表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=57)		TAK-385 10mg (N=48)		TAK-385 20mg (N=55)		TAK-385 40mg (N=54)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 0								
N	57		48		55		54	
Mean	0.67		0.74		0.69		0.72	
SD	0.394		0.500		0.418		0.386	
Minimum	0.1		0.0		0.2		0.2	
Q1	0.40		0.40		0.40		0.40	
Median	0.60		0.60		0.60		0.65	
Q3	0.90		0.95		1.00		1.00	
Maximum	2.0		2.3		2.0		1.9	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	0.66	-0.02	0.79	0.05	0.84	0.15	0.78	0.06
SD	0.461	0.284	0.598	0.455	0.536	0.411	0.454	0.440
Minimum	0.1	-0.5	0.0	-1.0	0.0	-0.6	0.2	-0.9
Q1	0.30	-0.20	0.40	-0.10	0.50	-0.10	0.50	-0.20
Median	0.60	0.00	0.60	0.00	0.70	0.10	0.70	0.00
Q3	0.80	0.10	0.95	0.20	1.10	0.30	1.00	0.30
Maximum	2.3	1.1	3.3	1.3	2.8	2.1	2.1	1.6
Week 8								
N	56	56	48	48	54	54	54	54
Mean	0.66	-0.01	0.70	-0.04	0.76	0.06	0.76	0.04
SD	0.346	0.308	0.489	0.423	0.455	0.331	0.518	0.465
Minimum	0.0	-1.0	0.0	-1.3	0.2	-0.9	0.2	-0.8
Q1	0.40	-0.20	0.40	-0.25	0.40	-0.10	0.40	-0.20
Median	0.60	0.00	0.60	0.00	0.60	0.05	0.70	0.00
Q3	0.90	0.10	0.75	0.20	0.90	0.30	0.90	0.20
Maximum	1.6	0.7	2.8	1.1	2.3	1.2	2.7	1.6
Week 12								
N	55	55	47	47	53	53	54	54
Mean	0.65	-0.02	0.70	-0.03	0.77	0.07	0.68	-0.04
SD	0.401	0.282	0.518	0.444	0.472	0.329	0.359	0.338
Minimum	0.1	-0.6	0.0	-0.8	0.2	-0.7	0.1	-1.0
Q1	0.30	-0.20	0.40	-0.30	0.40	-0.10	0.40	-0.30
Median	0.60	0.00	0.50	0.00	0.60	0.10	0.60	0.00
Q3	0.80	0.10	0.90	0.20	1.00	0.30	0.90	0.10
Maximum	2.1	0.8	2.7	1.5	2.3	0.9	1.8	0.9

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	0.67	0.00	0.68	-0.06	0.67	-0.02	0.57	-0.15
SD	0.332	0.271	0.636	0.527	0.390	0.380	0.309	0.347
Minimum	0.2	-0.6	0.0	-0.9	0.2	-0.8	0.1	-1.2
Q1	0.50	-0.20	0.35	-0.40	0.40	-0.30	0.30	-0.30
Median	0.60	0.00	0.50	-0.05	0.60	0.10	0.50	-0.10
Q3	0.90	0.10	0.85	0.10	0.90	0.20	0.70	0.00
Maximum	1.6	0.7	3.2	2.3	2.4	1.3	1.3	0.6

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	28.40		33.11		29.57		28.51	
SD	6.533		8.219		8.124		6.453	
Minimum	16.8		8.4		13.7		11.8	
Q1	22.80		28.90		23.50		23.80	
Median	27.40		33.20		28.20		28.80	
Q3	32.40		38.70		36.20		33.00	
Maximum	43.4		47.7		45.2		43.2	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	29.43	1.03	32.92	-0.20	33.55	3.98	32.92	4.41
SD	6.288	6.105	6.860	8.185	7.674	6.608	7.926	7.153
Minimum	16.9	-19.3	17.6	-20.4	18.9	-10.6	11.6	-10.7
Q1	25.30	-2.40	28.45	-5.05	28.40	-0.40	27.60	0.30
Median	29.20	1.30	32.65	-0.40	32.70	4.10	33.60	3.75
Q3	33.70	4.70	37.15	2.95	38.60	8.50	37.10	7.40
Maximum	44.3	14.2	51.8	20.0	50.5	20.2	52.7	27.4
Week 8								
N	56	56	48	48	54	54	54	54
Mean	29.01	0.61	33.53	0.42	34.40	4.72	32.79	4.27
SD	7.479	7.902	7.427	7.240	7.574	6.842	7.971	8.381
Minimum	11.5	-23.1	19.5	-18.1	19.3	-7.9	17.9	-10.0
Q1	25.20	-4.05	28.95	-3.25	30.70	0.00	27.20	-2.30
Median	28.05	-0.10	33.10	-0.55	33.50	4.65	31.80	3.10
Q3	34.25	5.40	36.45	5.05	38.90	8.10	38.00	7.50
Maximum	44.4	22.7	53.1	19.8	57.9	21.9	53.4	32.9
Week 12								
N	55	55	47	47	53	53	54	54
Mean	27.48	-1.11	33.53	0.65	33.00	3.48	32.79	4.28
SD	7.503	7.144	6.891	6.461	7.531	6.878	8.350	8.023
Minimum	9.1	-24.1	19.4	-12.0	7.1	-11.3	10.2	-15.6
Q1	22.80	-4.20	28.10	-3.10	28.90	-1.70	27.50	0.20
Median	27.50	-0.70	32.30	-0.10	33.20	3.40	32.40	3.75
Q3	32.80	2.30	37.80	3.90	37.70	8.00	39.30	7.60
Maximum	40.7	16.7	48.0	19.3	48.3	17.5	51.4	27.5

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	28.74	0.34	31.44	-1.68	30.74	1.17	29.34	0.83
SD	6.400	6.613	7.189	8.624	6.773	6.248	6.188	6.486
Minimum	15.1	-19.3	16.2	-25.4	20.3	-11.3	19.0	-13.4
Q1	24.60	-3.40	26.80	-4.10	25.90	-4.20	24.50	-3.10
Median	28.20	1.00	31.10	-2.30	30.20	1.60	29.40	0.40
Q3	33.40	4.90	36.15	4.05	34.00	5.80	33.40	3.90
Maximum	42.8	14.8	51.2	19.3	52.5	12.8	52.3	26.1

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	5.84		5.57		5.62		5.50	
SD	1.700		1.329		1.304		1.319	
Minimum	3.5		3.4		3.5		2.7	
Q1	4.50		4.60		4.60		4.60	
Median	5.40		5.50		5.30		5.45	
Q3	6.90		6.25		6.40		6.50	
Maximum	10.9		8.9		9.8		8.0	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	5.85	0.01	5.90	0.33	5.66	0.03	5.42	-0.08
SD	1.647	1.443	1.839	1.345	1.543	1.204	1.159	1.296
Minimum	2.7	-4.1	3.4	-2.5	2.9	-3.5	3.2	-2.5
Q1	4.80	-0.70	4.70	-0.30	4.80	-0.60	4.50	-0.60
Median	5.50	0.10	5.50	0.25	5.40	-0.10	5.40	-0.15
Q3	6.40	0.80	6.50	0.90	6.30	0.70	6.00	0.60
Maximum	11.9	5.4	12.3	3.7	11.2	4.2	8.3	4.2
Week 8								
N	56	56	48	48	54	54	54	54
Mean	5.80	-0.03	5.91	0.34	5.44	-0.15	5.36	-0.14
SD	1.431	1.294	1.887	1.501	1.197	0.960	1.329	1.264
Minimum	2.8	-3.8	3.6	-1.9	3.4	-3.1	2.6	-4.0
Q1	4.90	-0.70	4.75	-0.70	4.50	-0.60	4.40	-0.80
Median	5.50	-0.05	5.25	0.15	5.40	-0.15	5.40	-0.10
Q3	6.80	0.75	6.75	1.00	6.30	0.50	6.10	0.50
Maximum	9.5	2.7	11.9	5.7	8.7	2.5	9.5	2.6
Week 12								
N	55	55	47	47	53	53	54	54
Mean	5.50	-0.23	5.72	0.22	5.36	-0.25	5.31	-0.19
SD	1.483	1.335	1.405	1.000	1.095	1.013	1.332	1.216
Minimum	3.1	-4.7	3.6	-2.3	3.6	-3.3	2.4	-2.3
Q1	4.30	-0.90	4.60	-0.30	4.60	-0.70	4.40	-1.00
Median	5.10	-0.20	5.80	0.30	5.10	-0.20	5.20	-0.35
Q3	6.90	0.50	6.80	0.60	6.10	0.20	6.00	0.50
Maximum	9.4	3.6	9.5	3.6	8.3	2.5	8.9	3.8

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	5.83	-0.01	5.90	0.32	5.56	-0.06	5.76	0.27
SD	1.592	1.261	1.436	1.082	1.237	1.165	1.527	1.518
Minimum	3.3	-3.0	3.2	-2.0	3.5	-2.9	3.2	-3.1
Q1	4.70	-0.50	4.75	-0.60	4.70	-1.00	4.70	-0.70
Median	5.60	-0.10	5.60	0.40	5.30	0.20	5.50	0.20
Q3	6.90	0.70	7.00	0.95	6.40	0.80	6.40	1.00
Maximum	11.5	3.5	9.1	2.7	8.5	2.0	11.3	5.7

