

14.3 Safety Data

14.3.1 Exposure to study treatment

Parameter	Statistic	Bazedoxifene (N = 3)
Duration of exposure [days]	n	3
	Mean (SD)	8.7 (4.73)
	95% CI	-3.1; 20.4
	Median	7.0
	Min - Max	5 - 14

n = Number of subjects, CI = Confidence interval, SD = Standard deviation.

14.3.2 Summary of all adverse events

	Bazedoxifene (N = 3)		
Adverse event	E	n	%
Any AE			
Number of subjects with at least one AE		1	33.3
Number of different AEs	1		
Total number of AEs	1		
D-dimer elevation: 3160	1	1	33.3

AE = Adverse event.
n = Number of subjects experiencing the event, % = Percentage of subjects, E = Number of events.
D-dimer elevation (3160 µg/L) occurred before administration of the first dose of Conbriza.

14.3.3 Summary of serious adverse events

No serious adverse events occurred.

14.3.4 Summary of adverse events leading to treatment/study discontinuation

No adverse events leading to study/study treatment discontinuation occurred.

14.3.5 Summary of adverse events related to study treatment

No adverse events related to study treatment occurred.

14.3.6 Summary of all adverse events by intensity

Bazedoxifene (N = 3)			
Intensity	E	n	%
Adverse event			
Any intensity			
Number of subjects with at least one AE		1	33.3
Number of different AEs	1		
Total number of AEs	1		
Mild (Grade 1)			
Number of subjects with at least one AE		1	33.3
Number of different AEs	1		
Total number of AEs	1		
D-dimer elevation: 3160	1	1	33.3

AE = Adverse event.

n = Number of subjects experiencing the event, % = Percentage of subjects, E = Number of events.

D-dimer elevation (3160 µg/L) occurred before administration of the first dose of Conbriza.

14.3.7 Summary of adverse events leading to death

No adverse events leading to death occurred.

14.3.8 Summary statistics and changes from baseline of hematology parameters

14.3.8.1 Hemoglobin [g/L]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
		95%	95%							95%	95%			95%	95%						
Visit	n	Mean	ICI	uCI	Median	SD	Min	Max	Mean	ICI	uCI	Median	Mean	ICI	uCI	Median	SD	Min	Max	NV AV	
Screening (-5 to D1)	3	145.0	129.5	160.5	147.0	6.24	138	150												3 0	
Baseline (D1)	3	145.0	129.5	160.5	147.0	6.24	138	150												3 0	
Day 2	3	141.0	125.9	156.1	144.0	6.08	134	145	145.0	129.5	160.5	147.0	-4.0	-6.5	-1.5	-4.0	1.00	-5	-3	3 0	
Day 3	3	139.7	116.1	163.3	140.0	9.50	130	149	145.0	129.5	160.5	147.0	-5.3	-21.3	10.6	-8.0	6.43	-10	2	3 0	
Day 5	2	133.0	107.6	158.4	133.0	2.83	131	135	144.0	67.8	220.2	144.0	-11.0	-61.8	39.8	-11.0	5.66	-15	-7	2 0	
Day 7	3	153.0	113.6	192.4	159.0	15.87	135	165	145.0	129.5	160.5	147.0	8.0	-18.2	34.2	9.0	10.54	-3	18	3 0	
Day 10	1	163.0			163.0		163	163	150.0			150.0	13.0			13.0		13	13	0 1	
Day 14	1	135.0			135.0		135	135	138.0			138.0	-3.0			-3.0		-3	-3	1 0	
EoT	1	159.0			159.0		159	159	150.0			150.0	9.0			9.0		9	9	1 0	
EoS (Day 21-28)	3	147.7	109.7	185.6	151.0	15.28	131	161	145.0	129.5	160.5	147.0	2.7	-23.7	29.0	1.0	10.60	-7	14	3 0	

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.2 Hematocrit [L/L]

																				Out of range		
----- Result -----										Baseline				---- Change from baseline ----								
Visit	n	Mean	ICI	95% uCI	95% Median	SD	Min	Max		Mean	ICI	95% uCI	95% Median	Mean	ICI	95% uCI	95% Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	0.425	0.341	0.510	0.412	0.0340	0.40	0.46													3	0
Baseline (D1)	3	0.425	0.341	0.510	0.412	0.0340	0.40	0.46													3	0
Day 2	3	0.411	0.358	0.465	0.406	0.0215	0.39	0.44	0.425	0.341	0.510	0.412	-0.014	-0.046	0.018	-0.007	0.0130	-0.03	-0.01		3	0
Day 3	3	0.409	0.353	0.466	0.421	0.0229	0.38	0.42	0.425	0.341	0.510	0.412	-0.016	-0.077	0.045	-0.017	0.0245	-0.04	0.01		3	0
Day 5	2	0.400	0.298	0.502	0.400	0.0113	0.39	0.41	0.432	0.025	0.839	0.432	-0.032	-0.337	0.273	-0.032	0.0339	-0.06	-0.01		2	0
Day 7	3	0.440	0.347	0.532	0.457	0.0372	0.40	0.47	0.425	0.341	0.510	0.412	0.014	-0.052	0.080	0.001	0.0266	-0.00	0.05		3	0
Day 10	1	0.482			0.482		0.48	0.48	0.464			0.464	0.018			0.018		0.02	0.02		0	1
Day 14	1	0.415			0.415		0.42	0.42	0.400			0.400	0.015			0.015		0.01	0.01		1	0
EoT	1	0.465			0.465		0.47	0.47	0.464			0.464	0.001			0.001		0.00	0.00		1	0
EoS (Day 21-28)	3	0.438	0.352	0.525	0.451	0.0348	0.40	0.47	0.425	0.341	0.510	0.412	0.013	-0.043	0.069	0.001	0.0225	-0.00	0.04		3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.3 Red blood cell count [$10^{12}/L$]

																				Out of range
----- Result -----										Baseline				---- Change from baseline ----						
		95%	95%							95%	95%			95%	95%					
Visit	n	Mean	ICI	uCI	Median	SD	Min	Max	Mean	ICI	uCI	Median	Mean	ICI	uCI	Median	SD	Min	Max	NV AV
Screening (-5 to D1)	3	4.960	4.063	5.857	4.820	0.3610	4.69	5.37												2 1
Baseline (D1)	3	4.960	4.063	5.857	4.820	0.3610	4.69	5.37												2 1
Day 2	3	4.773	4.102	5.445	4.670	0.2702	4.57	5.08	4.960	4.063	5.857	4.820	-0.187	-0.412	0.039	-0.150	0.0907	-0.29	-0.12	3 0
Day 3	3	4.690	4.065	5.315	4.820	0.2516	4.40	4.85	4.960	4.063	5.857	4.820	-0.270	-0.917	0.377	-0.290	0.2606	-0.52	0.00	3 0
Day 5	2	4.650	3.252	6.048	4.650	0.1556	4.54	4.76	5.030	0.710	9.350	5.030	-0.380	-3.302	2.542	-0.380	0.3253	-0.61	-0.15	2 0
Day 7	3	5.120	3.998	6.242	5.210	0.4518	4.63	5.52	4.960	4.063	5.857	4.820	0.160	-0.399	0.719	0.150	0.2252	-0.06	0.39	2 1
Day 10	1	5.700			5.700		5.70	5.70	5.370			5.370	0.330			0.330		0.33	0.33	0 1
Day 14	1	4.740			4.740		4.74	4.74	4.690			4.690	0.050			0.050		0.05	0.05	1 0
EoT	1	5.520			5.520		5.52	5.52	5.370			5.370	0.150			0.150		0.15	0.15	0 1
EoS (Day 21-28)	3	5.017	3.970	6.063	5.100	0.4212	4.56	5.39	4.960	4.063	5.857	4.820	0.057	-0.459	0.572	0.020	0.2074	-0.13	0.28	2 1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.4 White blood cell count [$10^9/L$]

																				Out of range	
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	6.77	0.04	13.49	7.40	2.706	3.8	9.1												2	1
Baseline (D1)	3	6.77	0.04	13.49	7.40	2.706	3.8	9.1												2	1
Day 2	3	10.93	3.55	18.31	11.90	2.970	7.6	13.3	6.77	0.04	13.49	7.40	4.17	-5.65	13.98	4.20	3.950	0.2	8.1	1	2
Day 3	3	12.27	3.05	21.49	12.60	3.711	8.4	15.8	6.77	0.04	13.49	7.40	5.50	-4.53	15.53	6.70	4.036	1.0	8.8	1	2
Day 5	2	12.30	9.76	14.84	12.30	0.283	12.1	12.5	6.45	-27.22	40.12	6.45	5.85	-30.36	42.06	5.85	4.031	3.0	8.7	0	2
Day 7	3	11.30	3.89	18.71	12.10	2.982	8.0	13.8	6.77	0.04	13.49	7.40	4.53	-7.60	16.67	3.00	4.884	0.6	10.0	1	2
Day 10	1	14.30			14.30		14.3	14.3	9.10			9.10	5.20			5.20		5.2	5.2	0	1
Day 14	1	20.10			20.10		20.1	20.1	3.80			3.80	16.30			16.30		16.3	16.3	0	1
EoT	1	12.10			12.10		12.1	12.1	9.10			9.10	3.00			3.00		3.0	3.0	0	1
EoS (Day 21-28)	3	9.43	-2.26	21.12	9.70	4.706	4.6	14.0	6.77	0.04	13.49	7.40	2.67	-9.16	14.49	4.90	4.761	-2.8	5.9	2	1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.5 Platelet count [$10^9/L$]

																					Out of range		
----- Result -----										Baseline				---- Change from baseline ----								N	A
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mea n	95% ICI	95% uCI	Median	Mea n	95% ICI	95% uCI	Median	SD	Min	Max	V	V		
Screening (-5 to D1)	3	282.0	55.1	508.9	238.0	91.33	221	387												3	0		
Baseline (D1)	3	282.0	55.1	508.9	238.0	91.33	221	387												3	0		
Day 2	3	327.0	27.8	626.2	262.0	120.46	253	466	282.0	55.1	508.9	238.0	45.0	-35.0	125.0	41.0	32.19	15	79	2	1		
Day 3	3	349.0	59.2	638.8	301.0	116.66	264	482	282.0	55.1	508.9	238.0	67.0	1.8	132.2	63.0	26.23	43	95	2	1		
Day 5	2	367.5	-1468.5	2203.5	367.5	204.35	223	512	304.0	-750.6	1358.6	304.0	63.5	-717.9	844.9	63.5	86.97	2	125	1	1		
Day 7	3	395.3	169.9	620.7	382.0	90.74	312	492	282.0	55.1	508.9	238.0	113.3	45.1	181.6	105.0	27.47	91	144	2	1		
Day 10	1	261.0			261.0		261	221.0				221.0	40.0			40.0		40	40	1	0		
Day 14	1	324.0			324.0		324	387.0				387.0	-63.0			-63.0		-63	-63	1	0		
EoT	1	312.0			312.0		312	221.0				221.0	91.0			91.0		91	91	1	0		
EoS (Day 21-28)	3	320.7	97.6	543.7	329.0	89.79	227	406	282.0	55.1	508.9	238.0	38.7	-75.1	152.4	19.0	45.79	6	91	2	1		

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.6 Basophils [%]

