		V3 (WEEK 12)	4	21.1					15	78.9	19	100.0
		V4 (WEEK 24)	6	31.6					13	68.4	19	100.0
		V5 (WEEK 36)	5	41.7					7	58.3	12	100.0
		V6 (WEEK 52)	4	26.7					11	73.3	15	100.0
		V7 (WEEK 56)	9	60.0					6	40.0	15	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: BLOOD [/µL]
Reference Range: < 5 /µL

Treatment	Sex	Visit	10 N	10 %	25 N	25 %	50 N	50 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Total	SCREENING	9	29.0					22	71.0	31	100.0
		V1 (WEEK 0)	6	20.0					24	80.0	30	100.0
		V3 (WEEK 12)	5	16.1					26	83.9	31	100.0
		V4 (WEEK 24)	7	22.6	1	3.2			23	74.2	31	100.0
		V5 (WEEK 36)	5	27.8					13	72.2	18	100.0
		V6 (WEEK 52)	5	20.0					20	80.0	25	100.0
		V7 (WEEK 56)	9	36.0					16	64.0	25	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/µL]
Reference Range: < 20 /µL

Treat-ment	Sex	Visit	(+) 100 N	%	25 N	%	500 N	%	NEGATIVE N	%	TOTAL N	%
ACI-91	Male	SCREENING			1	8.3			11	91.7	12	100.0
		V1 (WEEK 0)			1	9.1			10	90.9	11	100.0
		V3 (WEEK 12)			2	15.4			11	84.6	13	100.0
		V4 (WEEK 24)							8	100.0	8	100.0
		V5 (WEEK 36)							3	100.0	3	100.0
		V6 (WEEK 52)			3	37.5			5	62.5	8	100.0
		V7 (WEEK 56)			1	12.5			7	87.5	8	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/µL]
Reference Range: < 20 /µL

Treat-ment	Sex	Visit	(+) N	(+) %	100 N	100 %	25 N	25 %	500 N	500 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Female	SCREENING			2	10.5	5	26.3	1	5.3	11	57.9	19	100.0
		V1 (WEEK 0)			2	11.1	2	11.1	2	11.1	12	66.7	18	100.0
		V3 (WEEK 12)			5	31.3	4	25.0			7	43.8	16	100.0
		V4 (WEEK 24)			1	7.1	9	64.3	1	7.1	3	21.4	14	100.0
		V5 (WEEK 36)			1	10.0	4	40.0	2	20.0	3	30.0	10	100.0
		V6 (WEEK 52)			4	25.0	3	18.8	3	18.8	6	37.5	16	100.0
		V7 (WEEK 56)					8	61.5	1	7.7	4	30.8	13	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/µL]
Reference Range: < 20 /µL

Treat-ment	Sex	Visit	(+) N	(+) %	100 N	100 %	25 N	25 %	500 N	500 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
ACI-91	Total	SCREENING			2	6.5	6	19.4	1	3.2	22	71.0	31	100.0
		V1 (WEEK 0)			2	6.9	3	10.3	2	6.9	22	75.9	29	100.0
		V3 (WEEK 12)			5	17.2	6	20.7			18	62.1	29	100.0
		V4 (WEEK 24)			1	4.5	9	40.9	1	4.5	11	50.0	22	100.0
		V5 (WEEK 36)			1	7.7	4	30.8	2	15.4	6	46.2	13	100.0
		V6 (WEEK 52)			4	16.7	6	25.0	3	12.5	11	45.8	24	100.0
		V7 (WEEK 56)					9	42.9	1	4.8	11	52.4	21	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/µL]
Reference Range: < 20 /µL

Treatment	Sex	Visit	(+) N	(+) %	100 N	100 %	25 N	25 %	500 N	500 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Male	SCREENING					3	25.0			9	75.0	12	100.0
		V1 (WEEK 0)					1	9.1			10	90.9	11	100.0
		V3 (WEEK 12)			1	8.3					11	91.7	12	100.0
		V4 (WEEK 24)					1	8.3			11	91.7	12	100.0
		V5 (WEEK 36)									6	100.0	6	100.0
		V6 (WEEK 52)					2	20.0			8	80.0	10	100.0
		V7 (WEEK 56)					3	30.0			7	70.0	10	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/µL]
Reference Range: < 20 /µL

Treat-ment	Sex	Visit	(+) N	(+) %	100 N	100 %	25 N	25 %	500 N	500 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Female	SCREENING			3	15.8	3	15.8	1	5.3	12	63.2	19	100.0
		V1 (WEEK 0)			3	15.8	4	21.1	1	5.3	11	57.9	19	100.0
		V3 (WEEK 12)	1	5.3			7	36.8	1	5.3	10	52.6	19	100.0
		V4 (WEEK 24)			4	22.2	2	11.1	2	11.1	10	55.6	18	100.0
		V5 (WEEK 36)					6	50.0	2	16.7	4	33.3	12	100.0
		V6 (WEEK 52)			1	6.7	3	20.0	2	13.3	9	60.0	15	100.0
		V7 (WEEK 56)					5	33.3	2	13.3	8	53.3	15	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.3: Urinalysis, descriptive statistics