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCH (pg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	27.78		27.72		28.10		27.56	
SD	2.890		2.419		2.808		2.885	
Minimum	20.3		23.0		22.3		19.4	
Q1	25.50		26.00		26.00		25.30	
Median	28.00		27.80		28.80		28.20	
Q3	30.50		29.65		30.40		29.60	
Maximum	33.0		33.3		32.5		32.6	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	28.13	0.35	27.83	0.11	28.19	0.09	27.50	-0.06
SD	2.799	1.165	2.366	1.081	2.721	1.182	3.209	1.058
Minimum	21.8	-3.4	23.5	-1.5	20.8	-2.8	17.4	-3.4
Q1	26.40	-0.40	26.15	-0.70	26.50	-0.70	25.60	-0.50
Median	28.60	0.10	27.80	-0.15	28.80	-0.10	28.30	-0.05
Q3	30.30	1.30	29.80	0.55	30.30	0.60	30.10	0.30
Maximum	33.1	3.7	33.2	2.9	32.4	3.5	32.3	2.8
Week 8								
N	56	56	48	48	54	54	54	54
Mean	28.26	0.34	27.92	0.20	28.21	0.16	27.62	0.06
SD	3.068	1.862	2.562	1.496	2.659	1.703	3.281	1.495
Minimum	18.7	-6.8	23.2	-3.2	21.1	-3.9	17.7	-4.9
Q1	26.55	-0.60	26.25	-0.70	27.20	-0.80	26.40	-0.60
Median	28.90	0.00	27.80	0.10	28.40	-0.20	28.80	0.10
Q3	30.65	1.25	29.70	0.55	30.10	0.80	29.70	0.70
Maximum	33.2	5.3	33.4	4.2	32.1	4.6	31.8	3.9
Week 12								
N	55	55	47	47	53	53	54	54
Mean	28.40	0.44	28.03	0.28	28.39	0.43	27.79	0.24
SD	2.931	2.085	2.770	1.941	2.709	2.026	3.088	1.708
Minimum	22.0	-3.5	22.7	-4.9	21.1	-4.1	18.4	-4.7
Q1	26.70	-0.80	25.60	-0.80	28.00	-0.80	26.40	-0.60
Median	29.30	-0.10	28.30	0.00	29.10	0.10	28.85	0.20
Q3	30.80	0.70	30.30	0.90	30.20	1.00	29.70	0.80
Maximum	32.3	6.8	33.4	5.1	32.3	5.3	31.8	5.3

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCH (pg)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	28.08	0.30	28.03	0.31	28.79	0.69	28.22	0.66
SD	3.192	2.201	2.942	2.234	2.802	2.302	3.094	2.005
Minimum	21.3	-4.3	21.2	-6.4	20.9	-4.3	18.2	-3.4
Q1	26.40	-0.80	26.45	-0.80	28.20	-0.50	26.90	-0.50
Median	28.90	-0.30	28.45	0.15	29.40	0.30	29.10	0.45
Q3	30.50	1.60	30.10	0.75	30.60	1.00	30.10	1.40
Maximum	33.1	5.5	33.2	6.4	32.3	6.6	32.4	7.4

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCHC (%)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	31.50		31.61		31.71		31.36	
SD	1.237		1.068		1.103		1.334	
Minimum	28.2		28.4		29.6		27.1	
Q1	30.70		31.10		30.90		30.70	
Median	31.50		31.70		31.80		31.55	
Q3	32.50		32.25		32.50		32.40	
Maximum	33.8		33.7		33.9		33.7	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	31.65	0.14	31.79	0.18	31.87	0.16	31.45	0.09
SD	1.164	0.720	0.913	0.824	1.173	0.833	1.454	0.787
Minimum	28.6	-1.6	29.9	-1.4	28.3	-1.6	26.0	-1.7
Q1	31.00	-0.40	31.25	-0.40	31.10	-0.30	30.80	-0.40
Median	31.80	0.10	31.80	0.15	32.20	0.10	31.70	0.00
Q3	32.30	0.50	32.50	0.60	32.70	0.70	32.40	0.60
Maximum	33.8	2.4	33.5	2.3	34.0	2.3	34.0	2.1
Week 8								
N	56	56	48	48	54	54	54	54
Mean	31.70	0.14	31.82	0.21	31.85	0.18	31.73	0.37
SD	1.351	0.949	0.868	0.863	1.173	0.982	1.510	0.878
Minimum	27.9	-3.3	29.9	-1.2	28.8	-1.9	26.0	-1.6
Q1	31.10	-0.35	31.20	-0.30	31.20	-0.50	31.10	-0.10
Median	31.80	0.15	31.95	0.10	32.10	0.10	32.10	0.25
Q3	32.65	0.70	32.40	0.70	32.60	0.70	32.60	0.90
Maximum	34.2	2.2	33.5	2.9	34.2	2.9	34.7	2.5
Week 12								
N	55	55	47	47	53	53	54	54
Mean	31.67	0.11	31.84	0.23	31.89	0.24	31.76	0.41
SD	1.129	0.955	0.947	1.061	1.380	1.004	1.368	0.936
Minimum	29.2	-1.6	30.0	-1.7	28.3	-2.2	26.0	-1.7
Q1	30.80	-0.60	31.00	-0.40	31.20	-0.40	31.40	-0.10
Median	31.70	0.00	32.00	0.10	32.20	0.00	31.85	0.30
Q3	32.40	0.60	32.50	0.90	32.60	0.90	32.60	0.80
Maximum	33.8	2.9	33.6	3.5	35.0	2.6	34.1	3.5

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCHC (%)

Visit / Statistics	Placebo (N=57)		TAK-385 10mg (N=48)		TAK-385 20mg (N=55)		TAK-385 40mg (N=54)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	31.51	0.01	31.83	0.21	31.95	0.24	31.93	0.57
SD	1.391	1.077	0.996	1.088	1.204	0.916	1.293	0.957
Minimum	27.1	-2.2	29.0	-2.7	28.8	-1.8	26.7	-1.3
Q1	30.50	-0.70	31.45	-0.45	31.40	-0.30	31.40	-0.10
Median	31.80	-0.10	31.80	0.20	32.20	0.20	32.15	0.60
Q3	32.30	0.50	32.65	0.70	32.70	0.80	32.80	1.00
Maximum	34.1	3.0	33.8	3.5	34.8	2.2	33.8	3.6

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCV (fL)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	88.03		87.61		88.48		87.73	
SD	6.812		5.751		6.572		6.645	
Minimum	71.9		76.7		74.5		71.2	
Q1	82.60		83.70		83.10		84.10	
Median	88.80		87.50		90.60		88.35	
Q3	93.80		91.10		93.20		92.60	
Maximum	98.7		103.4		100.0		102.8	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	88.77	0.74	87.44	-0.16	88.29	-0.19	87.21	-0.52
SD	6.759	2.484	5.542	2.171	6.241	2.369	7.390	2.303
Minimum	73.4	-7.1	76.6	-5.9	73.5	-6.3	67.0	-7.1
Q1	85.00	-0.40	83.80	-1.30	84.40	-1.50	82.10	-1.80
Median	89.00	0.30	87.80	-0.35	89.50	-0.40	89.15	-0.60
Q3	94.30	1.90	91.10	1.05	92.30	0.60	92.40	0.60
Maximum	99.8	7.7	101.8	5.2	100.7	6.5	102.0	4.5
Week 8								
N	56	56	48	48	54	54	54	54
Mean	88.98	0.66	87.63	0.02	88.37	-0.03	86.78	-0.95
SD	7.490	3.983	6.179	3.054	6.030	3.654	7.366	3.260
Minimum	67.0	-14.7	76.9	-6.6	71.7	-9.4	64.7	-12.1
Q1	85.35	-1.05	83.00	-1.65	85.60	-2.30	82.40	-2.80
Median	89.10	-0.15	86.75	-0.45	89.15	-0.55	89.35	-0.90
Q3	94.55	2.90	92.00	1.45	92.70	0.60	91.80	1.40
Maximum	101.2	12.0	101.0	7.9	97.6	10.6	98.4	6.3
Week 12								
N	55	55	47	47	53	53	54	54
Mean	89.55	1.11	87.86	0.15	88.90	0.72	87.27	-0.46
SD	7.564	4.756	6.667	4.036	6.087	4.668	7.095	3.847
Minimum	71.9	-10.3	75.7	-10.9	72.3	-8.9	65.4	-11.4
Q1	85.60	-1.50	82.70	-2.10	85.70	-1.60	83.10	-1.80
Median	90.20	-0.30	88.00	-0.20	90.10	0.00	89.20	-0.20
Q3	94.80	3.30	93.50	2.20	92.30	1.90	92.20	0.90
Maximum	104.0	15.0	103.2	11.5	98.0	15.6	97.3	9.0