																				Out of range	
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	ICI	95% uCI	95% Median	SD	Min	Max	Mean	ICI	95% uCI	95% Median	Mean	ICI	95% uCI	95% Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	0.17	-0.12	0.45	0.10	0.115	0.1	0.3												3	0
Baseline (D1)	3	0.17	-0.12	0.45	0.10	0.115	0.1	0.3												3	0
Day 2	3	0.17	-0.12	0.45	0.10	0.115	0.1	0.3	0.17	-0.12	0.45	0.10	0.00	-0.50	0.50	0.00	0.200	-0.2	0.2	3	0
Day 3	3	0.13	-0.01	0.28	0.10	0.058	0.1	0.2	0.17	-0.12	0.45	0.10	-0.03	-0.41	0.35	0.00	0.153	-0.2	0.1	3	0
Day 5	2	0.05	-0.59	0.69	0.05	0.071	0.0	0.1	0.20	-1.07	1.47	0.20	-0.15	-0.79	0.49	-0.15	0.071	-0.2	-0.1	2	0
Day 7	3	0.43	-0.37	1.23	0.30	0.321	0.2	0.8	0.17	-0.12	0.45	0.10	0.27	-0.74	1.27	0.20	0.404	-0.1	0.7	3	0
Day 10	1	0.20			0.20		0.2	0.2	0.10			0.10	0.10			0.10		0.1	0.1	1	0
Day 14	1	0.20			0.20		0.2	0.2	0.30			0.30	-0.10			-0.10		-0.1	-0.1	1	0
EoT	1	0.80			0.80		0.8	0.8	0.10			0.10	0.70			0.70		0.7	0.7	1	0
EoS (Day 21-28)	3	0.20			0.20	0.000	0.2	0.2	0.17	-0.12	0.45	0.10	0.03	-0.25	0.32	0.10	0.115	-0.1	0.1	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.7 Eosinophils [%]

----- Result -----																			Baseline				---- Change from baseline ----							Out of range	
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV										
Screening (-5 to D1)	3	0.00			0.00	0.000	0.0	0.0												3	0										
Baseline (D1)	3	0.00			0.00	0.000	0.0	0.0												3	0										
Day 2	3	0.00			0.00	0.000	0.0	0.0	0.00				0.00	0.00			0.00	0.000	0.0	0.0	3	0									
Day 3	3	0.00			0.00	0.000	0.0	0.0	0.00				0.00	0.00			0.00	0.000	0.0	0.0	3	0									
Day 5	2	0.00			0.00	0.000	0.0	0.0	0.00				0.00	0.00			0.00	0.000	0.0	0.0	2	0									
Day 7	3	0.40	-0.74	1.54	0.30	0.458	0.0	0.9	0.00				0.00	0.40	-0.74	1.54	0.30	0.458	0.0	0.9	3	0									
Day 10	1	0.80			0.80		0.8	0.8	0.00				0.00	0.80			0.80		0.8	0.8	1	0									
Day 14	1	0.00			0.00		0.0	0.0	0.00				0.00	0.00			0.00		0.0	0.0	1	0									
EoT	1	0.30			0.30		0.3	0.3	0.00				0.00	0.30			0.30		0.3	0.3	1	0									
EoS (Day 21-28)	3	0.87	-0.75	2.48	0.90	0.651	0.2	1.5	0.00				0.00	0.87	-0.75	2.48	0.90	0.651	0.2	1.5	3	0									

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.8 Neutrophils [%]

Visit	n	----- Result -----							Baseline				---- Change from baseline ----							Out of range	
		95%	95%	Median	SD	Min	Max	Mean	95%	95%	Median	Mean	95%	95%	Median	SD	Min	Max	NV	AV	
		ICI	uCI						ICI	uCI			ICI	uCI							
Screening (-5 to D1)	3	83.43	79.02	87.85	84.20	1.779	81.4	84.7												0	3
Baseline (D1)	3	83.43	79.02	87.85	84.20	1.779	81.4	84.7												0	3
Day 2	3	79.43	65.36	93.51	82.40	5.666	72.9	83.0	83.43	79.02	87.85	84.20	-4.00	-20.06	12.06	-1.70	6.465	-11.3	1.0	0	3
Day 3	3	79.93	60.21	99.65	83.10	7.939	70.9	85.8	83.43	79.02	87.85	84.20	-3.50	-24.60	17.60	1.10	8.492	-13.3	1.7	0	3
Day 5	2	78.80	55.93	101.67	78.80	2.546	77.0	80.6	83.05	62.08	104.02	83.05	-4.25	-48.09	39.59	-4.25	4.879	-7.7	-0.8	0	2
Day 7	3	63.60	26.72	100.48	56.10	14.846	54.0	80.7	83.43	79.02	87.85	84.20	-19.83	-61.04	21.38	-28.60	16.589	-30.2	-0.7	2	1
Day 10	1	62.20		62.20		62.2	62.2	84.70				84.70	-22.50			-22.50		-22.5	-22.5	1	0
Day 14	1	90.50		90.50		90.5	90.5	81.40				81.40	9.10			9.10		9.1	9.1	0	1
EoT	1	56.10		56.10		56.1	56.1	84.70				84.70	-28.60			-28.60		-28.6	-28.6	1	0
EoS (Day 21-28)	3	70.97	30.60	111.33	77.90	16.250	52.4	82.6	83.43	79.02	87.85	84.20	-12.47	-55.23	30.30	-6.80	17.214	-31.8	1.2	1	2

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.9 Monocytes [%]

Visit	n	----- Result -----							Baseline				---- Change from baseline ----							Out of range	
		95%	95%	Median	SD	Min	Max	Mean	95%	95%	Median	Mean	95%	95%	Median	SD	Min	Max	NV	AV	
		ICI	uCI						ICI	uCI			ICI	uCI							
Screening (-5 to D1)	3	2.63	-2.07	7.34	1.80	1.893	1.3	4.8												1	2
Baseline (D1)	3	2.63	-2.07	7.34	1.80	1.893	1.3	4.8												1	2
Day 2	3	6.60	-2.28	15.48	6.10	3.576	3.3	10.4	2.63	-2.07	7.34	1.80	3.97	-0.56	8.50	4.30	1.823	2.0	5.6	3	0
Day 3	3	7.00	-1.95	15.95	7.20	3.604	3.3	10.5	2.63	-2.07	7.34	1.80	4.37	-0.74	9.47	5.40	2.055	2.0	5.7	3	0
Day 5	2	5.95	-11.20	23.10	5.95	1.909	4.6	7.3	1.55	-1.63	4.73	1.55	4.40	-9.58	18.38	4.40	1.556	3.3	5.5	2	0
Day 7	3	7.87	-0.18	15.91	6.20	3.239	5.8	11.6	2.63	-2.07	7.34	1.80	5.23	1.86	8.61	4.50	1.358	4.4	6.8	3	0
Day 10	1	5.70		5.70		5.7	5.7	1.30				1.30	4.40			4.40		4.4	4.4	1	0
Day 14	1	2.60		2.60		2.6	2.6	1.80				1.80	0.80			0.80		0.8	0.8	1	0
EoT	1	5.80		5.80		5.8	5.8	1.30				1.30	4.50			4.50		4.5	4.5	1	0
EoS (Day 21-28)	3	7.90	-5.55	21.35	5.50	5.415	4.1	14.1	2.63	-2.07	7.34	1.80	5.27	-3.48	14.02	3.70	3.522	2.8	9.3	2	1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.10 Lymphocytes [%]

Visit	n	----- Result -----							Baseline				---- Change from baseline ----							Out of range	
		95%	95%	Median	SD	Min	Max	Mean	95%	95%	Median	Mean	95%	95%	Median	SD	Min	Max	NV	AV	
		ICI	uCI						ICI	uCI			ICI	uCI							
Screening (-5 to D1)	3	7.94	-8.52	24.39	9.70	6.623	0.6	13.5												0	3
Baseline (D1)	3	7.94	-8.52	24.39	9.70	6.623	0.6	13.5												0	3
Day 2	3	13.07	7.60	18.53	13.00	2.201	10.9	15.3	7.94	-8.52	24.39	9.70	5.13	-8.31	18.57	5.60	5.410	-0.5	10.3	0	3
Day 3	3	11.87	1.66	22.08	9.80	4.110	9.2	16.6	7.94	-8.52	24.39	9.70	3.93	-12.62	20.48	6.90	6.662	-3.7	8.6	0	3
Day 5	2	12.55	-3.33	28.43	12.55	1.768	11.3	13.8	7.06	-74.84	88.95	7.06	5.50	-60.51	71.50	5.50	7.347	0.3	10.7	0	2
Day 7	3	24.50	-2.64	51.64	30.30	10.923	11.9	31.3	7.94	-8.52	24.39	9.70	16.56	3.75	29.38	16.80	5.159	11.3	21.6	2	1
Day 10	1	28.90		28.90		28.9	28.9	13.50				13.50	15.40			15.40		15.4	15.4	1	0
Day 14	1	5.50		5.50		5.5	5.5	0.61				0.61	4.89			4.89		4.9	4.9	0	1
EoT	1	30.30		30.30		30.3	30.3	13.50				13.50	16.80			16.80		16.8	16.8	1	0
EoS (Day 21-28)	3	19.47	-7.13	46.06	16.30	10.707	10.7	31.4	7.94	-8.52	24.39	9.70	11.53	-12.15	35.21	10.09	9.532	2.8	21.7	1	2

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.11 Mean corpuscular volume [fL]

----- Result -----																			Baseline				---- Change from baseline ----							Out of range	
Visit	n	95%		95%		Median	SD	Min	Max	Mean	95%		Median	Mean	95%		SD	Min	Max	NV	AV										
		ICI	uCI	ICI	uCI						ICI	uCI																			
Screening (-5 to D1)	3	85.73	84.28	87.19	85.50	0.586	85.3	86.4												3	0										
Baseline (D1)	3	85.73	84.28	87.19	85.50	0.586	85.3	86.4												3	0										
Day 2	3	86.17	84.51	87.82	86.00	0.666	85.6	86.9	85.73	84.28	87.19	85.50	0.43	-2.36	3.23	0.70	1.124	-0.8	1.4	3	0										
Day 3	3	87.23	86.72	87.75	87.30	0.208	87.0	87.4	85.73	84.28	87.19	85.50	1.50	0.42	2.58	1.70	0.436	1.0	1.8	3	0										
Day 5	2	86.00	82.19	89.81	86.00	0.424	85.7	86.3	85.85	78.86	92.84	85.85	0.15	-10.65	10.95	0.15	1.202	-0.7	1.0	2	0										
Day 7	3	85.87	81.50	90.23	85.70	1.756	84.2	87.7	85.73	84.28	87.19	85.50	0.13	-5.36	5.63	0.40	2.212	-2.2	2.2	3	0										
Day 10	1	84.60			84.60		84.6	84.6	86.40			86.40	-1.80			-1.80		-1.8	-1.8	1	0										
Day 14	1	87.60			87.60		87.6	87.6	85.30			85.30	2.30			2.30		2.3	2.3	1	0										
EoT	1	84.20			84.20		84.2	84.2	86.40			86.40	-2.20			-2.20		-2.2	-2.2	1	0										
EoS (Day 21-28)	3	87.40	84.78	90.02	87.50	1.054	86.3	88.4	85.73	84.28	87.19	85.50	1.67	-2.23	5.57	2.20	1.570	-0.1	2.9	3	0										

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.12 Mean corpuscular hemoglobin [pg]

Visit	n	----- Result -----								Baseline				---- Change from baseline ----								Out of range	
		95%		95%		SD	Min	Max	Mean	95%		95%		95%		95%		SD	Min	Max	NV	AV	
		ICI	uCI	Median	ICI					uCI	Median	Mean	ICI	uCI	Median	Mean	ICI						uCI
Screening (-5 to D1)	3	29.27	26.02	32.51	29.40	1.305	27.9	30.5													2	1	
Baseline (D1)	3	29.27	26.02	32.51	29.40	1.305	27.9	30.5													2	1	
Day 2	3	29.53	26.63	32.43	29.30	1.168	28.5	30.8	29.27	26.02	32.51	29.40	0.27	-0.61	1.14	0.30	0.351	-0.1	0.6	3	0		
Day 3	3	29.77	27.22	32.32	29.50	1.026	28.9	30.9	29.27	26.02	32.51	29.40	0.50	-0.64	1.64	0.40	0.458	0.1	1.0	3	0		
Day 5	2	28.65	25.47	31.83	28.65	0.354	28.4	28.9	28.65	19.12	38.18	28.65	0.00	-6.35	6.35	0.00	0.707	-0.5	0.5	2	0		
Day 7	3	29.90	26.00	33.80	29.20	1.572	28.8	31.7	29.27	26.02	32.51	29.40	0.63	-1.20	2.46	0.90	0.737	-0.2	1.2	3	0		
Day 10	1	28.60			28.60		28.6	28.6	27.90			27.90	0.70			0.70		0.7	0.7	1	0		
Day 14	1	28.50			28.50		28.5	28.5	29.40			29.40	-0.90			-0.90		-0.9	-0.9	1	0		
EoT	1	28.80			28.80		28.8	28.8	27.90			27.90	0.90			0.90		0.9	0.9	1	0		
EoS (Day 21-28)	3	29.43	24.69	34.17	28.70	1.909	28.0	31.6	29.27	26.02	32.51	29.40	0.17	-2.07	2.41	0.10	0.902	-0.7	1.1	3	0		