 14FEB2013

Safety Population

Parameter: LEUKOCYTES [/µL]
Reference Range: < 20 /µL

Treatment	Sex	Visit	(+) N	(+) %	100 N	100 %	25 N	25 %	500 N	500 %	NEGATIVE N	NEGATIVE %	TOTAL N	TOTAL %
Placebo	Total	SCREENING			3	9.7	6	19.4	1	3.2	21	67.7	31	100.0
		V1 (WEEK 0)			3	10.0	5	16.7	1	3.3	21	70.0	30	100.0
		V3 (WEEK 12)	1	3.2	1	3.2	7	22.6	1	3.2	21	67.7	31	100.0
		V4 (WEEK 24)			4	13.3	3	10.0	2	6.7	21	70.0	30	100.0
		V5 (WEEK 36)					6	33.3	2	11.1	10	55.6	18	100.0
		V6 (WEEK 52)			1	4.0	5	20.0	2	8.0	17	68.0	25	100.0
		V7 (WEEK 56)					8	32.0	2	8.0	15	60.0	25	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Systolic blood pressure - Sitting [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	32	133.69	13.61	10.18	110.0	130.0	160.0
	V1 (WEEK 0)	32	135.81	15.13	11.14	110.0	134.5	170.0
	V2 (WEEK 4)	31	131.61	15.82	12.02	108.0	130.0	166.0
	V3 (WEEK 12)	30	136.53	17.86	13.08	110.0	130.5	186.0
	V4 (WEEK 24)	24	134.13	22.76	16.97	100.0	130.0	194.0
	V5 (WEEK 36)	22	137.59	18.82	13.68	100.0	140.0	174.0
	V6 (WEEK 52)	25	136.08	19.47	14.31	100.0	130.0	182.0
	V7 (WEEK 56)	23	135.43	20.00	14.77	110.0	125.0	175.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	-4.23	15.17		-40.0	-5.0	30.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	0.83	16.62		-30.0	0.0	35.0
	V4 (WEEK 24) - V1 (WEEK 0)	24	-0.38	21.81		-40.0	-3.0	45.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	2.86	19.10		-40.0	0.0	40.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	1.76	22.53		-40.0	0.0	50.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	0.48	24.70		-50.0	0.0	43.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Systolic blood pressure - Sitting [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	144.32	20.04	13.88	115.0	139.0	190.0
	V1 (WEEK 0)	31	141.19	22.35	15.83	110.0	135.0	188.0
	V2 (WEEK 4)	31	136.55	20.96	15.35	95.0	130.0	190.0
	V3 (WEEK 12)	31	139.29	15.24	10.94	110.0	140.0	180.0
	V4 (WEEK 24)	31	138.45	14.67	10.59	110.0	140.0	165.0
	V5 (WEEK 36)	29	136.93	17.58	12.84	110.0	133.0	180.0
	V6 (WEEK 52)	28	141.89	20.12	14.18	100.0	145.0	175.0
	V7 (WEEK 56)	28	135.79	21.46	15.80	95.0	136.5	180.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	-4.65	22.74		-70.0	0.0	40.0
	V3 (WEEK 12) - V1 (WEEK 0)	31	-1.90	18.95		-48.0	0.0	35.0
	V4 (WEEK 24) - V1 (WEEK 0)	31	-2.74	17.93		-50.0	0.0	32.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	-2.90	18.78		-45.0	0.0	40.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	2.86	16.86		-45.0	0.5	40.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	-3.25	20.46		-65.0	-1.5	35.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Systolic blood pressure - Standing [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	31	133.26	14.36	10.78	100.0	131.0	170.0
	V1 (WEEK 0)	32	136.75	17.93	13.11	105.0	131.0	180.0
	V2 (WEEK 4)	31	133.65	13.89	10.40	110.0	131.0	164.0
	V3 (WEEK 12)	30	137.47	20.10	14.62	90.0	134.0	175.0
	V4 (WEEK 24)	24	133.96	21.96	16.39	95.0	130.0	182.0
	V5 (WEEK 36)	22	136.91	18.06	13.19	95.0	135.5	165.0
	V6 (WEEK 52)	24	138.33	18.53	13.40	104.0	132.5	182.0
	V7 (WEEK 56)	23	136.87	20.25	14.79	100.0	135.0	172.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	-3.32	12.98		-25.0	-1.0	25.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	0.60	15.32		-35.0	0.0	40.0
	V4 (WEEK 24) - V1 (WEEK 0)	24	-1.29	19.78		-40.0	0.0	45.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	1.50	18.03		-40.0	1.5	30.0
	V6 (WEEK 52) - V1 (WEEK 0)	24	2.08	22.55		-40.0	0.5	50.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	1.26	20.62		-30.0	-2.0	40.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Systolic blood pressure - Standing [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	144.68	20.51	14.17	103.0	145.0	190.0
	V1 (WEEK 0)	31	140.32	21.00	14.97	110.0	130.0	180.0
	V2 (WEEK 4)	31	141.19	21.26	15.06	105.0	135.0	187.0
	V3 (WEEK 12)	31	140.71	19.81	14.08	94.0	140.0	190.0
	V4 (WEEK 24)	31	138.84	15.69	11.30	110.0	140.0	180.0
	V5 (WEEK 36)	29	139.55	20.03	14.35	108.0	133.0	195.0
	V6 (WEEK 52)	28	140.00	18.13	12.95	105.0	144.0	170.0
	V7 (WEEK 56)	28	138.64	20.21	14.58	110.0	131.5	185.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	0.87	16.63		-40.0	0.0	35.0
	V3 (WEEK 12) - V1 (WEEK 0)	31	0.39	23.03		-71.0	4.0	40.0
	V4 (WEEK 24) - V1 (WEEK 0)	31	-1.48	15.40		-35.0	0.0	30.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	0.24	20.27		-57.0	0.0	50.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	1.29	15.71		-30.0	0.0	40.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	-0.07	17.67		-45.0	1.0	45.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Systolic blood pressure - Standing minus sitting [mmHg]

Treatment	Visit	N	Mean	SD	Minimum	Median	Maximum
ACI-91	SCREENING	31	0.42	10.33	-31.0	5.0	15.0
	V1 (WEEK 0)	32	0.94	11.41	-30.0	1.5	20.0
	V2 (WEEK 4)	31	2.03	13.17	-39.0	5.0	30.0
	V3 (WEEK 12)	30	0.93	12.37	-36.0	1.0	20.0
	V4 (WEEK 24)	24	-0.17	10.74	-22.0	0.0	15.0
	V5 (WEEK 36)	22	-0.68	9.61	-23.0	2.5	12.0
	V6 (WEEK 52)	24	0.75	9.06	-20.0	0.0	16.0
	V7 (WEEK 56)	23	1.43	13.90	-24.0	0.0	31.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Systolic blood pressure - Standing minus sitting [mmHg]