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCV (fL)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	88.94	0.91	87.92	0.32	89.94	1.46	88.20	0.47
SD	7.835	4.826	7.270	4.791	6.617	5.508	7.329	4.346
Minimum	71.7	-10.2	73.3	-13.1	71.6	-11.3	67.9	-8.9
Q1	85.60	-2.20	82.75	-1.80	87.20	-1.00	83.90	-1.50
Median	89.70	-0.80	87.65	-0.40	91.70	0.50	89.65	-0.10
Q3	95.20	4.40	94.10	1.85	93.40	3.30	93.10	2.30
Maximum	101.0	11.9	102.2	12.7	100.7	16.8	100.0	13.4

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Reticulocytes (permil)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Week 0								
N	57		48		55		54	
Mean	10.6		10.6		10.4		10.8	
SD	4.91		3.71		3.22		3.95	
Minimum	5		3		4		6	
Q1	8.0		7.5		8.0		8.0	
Median	10.0		11.0		11.0		10.0	
Q3	12.0		13.5		12.0		13.0	
Maximum	39		18		20		28	
Week 4								
N	57	57	48	48	55	55	54	54
Mean	11.6	1.0	10.2	-0.4	8.9	-1.5	9.5	-1.3
SD	5.80	3.57	2.93	2.57	3.10	2.39	3.44	3.14
Minimum	5	-8	4	-11	4	-8	4	-13
Q1	8.0	-1.0	8.0	-1.0	7.0	-3.0	8.0	-3.0
Median	11.0	1.0	10.0	0.0	9.0	-1.0	9.0	-1.0
Q3	13.0	3.0	12.5	1.0	11.0	0.0	11.0	0.0
Maximum	40	14	16	5	19	4	26	10
Week 8								
N	56	56	48	48	54	54	54	54
Mean	11.1	0.4	10.6	0.0	9.5	-0.9	9.4	-1.4
SD	4.27	4.57	3.10	2.94	3.41	2.94	2.80	3.92
Minimum	4	-22	4	-9	4	-8	5	-20
Q1	8.0	-1.0	8.0	-1.0	8.0	-3.0	8.0	-3.0
Median	10.0	0.0	10.5	0.0	9.0	-1.0	9.0	-1.0
Q3	13.0	2.5	12.5	1.5	11.0	1.0	11.0	1.0
Maximum	30	11	18	6	21	7	16	6
Week 12								
N	55	55	47	47	53	53	54	54
Mean	11.2	0.6	11.1	0.4	10.2	-0.1	9.6	-1.3
SD	3.86	5.46	3.36	3.43	3.03	2.83	2.76	3.63
Minimum	3	-32	4	-7	5	-5	4	-18
Q1	9.0	-1.0	9.0	-2.0	8.0	-2.0	8.0	-3.0
Median	10.0	0.0	11.0	0.0	10.0	0.0	9.0	-1.0
Q3	14.0	2.0	14.0	2.0	12.0	2.0	11.0	1.0
Maximum	23	10	18	9	16	8	18	5

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-21　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-001 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Reticulocytes (permil)

Visit / Statistics	Placebo (N=57) Observed Value at Visit	Placebo (N=57) Change from Baseline	TAK-385 10mg (N=48) Observed Value at Visit	TAK-385 10mg (N=48) Change from Baseline	TAK-385 20mg (N=55) Observed Value at Visit	TAK-385 20mg (N=55) Change from Baseline	TAK-385 40mg (N=54) Observed Value at Visit	TAK-385 40mg (N=54) Change from Baseline
Follow-up								
N	57	57	48	48	55	55	54	54
Mean	12.8	2.1	11.8	1.2	12.6	2.2	13.0	2.2
SD	7.27	7.49	3.77	3.42	4.30	4.48	4.65	4.50
Minimum	5	-19	4	-4	6	-4	5	-12
Q1	9.0	0.0	9.0	-1.0	9.0	-1.0	10.0	-1.0
Median	11.0	1.0	12.0	1.0	12.0	2.0	12.0	2.0
Q3	15.0	3.0	14.0	3.0	16.0	5.0	16.0	5.0
Maximum	53	43	18	11	26	22	25	15

治験総括報告書 Table 3.3.1.1.1（Section 16.1.9.5）（5.3.5.1-1）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	414.9		416.1	
SD	35.87		40.59	
Minimum	263		311	
Q1	392.0		389.0	
Median	415.5		417.5	
Q3	440.0		442.0	
Maximum	508		518	
Week 4				
N	138	138	142	142
Mean	444.7	29.8	435.5	19.4
SD	36.37	25.58	43.05	25.79
Minimum	320	-21	307	-57
Q1	418.0	13.0	408.0	3.0
Median	442.0	28.5	437.5	19.0
Q3	467.0	47.0	467.0	36.0
Maximum	572	112	552	78
Week 8				
N	135	135	142	142
Mean	457.2	41.2	452.2	36.2
SD	33.60	36.48	37.96	28.19
Minimum	362	-60	307	-36
Q1	434.0	17.0	428.0	18.0
Median	457.0	37.0	447.0	35.0
Q3	476.0	61.0	482.0	55.0
Maximum	575	180	573	106

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	459.2	43.1	456.0	39.8
SD	35.56	38.55	37.32	33.62
Minimum	379	-29	347	-40
Q1	437.0	18.0	430.0	21.0
Median	458.0	36.0	452.0	35.0
Q3	487.0	62.0	482.0	65.0
Maximum	556	161	556	114
Week 16				
N	129	129	136	136
Mean	454.2	38.4	451.6	36.6
SD	34.48	40.00	34.78	35.11
Minimum	375	-51	353	-55
Q1	431.0	14.0	429.5	15.0
Median	453.0	32.0	451.0	35.0
Q3	476.0	57.0	474.5	57.0
Maximum	541	156	546	133
Week 20				
N	126	126	132	132
Mean	451.3	35.4	451.7	35.8
SD	35.59	38.74	35.64	33.19
Minimum	373	-49	360	-37
Q1	427.0	10.0	429.0	13.0
Median	448.5	26.0	450.0	35.0
Q3	471.0	52.0	474.5	57.5
Maximum	562	156	560	124

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	451.5	35.3	449.0	33.3
SD	31.32	34.06	35.58	29.14
Minimum	367	-41	365	-46
Q1	429.0	11.0	423.0	11.0
Median	448.5	30.5	448.0	37.0
Q3	473.0	55.0	475.0	49.0
Maximum	538	139	549	108
Follow-up				
N	135	135	141	141
Mean	438.8	23.1	451.1	35.2
SD	33.70	32.49	34.85	30.97
Minimum	352	-39	368	-34
Q1	416.0	-1.0	427.0	16.0
Median	436.0	20.0	451.0	32.0
Q3	462.0	42.0	475.0	56.0
Maximum	528	148	559	137

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	26.82		27.73	
SD	5.972		5.880	
Minimum	16.2		15.8	
Q1	22.90		23.90	
Median	26.35		27.25	
Q3	30.30		30.40	
Maximum	51.2		46.3	
Week 4				
N	138	138	141	141
Mean	26.18	-0.64	27.85	0.12
SD	6.767	3.897	6.266	3.624
Minimum	14.3	-7.9	17.2	-11.2
Q1	21.50	-2.60	23.30	-1.70
Median	25.60	-0.85	26.90	0.20
Q3	28.50	0.80	31.10	1.80
Maximum	52.0	29.3	46.2	15.6
Week 8				
N	135	135	142	142
Mean	25.97	-0.94	25.80	-1.92
SD	5.860	2.979	5.229	3.513
Minimum	13.3	-8.1	15.8	-10.2
Q1	22.10	-2.90	22.00	-4.10
Median	25.40	-0.50	25.50	-1.80
Q3	29.40	1.10	28.00	0.20
Maximum	45.7	6.2	43.7	9.7

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	139	139
Mean	25.97	-1.04	25.95	-1.84
SD	6.558	3.795	5.088	3.367
Minimum	14.4	-10.2	15.9	-10.8
Q1	21.90	-3.30	22.20	-4.10
Median	25.40	-1.15	25.10	-1.50
Q3	28.80	0.90	29.20	0.60
Maximum	56.6	16.8	39.6	6.9
Week 16				
N	128	128	136	136
Mean	25.77	-1.30	25.77	-1.93
SD	5.855	3.284	4.558	3.477
Minimum	16.0	-11.1	16.0	-11.5
Q1	22.10	-3.30	22.45	-4.25
Median	24.80	-1.00	25.60	-1.50
Q3	28.50	0.85	28.85	0.20
Maximum	47.4	9.1	38.5	7.9
Week 20				
N	125	125	130	130
Mean	25.60	-1.46	25.89	-1.84
SD	5.531	3.801	4.671	3.500
Minimum	15.4	-11.9	16.5	-14.1
Q1	22.00	-3.80	22.00	-4.10
Median	25.20	-1.20	25.45	-1.60
Q3	27.80	0.90	29.20	0.30
Maximum	47.4	11.4	37.7	6.6