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.13 Mean corpuscular hemoglobin concentration [g/L]

----- Result -----																				Baseline				---- Change from baseline ----								Out of range		
Visit	n	95%		95%		SD	Min	Max	Mean	95%		95%		Mean	95%		95%		SD	Min	Max	NV	AV											
		ICI	uCI	Median	Median					ICI	uCI	Median	Median		ICI	uCI	Median	Median																
Screening (-5 to D1)	3	341.7	298.8	384.5	345.0	17.24	323	357														3	0											
Baseline (D1)	3	341.7	298.8	384.5	345.0	17.24	323	357														3	0											
Day 2	3	343.0	315.3	370.7	341.0	11.14	333	355	341.7	298.8	384.5	345.0	1.3	-17.5	20.1	-2.0	7.57	-4	10	3	0													
Day 3	3	341.0	310.9	371.1	339.0	12.12	330	354	341.7	298.8	384.5	345.0	-0.7	-17.6	16.2	-3.0	6.81	-6	7	3	0													
Day 5	2	332.5	313.4	351.6	332.5	2.12	331	334	334.0	194.2	473.8	334.0	-1.5	-122.2	119.2	-1.5	13.44	-11	8	2	0													
Day 7	3	347.7	318.9	376.5	342.0	11.59	340	361	341.7	298.8	384.5	345.0	6.0	-24.1	36.1	4.0	12.12	-5	19	2	1													
Day 10	1	338.0			338.0		338	338	323.0			323.0	15.0					15	15	1	0													
Day 14	1	325.0			325.0		325	325	345.0			345.0	-20.0			-20.0		-20	-20	1	0													
EoT	1	342.0			342.0		342	342	323.0			323.0	19.0					19	19	1	0													
EoS (Day 21-28)	3	336.7	292.8	380.6	328.0	17.67	325	357	341.7	298.8	384.5	345.0	-5.0	-30.9	20.9	0.0	10.44	-17	2	3	0													

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.14 Red cell distribution width [%]

----- Result -----																				Baseline				--- Change from baseline ---								Out of range	
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV												
Screening (-5 to D1)	3	12.90	9.89	15.91	12.70	1.212	11.8	14.2												3	0												
Baseline (D1)	3	12.90	9.89	15.91	12.70	1.212	11.8	14.2												3	0												
Day 2	3	12.80	9.82	15.78	12.80	1.200	11.6	14.0	12.90	9.89	15.91	12.70	-0.10	-0.53	0.33	-0.20	0.173	-0.2	0.1	3	0												
Day 3	3	12.83	9.73	15.94	12.80	1.250	11.6	14.1	12.90	9.89	15.91	12.70	-0.07	-0.45	0.31	-0.10	0.153	-0.2	0.1	3	0												
Day 5	2	13.15	7.43	18.87	13.15	0.636	12.7	13.6	13.45	3.92	22.98	13.45	-0.30	-4.11	3.51	-0.30	0.424	-0.6	0.0	2	0												
Day 7	3	12.40	9.42	15.38	12.40	1.200	11.2	13.6	12.90	9.89	15.91	12.70	-0.50	-3.12	2.12	-0.60	1.054	-1.5	0.6	3	0												
Day 10	1	14.50			14.50		14.5	14.5	14.20			14.20	0.30			0.30		0.3	0.3	1	0												
Day 14	1	13.20			13.20		13.2	13.2	12.70			12.70	0.50			0.50		0.5	0.5	1	0												
EoT	1	13.60			13.60		13.6	13.6	14.20			14.20	-0.60			-0.60		-0.6	-0.6	1	0												
EoS (Day 21-28)	3	14.43	10.83	18.04	14.40	1.450	13.0	15.9	12.90	9.89	15.91	12.70	1.53	0.82	2.25	1.70	0.289	1.2	1.7	2	1												

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.15 D-dimers [µg/L]

																				Out of range	
----- Result -----										Baseline					--- Change from baseline ---					N	A
Visit	n	Mean	95% ICI	95% uCI	Media n	SD	Min	Max	Mean	95% ICI	95% uCI	Media n	Mean	95% ICI	95% uCI	Media n	SD	Min	Max	V	V
Screening (-5 to D1)	3	1293.3	-2722.6	5309.2	370.0	1616.61	350	3160												2	1
Baseline (D1)	3	1293.3	-2722.6	5309.2	370.0	1616.61	350	3160												2	1
Day 2	3	806.7	-947.5	2560.8	450.0	706.14	350	1620	1293.3	-2722.6	5309.2	370.0	-486.7	-2754.9	1781.6	0.0	913.09	-1540	80	2	1
Day 3	2	800.0	-4917.8	6517.8	800.0	636.40	350	1250	1765.0	-15960	19490.2	1765.0	-965.0	-12972	11042.4	-965.0	1336.43	-1910	-20	1	1
Day 5	2	895.0	-5013.4	6803.4	895.0	657.61	430	1360	1765.0	-15960	19490.2	1765.0	-870.0	-12687	10946.8	-870.0	1315.22	-1800	60	1	1
Day 7	3	836.7	-827.2	2500.5	460.0	669.80	440	1610	1293.3	-2722.6	5309.2	370.0	-456.7	-2809.3	1896.0	70.0	947.07	-1550	110	2	1
Day 10	1	350.0			350.0		350	350	370.0			370.0	-20.0			-20.0		-20	-20	1	0
Day 14	1	1380.0			1380.0		138	1380	3160.0			3160.0	-1780.0			-1780.0		-1780	-1780	0	1
						0															
EoT	1	440.0			440.0		440	440	370.0			370.0	70.0			70.0		70	70	1	0
EoS (Day 21-28)	3	786.7	-683.9	2257.2	460.0	591.97	430	1470	1293.3	-2722.6	5309.2	370.0	-506.7	-3052.4	2039.1	80.0	1024.81	-1690	90	2	1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.16 Prothrombin time [s]

																				Out of range	
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	14.27	10.46	18.07	13.70	1.531	13.1	16.0												3	0
Baseline (D1)	3	14.27	10.46	18.07	13.70	1.531	13.1	16.0												3	0
Day 2	2	14.70	0.72	28.68	14.70	1.556	13.6	15.8	14.85	0.24	29.46	14.85	-0.15	-0.79	0.49	-0.15	0.071	-0.2	-0.1	2	0
Day 3	2	15.10	10.02	20.18	15.10	0.566	14.7	15.5	14.85	0.24	29.46	14.85	0.25	-9.28	9.78	0.25	1.061	-0.5	1.0	2	0
Day 5	1	14.00			14.00		14.0	14.0	13.70			13.70	0.30			0.30		0.3	0.3	1	0
Day 7	2	13.10	2.94	23.26	13.10	1.131	12.3	13.9	14.85	0.24	29.46	14.85	-1.75	-26.53	23.03	-1.75	2.758	-3.7	0.2	2	0
Day 10	1	13.40			13.40		13.4	13.4	13.70			13.70	-0.30			-0.30		-0.3	-0.3	1	0
Day 14	1	12.20			12.20		12.2	12.2	13.10			13.10	-0.90			-0.90		-0.9	-0.9	1	0
EoT	1	13.90			13.90		13.9	13.9	13.70			13.70	0.20			0.20		0.2	0.2	1	0
EoS (Day 21-28)	3	16.63	-2.90	36.16	12.50	7.862	11.7	25.7	14.27	10.46	18.07	13.70	2.37	-18.52	23.25	-1.40	8.409	-3.5	12.0	2	1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.17 Activated partial thromboplastin time [s]

																				Out of range	
----- Result -----										Baseline					---- Change from baseline ----						
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	42.40	34.75	50.05	41.20	3.081	40.1	45.9												2	1
Baseline (D1)	3	42.40	34.75	50.05	41.20	3.081	40.1	45.9												2	1
Day 2	2	40.00	24.75	55.25	40.00	1.697	38.8	41.2	40.65	33.66	47.64	40.65	-0.65	-8.91	7.61	-0.65	0.919	-1.3	0.0	2	0
Day 3	2	38.15	26.08	50.22	38.15	1.344	37.2	39.1	40.65	33.66	47.64	40.65	-2.50	-7.58	2.58	-2.50	0.566	-2.9	-2.1	2	0
Day 5	1	42.50			42.50		42.5	42.5	41.20			41.20	1.30			1.30		1.3	1.3	1	0
Day 7	2	32.70	-6.69	72.09	32.70	4.384	29.6	35.8	40.65	33.66	47.64	40.65	-7.95	-40.35	24.45	-7.95	3.606	-10.5	-5.4	2	0
Day 10	1	33.10			33.10		33.1	33.1	41.20			41.20	-8.10			-8.10		-8.1	-8.1	1	0
Day 14	1	28.50			28.50		28.5	28.5	45.90			45.90	-17.40			-17.40		-17.4	-17.4	1	0
EoT	1	35.80			35.80		35.8	35.8	41.20			41.20	-5.40			-5.40		-5.4	-5.4	1	0
EoS (Day 21-28)	3	35.90	27.49	44.31	34.20	3.387	33.7	39.8	42.40	34.75	50.05	41.20	-6.50	-19.30	6.30	-6.40	5.151	-11.7	-1.4	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.8.18 International normalized ratio

																				Out of range
----- Result -----										Baseline					---- Change from baseline ----					
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV AV
Screening (-5 to D1)	3	1.240	0.793	1.687	1.240	0.1800	1.06	1.42												2 1
Baseline (D1)	3	1.240	0.793	1.687	1.240	0.1800	1.06	1.42												2 1
Day 2	2	1.130	-0.014	2.274	1.130	0.1273	1.04	1.22	1.150	0.006	2.294	1.150	-0.020			-0.020	0.0000	-0.02	-0.02	2 0
Day 3	2	1.170	0.789	1.551	1.170	0.0424	1.14	1.20	1.150	0.006	2.294	1.150	0.020	-0.742	0.782	0.020	0.0849	-0.04	0.08	2 0
Day 5	1	1.080			1.080		1.08	1.08	1.060			1.060	0.020			0.020		0.02	0.02	1 0
Day 7	2	1.005	0.179	1.831	1.005	0.0919	0.94	1.07	1.150	0.006	2.294	1.150	-0.145	-2.114	1.824	-0.145	0.2192	-0.30	0.01	2 0
Day 10	1	1.030			1.030		1.03	1.03	1.060			1.060	-0.030			-0.030		-0.03	-0.03	1 0
Day 14	1	0.930			0.930		0.93	0.93	1.420			1.420	-0.490			-0.490		-0.49	-0.49	1 0
EoT	1	1.070			1.070		1.07	1.07	1.060			1.060	0.010			0.010		0.01	0.01	1 0
EoS (Day 21-28)	3	1.283	-0.282	2.848	0.950	0.6300	0.89	2.01	1.240	0.793	1.687	1.240	0.043	-1.930	2.017	-0.290	0.7943	-0.53	0.95	2 1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9 Summary statistics and changes from baseline of biochemistry parameters