Treatment	Visit	N	Mean	SD	Minimum	Median	Maximum
Placebo	SCREENING	31	0.35	9.15	-23.0	-1.0	20.0
	V1 (WEEK 0)	31	-0.87	7.67	-15.0	0.0	10.0
	V2 (WEEK 4)	31	4.65	13.00	-30.0	4.0	34.0
	V3 (WEEK 12)	31	1.42	14.83	-52.0	4.0	30.0
	V4 (WEEK 24)	31	0.39	9.16	-20.0	2.0	15.0
	V5 (WEEK 36)	29	2.62	14.28	-25.0	0.0	45.0
	V6 (WEEK 52)	28	-1.89	9.03	-25.0	-2.5	13.0
	V7 (WEEK 56)	28	2.86	12.61	-22.0	5.0	34.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Diastolic blood pressure - Sitting [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	32	78.03	9.10	11.66	60.0	80.0	95.0
	V1 (WEEK 0)	32	81.38	9.11	11.19	65.0	80.0	106.0
	V2 (WEEK 4)	31	78.77	9.71	12.33	67.0	80.0	105.0
	V3 (WEEK 12)	30	82.20	12.06	14.67	65.0	80.0	118.0
	V4 (WEEK 24)	24	80.54	13.61	16.90	60.0	80.0	125.0
	V5 (WEEK 36)	22	83.59	15.65	18.72	60.0	80.0	126.0
	V6 (WEEK 52)	25	82.28	9.92	12.05	68.0	80.0	112.0
	V7 (WEEK 56)	23	82.70	10.70	12.94	65.0	80.0	115.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	-2.32	8.46		-20.0	-2.0	19.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	1.40	9.29		-20.0	2.0	25.0
	V4 (WEEK 24) - V1 (WEEK 0)	24	-1.33	13.03		-40.0	-1.5	25.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	1.41	13.66		-40.0	0.5	24.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	-0.96	11.02		-20.0	0.0	20.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	0.17	9.49		-20.0	0.0	14.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Diastolic blood pressure - Sitting [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	83.35	12.49	14.98	49.0	80.0	112.0
	V1 (WEEK 0)	31	81.13	11.87	14.63	55.0	80.0	110.0
	V2 (WEEK 4)	31	82.48	9.72	11.78	55.0	80.0	110.0
	V3 (WEEK 12)	31	81.58	11.54	14.15	60.0	80.0	109.0
	V4 (WEEK 24)	31	83.48	9.57	11.47	60.0	81.0	103.0
	V5 (WEEK 36)	29	82.97	9.57	11.54	60.0	80.0	98.0
	V6 (WEEK 52)	28	83.82	10.14	12.10	60.0	81.5	103.0
	V7 (WEEK 56)	28	79.18	11.10	14.02	55.0	80.0	102.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	1.35	12.38		-35.0	1.0	35.0
	V3 (WEEK 12) - V1 (WEEK 0)	31	0.45	10.28		-20.0	0.0	20.0
	V4 (WEEK 24) - V1 (WEEK 0)	31	2.35	10.63		-25.0	5.0	20.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	2.48	8.78		-20.0	3.0	18.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	3.54	12.29		-20.0	4.0	27.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	-1.11	12.33		-30.0	0.0	21.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Diastolic blood pressure - Standing [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	31	79.35	9.54	12.02	60.0	80.0	98.0
	V1 (WEEK 0)	32	83.44	11.96	14.33	65.0	83.0	125.0
	V2 (WEEK 4)	31	81.65	10.79	13.21	60.0	80.0	111.0
	V3 (WEEK 12)	30	81.90	14.16	17.29	60.0	80.0	135.0
	V4 (WEEK 24)	24	80.83	12.88	15.94	60.0	80.0	123.0
	V5 (WEEK 36)	22	83.45	13.44	16.10	60.0	85.0	122.0
	V6 (WEEK 52)	24	85.38	10.64	12.47	72.0	84.0	119.0
	V7 (WEEK 56)	23	85.52	12.00	14.03	65.0	80.0	122.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	-1.74	9.20		-23.0	0.0	18.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	-1.10	8.88		-20.0	0.0	16.0
	V4 (WEEK 24) - V1 (WEEK 0)	24	-3.21	10.08		-30.0	-3.0	20.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	-1.09	10.79		-30.0	0.0	20.0
	V6 (WEEK 52) - V1 (WEEK 0)	24	-0.58	9.61		-21.0	0.0	10.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	0.52	10.44		-20.0	1.0	22.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Diastolic blood pressure - Standing [mmHg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	85.35	11.77	13.79	61.0	85.0	122.0
	V1 (WEEK 0)	31	83.74	11.67	13.93	60.0	80.0	112.0
	V2 (WEEK 4)	31	86.65	11.28	13.02	60.0	85.0	114.0
	V3 (WEEK 12)	31	82.23	11.79	14.34	56.0	82.0	101.0
	V4 (WEEK 24)	31	86.32	10.36	12.00	65.0	85.0	107.0
	V5 (WEEK 36)	29	84.45	10.12	11.99	65.0	80.0	102.0
	V6 (WEEK 52)	28	84.43	9.91	11.74	65.0	82.0	110.0
	V7 (WEEK 56)	28	82.39	12.08	14.67	60.0	80.0	120.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	2.90	9.33		-20.0	3.0	25.0
	V3 (WEEK 12) - V1 (WEEK 0)	31	-1.52	14.92		-56.0	0.0	30.0
	V4 (WEEK 24) - V1 (WEEK 0)	31	2.58	10.66		-21.0	5.0	30.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	1.38	10.22		-26.0	0.0	20.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	1.86	10.62		-15.0	0.0	25.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	-0.18	9.12		-15.0	0.0	18.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Diastolic blood pressure - Standing minus sitting [mmHg]

Treatment	Visit	N	Mean	SD	Minimum	Median	Maximum
ACI-91	SCREENING	31	1.87	7.99	-10.0	0.0	17.0
	V1 (WEEK 0)	32	2.06	6.12	-10.0	0.0	19.0
	V2 (WEEK 4)	31	2.87	8.15	-19.0	5.0	16.0
	V3 (WEEK 12)	30	-0.30	8.42	-20.0	0.0	20.0
	V4 (WEEK 24)	24	0.29	5.61	-10.0	0.0	10.0
	V5 (WEEK 36)	22	-0.14	8.98	-19.0	0.0	18.0
	V6 (WEEK 52)	24	2.58	5.95	-10.0	4.0	10.0
	V7 (WEEK 56)	23	2.83	4.71	-6.0	2.0	11.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Diastolic blood pressure - Standing minus sitting [mmHg]