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	119	119	129	129
Mean	25.19	-1.88	25.60	-2.13
SD	5.768	3.526	4.352	3.489
Minimum	14.3	-11.7	16.3	-12.1
Q1	21.50	-4.20	22.90	-4.30
Median	24.50	-1.60	25.20	-1.80
Q3	28.20	0.00	28.30	0.50
Maximum	44.9	10.4	38.4	4.5
Follow-up				
N	134	134	140	140
Mean	25.53	-1.35	25.48	-2.23
SD	5.816	3.794	4.537	3.603
Minimum	14.0	-10.8	14.7	-11.0
Q1	21.30	-3.80	22.10	-4.50
Median	24.90	-1.05	25.15	-1.90
Q3	28.80	0.80	28.40	0.40
Maximum	47.6	11.2	40.0	5.1

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	5443.5		5424.6	
SD	1544.80		1610.52	
Minimum	2600		2700	
Q1	4300.0		4300.0	
Median	5250.0		5050.0	
Q3	6000.0		6400.0	
Maximum	10300		11400	
Week 4				
N	138	138	142	142
Mean	5187.7	-255.8	5290.1	-134.5
SD	1419.34	1232.29	1511.95	1217.49
Minimum	2600	-4000	2800	-7500
Q1	4300.0	-1100.0	4200.0	-600.0
Median	4900.0	-100.0	5150.0	0.0
Q3	6100.0	500.0	6300.0	500.0
Maximum	10400	3500	10300	2700
Week 8				
N	135	135	142	142
Mean	5216.3	-225.9	5347.9	-76.8
SD	1293.62	1474.36	1504.07	1223.62
Minimum	2700	-4400	2500	-6100
Q1	4400.0	-800.0	4200.0	-600.0
Median	5100.0	-100.0	5100.0	-100.0
Q3	5900.0	600.0	6000.0	600.0
Maximum	11900	8100	10700	3200

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	5343.1	-143.1	5405.0	-17.0
SD	1339.90	1407.78	1602.38	1336.41
Minimum	2900	-5300	2900	-6200
Q1	4400.0	-1000.0	4400.0	-600.0
Median	5100.0	100.0	5100.0	0.0
Q3	6200.0	600.0	6200.0	800.0
Maximum	10000	5800	11400	5400
Week 16				
N	129	129	136	136
Mean	5269.0	-230.2	5283.1	-78.7
SD	1345.23	1335.84	1458.44	1190.61
Minimum	2600	-5000	2900	-6600
Q1	4300.0	-1000.0	4150.0	-650.0
Median	5200.0	-100.0	5000.0	100.0
Q3	6100.0	700.0	6050.0	700.0
Maximum	12100	4200	10400	2600
Week 20				
N	126	126	132	132
Mean	5321.4	-184.9	5437.1	72.0
SD	1284.53	1495.01	1541.11	1345.58
Minimum	2800	-5200	3200	-6300
Q1	4500.0	-1100.0	4300.0	-500.0
Median	5200.0	-50.0	5200.0	200.0
Q3	6000.0	700.0	6200.0	800.0
Maximum	9500	5000	10900	4400

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/uL)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	5336.9	-202.5	5342.0	-38.2
SD	1698.43	1676.25	1485.98	1357.40
Minimum	2800	-5100	2700	-6400
Q1	4300.0	-1200.0	4300.0	-600.0
Median	5200.0	-150.0	5200.0	0.0
Q3	6100.0	600.0	5900.0	700.0
Maximum	15900	6800	11000	4300
Follow-up				
N	135	135	141	141
Mean	5625.2	161.5	5402.8	-7.8
SD	1360.35	1442.94	1677.37	1439.25
Minimum	2600	-4400	3000	-7700
Q1	4600.0	-700.0	4300.0	-800.0
Median	5700.0	200.0	5000.0	100.0
Q3	6400.0	1100.0	6200.0	700.0
Maximum	9600	3200	13400	4700

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	60.18		59.95	
SD	8.513		7.016	
Minimum	32.7		38.2	
Q1	55.30		55.00	
Median	61.25		60.20	
Q3	66.10		64.20	
Maximum	76.0		85.5	
Week 4				
N	138	138	142	142
Mean	56.00	-4.18	56.61	-3.33
SD	8.469	7.918	8.171	7.306
Minimum	29.3	-26.8	33.3	-27.5
Q1	50.80	-9.20	51.20	-8.00
Median	55.80	-3.45	57.55	-3.35
Q3	62.10	0.40	61.00	2.10
Maximum	77.3	15.1	82.7	19.1
Week 8				
N	135	135	142	142
Mean	56.43	-3.69	56.14	-3.81
SD	8.862	8.153	8.033	7.428
Minimum	28.9	-30.0	36.0	-26.7
Q1	50.40	-8.30	50.50	-8.50
Median	56.10	-3.40	55.80	-4.10
Q3	62.50	2.00	61.00	0.60
Maximum	83.0	19.4	78.7	14.2

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	56.51	-3.74	56.01	-3.98
SD	8.917	8.738	8.069	7.359
Minimum	33.1	-29.0	35.3	-25.7
Q1	49.70	-8.00	50.50	-9.20
Median	56.10	-2.85	55.90	-3.30
Q3	62.80	1.10	61.00	0.50
Maximum	77.8	24.7	83.5	23.5
Week 16				
N	129	129	136	136
Mean	55.86	-4.44	55.64	-4.23
SD	8.559	7.660	7.713	6.794
Minimum	32.5	-28.7	37.5	-23.5
Q1	50.20	-8.90	50.70	-8.85
Median	56.80	-3.50	56.25	-3.75
Q3	61.40	0.40	60.30	0.40
Maximum	74.5	14.5	76.7	12.4
Week 20				
N	126	126	131	131
Mean	56.98	-3.29	57.26	-2.56
SD	9.018	9.628	8.759	8.884
Minimum	21.0	-26.4	32.0	-35.8
Q1	51.20	-8.90	52.00	-7.70
Median	56.75	-2.50	57.30	-3.70
Q3	62.20	1.50	62.00	2.00
Maximum	80.5	25.1	80.5	26.0

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	56.72	-3.88	56.37	-3.45
SD	9.469	9.669	8.687	8.339
Minimum	38.0	-28.9	32.2	-25.8
Q1	48.50	-9.10	51.00	-8.70
Median	56.80	-2.70	57.10	-3.20
Q3	63.20	1.20	62.00	1.70
Maximum	80.0	18.7	80.5	25.5
Follow-up				
N	135	135	141	141
Mean	59.81	-0.40	56.11	-3.76
SD	7.584	8.724	7.043	7.214
Minimum	34.8	-24.0	26.6	-30.2
Q1	54.40	-5.30	51.60	-8.90
Median	61.00	0.00	56.20	-3.80
Q3	65.70	5.10	61.00	0.70
Maximum	74.5	23.3	78.3	13.5

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	3.27		2.87	
SD	3.488		1.938	
Minimum	0.0		0.0	
Q1	1.30		1.40	
Median	2.30		2.55	
Q3	4.00		3.70	
Maximum	32.5		11.2	
Week 4				
N	138	138	142	142
Mean	3.73	0.47	3.37	0.50
SD	3.363	1.858	2.504	1.444
Minimum	0.0	-7.3	0.3	-3.3
Q1	1.60	-0.40	1.50	-0.20
Median	2.95	0.45	2.90	0.35
Q3	4.90	1.40	4.20	1.00
Maximum	27.5	8.2	16.4	8.4
Week 8				
N	135	135	142	142
Mean	3.52	0.27	3.42	0.55
SD	4.140	1.990	2.557	2.055
Minimum	0.0	-7.2	0.0	-3.9
Q1	1.60	-0.70	1.80	-0.30
Median	2.70	0.20	2.95	0.40
Q3	4.10	1.00	4.30	1.10
Maximum	41.5	9.0	17.5	14.5

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	3.50	0.25	3.29	0.40
SD	3.265	2.138	2.049	1.564
Minimum	0.2	-7.4	0.0	-5.2
Q1	1.70	-0.50	1.70	-0.40
Median	2.65	0.10	3.00	0.20
Q3	4.20	1.00	4.30	1.30
Maximum	25.5	8.2	10.8	5.9
Week 16				
N	129	129	136	136
Mean	3.62	0.38	3.46	0.62
SD	3.552	2.219	2.893	2.585
Minimum	0.0	-8.9	0.5	-5.1
Q1	1.60	-0.50	1.80	-0.30
Median	3.00	0.30	2.80	0.30
Q3	4.50	1.30	4.70	1.15
Maximum	30.0	7.3	26.5	25.2
Week 20				
N	126	126	131	131
Mean	3.45	0.21	3.37	0.53
SD	3.332	2.187	2.578	1.924
Minimum	0.2	-7.1	0.0	-3.2
Q1	1.50	-0.80	1.60	-0.50
Median	2.50	0.20	2.90	0.20
Q3	4.30	0.90	4.00	1.20
Maximum	27.0	11.2	15.0	10.8