14.3.9.1 Alanine aminotransferase [$\mu\text{kat/L}$]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	ICI	95% uCI	Median	SD	Min	Max	Mean	ICI	95% uCI	Median	Mean	ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	0.930	-0.880	2.740	0.550	0.7286	0.47	1.77												2	1
Baseline (D1)	3	0.930	-0.880	2.740	0.550	0.7286	0.47	1.77												2	1
Day 2	3	0.847	-0.263	1.956	0.730	0.4466	0.47	1.34	0.930	-0.880	2.740	0.550	-0.083	-0.940	0.774	-0.080	0.3450	-0.43	0.26	2	1
Day 3	3	0.843	-0.157	1.844	1.040	0.4028	0.38	1.11	0.930	-0.880	2.740	0.550	-0.087	-1.798	1.624	-0.170	0.6888	-0.73	0.64	1	2
Day 5	2	0.570	-1.590	2.730	0.570	0.2404	0.40	0.74	1.160	-6.591	8.911	1.160	-0.590	-6.181	5.001	-0.590	0.6223	-1.03	-0.15	1	1
Day 7	3	0.620	-0.007	1.247	0.550	0.2524	0.41	0.90	0.930	-0.880	2.740	0.550	-0.310	-2.392	1.772	-0.140	0.8380	-1.22	0.43	2	1
Day 10	1	0.490			0.490		0.49	0.49	0.550				0.550	-0.060		-0.060		-0.06	-0.06	1	0
Day 14	1	0.740			0.740		0.74	0.74	1.770				1.770	-1.030		-1.030		-1.03	-1.03	0	1
EoT	1	0.410			0.410		0.41	0.41	0.550				0.550	-0.140		-0.140		-0.14	-0.14	1	0
EoS (Day 21-28)	3	0.573	0.257	0.890	0.510	0.1274	0.49	0.72	0.930	-0.880	2.740	0.550	-0.357	-1.853	1.140	-0.060	0.6025	-1.05	0.04	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.2 Aspartate aminotransferase [$\mu\text{kat/L}$]

																				Out of range	
----- Result -----										Baseline					---- Change from baseline ----						
Visit	n	Mean	ICI	95% uCI	95% Median	SD	Min	Max	Mean	ICI	95% uCI	95% Median	Mean	ICI	95% uCI	95% Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	0.730	-0.265	1.725	0.540	0.4004	0.46	1.19												2	1
Baseline (D1)	3	0.730	-0.265	1.725	0.540	0.4004	0.46	1.19												2	1
Day 2	3	0.557	0.094	1.019	0.580	0.1861	0.36	0.73	0.730	-0.265	1.725	0.540	-0.173	-1.179	0.833	-0.100	0.4050	-0.61	0.19	3	0
Day 3	3	0.513	-0.205	1.232	0.410	0.2892	0.29	0.84	0.730	-0.265	1.725	0.540	-0.217	-1.562	1.129	-0.170	0.5415	-0.78	0.30	3	0
Day 5	2	0.300	0.046	0.554	0.300	0.0283	0.28	0.32	0.825	-3.813	5.463	0.825	-0.525	-5.417	4.367	-0.525	0.5445	-0.91	-0.14	2	0
Day 7	3	0.347	0.026	0.667	0.310	0.1290	0.24	0.49	0.730	-0.265	1.725	0.540	-0.383	-1.609	0.842	-0.150	0.4933	-0.95	-0.05	3	0
Day 10	1	0.340			0.340		0.34	0.34	0.460			0.460	-0.120			-0.120		-0.12	-0.12	1	0
Day 14	1	0.320			0.320		0.32	0.32	1.190			1.190	-0.870			-0.870		-0.87	-0.87	1	0
EoT	1	0.310			0.310		0.31	0.31	0.460			0.460	-0.150			-0.150		-0.15	-0.15	1	0
EoS (Day 21-28)	3	0.383	0.197	0.570	0.340	0.0751	0.34	0.47	0.730	-0.265	1.725	0.540	-0.347	-1.431	0.738	-0.120	0.4366	-0.85	-0.07	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.3 Alkaline phosphatase [$\mu\text{kat/L}$]

																						Out of range
----- Result -----											Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV	
Screening (-5 to D1)	2	2.05	-7.48	11.58	2.05	1.061	1.3	2.8												1	1	
Baseline (D1)	2	2.05	-7.48	11.58	2.05	1.061	1.3	2.8												1	1	
Day 2	2	1.80	-5.82	9.42	1.80	0.849	1.2	2.4	2.05	-7.48	11.58	2.05	-0.25	-2.16	1.66	-0.25	0.212	-0.4	-0.1	1	1	
Day 3	2	1.50	-4.85	7.85	1.50	0.707	1.0	2.0	2.05	-7.48	11.58	2.05	-0.55	-3.73	2.63	-0.55	0.354	-0.8	-0.3	1	1	
Day 5	2	1.25	-3.20	5.70	1.25	0.495	0.9	1.6	2.05	-7.48	11.58	2.05	-0.80	-5.88	4.28	-0.80	0.566	-1.2	-0.4	2	0	
Day 7	2	1.10	-1.44	3.64	1.10	0.283	0.9	1.3	1.30			1.30	-0.40			-0.40		-0.4	-0.4	2	0	
Day 10	1	1.00			1.00		1.0	1.0	1.30			1.30	-0.30			-0.30		-0.3	-0.3	1	0	
Day 14	1	1.60			1.60		1.6	1.6	2.80			2.80	-1.20			-1.20		-1.2	-1.2	1	0	
EoT	1	0.90			0.90		0.9	0.9	1.30			1.30	-0.40			-0.40		-0.4	-0.4	1	0	
EoS (Day 21-28)	3	1.40	0.32	2.48	1.60	0.436	0.9	1.7	2.05	-7.48	11.58	2.05	-0.75	-5.20	3.70	-0.75	0.495	-1.1	-0.4	3	0	

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.4 Lactate dehydrogenase [$\mu\text{kat/L}$]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mea n	95% ICI	95% uCI	Median	SD	Min	Max	Mea n	95% ICI	95% uCI	Median	Mea n	95% ICI	95% uCI	Media n	SD	Min	Max	N	
Screening (-5 to D1)	3	4.593	3.132	6.055	4.450	0.5882	4.09	5.24												1 2	
Baseline (D1)	3	4.593	3.132	6.055	4.450	0.5882	4.09	5.24												1 2	
Day 2	3	4.173	3.542	4.805	4.310	0.2542	3.88	4.33	4.593	3.132	6.055	4.450	-0.420	-1.478	0.638	-0.210	0.4258	-0.91	-0.14	1 2	
Day 3	3	4.020	2.628	5.412	4.110	0.5604	3.42	4.53	4.593	3.132	6.055	4.450	-0.573	-2.091	0.944	-0.670	0.6108	-1.13	0.08	2 1	
Day 5	2	4.090	0.024	8.156	4.090	0.4525	3.77	4.41	4.665	-2.641	11.971	4.665	-0.575	-11.947	10.797	-0.575	1.2657	-1.47	0.32	1 1	
Day 7	3	3.863	3.131	4.596	3.970	0.2948	3.53	4.09	4.593	3.132	6.055	4.450	-0.730	-2.859	1.399	-0.360	0.8571	-1.71	-0.12	3 0	
Day 10	1	3.730			3.730		3.73	3.73	4.090			4.090	-0.360			-0.360		-0.36	-0.36	1 0	
Day 14	1	4.700			4.700		4.70	4.70	5.240			5.240	-0.540			-0.540		-0.54	-0.54	0 1	
EoT	1	3.970			3.970		3.97	3.97	4.090			4.090	-0.120			-0.120		-0.12	-0.12	1 0	
EoS (Day 21-28)	3	4.070	3.483	4.657	3.970	0.2364	3.90	4.34	4.593	3.132	6.055	4.450	-0.523	-2.412	1.365	-0.550	0.7604	-1.27	0.25	2 1	

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.5 Magnesium [mmol/L]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	2	0.895	0.323	1.467	0.895	0.0636	0.85	0.94												2	0
Baseline (D1)	2	0.895	0.323	1.467	0.895	0.0636	0.85	0.94												2	0
Day 2	2	0.925	0.861	0.989	0.925	0.0071	0.92	0.93	0.895	0.323	1.467	0.895	0.030	-0.478	0.538	0.030	0.0566	-0.01	0.07	2	0
Day 3	2	0.985	0.921	1.049	0.985	0.0071	0.98	0.99	0.895	0.323	1.467	0.895	0.090	-0.418	0.598	0.090	0.0566	0.05	0.13	2	0
Day 5	1	0.900			0.900		0.90	0.90	0.850			0.850	0.050			0.050		0.05	0.05	1	0
Day 7	2	0.885	0.059	1.711	0.885	0.0919	0.82	0.95	0.895	0.323	1.467	0.895	-0.010	-0.264	0.244	-0.010	0.0283	-0.03	0.01	2	0
Day 14	1	0.860			0.860		0.86	0.86												1	0
EoT	1	0.820			0.820		0.82	0.82	0.850			0.850	-0.030			-0.030		-0.03	-0.03	1	0
EoS (Day 21-28)	1	0.890			0.890		0.89	0.89												1	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.6 Total bilirubin [$\mu\text{mol/L}$]

Visit	n	----- Result -----							Baseline				---- Change from baseline ----							Out of range	
		95%		95%		SD	Min	Max	Mean	95%		Median	Mean	95%		SD	Min	Max	NV	AV	
		Mean	ICI	uCI	Median					ICI	uCI			ICI	uCI						
Screening (-5 to D1)	3	6.0	1.0	11.0	6.0	2.00	4	8												3	0
Baseline (D1)	3	6.0	1.0	11.0	6.0	2.00	4	8												3	0
Day 2	3	5.7	-0.6	11.9	6.0	2.52	3	8	6.0	1.0	11.0	6.0	-0.3	-1.8	1.1	0.0	0.58	-1	0	3	0
Day 3	3	6.3	-2.4	15.1	6.0	3.51	3	10	6.0	1.0	11.0	6.0	0.3	-3.5	4.1	0.0	1.53	-1	2	3	0
Day 5	2	6.5	0.1	12.9	6.5	0.71	6	7	5.0	-7.7	17.7	5.0	1.5	-4.9	7.9	1.5	0.71	1	2	2	0
Day 7	3	8.3	4.5	12.1	8.0	1.53	7	10	6.0	1.0	11.0	6.0	2.3	-1.5	6.1	2.0	1.53	1	4	3	0
Day 10	1	8.0			8.0		8	8	4.0			4.0	4.0			4.0		4	4	1	0
Day 14	1	7.0			7.0		7	7	6.0			6.0	1.0			1.0		1	1	1	0
EoT	1	8.0			8.0		8	8	4.0			4.0	4.0			4.0		4	4	1	0
EoS (Day 21-28)	3	6.7	0.4	12.9	7.0	2.52	4	9	6.0	1.0	11.0	6.0	0.7	-5.6	6.9	1.0	2.52	-2	3	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.7 Direct bilirubin [$\mu\text{mol/L}$]

Visit	n	----- Result -----							Baseline				---- Change from baseline ----							Out of range	
		95%		95%		SD	Min	Max	Mean	95%		Median	Mean	95%		SD	Min	Max	NV	AV	
		Mean	ICI	uCI	Median					ICI	uCI			ICI	uCI						
Screening (-5 to D1)	2	3.70	-5.19	12.59	3.70	0.990	3.0	4.4												1	1
Baseline (D1)	2	3.70	-5.19	12.59	3.70	0.990	3.0	4.4												1	1
Day 2	3	3.50	1.76	5.24	3.20	0.700	3.0	4.3	3.70	-5.19	12.59	3.70	-0.05	-0.69	0.59	-0.05	0.071	-0.1	0.0	2	1
Day 3	2	4.15	-10.46	18.76	4.15	1.626	3.0	5.3	3.70	-5.19	12.59	3.70	0.45	-5.27	6.17	0.45	0.636	0.0	0.9	1	1
Day 5	1	3.00			3.00		3.0	3.0	3.00			3.00	0.00			0.00		0.0	0.0	1	0
Day 7	2	4.30	-3.32	11.92	4.30	0.849	3.7	4.9	3.70	-5.19	12.59	3.70	0.60	-0.67	1.87	0.60	0.141	0.5	0.7	0	2
Day 10	1	3.70			3.70		3.7	3.7	3.00			3.00	0.70			0.70		0.7	0.7	0	1
EoT	1	3.70			3.70		3.7	3.7	3.00			3.00	0.70			0.70		0.7	0.7	0	1
EoS (Day 21-28)	1	1.50			1.50		1.5	1.5												1	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.8 Blood urea nitrogen [mmol/L]