Treatment	Visit	N	Mean	SD	Minimum	Median	Maximum
Placebo	SCREENING	31	2.00	6.54	-15.0	0.0	12.0
	V1 (WEEK 0)	31	2.61	5.21	-10.0	3.0	14.0
	V2 (WEEK 4)	31	4.16	6.60	-10.0	5.0	16.0
	V3 (WEEK 12)	31	0.65	11.71	-53.0	0.0	17.0
	V4 (WEEK 24)	31	2.84	4.84	-10.0	2.0	11.0
	V5 (WEEK 36)	29	1.48	6.26	-12.0	1.0	13.0
	V6 (WEEK 52)	28	0.61	4.43	-8.0	0.0	10.0
	V7 (WEEK 56)	28	3.21	7.99	-17.0	1.0	18.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Pulse rate - Sitting [bpm]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	32	68.19	14.42	21.15	50.0	66.0	108.0
	V1 (WEEK 0)	32	66.03	9.56	14.48	49.0	64.0	84.0
	V2 (WEEK 4)	31	67.97	8.00	11.77	55.0	68.0	87.0
	V3 (WEEK 12)	30	67.87	11.20	16.50	47.0	66.0	96.0
	V4 (WEEK 24)	24	66.75	9.61	14.40	44.0	68.0	88.0
	V5 (WEEK 36)	22	68.00	10.93	16.07	50.0	65.5	96.0
	V6 (WEEK 52)	25	70.20	11.51	16.39	44.0	69.0	96.0
	V7 (WEEK 56)	23	70.96	10.65	15.01	52.0	69.0	94.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	1.87	9.47		-21.0	2.0	22.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	1.97	7.93		-14.0	0.0	20.0
	V4 (WEEK 24) - V1 (WEEK 0)	24	1.33	7.51		-16.0	3.5	12.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	3.05	8.03		-14.0	2.5	20.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	3.24	8.93		-20.0	3.0	17.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	5.70	11.42		-17.0	4.0	44.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Pulse rate - Sitting [bpm]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	67.16	11.29	16.82	46.0	69.0	90.0
	V1 (WEEK 0)	31	68.32	10.11	14.79	52.0	70.0	100.0
	V2 (WEEK 4)	31	70.00	10.62	15.17	51.0	68.0	116.0
	V3 (WEEK 12)	31	66.65	8.97	13.46	50.0	65.0	89.0
	V4 (WEEK 24)	31	67.87	10.80	15.91	50.0	68.0	97.0
	V5 (WEEK 36)	29	67.79	9.01	13.30	52.0	67.0	86.0
	V6 (WEEK 52)	28	68.21	8.04	11.78	51.0	68.5	84.0
	V7 (WEEK 56)	28	70.07	12.59	17.96	47.0	68.0	103.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	1.68	9.86		-20.0	0.0	30.0
	V3 (WEEK 12) - V1 (WEEK 0)	31	-1.68	10.34		-25.0	-1.0	21.0
	V4 (WEEK 24) - V1 (WEEK 0)	31	-0.45	11.12		-36.0	2.0	18.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	0.00	11.53		-40.0	0.0	18.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	0.43	9.52		-32.0	0.0	20.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	2.29	10.84		-13.0	1.0	32.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Pulse rate - Standing [bpm]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	31	70.61	13.92	19.71	52.0	71.0	112.0
	V1 (WEEK 0)	32	70.16	10.18	14.51	48.0	68.0	84.0
	V2 (WEEK 4)	31	73.81	9.02	12.22	59.0	72.0	92.0
	V3 (WEEK 12)	30	70.73	10.42	14.73	51.0	71.0	100.0
	V4 (WEEK 24)	24	71.42	8.93	12.50	47.0	72.0	88.0
	V5 (WEEK 36)	22	72.14	8.97	12.44	56.0	72.0	96.0
	V6 (WEEK 52)	24	72.67	10.83	14.91	49.0	75.0	92.0
	V7 (WEEK 56)	23	75.22	9.37	12.45	57.0	75.0	92.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	3.32	8.89		-20.0	2.0	36.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	0.17	8.70		-23.0	0.0	20.0
	V4 (WEEK 24) - V1 (WEEK 0)	24	1.29	8.09		-17.0	2.0	18.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	2.36	8.95		-20.0	1.0	22.0
	V6 (WEEK 52) - V1 (WEEK 0)	24	2.00	10.12		-20.0	1.0	20.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	5.52	11.10		-7.0	3.0	42.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Pulse rate - Standing [bpm]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	70.87	12.05	17.00	48.0	72.0	98.0
	V1 (WEEK 0)	31	71.71	10.72	14.94	52.0	72.0	100.0
	V2 (WEEK 4)	31	73.03	10.97	15.02	53.0	72.0	116.0
	V3 (WEEK 12)	31	70.58	11.51	16.31	48.0	68.0	96.0
	V4 (WEEK 24)	31	71.00	11.27	15.88	48.0	72.0	99.0
	V5 (WEEK 36)	29	71.28	9.96	13.98	55.0	70.0	93.0
	V6 (WEEK 52)	28	71.04	10.99	15.47	50.0	71.5	100.0
	V7 (WEEK 56)	28	74.36	12.18	16.39	55.0	72.5	105.0
	V2 (WEEK 4) - V1 (WEEK 0)	31	1.32	9.09		-16.0	1.0	20.0
	V3 (WEEK 12) - V1 (WEEK 0)	31	-1.13	11.18		-24.0	0.0	23.0
	V4 (WEEK 24) - V1 (WEEK 0)	31	-0.71	11.13		-36.0	0.0	16.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	-0.38	10.35		-36.0	0.0	20.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	-0.36	12.02		-28.0	0.0	36.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	2.96	12.85		-16.0	0.0	34.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Pulse rate - Standing minus sitting [bpm]

Treatment	Visit	N	Mean	SD	Minimum	Median	Maximum
ACI-91	SCREENING	31	3.39	4.77	-4.0	4.0	19.0
	V1 (WEEK 0)	32	4.13	6.50	-10.0	4.0	23.0
	V2 (WEEK 4)	31	5.84	7.19	-4.0	4.0	27.0
	V3 (WEEK 12)	30	2.87	5.49	-6.0	4.0	14.0
	V4 (WEEK 24)	24	4.67	5.69	-4.0	2.0	19.0
	V5 (WEEK 36)	22	4.14	4.96	-4.0	4.0	15.0
	V6 (WEEK 52)	24	3.54	4.98	-7.0	4.0	13.0
	V7 (WEEK 56)	23	4.26	7.26	-8.0	4.0	20.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Pulse rate - Standing minus sitting [bpm]

Treatment	Visit	N	Mean	SD	Minimum	Median	Maximum
Placebo	SCREENING	31	3.71	5.63	-10.0	3.0	17.0
	V1 (WEEK 0)	31	3.39	4.80	-8.0	4.0	11.0
	V2 (WEEK 4)	31	3.03	4.56	-8.0	4.0	10.0
	V3 (WEEK 12)	31	3.94	5.17	-4.0	4.0	22.0
	V4 (WEEK 24)	31	3.13	4.49	-5.0	2.0	15.0
	V5 (WEEK 36)	29	3.48	4.40	-7.0	4.0	15.0
	V6 (WEEK 52)	28	2.82	5.70	-6.0	1.5	16.0
	V7 (WEEK 56)	28	4.29	5.70	-8.0	4.0	20.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Body temperature [°C]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	32	36.43	0.47	1.28	35.0	36.4	37.4
	V1 (WEEK 0)	32	36.37	0.56	1.55	34.7	36.5	37.2
	V2 (WEEK 4)	31	36.58	0.44	1.20	35.5	36.6	37.5
	V3 (WEEK 12)	30	36.44	0.48	1.31	35.2	36.5	37.2
	V4 (WEEK 24)	24	36.43	0.62	1.70	34.9	36.6	37.6
	V5 (WEEK 36)	22	36.42	0.46	1.25	35.5	36.5	37.5
	V6 (WEEK 52)	24	36.35	0.39	1.06	35.6	36.4	37.2
	V7 (WEEK 56)	23	36.37	0.46	1.26	35.0	36.4	36.9
	V2 (WEEK 4) - V1 (WEEK 0)	31	0.21	0.61		-0.8	0.0	2.0
	V3 (WEEK 12) - V1 (WEEK 0)	30	0.07	0.66		-1.2	0.0	1.9
	V4 (WEEK 24) - V1 (WEEK 0)	24	0.09	0.42		-0.6	0.0	1.1
	V5 (WEEK 36) - V1 (WEEK 0)	22	0.09	0.64		-1.0	-0.1	2.0
	V6 (WEEK 52) - V1 (WEEK 0)	24	0.05	0.52		-0.6	-0.1	1.5
	V7 (WEEK 56) - V1 (WEEK 0)	23	0.03	0.64		-1.2	0.0	1.4