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	3.44	0.26	3.48	0.63
SD	3.193	2.369	2.664	2.039
Minimum	0.0	-8.0	0.0	-4.0
Q1	1.80	-0.70	1.90	-0.20
Median	2.50	0.20	2.90	0.40
Q3	3.90	1.10	4.40	1.20
Maximum	26.5	12.2	17.7	12.8
Follow-up				
N	135	135	141	141
Mean	3.12	-0.15	3.53	0.65
SD	3.091	2.272	2.363	1.826
Minimum	0.0	-9.3	0.6	-2.8
Q1	1.50	-1.10	1.90	-0.20
Median	2.40	0.00	3.10	0.40
Q3	3.80	0.90	4.50	1.20
Maximum	25.5	7.1	12.5	10.3

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	0.48		0.43	
SD	0.463		0.355	
Minimum	0.0		0.0	
Q1	0.20		0.20	
Median	0.40		0.40	
Q3	0.70		0.60	
Maximum	3.5		1.8	
Week 4				
N	138	138	142	142
Mean	0.50	0.02	0.54	0.11
SD	0.341	0.570	0.457	0.524
Minimum	0.0	-3.1	0.0	-1.0
Q1	0.30	-0.20	0.30	-0.20
Median	0.50	0.05	0.50	0.05
Q3	0.70	0.40	0.80	0.40
Maximum	2.3	1.1	2.6	2.0
Week 8				
N	135	135	142	142
Mean	0.47	0.00	0.49	0.06
SD	0.334	0.553	0.344	0.495
Minimum	0.0	-3.5	0.0	-1.3
Q1	0.20	-0.20	0.30	-0.20
Median	0.40	0.00	0.40	0.00
Q3	0.60	0.30	0.70	0.30
Maximum	1.9	1.6	2.0	2.0

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	0.55	0.09	0.59	0.16
SD	0.414	0.537	0.414	0.505
Minimum	0.0	-1.5	0.0	-1.2
Q1	0.30	-0.20	0.30	-0.20
Median	0.50	0.05	0.50	0.10
Q3	0.70	0.40	0.80	0.40
Maximum	3.0	2.5	2.2	2.0
Week 16				
N	129	129	136	136
Mean	0.56	0.09	0.52	0.08
SD	0.485	0.552	0.360	0.494
Minimum	0.0	-1.4	0.0	-1.7
Q1	0.20	-0.20	0.30	-0.20
Median	0.40	0.10	0.50	0.10
Q3	0.80	0.40	0.70	0.30
Maximum	2.3	1.8	2.0	1.5
Week 20				
N	126	126	131	131
Mean	0.50	0.04	0.55	0.11
SD	0.369	0.529	0.424	0.452
Minimum	0.0	-2.0	0.0	-1.1
Q1	0.30	-0.20	0.30	-0.20
Median	0.40	0.00	0.40	0.10
Q3	0.70	0.40	0.70	0.40
Maximum	1.7	1.2	2.1	1.4

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	0.49	0.05	0.51	0.07
SD	0.330	0.464	0.372	0.492
Minimum	0.0	-1.2	0.0	-1.2
Q1	0.30	-0.30	0.30	-0.20
Median	0.40	0.00	0.40	0.00
Q3	0.70	0.30	0.60	0.30
Maximum	1.4	1.3	2.2	1.8
Follow-up				
N	135	135	141	141
Mean	0.49	0.01	0.52	0.09
SD	0.395	0.582	0.409	0.483
Minimum	0.0	-2.9	0.0	-1.3
Q1	0.30	-0.30	0.30	-0.20
Median	0.40	0.00	0.40	0.00
Q3	0.60	0.30	0.70	0.30
Maximum	2.0	1.5	2.3	1.7

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	29.82		30.15	
SD	7.432		6.328	
Minimum	15.0		10.0	
Q1	24.00		26.30	
Median	29.00		29.60	
Q3	35.10		34.20	
Maximum	56.1		49.0	
Week 4				
N	138	138	142	142
Mean	33.33	3.51	33.14	2.99
SD	7.744	6.566	7.036	6.824
Minimum	14.8	-13.0	13.8	-14.9
Q1	27.80	-1.10	28.00	-2.10
Median	32.95	3.10	33.00	3.10
Q3	37.90	7.90	37.80	7.10
Maximum	59.0	21.4	54.3	26.6
Week 8				
N	135	135	142	142
Mean	33.05	3.17	33.67	3.52
SD	7.658	6.973	6.992	7.090
Minimum	10.5	-18.6	13.7	-14.5
Q1	28.20	-1.20	28.60	-1.00
Median	32.70	2.80	34.10	3.40
Q3	37.70	7.00	38.40	7.30
Maximum	61.9	22.4	53.0	24.8

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	33.04	3.25	33.53	3.44
SD	8.004	7.523	7.197	6.770
Minimum	16.1	-20.1	11.0	-16.9
Q1	27.50	-1.30	29.70	-0.90
Median	32.30	2.70	33.30	3.40
Q3	38.60	8.00	38.20	7.80
Maximum	56.0	30.4	51.0	25.1
Week 16				
N	129	129	136	136
Mean	33.58	3.83	33.93	3.66
SD	8.180	6.817	7.261	6.764
Minimum	17.7	-10.1	16.0	-10.0
Q1	27.00	-0.80	29.20	-1.10
Median	33.50	3.10	33.50	2.70
Q3	38.90	7.80	39.00	7.55
Maximum	57.0	25.9	52.0	22.7
Week 20				
N	126	126	131	131
Mean	32.55	2.78	32.37	2.06
SD	8.517	8.424	7.593	8.263
Minimum	13.4	-22.9	11.9	-24.0
Q1	26.80	-1.30	28.50	-2.20
Median	33.25	2.00	32.40	2.10
Q3	36.90	7.50	37.10	7.10
Maximum	67.0	26.5	52.6	26.9

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	32.83	3.26	33.22	2.91
SD	8.253	8.095	7.693	7.647
Minimum	11.5	-18.5	14.5	-21.5
Q1	26.60	-1.50	28.20	-2.10
Median	34.00	2.30	32.20	2.10
Q3	38.50	7.60	37.70	7.60
Maximum	51.8	29.8	60.7	25.7
Follow-up				
N	135	135	141	141
Mean	30.01	0.22	33.07	2.86
SD	6.571	7.376	6.551	7.060
Minimum	15.4	-16.6	15.2	-16.9
Q1	25.40	-3.80	28.70	-1.20
Median	29.00	0.20	33.30	2.70
Q3	33.50	4.20	36.80	7.40
Maximum	56.4	25.1	62.4	27.9

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Baseline				
N	138		142	
Mean	6.25		6.60	
SD	1.864		1.858	
Minimum	2.0		3.0	
Q1	4.90		5.40	
Median	6.10		6.40	
Q3	7.50		7.70	
Maximum	12.0		12.7	
Week 4				
N	138	138	142	142
Mean	6.44	0.19	6.34	-0.26
SD	1.808	2.158	1.668	1.781
Minimum	1.6	-6.0	2.4	-6.4
Q1	5.20	-1.00	5.20	-1.30
Median	6.25	0.00	6.40	-0.25
Q3	7.60	1.10	7.30	0.90
Maximum	11.3	8.6	11.4	5.6
Week 8				
N	135	135	142	142
Mean	6.52	0.25	6.28	-0.31
SD	1.901	1.898	1.773	1.921
Minimum	2.5	-6.5	3.0	-7.7
Q1	5.00	-0.90	5.00	-1.50
Median	6.60	0.10	6.30	-0.40
Q3	7.50	1.40	7.40	1.10
Maximum	12.5	5.4	12.5	5.3

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 12				
N	130	130	141	141
Mean	6.39	0.15	6.58	-0.02
SD	1.784	1.964	1.754	1.913
Minimum	2.4	-5.9	2.5	-6.9
Q1	5.10	-1.20	5.50	-1.00
Median	6.40	0.10	6.30	-0.10
Q3	7.50	1.50	7.20	1.20
Maximum	11.6	4.7	12.0	6.8
Week 16				
N	129	129	136	136
Mean	6.38	0.14	6.44	-0.13
SD	1.765	1.954	1.773	1.997
Minimum	3.0	-7.0	2.0	-7.7
Q1	5.20	-1.10	5.35	-0.95
Median	6.10	0.10	6.30	-0.10
Q3	7.50	1.10	7.30	0.80
Maximum	13.0	6.2	12.2	5.2
Week 20				
N	126	126	131	131
Mean	6.52	0.26	6.45	-0.15
SD	1.918	2.120	1.891	1.993
Minimum	3.0	-4.8	2.8	-5.5
Q1	5.00	-1.20	5.30	-1.10
Median	6.25	0.20	6.20	-0.20
Q3	7.40	1.60	7.40	1.00
Maximum	13.5	6.7	14.5	7.1