Visit	n	----- Result -----							Baseline				---- Change from baseline ----							Out of range	
		95%		95%		SD	Min	Max	Mean	95%		Median	Mean	95%		SD	Min	Max	NV	AV	
		Mean	ICI	uCI	Median					ICI	uCI			ICI	uCI						
Screening (-5 to D1)	3	5.47	2.67	8.26	5.20	1.124	4.5	6.7												3	0
Baseline (D1)	3	5.47	2.67	8.26	5.20	1.124	4.5	6.7												3	0
Day 2	3	6.33	4.84	7.83	6.40	0.603	5.7	6.9	5.47	2.67	8.26	5.20	0.87	-3.42	5.15	1.20	1.724	-1.0	2.4	3	0
Day 3	3	6.80	4.35	9.25	6.50	0.985	6.0	7.9	5.47	2.67	8.26	5.20	1.33	-3.13	5.79	2.00	1.795	-0.7	2.7	3	0
Day 5	2	6.05	-2.21	14.31	6.05	0.919	5.4	6.7	4.85	0.40	9.30	4.85	1.20	-2.61	5.01	1.20	0.424	0.9	1.5	2	0
Day 7	3	5.77	2.46	9.07	5.10	1.332	4.9	7.3	5.47	2.67	8.26	5.20	0.30	-4.30	4.90	0.40	1.852	-1.6	2.1	3	0
Day 10	1	8.20			8.20		8.2	8.2	5.20			5.20	3.00			3.00		3.0	3.0	0	1
Day 14	1	7.80			7.80		7.8	7.8	4.50			4.50	3.30			3.30		3.3	3.3	1	0
EoT	1	7.30			7.30		7.3	7.3	5.20			5.20	2.10			2.10		2.1	2.1	1	0
EoS (Day 21-28)	3	6.77	3.39	10.14	6.60	1.358	5.5	8.2	5.47	2.67	8.26	5.20	1.30	-4.19	6.79	2.10	2.211	-1.2	3.0	2	1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.9 Creatinine [$\mu\text{mol/L}$]

																						Out of range		
----- Result -----											Baseline				---- Change from baseline ----									
Visit	n	Mean	95%		SD	Min	Max	Mean	ICI	uCI	Median	Mean	ICI	uCI	Median	SD	Min	Max	NV	AV				
			ICI	uCI																				
Screening (-5 to D1)	3	61.0	42.2	79.8	62.0	7.55	53	68											3	0				
Baseline (D1)	3	61.0	42.2	79.8	62.0	7.55	53	68											3	0				
Day 2	3	58.0	40.8	75.2	54.0	6.93	54	66	61.0	42.2	79.8	62.0	-3.0	-14.4	8.4	-2.0	4.58	-8	1	3	0			
Day 3	3	62.0	39.6	84.4	62.0	9.00	53	71	61.0	42.2	79.8	62.0	1.0	-3.3	5.3	0.0	1.73	0	3	3	0			
Day 5	2	57.0	44.3	69.7	57.0	1.41	56	58	57.5	0.3	114.7	57.5	-0.5	-70.4	69.4	-0.5	7.78	-6	5	2	0			
Day 7	3	71.0	45.8	96.2	73.0	10.15	60	80	61.0	42.2	79.8	62.0	10.0	3.4	16.6	11.0	2.65	7	12	3	0			
Day 10	1	80.0			80.0		80	80	62.0			62.0	18.0			18.0		18	18	1	0			
Day 14	1	61.0			61.0		61	61	53.0			53.0	8.0			8.0		8	8	1	0			
EoT	1	73.0			73.0		73	73	62.0			62.0	11.0			11.0		11	11	1	0			
EoS (Day 21-28)	3	72.7	40.2	105.1	77.0	13.05	58	83	61.0	42.2	79.8	62.0	11.7	-2.7	26.0	15.0	5.77	5	15	3	0			

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.10 Phosphorus [mmol/L]

																							Out of range
----- Result -----											Baseline				---- Change from baseline ----								
Visit	n	Mean	ICI	95% uCI	95% Median	SD	Min	Max	Mean	ICI	95% uCI	95% Median	Mean	ICI	95% uCI	95% Median	SD	Min	Max	NV	AV		
Screening (-5 to D1)	2	1.030	-0.241	2.301	1.030	0.1414	0.93	1.13												2	0		
Baseline (D1)	2	1.030	-0.241	2.301	1.030	0.1414	0.93	1.13												2	0		
Day 2	2	1.140	0.251	2.029	1.140	0.0990	1.07	1.21	1.030	-0.241	2.301	1.030	0.110	-2.050	2.270	0.110	0.2404	-0.06	0.28	2	0		
Day 3	2	1.055	0.991	1.119	1.055	0.0071	1.05	1.06	1.030	-0.241	2.301	1.030	0.025	-1.182	1.232	0.025	0.1344	-0.07	0.12	2	0		
Day 5	1	0.920			0.920		0.92	0.92	1.130			1.130	-0.210			-0.210		-0.21	-0.21	1	0		
Day 7	2	1.070	-0.582	2.722	1.070	0.1838	0.94	1.20	1.030	-0.241	2.301	1.030	0.040	-0.341	0.421	0.040	0.0424	0.01	0.07	2	0		
Day 10	1	1.250			1.250		1.25	1.25	1.130			1.130	0.120			0.120		0.12	0.12	1	0		
EoT	1	1.200			1.200		1.20	1.20	1.130			1.130	0.070			0.070		0.07	0.07	1	0		
EoS (Day 21-28)	2	0.975	-0.994	2.944	0.975	0.2192	0.82	1.13	0.930			0.930	-0.110			-0.110		-0.11	-0.11	2	0		

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.11 Chloride [mmol/L]

																					Out of range	
----- Result -----											Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV	
Screening (-5 to D1)	3	103.0	94.0	112.0	102.0	3.61	100	107												3	0	
Baseline (D1)	3	103.0	94.0	112.0	102.0	3.61	100	107												3	0	
Day 2	3	105.3	103.9	106.8	105.0	0.58	105	106	103.0	94.0	112.0	102.0	2.3	-5.3	9.9	3.0	3.06	-1	5	3	0	
Day 3	3	104.3	99.2	109.5	105.0	2.08	102	106	103.0	94.0	112.0	102.0	1.3	-12.8	15.5	3.0	5.69	-5	6	3	0	
Day 5	2	106.0	93.3	118.7	106.0	1.41	105	107	101.0	88.3	113.7	101.0	5.0			5.0	0.00	5	5	2	0	
Day 7	3	103.0	96.4	109.6	104.0	2.65	100	105	103.0	94.0	112.0	102.0	0.0	-5.0	5.0	0.0	2.00	-2	2	3	0	
Day 10	1	101.0			101.0		101	101	100.0			100.0	1.0			1.0		1	1	1	0	
Day 14	1	104.0			104.0		104	104	102.0			102.0	2.0			2.0		2	2	1	0	
EoT	1	100.0			100.0		100	100	100.0			100.0	0.0			0.0		0	0	1	0	
EoS (Day 21-28)	3	102.7	96.9	108.4	104.0	2.31	100	104	103.0	94.0	112.0	102.0	-0.3	-6.6	5.9	0.0	2.52	-3	2	3	0	

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.12 Calcium [mmol/L]

																				Out of range
----- Result -----										Baseline					---- Change from baseline ----					
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV AV
Screening (-5 to D1)	2	2.245	2.181	2.309	2.245	0.0071	2.24	2.25												2 0
Baseline (D1)	2	2.245	2.181	2.309	2.245	0.0071	2.24	2.25												2 0
Day 2	2	2.210	2.083	2.337	2.210	0.0141	2.20	2.22	2.245	2.181	2.309	2.245	-0.035	-0.226	0.156	-0.035	0.0212	-0.05	-0.02	2 0
Day 3	2	2.240	1.224	3.256	2.240	0.1131	2.16	2.32	2.245	2.181	2.309	2.245	-0.005	-0.958	0.948	-0.005	0.1061	-0.08	0.07	2 0
Day 5	1	2.050			2.050		2.05	2.05	2.240			2.240	-0.190			-0.190		-0.19	-0.19	0 1
Day 7	2	2.275	1.068	3.482	2.275	0.1344	2.18	2.37	2.245	2.181	2.309	2.245	0.030	-1.114	1.174	0.030	0.1273	-0.06	0.12	2 0
Day 10	1	2.290			2.290		2.29	2.29	2.240			2.240	0.050			0.050		0.05	0.05	1 0
Day 14	1	2.450			2.450		2.45	2.45												1 0
EoT	1	2.180			2.180		2.18	2.18	2.240			2.240	-0.060			-0.060		-0.06	-0.06	1 0
EoS (Day 21-28)	1	2.460			2.460		2.46	2.46												1 0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.13 Potassium [mmol/L]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	3	4.47	2.81	6.12	4.80	0.666	3.7	4.9												3	0
Baseline (D1)	3	4.47	2.81	6.12	4.80	0.666	3.7	4.9												3	0
Day 2	3	4.13	3.75	4.51	4.10	0.153	4.0	4.3	4.47	2.81	6.12	4.80	-0.33	-1.70	1.03	-0.60	0.551	-0.7	0.3	3	0
Day 3	3	4.40	3.90	4.90	4.40	0.200	4.2	4.6	4.47	2.81	6.12	4.80	-0.07	-1.83	1.70	-0.20	0.709	-0.7	0.7	3	0
Day 5	2	4.10			4.10	0.000	4.1	4.1	4.85	4.21	5.49	4.85	-0.75	-1.39	-0.11	-0.75	0.071	-0.8	-0.7	2	0
Day 7	3	4.33	3.39	5.27	4.50	0.379	3.9	4.6	4.47	2.81	6.12	4.80	-0.13	-2.44	2.17	-0.40	0.929	-0.9	0.9	3	0
Day 10	1	4.50			4.50		4.5	4.5	4.80			4.80	-0.30			-0.30		-0.3	-0.3	1	0
Day 14	1	5.50			5.50		5.5	5.5	4.90			4.90	0.60			0.60		0.6	0.6	0	1
EoT	1	3.90			3.90		3.9	3.9	4.80			4.80	-0.90			-0.90		-0.9	-0.9	1	0
EoS (Day 21-28)	3	4.57	4.42	4.71	4.60	0.058	4.5	4.6	4.47	2.81	6.12	4.80	0.10	-1.64	1.84	-0.20	0.700	-0.4	0.9	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.14 Sodium [mmol/L]

																				Out of range
----- Result -----										Baseline				---- Change from baseline ----						
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV AV
Screening (-5 to D1)	3	140.7	134.4	146.9	141.0	2.52	138	143												3 0
Baseline (D1)	3	140.7	134.4	146.9	141.0	2.52	138	143												3 0
Day 2	3	143.3	139.5	147.1	143.0	1.53	142	145	140.7	134.4	146.9	141.0	2.7	-5.3	10.7	4.0	3.21	-1	5	3 0
Day 3	3	144.0	141.5	146.5	144.0	1.00	143	145	140.7	134.4	146.9	141.0	3.3	-4.3	10.9	4.0	3.06	0	6	3 0
Day 5	2	143.5	111.7	175.3	143.5	3.54	141	146	139.5	120.4	158.6	139.5	4.0	-8.7	16.7	4.0	1.41	3	5	1 1
Day 7	3	142.3	135.2	149.5	144.0	2.89	139	144	140.7	134.4	146.9	141.0	1.7	-1.2	4.5	1.0	1.15	1	3	3 0
Day 10	1	138.0			138.0		138	138	138.0			138.0	0.0			0.0		0	0	1 0
Day 14	1	141.0			141.0		141	141	141.0			141.0	0.0			0.0		0	0	1 0
EoT	1	139.0			139.0		139	139	138.0			138.0	1.0			1.0		1	1	1 0
EoS (Day 21-28)	3	140.0			140.0	0.00	140	140	140.7	134.4	146.9	141.0	-0.7	-6.9	5.6	-1.0	2.52	-3	2	3 0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.15 Glucose [mmol/L]