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Body temperature [°C]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	31	36.44	0.49	1.34	35.2	36.4	37.3
	V1 (WEEK 0)	31	36.37	0.66	1.82	34.9	36.5	37.6
	V2 (WEEK 4)	31	36.32	0.53	1.46	34.7	36.4	37.1
	V3 (WEEK 12)	30	36.29	0.60	1.65	34.4	36.4	37.3
	V4 (WEEK 24)	31	36.38	0.43	1.17	35.2	36.3	37.1
	V5 (WEEK 36)	29	36.49	0.46	1.25	35.3	36.6	37.3
	V6 (WEEK 52)	28	36.23	0.64	1.76	34.6	36.3	37.0
	V7 (WEEK 56)	28	36.46	0.48	1.33	35.3	36.5	37.2
	V2 (WEEK 4) - V1 (WEEK 0)	31	-0.05	0.73		-1.5	-0.1	2.2
	V3 (WEEK 12) - V1 (WEEK 0)	30	-0.06	0.72		-1.5	-0.1	1.9
	V4 (WEEK 24) - V1 (WEEK 0)	31	0.02	0.57		-1.1	-0.1	1.8
	V5 (WEEK 36) - V1 (WEEK 0)	29	0.13	0.82		-0.8	-0.1	2.3
	V6 (WEEK 52) - V1 (WEEK 0)	28	-0.16	0.75		-1.9	-0.1	1.8
	V7 (WEEK 56) - V1 (WEEK 0)	28	0.06	0.73		-1.0	0.0	2.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

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Safety Population

Body weight [kg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	26	70.92	13.78	19.43	50.0	68.5	96.0
	V1 (WEEK 0)	32	71.22	12.52	17.57	51.0	70.0	97.0
	V2 (WEEK 4)	24	70.46	13.37	18.97	52.0	66.5	97.0
	V3 (WEEK 12)	28	71.50	13.63	19.06	52.0	66.5	98.0
	V4 (WEEK 24)	23	71.78	13.77	19.18	52.0	68.0	102.0
	V5 (WEEK 36)	22	70.00	12.36	17.65	53.0	66.0	95.0
	V6 (WEEK 52)	25	70.56	12.06	17.10	52.0	68.0	96.0
	V7 (WEEK 56)	23	70.74	12.25	17.32	53.0	67.0	96.0
	V2 (WEEK 4) - V1 (WEEK 0)	24	0.71	3.09		-6.0	0.0	10.0
	V3 (WEEK 12) - V1 (WEEK 0)	28	0.14	2.52		-4.0	0.0	9.0
	V4 (WEEK 24) - V1 (WEEK 0)	23	0.39	4.08		-13.0	0.0	8.0
	V5 (WEEK 36) - V1 (WEEK 0)	22	0.36	2.87		-5.0	0.5	9.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	0.72	3.08		-6.0	1.0	7.0
	V7 (WEEK 56) - V1 (WEEK 0)	23	1.00	2.92		-4.0	1.0	7.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.4: Vital signs, descriptive statistics

 14FEB2013

Safety Population

Body weight [kg]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	24	73.25	10.99	15.00	58.0	69.5	99.0
	V1 (WEEK 0)	31	73.84	11.01	14.91	58.0	70.0	104.0
	V2 (WEEK 4)	26	74.19	10.82	14.58	60.0	72.0	102.0
	V3 (WEEK 12)	28	74.89	11.55	15.43	55.0	71.5	102.0
	V4 (WEEK 24)	29	73.66	10.80	14.66	56.0	71.0	101.0
	V5 (WEEK 36)	29	73.93	10.22	13.83	58.0	70.0	98.0
	V6 (WEEK 52)	28	73.96	10.22	13.82	58.0	72.5	97.0
	V7 (WEEK 56)	28	74.36	10.29	13.83	59.0	74.5	101.0
	V2 (WEEK 4) - V1 (WEEK 0)	26	0.23	2.05		-6.0	1.0	3.0
	V3 (WEEK 12) - V1 (WEEK 0)	28	0.64	1.66		-3.0	1.0	3.0
	V4 (WEEK 24) - V1 (WEEK 0)	29	-0.28	3.76		-17.0	0.0	4.0
	V5 (WEEK 36) - V1 (WEEK 0)	29	0.83	1.63		-2.0	1.0	4.0
	V6 (WEEK 52) - V1 (WEEK 0)	28	0.71	2.73		-6.0	0.5	6.0
	V7 (WEEK 56) - V1 (WEEK 0)	28	1.11	3.48		-7.0	0.5	8.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

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Safety Population

Heart rate [bpm]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	64.21	12.55	19.55	48.0	65.0	96.0
	V1 (WEEK 0)	29	63.03	11.59	18.38	49.0	59.0	97.0
	V3 (WEEK 12)	27	64.89	10.89	16.79	42.0	63.0	98.0
	V4 (WEEK 24)	23	63.17	10.49	16.60	42.0	62.0	83.0
	V5 (WEEK 36)	19	67.37	13.29	19.73	52.0	67.0	97.0
	V6 (WEEK 52)	22	64.95	9.39	14.46	52.0	62.0	92.0
	V3 (WEEK 12) - V1 (WEEK 0)	25	1.60	6.90		-17.0	3.0	14.0
	V4 (WEEK 24) - V1 (WEEK 0)	20	0.05	8.25		-27.0	1.5	13.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	5.00	5.45		-7.0	6.0	13.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	1.84	11.60		-37.0	4.0	20.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

14FEB2013

Safety Population

Heart rate [bpm]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	62.26	10.60	17.03	46.0	60.0	87.0
	V1 (WEEK 0)	29	64.97	8.46	13.03	45.0	66.0	87.0
	V3 (WEEK 12)	29	63.34	9.31	14.69	43.0	65.0	80.0
	V4 (WEEK 24)	29	64.34	12.00	18.66	47.0	62.0	94.0
	V5 (WEEK 36)	27	64.74	9.44	14.59	49.0	64.0	86.0
	V6 (WEEK 52)	26	64.12	8.33	12.98	50.0	64.0	79.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	-1.56	8.20		-30.0	0.0	12.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	-0.07	8.94		-25.0	0.0	20.0
	V5 (WEEK 36) - V1 (WEEK 0)	26	0.19	7.29		-12.0	0.0	18.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	-1.08	9.36		-16.0	-2.0	20.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