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-22　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-002 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	TAK-385 40mg (N=138) Observed Value at Visit	TAK-385 40mg (N=138) Change from Baseline	Leuprorelin (N=142) Observed Value at Visit	Leuprorelin (N=142) Change from Baseline
Week 24				
N	122	122	131	131
Mean	6.53	0.31	6.43	-0.16
SD	1.961	1.956	1.836	1.893
Minimum	2.0	-6.0	1.0	-6.7
Q1	5.00	-0.80	5.40	-1.30
Median	6.40	0.10	6.10	-0.10
Q3	7.80	1.60	7.20	0.80
Maximum	11.9	6.0	12.2	4.2
Follow-up				
N	135	135	141	141
Mean	6.56	0.32	6.76	0.16
SD	2.151	2.305	1.791	2.053
Minimum	1.2	-6.3	3.0	-8.4
Q1	5.30	-0.90	5.70	-1.00
Median	6.10	0.20	6.50	0.20
Q3	7.70	1.80	7.60	1.40
Maximum	17.5	8.5	12.8	5.9

治験総括報告書 Table 15.3.2.1.1.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	429.3		421.3	
SD	41.02		36.53	
Minimum	370		345	
Q1	404.0		397.5	
Median	425.0		427.5	
Q3	446.0		444.5	
Maximum	526		498	
Week 4				
N	33	33	32	32
Mean	452.9	23.6	424.7	3.4
SD	46.63	22.37	37.31	17.29
Minimum	374	-17	360	-54
Q1	433.0	6.0	393.5	-3.5
Median	444.0	24.0	432.5	6.0
Q3	488.0	35.0	442.5	13.0
Maximum	544	73	509	45
Week 8				
N	32	32	31	31
Mean	455.1	25.4	428.5	8.2
SD	43.52	30.94	41.07	21.48
Minimum	363	-49	366	-26
Q1	427.5	7.5	387.0	-8.0
Median	457.5	19.0	435.0	9.0
Q3	488.0	38.5	459.0	21.0
Maximum	534	102	508	57

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	453.2	23.5	426.6	6.3
SD	43.00	29.89	38.65	17.82
Minimum	374	-44	349	-44
Q1	422.0	10.0	387.0	-5.0
Median	460.5	19.5	433.0	8.0
Q3	480.0	30.5	446.0	17.0
Maximum	564	123	508	44
Follow-up				
N	33	33	32	32
Mean	438.1	8.8	431.9	10.7
SD	38.50	30.50	37.55	17.55
Minimum	372	-75	362	-25
Q1	411.0	-5.0	395.5	2.0
Median	433.0	5.0	434.5	10.0
Q3	461.0	27.0	452.5	18.0
Maximum	512	78	505	62

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/uL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	5645.5		5359.4	
SD	1534.21		1786.48	
Minimum	2900		3100	
Q1	4700.0		4000.0	
Median	5300.0		5050.0	
Q3	6500.0		5950.0	
Maximum	9900		10500	
Week 4				
N	33	33	32	32
Mean	5578.8	-66.7	5768.8	409.4
SD	1465.38	1214.67	1850.80	959.62
Minimum	2700	-2900	3300	-2100
Q1	4600.0	-700.0	4750.0	-200.0
Median	5600.0	-100.0	5250.0	350.0
Q3	6600.0	700.0	6500.0	950.0
Maximum	8900	2400	11500	2600
Week 8				
N	32	32	31	31
Mean	5340.6	-171.9	5980.6	571.0
SD	1093.05	1082.48	1963.91	954.71
Minimum	3100	-3300	3000	-1200
Q1	4600.0	-900.0	4700.0	-200.0
Median	5250.0	-150.0	5400.0	500.0
Q3	6100.0	550.0	6500.0	1300.0
Maximum	7700	2400	11600	2400

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/uL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	5356.3	-156.3	5861.3	451.6
SD	1385.63	1194.59	2064.09	1072.65
Minimum	2900	-4000	2900	-1300
Q1	4400.0	-850.0	4500.0	-300.0
Median	5200.0	0.0	5300.0	200.0
Q3	6250.0	300.0	6300.0	1500.0
Maximum	8400	2400	11300	2700
Follow-up				
N	33	33	32	32
Mean	6342.4	697.0	6206.3	846.9
SD	1625.97	1332.87	2294.59	1010.26
Minimum	3000	-3000	2900	-1100
Q1	5300.0	-200.0	4800.0	200.0
Median	6400.0	800.0	5750.0	750.0
Q3	7300.0	1400.0	6450.0	1300.0
Maximum	10600	3200	14400	3900

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	59.88		58.81	
SD	8.747		8.568	
Minimum	44.0		40.3	
Q1	54.10		54.25	
Median	59.50		59.55	
Q3	66.00		64.20	
Maximum	78.5		75.3	
Week 4				
N	33	33	32	32
Mean	56.68	-3.20	58.87	0.06
SD	9.768	6.805	7.589	6.372
Minimum	36.3	-17.1	40.8	-20.2
Q1	51.50	-7.40	54.90	-3.10
Median	57.70	-3.60	60.25	0.45
Q3	62.10	1.00	64.00	4.60
Maximum	82.5	12.0	72.1	11.2
Week 8				
N	32	32	31	31
Mean	58.03	-1.95	61.27	1.86
SD	8.644	6.065	8.255	7.491
Minimum	35.5	-13.4	47.0	-10.5
Q1	52.45	-6.75	56.40	-2.50
Median	58.00	-3.00	60.00	0.00
Q3	63.55	2.20	67.90	6.20
Maximum	77.5	10.5	77.1	22.7

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	56.61	-3.36	60.12	0.71
SD	9.643	6.176	6.572	7.537
Minimum	32.6	-13.8	45.6	-16.1
Q1	50.50	-9.00	56.20	-4.60
Median	57.15	-3.00	61.10	0.90
Q3	62.45	0.05	63.40	5.60
Maximum	77.5	9.5	73.1	23.6
Follow-up				
N	33	33	32	32
Mean	61.83	1.95	60.35	1.54
SD	7.953	6.804	7.429	7.270
Minimum	42.0	-15.5	46.9	-10.5
Q1	55.90	-1.60	56.00	-2.95
Median	61.00	3.00	60.35	0.05
Q3	67.80	7.50	64.45	6.30
Maximum	77.2	13.2	74.6	20.0

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	2.76		2.91	
SD	2.035		1.900	
Minimum	0.0		0.2	
Q1	1.10		1.65	
Median	2.00		2.25	
Q3	4.00		3.75	
Maximum	9.0		8.3	
Week 4				
N	33	33	32	32
Mean	2.74	-0.02	2.65	-0.25
SD	1.758	1.373	1.331	1.004
Minimum	0.5	-3.5	0.6	-3.7
Q1	1.20	-0.80	1.70	-0.60
Median	2.50	0.00	2.35	-0.25
Q3	3.70	0.90	3.50	0.35
Maximum	7.1	2.8	6.8	1.7
Week 8				
N	32	32	31	31
Mean	2.88	0.07	2.64	-0.31
SD	1.644	1.554	1.611	1.473
Minimum	0.0	-3.9	0.1	-3.2
Q1	1.85	-1.00	1.10	-1.40
Median	3.00	-0.05	2.40	-0.20
Q3	4.10	1.00	3.60	0.50
Maximum	6.0	3.1	6.2	2.8

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	3.17	0.36	2.86	-0.08
SD	2.487	1.888	1.774	1.401
Minimum	0.0	-3.0	0.2	-3.1
Q1	1.25	-0.45	1.60	-0.60
Median	2.70	0.05	2.50	-0.30
Q3	4.55	1.55	3.90	0.90
Maximum	11.5	6.5	8.1	3.9
Follow-up				
N	33	33	32	32
Mean	2.54	-0.22	2.75	-0.16
SD	1.588	1.695	1.823	1.370
Minimum	0.2	-5.0	0.0	-4.0
Q1	1.30	-1.00	1.10	-0.75
Median	2.00	0.00	2.40	-0.15
Q3	3.90	0.80	3.55	0.85
Maximum	6.6	2.7	7.0	2.9

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	0.55		0.56	
SD	0.526		0.449	
Minimum	0.0		0.0	
Q1	0.20		0.25	
Median	0.40		0.40	
Q3	0.70		0.85	
Maximum	2.0		1.9	
Week 4				
N	33	33	32	32
Mean	0.45	-0.10	0.52	-0.04
SD	0.460	0.578	0.376	0.621
Minimum	0.0	-1.4	0.0	-1.8
Q1	0.00	-0.50	0.20	-0.45
Median	0.40	0.00	0.50	-0.05
Q3	0.70	0.40	0.70	0.30
Maximum	1.8	0.9	1.8	0.9
Week 8				
N	32	32	31	31
Mean	0.55	-0.02	0.46	-0.08
SD	0.570	0.799	0.450	0.695
Minimum	0.0	-2.0	0.0	-1.9
Q1	0.20	-0.40	0.20	-0.30
Median	0.35	-0.15	0.40	-0.10
Q3	0.70	0.30	0.70	0.20
Maximum	2.1	2.1	2.3	2.3