																				Out of range
----- Result -----										Baseline					---- Change from baseline ----					
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV AV
Screening (-5 to D1)	2	18.15	-54.91	91.21	18.15	8.132	12.4	23.9												0 2
Baseline (D1)	2	18.15	-54.91	91.21	18.15	8.132	12.4	23.9												0 2
Day 2	1	16.00			16.00		16.0	16.0	23.90			23.90	-7.90			-7.90		-7.9	-7.9	0 1
Day 3	1	11.80			11.80		11.8	11.8	23.90			23.90	-12.10			-12.10		-12.1	-12.1	0 1
Day 5	2	11.15	-4.73	27.03	11.15	1.768	9.9	12.4	18.15	-54.91	91.21	18.15	-7.00	-95.94	81.94	-7.00	9.899	-14.0	0.0	0 2
Day 7	3	6.93	2.18	11.69	7.20	1.914	4.9	8.7	18.15	-54.91	91.21	18.15	-10.20	-92.79	72.39	-10.20	9.192	-16.7	-3.7	1 2
Day 10	1	7.10			7.10		7.1	7.1	23.90			23.90	-16.80			-16.80		-16.8	-16.8	0 1
Day 14	1	9.80			9.80		9.8	9.8	12.40			12.40	-2.60			-2.60		-2.6	-2.6	0 1
EoT	1	7.20			7.20		7.2	7.2	23.90			23.90	-16.70			-16.70		-16.7	-16.7	0 1
EoS (Day 21-28)	3	7.50	3.82	11.18	8.20	1.480	5.8	8.5	18.15	-54.91	91.21	18.15	-9.80	-80.95	61.35	-9.80	7.920	-15.4	-4.2	0 3

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.16 CRP [mg/L]

																				Out of range
----- Result -----										Baseline			---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Media n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV AV
Screening (-5 to D1)	3	68.60	-62.13	199.33	85.10	52.627	9.7	111.0												0 3
Baseline (D1)	3	68.60	-62.13	199.33	85.10	52.627	9.7	111.0												0 3
Day 2	3	42.70	-41.98	127.38	52.10	34.086	4.9	71.1	68.60	-62.13	199.33	85.10	-25.90	-72.09	20.29	-33.00	18.596	-39.9	-4.8	1 2
Day 3	3	19.93	-17.30	57.16	25.80	14.987	2.9	31.1	68.60	-62.13	199.33	85.10	-48.67	-142.30	44.97	-59.30	37.692	-79.9	-6.8	1 2
Day 5	2	10.95	1.42	20.48	10.95	1.061	10.2	11.7	98.05	-66.50	262.60	98.05	-87.10	-242.12	67.92	-87.10	17.253	-99.3	-74.9	0 2
Day 7	3	3.33	-2.68	9.34	4.20	2.419	0.6	5.2	68.60	-62.13	199.33	85.10	-65.27	-189.99	59.46	-80.90	50.210	-105.8	-9.1	2 1
Day 10	1	2.60			2.60		2.6	2.6	111.00			111.00	-108.40			-108.40		-108.4	-108.4	1 0
Day 14	1	1.60			1.60		1.6	1.6	85.10			85.10	-83.50			-83.50		-83.5	-83.5	1 0
EoT	1	5.20			5.20		5.2	5.2	111.00			111.00	-105.80			-105.80		-105.8	-105.8	0 1
EoS (Day 21-28)	3	4.67	-12.40	21.74	0.80	6.871	0.6	12.6	68.60	-62.13	199.33	85.10	-63.93	-190.85	62.99	-72.50	51.092	-110.2	-9.1	2 1

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.17 Ferritin [µg/L]

																				Out of range		
----- Result -----										Baseline				---- Change from baseline ----								
Visit	n	Mea	95%	95%						Mea	95%	95%		Mea	95%	95%	Media			N		
		n	ICI	uCI	Median	SD	Min	Max		n	ICI	uCI	Median	n	ICI	uCI	n	SD	Min	Max	V	AV
Screening (-5 to D1)	3	604.0	280.8	927.2	672.0	130.09	454	686													0	3
Baseline (D1)	3	604.0	280.8	927.2	672.0	130.09	454	686													0	3
Day 2	3	633.7	292.6	974.8	608.0	137.31	511	782	604.0	280.8	927.2	672.0	29.7	-211.1	270.5	57.0	96.93	-78	110	0	3	
Day 3	3	675.7	402.1	949.3	648.0	110.14	582	797	604.0	280.8	927.2	672.0	71.7	-164.3	307.6	125.0	94.99	-38	128	0	3	
Day 5	2	816.0			816.0	0.00	816	816	563.0	-822.0	1948.0	563.0	253.0	-1132.0	1638.0	253.0	154.15	144	362	0	2	
Day 7	3	725.7	360.2	1091.1	697.0	147.11	595	885	604.0	280.8	927.2	672.0	121.7	-337.4	580.7	213.0	184.78	-91	243	0	3	
Day 10	1	624.0			624.0		624	624	454.0			454.0	170.0			170.0		170	170	0	1	
Day 14	1	751.0			751.0		751	751	672.0			672.0	79.0			79.0		79	79	0	1	
EoT	1	697.0			697.0		697	697	454.0			454.0	243.0			243.0		243	243	0	1	
EoS (Day 21-28)	3	267.0	173.9	360.1	255.0	37.47	237	309	604.0	280.8	927.2	672.0	-337.0	-599.9	-74.1	-377.0	105.83	-417	-217	3	0	

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.9.18 Interleukin-6 [ng/L]

																				Out of range	
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Screening (-5 to D1)	2	8.70	-57.37	74.77	8.70	7.354	3.5	13.9												1	1
Baseline (D1)	2	8.70	-57.37	74.77	8.70	7.354	3.5	13.9												1	1
Day 2	1	3.50			3.50		3.5	3.5	3.50		3.50		0.00			0.00		0.0	0.0	1	0
Day 3	1	3.50			3.50		3.5	3.5	3.50		3.50		0.00			0.00		0.0	0.0	1	0
Day 5	1	3.50			3.50		3.5	3.5	3.50		3.50		0.00			0.00		0.0	0.0	1	0
Day 7	2	5.53	-11.95	23.00	5.53	1.945	4.2	6.9	3.50		3.50		3.40			3.40		3.4	3.4	2	0
Day 10	1	6.66			6.66		6.7	6.7	3.50		3.50		3.16			3.16		3.2	3.2	1	0
EoT	1	6.90			6.90		6.9	6.9	3.50		3.50		3.40			3.40		3.4	3.4	1	0
EoS (Day 21-28)	3	3.54	-0.32	7.40	4.41	1.553	1.8	4.5	8.70	-57.37	74.77	8.70	-5.62	-54.79	43.55	-5.62	5.473	-9.5	-1.8	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.10 Summary statistics and changes from baseline of immunology parameters

14.3.10.1 CD3+ abs [10⁹/L]

----- Result -----																					Baseline				---- Change from baseline ----								Out of range	
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV													
Baseline (D1)	2	328.0	-15.1	671.1	328.0	38.18	301	355												0	2													
Day 2	2	490.0	-1682.8	2662.8	490.0	241.83	319	661	328.0	-15.1	671.1	328.0	162.0	-1667.7	1991.7	162.0	203.65	18	306	0	2													
Day 3	3	801.3	670.8	931.8	826.0	52.54	741	837	328.0	-15.1	671.1	328.0	455.5	258.6	652.4	455.5	21.92	440	471	2	1													
Day 5	1	1090.0			1090.0		1090	1090												1	0													
Day 7	3	1782.7	-95.9	3661.3	1643.0	756.24	1106	2599	328.0	-15.1	671.1	328.0	1046.5	-2022.0	4115.0	1046.5	341.53	805	1288	3	0													
Day 10	1	3008.0			3008.0		3008	3008												0	1													
Day 14	1	633.0			633.0		633	633	301.0			301.0	332.0			332.0		332	332	0	1													
EoT	1	2599.0			2599.0		2599	2599												1	0													
EoS (Day 21-28)	3	1039.7	-138.2	2217.5	972.0	474.14	603	1544	328.0	-15.1	671.1	328.0	459.5	-1541.7	2460.7	459.5	222.74	302	617	2	1													

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.10.2 CD3+ [%]

																				Out of range	
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	95%	95%	Median	SD	Min	Max	Mean	95%	95%	Median	Mean	95%	95%	SD	Min	Max	NV	AV	
			ICI	uCI						ICI	uCI			ICI	uCI						
Baseline (D1)	2	50.5	44.1	56.9	50.5	0.71	50	51											0	2	
Day 2	2	55.5	36.4	74.6	55.5	2.12	54	57	50.5	44.1	56.9	50.5	5.0	-20.4	30.4	5.0	2.83	3	7	1	1
Day 3	3	56.7	50.4	62.9	57.0	2.52	54	59	50.5	44.1	56.9	50.5	7.5	-11.6	26.6	7.5	2.12	6	9	2	1
Day 5	1	63.0			63.0		63	63											1	0	
Day 7	3	68.0	61.4	74.6	67.0	2.65	66	71	50.5	44.1	56.9	50.5	16.0			16.0	0.00	16	16	3	0
Day 10	1	73.0			73.0		73	73											1	0	
Day 14	1	57.0			57.0		57	57	51.0			51.0	6.0			6.0		6	6	1	0
EoT	1	71.0			71.0		71	71											1	0	
EoS (Day 21-28)	3	64.3	50.7	78.0	67.0	5.51	58	68	50.5	44.1	56.9	50.5	12.0	-51.5	75.5	12.0	7.07	7	17	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.10.3 CD4+ abs [10⁹/L]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	Mean	ICI	95% uCI	Median	SD	Min	Max	Mean	ICI	95% uCI	Median	Mean	ICI	95% uCI	Median	SD	Min	Max	NV	AV
Baseline (D1)	2	194.0	-110.9	498.9	194.0	33.94	170	218												0	2
Day 2	2	266.0	-38.9	570.9	266.0	33.94	242	290	194.0	-110.9	498.9	194.0	72.0	-537.9	681.9	72.0	67.88	24	120	0	2
Day 3	3	487.3	380.9	593.8	481.0	42.85	448	533	194.0	-110.9	498.9	194.0	296.5	61.4	531.6	296.5	26.16	278	315	3	0
Day 5	1	692.0			692.0		692	692												1	0
Day 7	3	1239.3	-428.6	2907.2	896.0	671.43	809	2013	194.0	-110.9	498.9	194.0	658.5	-199.2	1516.2	658.5	95.46	591	726	2	1
Day 10	1	2101.0			2101.0		2101	2101												0	1
Day 14	1	455.0			455.0		455	455	218.0			218.0	237.0			237.0		237	237	1	0
EoT	1	2013.0			2013.0		2013	2013												0	1
EoS (Day 21-28)	3	592.7	-36.9	1222.2	458.0	253.43	435	885	194.0	-110.9	498.9	194.0	252.5	93.7	411.3	252.5	17.68	240	265	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.10.4 CD4+ [%]

																					Out of range
----- Result -----										Baseline				---- Change from baseline ----							
Visit	n	95%		95%	Median	SD	Min	Max	Mean	95%		95%	Mean	95%		95%	SD	Min	Max	NV	AV
		ICI	uCI	ICI						uCI	Median	ICI		uCI	Median	SD					
Baseline (D1)	2	30.5	-52.1	113.1	30.5	9.19	24	37												2	0
Day 2	2	33.0	-68.6	134.6	33.0	11.31	25	41	30.5	-52.1	113.1	30.5	2.5	-16.6	21.6	2.5	2.12	1	4	2	0
Day 3	3	34.7	21.0	48.3	32.0	5.51	31	41	30.5	-52.1	113.1	30.5	6.0	-19.4	31.4	6.0	2.83	4	8	3	0
Day 5	1	40.0			40.0		40	40												1	0
Day 7	3	46.7	22.5	70.8	49.0	9.71	36	55	30.5	-52.1	113.1	30.5	12.0			12.0	0.00	12	12	3	0
Day 10	1	51.0			51.0		51	51												1	0
Day 14	1	41.0			41.0		41	41	37.0			37.0	4.0			4.0		4	4	1	0
EoT	1	55.0			55.0		55	55												1	0
EoS (Day 21-28)	3	37.7	20.0	55.3	39.0	7.09	30	44	30.5	-52.1	113.1	30.5	6.5	0.1	12.9	6.5	0.71	6	7	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.10.5 CD8+ abs [10⁹/L]