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Safety Population

PR Interval [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	168.07	28.75	17.11	106.0	170.0	226.0
	V1 (WEEK 0)	29	164.86	27.98	16.97	102.0	160.0	222.0
	V3 (WEEK 12)	28	165.89	34.07	20.54	100.0	164.0	246.0
	V4 (WEEK 24)	24	168.92	26.98	15.97	112.0	168.0	232.0
	V5 (WEEK 36)	19	166.26	30.36	18.26	103.0	164.0	211.0
	V6 (WEEK 52)	22	165.18	33.59	20.34	80.0	168.5	214.0
	V3 (WEEK 12) - V1 (WEEK 0)	26	2.81	13.50		-32.0	1.5	29.0
	V4 (WEEK 24) - V1 (WEEK 0)	21	5.81	18.15		-43.0	3.0	54.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	1.19	11.19		-29.0	2.0	18.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	3.68	16.87		-22.0	3.0	45.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

 14FEB2013

Safety Population

PR Interval [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	163.00	23.05	14.14	107.0	170.0	193.0
	V1 (WEEK 0)	29	161.66	24.01	14.85	113.0	166.0	226.0
	V3 (WEEK 12)	29	167.34	24.85	14.85	114.0	170.0	216.0
	V4 (WEEK 24)	29	166.83	20.39	12.22	114.0	165.0	213.0
	V5 (WEEK 36)	26	159.92	22.41	14.01	110.0	165.5	186.0
	V6 (WEEK 52)	25	169.04	22.13	13.09	108.0	173.0	211.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	3.19	9.32		-13.0	3.0	27.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	2.00	11.59		-37.0	1.0	23.0
	V5 (WEEK 36) - V1 (WEEK 0)	25	-3.68	14.94		-46.0	0.0	26.0
	V6 (WEEK 52) - V1 (WEEK 0)	24	3.04	10.87		-24.0	3.5	20.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

14FEB2013

Safety Population

QRS Complex [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	95.34	18.70	19.61	73.0	91.0	161.0
	V1 (WEEK 0)	29	95.90	19.81	20.66	72.0	90.0	157.0
	V3 (WEEK 12)	28	96.89	19.35	19.97	74.0	90.5	161.0
	V4 (WEEK 24)	24	96.13	19.35	20.13	76.0	87.5	146.0
	V5 (WEEK 36)	19	95.21	20.35	21.38	79.0	85.0	152.0
	V6 (WEEK 52)	22	90.77	17.17	18.91	73.0	86.0	154.0
	V3 (WEEK 12) - V1 (WEEK 0)	26	0.23	4.25		-11.0	0.0	9.0
	V4 (WEEK 24) - V1 (WEEK 0)	21	0.10	18.81		-65.0	1.0	46.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	0.69	3.86		-7.0	1.5	7.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	0.32	4.91		-10.0	1.0	11.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

14FEB2013

Safety Population

QRS Complex [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	96.37	14.80	15.36	74.0	93.0	146.0
	V1 (WEEK 0)	29	97.55	20.49	21.00	72.0	91.0	158.0
	V3 (WEEK 12)	29	98.28	18.67	19.00	74.0	93.0	157.0
	V4 (WEEK 24)	29	96.76	18.96	19.59	73.0	92.0	161.0
	V5 (WEEK 36)	27	98.85	18.75	18.97	73.0	94.0	163.0
	V6 (WEEK 52)	26	99.54	19.58	19.67	71.0	95.0	165.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	0.19	5.46		-19.0	1.0	8.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	-0.96	14.18		-55.0	0.0	42.0
	V5 (WEEK 36) - V1 (WEEK 0)	26	0.73	14.16		-53.0	0.0	41.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	1.08	13.84		-50.0	1.0	41.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

 14FEB2013

Safety Population

QT Interval [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	400.86	43.40	10.83	317.0	397.0	508.0
	V1 (WEEK 0)	29	401.45	40.83	10.17	309.0	401.0	517.0
	V3 (WEEK 12)	28	391.68	37.34	9.53	307.0	396.0	476.0
	V4 (WEEK 24)	24	403.83	31.32	7.76	351.0	397.5	473.0
	V5 (WEEK 36)	19	397.63	41.75	10.50	331.0	403.0	471.0
	V6 (WEEK 52)	22	392.36	23.84	6.08	352.0	396.0	450.0
	V3 (WEEK 12) - V1 (WEEK 0)	26	-8.96	26.39		-74.0	-8.5	38.0
	V4 (WEEK 24) - V1 (WEEK 0)	21	2.90	30.94		-45.0	4.0	73.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	-7.56	31.87		-70.0	-5.5	76.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	-6.58	22.07		-36.0	-11.0	39.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

 14FEB2013

Safety Population

QT Interval [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	406.63	38.26	9.41	319.0	400.0	485.0
	V1 (WEEK 0)	29	403.97	31.25	7.74	340.0	400.0	471.0
	V3 (WEEK 12)	29	403.66	26.46	6.55	355.0	406.0	464.0
	V4 (WEEK 24)	29	402.93	33.68	8.36	345.0	398.0	493.0
	V5 (WEEK 36)	27	403.70	27.19	6.73	350.0	402.0	454.0
	V6 (WEEK 52)	26	407.12	27.83	6.84	366.0	404.0	467.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	-0.33	24.88		-45.0	2.0	65.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	-1.67	30.05		-48.0	-7.0	109.0
	V5 (WEEK 36) - V1 (WEEK 0)	26	-0.50	28.98		-68.0	-1.0	62.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	5.20	24.36		-34.0	10.0	67.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

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Safety Population

QTc Interval Bazett [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	412.69	23.96	5.81	348.0	413.0	478.0
	V1 (WEEK 0)	29	408.69	26.94	6.59	320.0	413.0	483.0
	V3 (WEEK 12)	28	403.11	19.32	4.79	352.0	408.0	439.0
	V4 (WEEK 24)	24	414.33	19.74	4.76	381.0	411.0	451.0
	V5 (WEEK 36)	19	415.47	29.49	7.10	357.0	421.0	480.0
	V6 (WEEK 52)	22	410.32	25.58	6.23	373.0	408.5	462.0
	V3 (WEEK 12) - V1 (WEEK 0)	26	-5.65	19.72		-54.0	0.0	32.0
	V4 (WEEK 24) - V1 (WEEK 0)	21	6.00	18.92		-21.0	5.0	51.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	6.88	25.94		-47.0	7.0	46.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	5.00	21.18		-43.0	2.0	48.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

14FEB2013

Safety Population

QTc Interval Bazett [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	411.96	29.52	7.17	365.0	406.0	508.0
	V1 (WEEK 0)	29	417.76	29.27	7.01	370.0	409.0	525.0
	V3 (WEEK 12)	29	416.52	26.01	6.25	379.0	413.0	481.0
	V4 (WEEK 24)	29	415.97	24.84	5.97	370.0	411.0	471.0
	V5 (WEEK 36)	27	421.37	31.67	7.52	357.0	421.0	511.0
	V6 (WEEK 52)	26	421.96	23.42	5.55	389.0	421.0	484.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	-0.96	24.99		-44.0	-1.0	62.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	-1.48	23.28		-54.0	-5.0	47.0
	V5 (WEEK 36) - V1 (WEEK 0)	26	3.73	35.82		-67.0	5.0	106.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	6.44	29.25		-78.0	5.0	50.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