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	0.56	-0.01	0.54	-0.01
SD	0.409	0.623	0.394	0.577
Minimum	0.0	-1.2	0.0	-1.9
Q1	0.30	-0.40	0.30	-0.20
Median	0.50	0.00	0.50	0.00
Q3	0.70	0.35	0.80	0.30
Maximum	1.6	1.6	1.5	1.3
Follow-up				
N	33	33	32	32
Mean	0.51	-0.04	0.53	-0.03
SD	0.463	0.613	0.438	0.597
Minimum	0.0	-1.0	0.0	-1.5
Q1	0.20	-0.50	0.30	-0.35
Median	0.40	0.00	0.40	0.00
Q3	0.80	0.30	0.70	0.30
Maximum	2.0	1.4	2.0	1.1

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	30.20		30.99	
SD	6.963		7.291	
Minimum	15.9		17.0	
Q1	25.30		26.60	
Median	30.80		30.00	
Q3	34.10		36.05	
Maximum	41.6		45.8	
Week 4				
N	33	33	32	32
Mean	33.43	3.23	30.96	-0.03
SD	8.687	5.979	7.197	5.203
Minimum	11.0	-11.0	17.7	-8.5
Q1	28.00	-0.20	26.75	-3.90
Median	33.60	3.20	30.45	-0.40
Q3	38.40	5.80	35.80	3.00
Maximum	50.3	16.6	45.2	17.6
Week 8				
N	32	32	31	31
Mean	32.00	1.89	28.96	-1.55
SD	7.519	4.968	7.260	6.451
Minimum	16.1	-9.5	13.4	-18.5
Q1	27.45	-0.95	22.10	-4.80
Median	32.00	2.85	30.00	-0.10
Q3	37.10	5.25	35.70	3.50
Maximum	48.0	12.0	41.3	9.5

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	32.69	2.58	29.92	-0.59
SD	7.923	4.788	5.877	5.767
Minimum	17.0	-8.3	17.3	-18.2
Q1	28.05	-0.10	27.40	-4.60
Median	32.45	1.75	29.40	0.00
Q3	37.85	5.45	34.20	2.60
Maximum	52.0	12.3	41.8	13.3
Follow-up				
N	33	33	32	32
Mean	28.69	-1.51	29.98	-1.01
SD	6.939	5.574	6.330	5.845
Minimum	18.0	-13.6	15.8	-15.6
Q1	23.80	-5.30	25.45	-4.30
Median	28.50	-2.50	30.55	-1.25
Q3	32.80	2.20	34.00	2.90
Maximum	49.0	11.0	41.9	10.8

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	6.61		6.73	
SD	1.648		2.326	
Minimum	3.0		3.0	
Q1	5.50		5.00	
Median	6.00		6.50	
Q3	8.20		7.80	
Maximum	9.6		12.1	
Week 4				
N	33	33	32	32
Mean	6.70	0.09	7.00	0.27
SD	1.658	2.166	2.061	2.351
Minimum	3.6	-5.4	3.0	-5.8
Q1	5.90	-1.00	5.55	-1.30
Median	6.50	0.00	6.95	0.45
Q3	8.00	0.70	8.15	1.95
Maximum	12.0	7.0	12.2	4.2
Week 8				
N	32	32	31	31
Mean	6.54	0.01	6.67	0.08
SD	1.885	1.757	1.538	2.095
Minimum	3.9	-4.0	3.0	-4.3
Q1	5.00	-1.05	5.70	-1.30
Median	6.20	-0.25	6.70	0.20
Q3	7.70	1.50	7.50	1.70
Maximum	11.4	3.2	9.1	4.1

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	6.96	0.43	6.56	-0.03
SD	1.898	2.229	1.834	2.589
Minimum	3.5	-3.9	3.8	-6.0
Q1	5.40	-1.00	5.00	-1.10
Median	6.75	0.20	6.60	0.40
Q3	8.35	2.45	8.40	1.30
Maximum	10.8	5.0	10.8	5.8
Follow-up				
N	33	33	32	32
Mean	6.43	-0.18	6.39	-0.34
SD	1.557	2.027	2.233	2.436
Minimum	3.0	-5.6	2.0	-7.0
Q1	5.60	-1.20	4.70	-1.10
Median	6.50	0.00	6.50	0.15
Q3	7.50	1.00	8.00	0.80
Maximum	9.1	4.5	12.2	4.2

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: HGB (g/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	12.27		12.14	
SD	1.433		1.186	
Minimum	9.0		9.6	
Q1	11.60		11.20	
Median	12.50		12.25	
Q3	13.10		13.10	
Maximum	15.2		14.4	
Week 4				
N	33	33	32	32
Mean	12.94	0.67	12.20	0.06
SD	1.325	0.696	1.192	0.575
Minimum	10.4	-0.6	9.8	-1.7
Q1	12.40	0.10	11.40	-0.20
Median	13.10	0.70	12.25	0.10
Q3	13.70	1.10	13.05	0.30
Maximum	15.6	2.6	14.4	1.5
Week 8				
N	32	32	31	31
Mean	13.03	0.78	12.33	0.23
SD	1.219	0.973	1.368	0.674
Minimum	10.4	-1.3	9.0	-2.1
Q1	12.35	0.15	11.50	-0.10
Median	13.25	0.55	12.30	0.30
Q3	13.95	1.50	13.20	0.60
Maximum	14.8	3.6	15.3	1.3

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: HGB (g/dL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	13.09	0.84	12.33	0.22
SD	1.176	1.001	1.271	0.491
Minimum	10.3	-1.2	10.0	-1.4
Q1	12.25	0.25	11.30	0.00
Median	13.35	0.65	12.50	0.30
Q3	13.85	1.05	13.00	0.40
Maximum	15.3	3.5	15.1	1.1
Follow-up				
N	33	33	32	32
Mean	12.87	0.60	12.54	0.40
SD	1.049	1.067	1.166	0.470
Minimum	10.0	-2.3	9.8	-0.7
Q1	12.30	0.00	11.75	0.25
Median	13.00	0.60	12.65	0.50
Q3	13.60	1.00	13.35	0.65
Maximum	14.7	2.6	14.9	1.5

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hematocrit (HCT) (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	36.66		36.33	
SD	3.733		3.226	
Minimum	28.0		29.7	
Q1	34.10		33.85	
Median	37.90		37.00	
Q3	38.60		38.95	
Maximum	44.0		42.8	
Week 4				
N	33	33	32	32
Mean	38.46	1.80	36.60	0.26
SD	3.439	1.989	3.199	1.592
Minimum	31.8	-2.0	30.3	-5.3
Q1	36.60	0.30	34.20	-0.55
Median	38.60	2.00	36.35	0.50
Q3	40.90	3.00	38.85	1.30
Maximum	45.1	7.3	44.2	2.9
Week 8				
N	32	32	31	31
Mean	38.66	2.04	36.80	0.56
SD	3.206	2.724	3.685	1.936
Minimum	31.6	-3.7	28.5	-4.5
Q1	36.90	0.15	34.50	-0.80
Median	39.30	1.60	36.40	0.70
Q3	41.40	3.85	39.40	1.60
Maximum	43.0	9.2	45.1	4.7

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hematocrit (HCT) (%)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	38.65	2.03	36.61	0.36
SD	3.086	3.002	3.412	1.676
Minimum	31.0	-3.1	29.7	-5.0
Q1	36.35	0.20	34.50	-0.40
Median	39.20	1.30	36.40	0.70
Q3	40.70	3.05	38.90	1.50
Maximum	44.9	9.5	43.8	3.4
Follow-up				
N	33	33	32	32
Mean	37.75	1.08	37.12	0.79
SD	2.651	2.837	3.061	1.479
Minimum	31.3	-5.9	30.4	-2.7
Q1	36.30	-0.80	35.15	0.05
Median	38.70	1.10	37.00	0.85
Q3	39.60	2.50	38.95	1.55
Maximum	42.9	6.1	43.7	3.6

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Baseline				
N	33		32	
Mean	27.15		27.12	
SD	7.266		5.487	
Minimum	16.4		15.9	
Q1	20.80		23.65	
Median	27.50		26.85	
Q3	32.40		29.60	
Maximum	43.9		37.8	
Week 4				
N	31	31	32	32
Mean	26.00	-1.32	27.80	0.68
SD	5.116	3.334	5.246	3.171
Minimum	18.6	-8.2	18.9	-5.8
Q1	21.60	-3.50	24.50	-1.10
Median	25.80	-0.80	27.00	0.10
Q3	29.20	0.70	32.25	2.20
Maximum	35.7	6.2	38.6	8.3
Week 8				
N	31	31	31	31
Mean	26.35	-0.53	27.70	0.55
SD	5.726	4.271	5.652	2.837
Minimum	15.7	-10.8	16.7	-3.7
Q1	22.30	-1.70	24.00	-1.60
Median	26.00	-0.30	27.20	0.20
Q3	30.30	1.50	32.30	2.60
Maximum	43.6	13.5	38.4	9.1

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-23　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（3008 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4/uL)