																						Out of range	
----- Result -----										Baseline				---- Change from baseline ----									
										95%	95%			95%									
Visit	n	Mean	95% ICI	uCI	Median	SD	Min	Max	Mean	ICI	uCI	Median	Mean	95% ICI	uCI	Median	SD	Min	Max	NV	AV		
Baseline (D1)	2	56.5	-280.2	393.2	56.5	37.48	30	83												0	2		
Day 2	2	221.5	-1538.3	1981.3	221.5	195.87	83	360	56.5	-280.2	393.2	56.5	165.0	-1931.5	2261.5	165.0	233.35	0	330	1	1		
Day 3	3	304.3	95.1	513.5	341.0	84.22	208	364	56.5	-280.2	393.2	56.5	229.5	-1098.3	1557.3	229.5	147.79	125	334	3	0		
Day 5	1	398.0			398.0		398	398												1	0		
Day 7	3	525.7	-55.3	1106.6	549.0	233.87	281	747	56.5	-280.2	393.2	56.5	457.5	-2839.8	3754.8	457.5	366.99	198	717	3	0		
Day 10	1	865.0			865.0		865	865												1	0		
Day 14	1	167.0			167.0		167	167	83.0			83.0	84.0			84.0		84	84	0	1		
EoT	1	549.0			549.0		549	549												1	0		
EoS (Day 21-28)	3	426.3	-220.3	1072.9	508.0	260.29	135	636	56.5	-280.2	393.2	56.5	265.0	-2441.4	2971.4	265.0	301.23	52	478	2	1		

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.10.6 CD8+ [%]

																					Out of range
----- Result -----											Baseline				---- Change from baseline ----						
Visit	n	Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max	NV	AV
Baseline (D1)	2	19.5	-50.4	89.4	19.5	7.78	14	25												2	0
Day 2	2	22.5	-85.5	130.5	22.5	12.02	14	31	19.5	-50.4	89.4	19.5	3.0	-35.1	41.1	3.0	4.24	0	6	2	0
Day 3	3	21.3	8.8	33.8	22.0	5.03	16	26	19.5	-50.4	89.4	19.5	1.5	-4.9	7.9	1.5	0.71	1	2	3	0
Day 5	1	23.0			23.0		23	23												1	0
Day 7	3	20.7	0.4	40.9	17.0	8.14	15	30	19.5	-50.4	89.4	19.5	4.0	-8.7	16.7	4.0	1.41	3	5	3	0
Day 10	1	21.0			21.0		21	21												1	0
Day 14	1	15.0			15.0		15	15	14.0			14.0	1.0			1.0		1	1	1	0
EoT	1	15.0			15.0		15	15												1	0
EoS (Day 21-28)	3	25.3	-2.6	53.3	28.0	11.24	13	35	19.5	-50.4	89.4	19.5	4.5	-65.4	74.4	4.5	7.78	-1	10	3	0

NV = Normal value, AV = Abnormal value.

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.11 Shift tables of hematology parameters

14.3.11.1 Hemoglobin [g/L]

Visit	Baseline	
	Normal value	Abnormal value
Day 2	Normal value	3 (100%)
	Abnormal value	0
Day 3	Normal value	3 (100%)
	Abnormal value	0
Day 5	Normal value	2 (100%)
	Abnormal value	0
Day 7	Normal value	3 (100%)
	Abnormal value	0
Day 10	Normal value	0
	Abnormal value	1 (100%)
Day 14	Normal value	1 (100%)
	Abnormal value	0
EoT	Normal value	1 (100%)
	Abnormal value	0
EoS (Day 21-28)	Normal value	3 (100%)
	Abnormal value	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.2 Hematocrit [L/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	1 (100%)	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.3 Red blood cell count [$10^{12}/L$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 3	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 5	Normal value	1 (50.0%)	1 (50.0%)
	Abnormal value	0	0
Day 7	Normal value	2 (66.7%)	0
	Abnormal value	0	1 (33.3%)
Day 10	Normal value	0	0
	Abnormal value	0	1 (100%)
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	0	1 (100%)
EoS (Day 21-28)	Normal value	2 (66.7%)	0
	Abnormal value	0	1 (33.3%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.4 White blood cell count [$10^9/L$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	1 (33.3%)	0
	Abnormal value	1 (33.3%)	1 (33.3%)
Day 3	Normal value	1 (33.3%)	0
	Abnormal value	1 (33.3%)	1 (33.3%)
Day 5	Normal value	0	0
	Abnormal value	1 (50.0%)	1 (50.0%)
Day 7	Normal value	1 (33.3%)	0
	Abnormal value	1 (33.3%)	1 (33.3%)
Day 10	Normal value	0	0
	Abnormal value	1 (100%)	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	0
	Abnormal value	1 (100%)	0
EoS (Day 21-28)	Normal value	1 (33.3%)	1 (33.3%)
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.5 Platelet count [$10^9/L$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0
Day 3	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0
Day 5	Normal value	1 (50.0%)	0
	Abnormal value	1 (50.0%)	0
Day 7	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.6 Basophils [%]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.7 Eosinophils [%]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.8 Neutrophils [%]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 3	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 5	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 7	Normal value	0	2 (66.7%)
	Abnormal value	0	1 (33.3%)
Day 10	Normal value	0	1 (100%)
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	1 (100%)
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	1 (33.3%)
	Abnormal value	0	2 (66.7%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.9 Monocytes [%]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	1 (33.3%)	2 (66.7%)
	Abnormal value	0	0
Day 3	Normal value	1 (33.3%)	2 (66.7%)
	Abnormal value	0	0
Day 5	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 7	Normal value	1 (33.3%)	2 (66.7%)
	Abnormal value	0	0
Day 10	Normal value	0	1 (100%)
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	0	1 (100%)
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	2 (66.7%)
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.10 *Lymphocytes [%]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 3	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 5	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 7	Normal value	0	2 (66.7%)
	Abnormal value	0	1 (33.3%)
Day 10	Normal value	0	1 (100%)
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	1 (100%)
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	1 (33.3%)
	Abnormal value	0	2 (66.7%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.11 *Mean corpuscular volume [fL]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.12 *Mean corpuscular hemoglobin [pg]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 3	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 5	Normal value	1 (50.0%)	1 (50.0%)
	Abnormal value	0	0
Day 7	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 10	Normal value	0	1 (100%)
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	0	1 (100%)
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.13 *Mean corpuscular hemoglobin concentration [g/L]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.14 *Red cell distribution width [%]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.15 *D-dimers [µg/L]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (66.7%)	0
	Abnormal value	0	1 (33.3%)
Day 3	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 5	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 7	Normal value	2 (66.7%)	0
	Abnormal value	0	1 (33.3%)
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	0
	Abnormal value	0	1 (33.3%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.16 *Prothrombin time [s]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.17 *Activated partial thromboplastin time [s]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.11.18 *International normalized ratio*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	1 (33.3%)	1 (33.3%)
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12 Shift tables of biochemistry parameters

14.3.12.1 *Alanine aminotransferase [μ kat/L]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (66.7%)	0
	Abnormal value	0	1 (33.3%)
Day 3	Normal value	1 (33.3%)	0
	Abnormal value	1 (33.3%)	1 (33.3%)
Day 5	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 7	Normal value	1 (33.3%)	1 (33.3%)
	Abnormal value	1 (33.3%)	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.2 Aspartate aminotransferase [μ kat/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 3	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 5	Normal value	1 (50.0%)	1 (50.0%)
	Abnormal value	0	0
Day 7	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	1 (33.3%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.3 Alkaline phosphatase [μ kat/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 3	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 5	Normal value	1 (50.0%)	1 (50.0%)
	Abnormal value	0	0
Day 7	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	1 (50.0%)	1 (50.0%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.4 Lactate dehydrogenase [$\mu\text{kat/L}$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	1 (33.3%)	0
	Abnormal value	0	2 (66.7%)
Day 3	Normal value	1 (33.3%)	1 (33.3%)
	Abnormal value	0	1 (33.3%)
Day 5	Normal value	0	1 (50.0%)
	Abnormal value	1 (50.0%)	0
Day 7	Normal value	1 (33.3%)	2 (66.7%)
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	2 (66.7%)
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.5 Magnesium [mmol/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.6 Total bilirubin [$\mu\text{mol/L}$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.7 Direct bilirubin [$\mu\text{mol/L}$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 3	Normal value	1 (50.0%)	0
	Abnormal value	0	1 (50.0%)
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	0	0
	Abnormal value	1 (50.0%)	1 (50.0%)
Day 10	Normal value	0	0
	Abnormal value	1 (100%)	0
Day 14	Normal value	0	0
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	1 (100%)	0
EoS (Day 21-28)	Normal value	0	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.8 Blood urea nitrogen [mmol/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	1 (100%)	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (66.7%)	0
	Abnormal value	1 (33.3%)	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.9 Creatinine [$\mu\text{mol/L}$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.10 *Phosphorus [mmol/L]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	1 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.11 *Chloride [mmol/L]*

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.12 Calcium [mmol/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	0	0
	Abnormal value	1 (100%)	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.13 Potassium [mmol/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	1 (100%)	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.14 Sodium [mmol/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (50.0%)	0
	Abnormal value	1 (50.0%)	0
Day 7	Normal value	3 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	3 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.15 Glucose [mmol/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	0
	Abnormal value	0	1 (100%)
Day 3	Normal value	0	0
	Abnormal value	0	1 (100%)
Day 5	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 7	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 10	Normal value	0	0
	Abnormal value	0	1 (100%)
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	0
	Abnormal value	0	1 (100%)
EoS (Day 21-28)	Normal value	0	0
	Abnormal value	0	2 (100%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.16 CRP [mg/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	1 (33.3%)
	Abnormal value	0	2 (66.7%)
Day 3	Normal value	0	1 (33.3%)
	Abnormal value	0	2 (66.7%)
Day 5	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 7	Normal value	0	2 (66.7%)
	Abnormal value	0	1 (33.3%)
Day 10	Normal value	0	1 (100%)
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	0	1 (100%)
EoS (Day 21-28)	Normal value	0	2 (66.7%)
	Abnormal value	0	1 (33.3%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.17 Ferritin [ug/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 3	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 5	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 7	Normal value	0	0
	Abnormal value	0	3 (100%)
Day 10	Normal value	0	0
	Abnormal value	0	1 (100%)
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	0
	Abnormal value	0	1 (100%)
EoS (Day 21-28)	Normal value	0	3 (100%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.12.18 Interleukin-6 [ng/L]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 7	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	1 (100%)	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	0
EoT	Normal value	1 (100%)	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	1 (100%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.13 Shift tables of immunology parameters

14.3.13.1 CD3+ abs [$10^9/L$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 3	Normal value	0	1 (50.0%)
	Abnormal value	0	1 (50.0%)
Day 5	Normal value	0	0
	Abnormal value	0	0
Day 7	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	1 (50.0%)
	Abnormal value	0	1 (50.0%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.13.2 CD3+ [%]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	1 (50.0%)
	Abnormal value	0	1 (50.0%)
Day 3	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 5	Normal value	0	0
	Abnormal value	0	0
Day 7	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	2 (100%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.13.3 CD4+ abs [$10^9/L$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	0
	Abnormal value	0	2 (100%)
Day 3	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 5	Normal value	0	0
	Abnormal value	0	0
Day 7	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	0	1 (100%)
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	2 (100%)
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.13.4 CD4+ [%]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	0	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.13.5 CD8+ abs [$10^9/L$]

		Baseline	
Visit		Normal value	Abnormal value
Day 2	Normal value	0	1 (50.0%)
	Abnormal value	0	1 (50.0%)
Day 3	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 5	Normal value	0	0
	Abnormal value	0	0
Day 7	Normal value	0	2 (100%)
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	0	0
	Abnormal value	0	1 (100%)
EoT	Normal value	0	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	0	1 (50.0%)
	Abnormal value	0	1 (50.0%)

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.
Baseline is defined as the last value measured prior to the study treatment start.