 14FEB2013

Safety Population

QTc Interval Friderica [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	408.31	27.17	6.66	342.0	406.0	488.0
	V1 (WEEK 0)	29	405.97	27.84	6.86	317.0	408.0	497.0
	V3 (WEEK 12)	28	398.93	22.17	5.56	337.0	399.5	434.0
	V4 (WEEK 24)	24	410.63	17.99	4.38	371.0	408.5	449.0
	V5 (WEEK 36)	19	408.89	28.71	7.02	361.0	415.0	448.0
	V6 (WEEK 52)	22	403.86	20.95	5.19	372.0	403.0	441.0
	V3 (WEEK 12) - V1 (WEEK 0)	26	-6.85	18.99		-64.0	-0.5	20.0
	V4 (WEEK 24) - V1 (WEEK 0)	21	5.14	20.76		-22.0	3.0	53.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	1.88	26.27		-54.0	2.5	56.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	1.05	14.44		-25.0	1.0	37.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

 14FEB2013

Safety Population

QTc Interval Friderica [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	409.93	28.59	6.97	365.0	407.0	488.0
	V1 (WEEK 0)	29	412.90	26.59	6.44	366.0	407.0	501.0
	V3 (WEEK 12)	29	411.97	20.53	4.98	378.0	406.0	466.0
	V4 (WEEK 24)	29	411.28	23.31	5.67	371.0	404.0	461.0
	V5 (WEEK 36)	27	415.11	26.79	6.45	358.0	414.0	487.0
	V6 (WEEK 52)	26	416.62	21.87	5.25	382.0	415.0	473.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	-0.78	19.31		-37.0	3.0	41.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	-1.67	20.39		-41.0	-1.0	48.0
	V5 (WEEK 36) - V1 (WEEK 0)	26	2.23	30.41		-52.0	8.0	91.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	5.88	23.39		-56.0	6.0	40.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

14FEB2013

Safety Population

RR Interval [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
ACI-91	SCREENING	29	946.03	170.44	18.02	620.0	928.0	1296.0
	V1 (WEEK 0)	29	976.14	165.36	16.94	625.0	1007.0	1330.0
	V3 (WEEK 12)	28	950.36	153.26	16.13	592.0	948.5	1367.0
	V4 (WEEK 24)	24	960.75	162.36	16.90	715.0	962.5	1418.0
	V5 (WEEK 36)	19	923.32	166.89	18.08	616.0	926.0	1219.0
	V6 (WEEK 52)	22	923.23	126.27	13.68	638.0	957.0	1130.0
	V3 (WEEK 12) - V1 (WEEK 0)	26	-23.50	123.09		-259.0	-29.5	255.0
	V4 (WEEK 24) - V1 (WEEK 0)	21	-14.90	121.75		-226.0	-18.0	210.0
	V5 (WEEK 36) - V1 (WEEK 0)	16	-70.94	102.99		-263.0	-67.0	140.0
	V6 (WEEK 52) - V1 (WEEK 0)	19	-52.74	146.89		-365.0	-76.0	345.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.1: ECG evaluation, descriptive statistics

 14FEB2013

Safety Population

RR Interval [ms]

Treatment	Visit / Difference to baseline	N	Mean	SD	CV	Minimum	Median	Maximum
Placebo	SCREENING	27	983.52	163.04	16.58	661.0	976.0	1285.0
	V1 (WEEK 0)	29	936.76	133.90	14.29	705.0	907.0	1301.0
	V3 (WEEK 12)	29	951.14	164.44	17.29	711.0	908.0	1353.0
	V4 (WEEK 24)	29	948.97	153.94	16.22	642.0	952.0	1246.0
	V5 (WEEK 36)	27	925.85	129.28	13.96	699.0	909.0	1214.0
	V6 (WEEK 52)	26	935.15	118.13	12.63	748.0	904.5	1163.0
	V3 (WEEK 12) - V1 (WEEK 0)	27	13.89	153.45		-218.0	4.0	547.0
	V4 (WEEK 24) - V1 (WEEK 0)	27	8.59	144.28		-282.0	12.0	420.0
	V5 (WEEK 36) - V1 (WEEK 0)	26	-12.04	122.75		-257.0	-1.5	177.0
	V6 (WEEK 52) - V1 (WEEK 0)	25	-1.56	145.25		-405.0	19.0	280.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.5.2: ECG evaluation, frequency table

 14FEB2013

Safety Population

Visit	Interpretation	ACI-91 N	ACI-91 %	Placebo N	Placebo %
SCREENING	NORMAL	3	10.3	7	25.9
	NORMAL VARIANT	20	69.0	15	55.6
	ABNORMAL	6	20.7	5	18.5
V1 (WEEK 0)	NORMAL	2	6.9	9	31.0
	NORMAL VARIANT	20	69.0	13	44.8
	ABNORMAL	7	24.1	7	24.1
V3 (WEEK 12)	NORMAL	2	7.1	5	17.2
	NORMAL VARIANT	19	67.9	18	62.1
	ABNORMAL	7	25.0	6	20.7
V4 (WEEK 24)	NORMAL	2	8.3	5	17.2
	NORMAL VARIANT	16	66.7	19	65.5
	ABNORMAL	6	25.0	5	17.2
V5 (WEEK 36)	NORMAL	2	10.5	6	22.2
	NORMAL VARIANT	13	68.4	16	59.3
	ABNORMAL	4	21.1	5	18.5
V6 (WEEK 52)	NORMAL	3	13.6	4	15.4
	NORMAL VARIANT	15	68.2	17	65.4
	ABNORMAL	4	18.2	5	19.2

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
HEAD, EYES	SCREENING	NORMAL	26	81.3	24	77.4
		ABNORMAL	6	18.8	7	22.6
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	28	93.3	31	100.0
		CHANGED	1	3.3		
	V4 (WEEK 24)	UNCHANGED	22	91.7	30	96.8
		CHANGED	2	8.3	1	3.2
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	25	96.2	28	100.0
		CHANGED	1	3.8		
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
EARS, NOSE, THROAT	SCREENING	NORMAL	29	90.6	28	90.3
		ABNORMAL	3	9.4	3	9.7
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	28	93.3	31	100.0
		CHANGED	1	3.3		
	V4 (WEEK 24)	UNCHANGED	23	95.8	31	100.0
		CHANGED	1	4.2		
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	25	96.2	28	100.0
		CHANGED	1	3.8		
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
HEART	SCREENING	NORMAL	32	100.0	29	93.5
		ABNORMAL			2	6.5
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	26	100.0	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
CHEST, LUNGS	SCREENING	NORMAL	32	100.0	31	100.0
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	25	96.2	28	100.0
		CHANGED	1	3.8		
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
ABDOMEN	SCREENING	NORMAL	32	100.0	31	100.0
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	26	100.0	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
EXTREMITIES	SCREENING	NORMAL	29	90.6	29	93.5
		ABNORMAL	3	9.4	2	6.5
	V1 (WEEK 0)	UNCHANGED	31	96.9	31	100.0
		CHANGED	1	3.1		
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	27	90.0	31	100.0
		CHANGED	2	6.7		
	V4 (WEEK 24)	UNCHANGED	22	91.7	31	100.0
		CHANGED	2	8.3		
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	24	92.3	28	100.0
		CHANGED	2	7.7		
	V7 (WEEK 56)	UNCHANGED	22	95.7	28	100.0
		CHANGED	1	4.3		

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
PERIPHERAL PULSES	SCREENING	NORMAL	32	100.0	31	100.0
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	26	100.0	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

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Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
SKIN	SCREENING	NORMAL	30	93.8	30	96.8
		ABNORMAL	2	6.3	1	3.2
	V1 (WEEK 0)	UNCHANGED	31	96.9	30	96.8
		CHANGED	1	3.1	1	3.2
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	27	90.0	30	96.8
		CHANGED	2	6.7	1	3.2
	V4 (WEEK 24)	UNCHANGED	23	95.8	30	96.8
		CHANGED	1	4.2	1	3.2
	V5 (WEEK 36)	UNCHANGED	22	100.0	29	96.7
		CHANGED			1	3.3
	V6 (WEEK 52)	UNCHANGED	25	96.2	28	100.0
		CHANGED	1	3.8		
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

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Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
OTHER PHYSICAL CONDITIONS	SCREENING	NORMAL	22	68.8	16	51.6
		ABNORMAL			2	6.5
		NOT DONE	10	31.3	13	41.9
	V1 (WEEK 0)	NOT DONE	11	34.4	13	41.9
		UNCHANGED	21	65.6	18	58.1
	V3 (WEEK 12)	NOT DONE	11	36.7	9	29.0
		UNCHANGED	19	63.3	21	67.7
		CHANGED			1	3.2
	V4 (WEEK 24)	NOT DONE	7	29.2	11	35.5
		UNCHANGED	16	66.7	20	64.5
		CHANGED	1	4.2		
	V5 (WEEK 36)	NOT DONE	5	22.7	11	36.7
		UNCHANGED	17	77.3	19	63.3
	V6 (WEEK 52)	NOT DONE	6	23.1	10	35.7
		UNCHANGED	19	73.1	18	64.3
		CHANGED	1	3.8		
	V7 (WEEK 56)	NOT DONE	5	21.7	8	28.6

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.6: Physical examination, frequency table

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Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
OTHER PHYSICAL CONDITIONS	V7 (WEEK 56)	UNCHANGED	18	78.3	18	64.3
		CHANGED			2	7.1

V6 (WEEK 52) does also include assessments performed due to early termination

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
CRANIAL NERVES	SCREENING	NORMAL	29	90.6	30	96.8
		ABNORMAL	3	9.4	1	3.2
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	26	100.0	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
MUSCLE STRENGTH UE	SCREENING	NORMAL	32	100.0	31	100.0
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	25	96.2	28	100.0
		CHANGED	1	3.8		
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
REFLEXES UE	SCREENING	NORMAL	31	96.9	31	100.0
		ABNORMAL	1	3.1		
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	26	100.0	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
SENSATION UE	SCREENING	NORMAL	31	96.9	31	100.0
		ABNORMAL	1	3.1		
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	23	95.8	31	100.0
		CHANGED	1	4.2		
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	24	92.3	28	100.0
		CHANGED	2	7.7		
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
CEREBELLAR FUNCTION UE	SCREENING	NORMAL	29	90.6	31	100.0
		ABNORMAL	3	9.4		
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	23	95.8	31	100.0
		CHANGED	1	4.2		
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	NOT DONE	1	3.8		
		UNCHANGED	25	96.2	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
MUSCLE STRENGTH LE	SCREENING	NORMAL	31	96.9	31	100.0
		ABNORMAL	1	3.1		
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	NOT DONE	1	3.8		
		UNCHANGED	25	96.2	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
REFLEXES LE	SCREENING	NORMAL	26	81.3	30	96.8
		ABNORMAL	6	18.8	1	3.2
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	UNCHANGED	26	100.0	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
SENSATION LE	SCREENING	NORMAL	30	93.8	30	96.8
		ABNORMAL	2	6.3	1	3.2
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	NOT DONE	1	3.8		
		UNCHANGED	25	96.2	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.7: Neurological examination, frequency table

 14FEB2013

Safety Population

Organ/system	Visit	Status	ACI-91 N	ACI-91 %	Placebo N	Placebo %
CEREBELLAR FUNCTION LE	SCREENING	NORMAL	31	96.9	31	100.0
		ABNORMAL	1	3.1		
	V1 (WEEK 0)	UNCHANGED	32	100.0	31	100.0
	V3 (WEEK 12)	NOT DONE	1	3.3		
		UNCHANGED	29	96.7	31	100.0
	V4 (WEEK 24)	UNCHANGED	24	100.0	31	100.0
	V5 (WEEK 36)	UNCHANGED	22	100.0	30	100.0
	V6 (WEEK 52)	NOT DONE	1	3.8		
		UNCHANGED	25	96.2	28	100.0
	V7 (WEEK 56)	UNCHANGED	23	100.0	28	100.0

V6 (WEEK 52) does also include assessments performed due to early termination
LE = lower extremities, UE = upper extremities

Table 14.3.5.8: Global assessment of tolerability, frequency table and Cochran-Mantel-Haenszel test

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Safety Population

Visit	Overall tolerability	ACI-91 N	ACI-91 %	Placebo N	Placebo %	p-Value
V2 (WEEK 4)	VERY GOOD	18	58.1	24	77.4	0.0001
	GOOD	9	29.0	7	22.6	
	MODERATE	2	6.5			
	POOR	2	6.5			
V3 (WEEK 12)	VERY GOOD	17	56.7	24	77.4	
	GOOD	10	33.3	7	22.6	
	MODERATE	3	10.0			
V4 (WEEK 24)	VERY GOOD	15	62.5	22	71.0	
	GOOD	6	25.0	9	29.0	
	MODERATE	3	12.5			
V5 (WEEK 36)	VERY GOOD	11	50.0	22	73.3	
	GOOD	8	36.4	8	26.7	
	MODERATE	3	13.6			
V6 (WEEK 52)	VERY GOOD	12	50.0	20	71.4	
	GOOD	9	37.5	8	28.6	
	MODERATE	2	8.3			
	VERY POOR	1	4.2			

V6 (WEEK 52) does also include assessments performed due to early termination
p-Value: Cochran-Mantel-Haenszel test for general association