14.3.13.6 CD8+ [%]

Visit		Baseline	
		Normal value	Abnormal value
Day 2	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 3	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 5	Normal value	0	0
	Abnormal value	0	0
Day 7	Normal value	2 (100%)	0
	Abnormal value	0	0
Day 10	Normal value	0	0
	Abnormal value	0	0
Day 14	Normal value	1 (100%)	0
	Abnormal value	0	0
EoT	Normal value	0	0
	Abnormal value	0	0
EoS (Day 21-28)	Normal value	2 (100%)	0
	Abnormal value	0	0

Percentage of subjects is calculated based on the number of subjects attending the corresponding visit.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.14 Summary statistics and changes from baseline

14.3.14.1 Summary statistics and changes from baseline of Systolic blood pressure [mmHg]

Visit	n	Result							Baseline				Change from baseline						
		Mean	95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max
Screening (-5 to D1)	3	136.7	117.7	155.6	135.0	7.64	130	145											
Baseline (D1)	3	139.3	119.1	159.6	143.0	8.14	130	145											
Day 2	3	120.7	72.9	168.4	124.0	19.22	100	138	139.3	119.1	159.6	143.0	-18.7	-75.3	38.0	-6.0	22.81	-45	-5
Day 3	3	138.3	100.4	176.3	135.0	15.28	125	155	139.3	119.1	159.6	143.0	-1.0	-42.8	40.8	5.0	16.82	-20	12
Day 4	3	139.0	134.7	143.3	140.0	1.73	137	140	139.3	119.1	159.6	143.0	-0.3	-23.4	22.7	-3.0	9.29	-8	10
Day 5	2	140.5	57.9	223.1	140.5	9.19	134	147	144.0	131.3	156.7	144.0	-3.5	-98.8	91.8	-3.5	10.61	-11	4
Day 6	2	137.5	42.2	232.8	137.5	10.61	130	145	144.0	131.3	156.7	144.0	-6.5	-114.5	101.5	-6.5	12.02	-15	2
Day 7	2	132.5	100.7	164.3	132.5	3.54	130	135	144.0	131.3	156.7	144.0	-11.5	-56.0	33.0	-11.5	4.95	-15	-8
Day 8	1	140.0			140.0		140	140	145.0			145.0	-5.0			-5.0		-5	-5
Day 9	1	134.0			134.0		134	134	145.0			145.0	-11.0			-11.0		-11	-11
Day 14	1	138.0			138.0		138	138	145.0			145.0	-7.0			-7.0		-7	-7
EoT	1	135.0			135.0		135	135	143.0			143.0	-8.0			-8.0		-8	-8
EoS (Day 21-28)	3	130.7	103.2	158.1	132.0	11.06	119	141	139.3	119.1	159.6	143.0	-8.7	-42.5	25.2	-4.0	13.61	-24	2

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.14.2 Summary statistics and changes from baseline of Diastolic blood pressure [mmHg]

Visit	n	Mean	----- Result -----					Baseline					---- Change from baseline ----						
			95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max
Screening (-5 to D1)	3	83.7	56.4	110.9	80.0	10.97	75	96											
Baseline (D1)	3	82.3	60.6	104.0	80.0	8.74	75	92											
Day 2	3	71.7	57.3	86.0	75.0	5.77	65	75	82.3	60.6	104.0	80.0	-10.7	-25.6	4.3	-10.0	6.03	-17	-5
Day 3	3	76.7	50.8	102.5	80.0	10.41	65	85	82.3	60.6	104.0	80.0	-5.7	-30.7	19.3	-7.0	10.07	-15	5
Day 4	3	81.7	74.5	88.8	80.0	2.89	80	85	82.3	60.6	104.0	80.0	-0.7	-15.6	14.3	0.0	6.03	-7	5
Day 5	2	77.5	71.1	83.9	77.5	0.71	77	78	83.5	-24.5	191.5	83.5	-6.0	-107.6	95.6	-6.0	11.31	-14	2
Day 6	2	85.0	-42.1	212.1	85.0	14.14	75	95	83.5	-24.5	191.5	83.5	1.5	-17.6	20.6	1.5	2.12	0	3
Day 7	2	87.0	48.9	125.1	87.0	4.24	84	90	83.5	-24.5	191.5	83.5	3.5	-66.4	73.4	3.5	7.78	-2	9
Day 8	1	80.0			80.0		80	80	75.0			75.0	5.0			5.0		5	5
Day 9	1	86.0			86.0		86	86	75.0			75.0	11.0			11.0		11	11
Day 14	1	80.0			80.0		80	80	75.0			75.0	5.0			5.0		5	5
EoT	1	90.0			90.0		90	90	92.0			92.0	-2.0			-2.0		-2	-2
EoS (Day 21-28)	3	85.0	72.6	97.4	85.0	5.00	80	90	82.3	60.6	104.0	80.0	2.7	-31.2	36.6	5.0	13.65	-12	15

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.14.3 Summary statistics and changes from baseline of Pulse [bpm]

Visit	n	Mean	----- Result -----					Baseline					---- Change from baseline ----						
			95% ICI	95% uCI	Median	SD	Min	Max	Mean	95% ICI	95% uCI	Median	Mean	95% ICI	95% uCI	Median	SD	Min	Max
Screening (-5 to D1)	3	82.7	22.2	143.1	78.0	24.34	61	109											
Baseline (D1)	3	67.0	43.3	90.7	62.0	9.54	61	78											
Day 2	3	70.3	46.7	93.9	70.0	9.50	61	80	67.0	43.3	90.7	62.0	3.3	-31.5	38.1	-1.0	14.01	-8	19
Day 3	3	69.7	56.0	83.3	70.0	5.51	64	75	67.0	43.3	90.7	62.0	2.7	-12.3	17.6	2.0	6.03	-3	9
Day 4	3	60.3	43.4	77.2	58.0	6.81	55	68	67.0	43.3	90.7	62.0	-6.7	-14.3	0.9	-6.0	3.06	-10	-4
Day 5	2	82.0	-95.9	259.9	82.0	19.80	68	96	61.5	55.1	67.9	61.5	20.5	-151.0	192.0	20.5	19.09	7	34
Day 6	2	68.0			68.0	0.00	68	68	61.5	55.1	67.9	61.5	6.5	0.1	12.9	6.5	0.71	6	7
Day 7	2	63.0	50.3	75.7	63.0	1.41	62	64	61.5	55.1	67.9	61.5	1.5	-17.6	20.6	1.5	2.12	0	3
Day 8	1	60.0			60.0		60	60	61.0			61.0	-1.0			-1.0		-1	-1
Day 9	1	75.0			75.0		75	75	61.0			61.0	14.0			14.0		14	14
Day 14	1	85.0			85.0		85	85	61.0			61.0	24.0			24.0		24	24
EoT	1	62.0			62.0		62	62	62.0			62.0	0.0			0.0		0	0
EoS (Day 21-28)	3	90.7	72.4	109.0	88.0	7.37	85	99	67.0	43.3	90.7	62.0	23.7	-15.2	62.5	26.0	15.63	7	38

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.14.4 Summary statistics and changes from baseline of Respiratory rate [bpm]

			----- Result -----							Baseline				---- Change from baseline ----						
Visit	n	Mean	95%	95%	Median	SD	Min	Max	95%	95%	Median	Mean	95%	95%	Median	SD	Min	Max		
			ICI	uCI					ICI	uCI			ICI	uCI						
Screening (-5 to D1)	3	13.3	7.6	19.1	12.0	2.31	12	16												
Baseline (D1)	3	14.7	8.9	20.4	16.0	2.31	12	16												
Day 2	3	14.7	8.9	20.4	16.0	2.31	12	16	14.7	8.9	20.4	16.0	0.0			0.0	0.00	0	0	
Day 3	3	14.3	9.2	19.5	15.0	2.08	12	16	14.7	8.9	20.4	16.0	-0.3	-1.8	1.1	0.0	0.58	-1	0	
Day 4	3	14.7	8.9	20.4	16.0	2.31	12	16	14.7	8.9	20.4	16.0	0.0			0.0	0.00	0	0	
Day 5	2	15.5	9.1	21.9	15.5	0.71	15	16	16.0			16.0	-0.5	-6.9	5.9	-0.5	0.71	-1	0	
Day 6	2	14.0			14.0	0.00	14	14	16.0			16.0	-2.0			-2.0	0.00	-2	-2	
Day 7	2	14.0			14.0	0.00	14	14	16.0			16.0	-2.0			-2.0	0.00	-2	-2	
Day 8	1	14.0			14.0		14	14	16.0			16.0	-2.0			-2.0		-2	-2	
Day 9	1	12.0			12.0		12	12	16.0			16.0	-4.0			-4.0		-4	-4	
Day 14	1	12.0			12.0		12	12	16.0			16.0	-4.0			-4.0		-4	-4	
EoT	1	14.0			14.0		14	14	16.0			16.0	-2.0			-2.0		-2	-2	
EoS (Day 21-28)	3	12.0			12.0	0.00	12	12	14.7	8.9	20.4	16.0	-2.7	-8.4	3.1	-4.0	2.31	-4	0	

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.

14.3.14.5 Summary statistics and changes from baseline of Temperature [°C]

----- Result -----																			Baseline				---- Change from baseline ----							
Visit	n	Mean	95%		Median	SD	Min	Max	Mean	95%		Mean	95%	Mean	95%		SD	Min	Max											
			ICI	uCI						ICI	uCI				ICI	uCI														
Screening (-5 to D1)	3	36.50	36.07	36.93	36.40	0.173	36.4	36.7																						
Baseline (D1)	3	36.60	36.17	37.03	36.70	0.173	36.4	36.7																						
Day 2	3	36.60	36.10	37.10	36.60	0.200	36.4	36.8	36.60	36.17	37.03	36.70	-0.00	-0.25	0.25	0.00	0.100	-0.1	0.1											
Day 3	3	36.43	36.15	36.72	36.50	0.115	36.3	36.5	36.60	36.17	37.03	36.70	-0.17	-0.31	-0.02	-0.20	0.058	-0.2	-0.1											
Day 4	3	36.50	35.75	37.25	36.50	0.300	36.2	36.8	36.60	36.17	37.03	36.70	-0.10	-0.53	0.33	-0.20	0.173	-0.2	0.1											
Day 5	2	36.55	35.91	37.19	36.55	0.071	36.5	36.6	36.70			36.70	-0.15	-0.79	0.49	-0.15	0.071	-0.2	-0.1											
Day 6	2	36.50	35.23	37.77	36.50	0.141	36.4	36.6	36.70			36.70	-0.20	-1.47	1.07	-0.20	0.141	-0.3	-0.1											
Day 7	2	36.40			36.40	0.000	36.4	36.4	36.70			36.70	-0.30			-0.30	0.000	-0.3	-0.3											
Day 8	1	36.50			36.50		36.5	36.5	36.70			36.70	-0.20			-0.20		-0.2	-0.2											
Day 9	1	36.50			36.50		36.5	36.5	36.70			36.70	-0.20			-0.20		-0.2	-0.2											
Day 14	1	36.70			36.70		36.7	36.7	36.70			36.70	0.00			0.00		0.0	0.0											
EoT	1	36.40			36.40		36.4	36.4	36.70			36.70	-0.30			-0.30		-0.3	-0.3											
EoS (Day 21-28)	3	36.57	36.28	36.85	36.50	0.115	36.5	36.7	36.60	36.17	37.03	36.70	-0.03	-0.41	0.35	0.00	0.153	-0.2	0.1											

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.

Baseline is defined as the last value measured prior to the study treatment start.