Visit / Statistics	TAK-385 40mg (N=33) Observed Value at Visit	TAK-385 40mg (N=33) Change from Baseline	Placebo (N=32) Observed Value at Visit	Placebo (N=32) Change from Baseline
Week 12				
N	32	32	31	31
Mean	26.18	-0.45	27.31	0.16
SD	5.633	3.630	5.436	2.446
Minimum	15.8	-9.5	17.6	-3.9
Q1	22.30	-2.20	22.40	-1.70
Median	25.35	-0.55	27.50	-0.10
Q3	30.35	2.05	30.50	1.40
Maximum	37.0	5.8	38.5	6.9
Follow-up				
N	33	33	31	31
Mean	26.56	-0.59	27.24	0.47
SD	5.849	3.758	5.647	3.037
Minimum	16.6	-9.4	16.9	-4.2
Q1	22.40	-2.00	23.60	-1.50
Median	25.40	-0.10	26.60	-0.30
Q3	29.90	1.80	30.70	1.70
Maximum	43.2	6.1	39.5	10.7

治験総括報告書 Table 15.3.2.1.1（5.3.5.1-3）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	426.9		427.1		421.9		425.7		427.1	
SD	29.71		27.82		32.13		30.66		30.17	
Minimum	364		355		333		355		361	
Q1	405.0		408.0		401.5		404.0		407.5	
Median	426.0		426.0		418.0		424.0		427.0	
Q3	447.0		446.0		446.5		445.0		444.5	
Maximum	499		484		516		511		500	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	429.6	2.6	441.0	13.8	442.4	20.5	450.9	25.3	445.6	18.4
SD	29.48	20.93	31.56	20.44	33.49	23.64	27.12	22.27	31.58	21.09
Minimum	368	-54	373	-37	343	-61	375	-32	385	-27
Q1	408.0	-11.0	418.0	-3.0	422.0	3.0	432.0	11.0	428.5	4.0
Median	428.0	2.0	439.0	14.0	445.5	21.5	452.0	26.0	442.0	19.0
Q3	448.0	16.0	459.0	29.0	463.0	38.0	471.0	38.0	461.5	28.5
Maximum	521	59	533	67	521	85	503	88	537	105
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	435.9	8.9	444.4	17.3	444.4	21.8	456.3	31.1	454.9	27.6
SD	32.49	23.18	31.26	23.49	33.01	22.89	28.91	26.39	32.04	21.11
Minimum	383	-55	380	-59	354	-56	373	-31	374	-17
Q1	409.0	-8.0	422.0	4.0	421.5	8.0	439.0	13.0	434.0	9.0
Median	436.0	12.0	445.0	16.0	445.0	21.5	456.0	28.0	451.0	28.0
Q3	455.0	26.0	467.0	32.0	466.0	37.0	478.0	52.0	471.0	41.0
Maximum	519	60	528	81	521	74	522	96	549	87
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	432.6	6.1	443.2	16.4	443.4	20.6	454.2	29.0	458.4	29.6
SD	33.02	28.82	30.25	22.59	30.84	23.03	30.12	25.91	31.07	26.04
Minimum	296	-160	373	-38	361	-53	387	-45	364	-50
Q1	415.0	-7.0	421.0	2.0	422.0	2.5	435.0	12.0	438.0	12.0
Median	435.0	5.0	446.0	17.0	446.0	21.0	456.0	25.0	454.0	31.0
Q3	451.0	24.0	466.0	32.0	464.5	38.0	474.0	47.0	477.0	45.0
Maximum	514	65	520	72	536	79	527	92	567	89
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	427.3	14.7	443.3	4.0	429.1	5.3	447.8	15.1	432.2	29.7
SD	27.04	22.27	34.25	27.86	23.79	21.66	26.25	32.56	32.97	19.88
Minimum	385	-33	365	-47	394	-37	408	-39	396	-8
Q1	406.0	2.0	418.0	-14.0	409.0	-4.0	430.0	0.0	405.0	20.0
Median	424.0	13.0	458.0	4.0	424.5	5.5	440.0	16.0	423.5	30.0
Q3	447.0	31.0	468.0	15.0	446.0	20.0	469.0	35.0	449.0	49.0
Maximum	480	52	487	62	474	40	494	75	506	57

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	5783.5		5574.8		5285.0		5451.5		5798.8	
SD	1518.75		1667.67		1443.09		1697.97		2076.42	
Minimum	2800		2700		2400		2000		2600	
Q1	4700.0		4500.0		4300.0		4300.0		4500.0	
Median	5500.0		5200.0		5200.0		5100.0		5300.0	
Q3	6800.0		6400.0		6250.0		6500.0		6550.0	
Maximum	10700		12400		9200		9800		15900	
Week 4										
N	96	96	103	103	100	100	103	103	80	80
Mean	5457.3	-310.4	5272.8	-301.9	4797.0	-488.0	4762.1	-689.3	5032.5	-766.3
SD	1510.86	1421.60	1461.28	1506.06	1256.86	1258.77	1200.25	1458.98	1570.28	1802.10
Minimum	2700	-4300	3000	-5500	2000	-4800	2300	-4900	2300	-8200
Q1	4300.0	-1050.0	4200.0	-1200.0	4050.0	-1100.0	3900.0	-1400.0	3900.0	-1500.0
Median	5150.0	-200.0	5100.0	-200.0	4700.0	-300.0	4700.0	-400.0	4850.0	-500.0
Q3	6300.0	500.0	6100.0	700.0	5500.0	300.0	5600.0	300.0	5700.0	100.0
Maximum	9500	3700	10400	3900	8300	1800	7900	2000	11800	4300
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	5567.4	-204.2	5137.9	-436.9	4888.5	-439.6	4758.4	-643.6	5161.5	-600.0
SD	1444.69	1246.09	1452.19	1483.37	1274.93	1535.92	1230.63	1368.31	1459.78	1599.11
Minimum	2800	-4500	2400	-5300	2700	-4600	2100	-4600	2800	-8000
Q1	4600.0	-1000.0	4000.0	-1100.0	4100.0	-1450.0	3900.0	-1200.0	4100.0	-1000.0
Median	5400.0	0.0	4900.0	-200.0	4700.0	-250.0	4700.0	-400.0	5050.0	-250.0
Q3	6500.0	600.0	6000.0	500.0	5400.0	500.0	5500.0	100.0	5900.0	300.0
Maximum	9800	2900	9600	2800	8200	4700	8500	2400	8400	2200
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	5679.6	-121.5	5023.8	-543.6	4990.2	-344.6	4928.7	-473.3	4970.7	-801.3
SD	1569.38	1502.02	1417.40	1417.00	1207.86	1400.81	1294.48	1523.94	1324.18	1838.22
Minimum	2900	-5200	2600	-6700	2400	-4200	2300	-4800	2900	-9300
Q1	4500.0	-900.0	4000.0	-1200.0	4200.0	-1250.0	4100.0	-1000.0	3900.0	-1400.0
Median	5500.0	-100.0	4700.0	-500.0	4900.0	-400.0	4800.0	-300.0	4700.0	-500.0
Q3	6400.0	700.0	5800.0	400.0	5600.0	500.0	5500.0	500.0	5600.0	0.0
Maximum	10400	4900	10800	3300	9200	3800	10000	3900	10500	3500
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	6477.8	888.9	5857.9	-47.4	5222.7	209.1	5715.4	84.6	5420.0	-160.0
SD	2474.47	1822.05	1580.20	1711.19	1667.03	1370.40	1175.33	1703.84	1209.04	1551.49
Minimum	3800	-1300	3700	-5000	2100	-2400	4000	-3500	4000	-1800
Q1	4200.0	-400.0	4300.0	-900.0	3800.0	-700.0	4900.0	-1000.0	4500.0	-1000.0
Median	6000.0	650.0	5700.0	100.0	5250.0	200.0	5500.0	0.0	5000.0	-650.0
Q3	8100.0	1500.0	7000.0	1000.0	6000.0	1100.0	6200.0	1400.0	6100.0	400.0
Maximum	11500	6000	8900	3500	8400	3300	7700	2500	7800	2600

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	62.81		62.03		61.73		62.37		63.49	
SD	8.847		9.107		8.724		8.753		8.314	
Minimum	39.9		39.7		25.5		40.7		42.3	
Q1	56.70		55.60		56.70		57.10		57.10	
Median	62.90		62.80		62.75		61.20		63.95	
Q3	68.60		68.90		67.45		68.40		69.10	
Maximum	83.3		83.0		77.1		84.5		82.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	60.33	-2.48	58.96	-3.07	55.65	-6.08	56.25	-6.12	57.00	-6.49
SD	9.106	8.592	8.385	9.315	7.890	9.783	8.848	10.376	8.473	8.941
Minimum	27.5	-35.9	40.7	-24.5	38.3	-34.4	33.8	-50.7	43.9	-28.7
Q1	55.90	-8.40	52.10	-10.00	50.30	-11.50	51.10	-12.30	50.25	-11.20
Median	62.70	-2.30	59.50	-1.90	55.60	-4.45	56.10	-5.90	55.75	-5.15
Q3	66.80	2.50	64.00	3.30	61.60	0.70	61.70	0.70	63.80	-0.90
Maximum	77.7	19.5	80.2	18.7	71.5	16.9	76.4	17.2	81.7	17.1
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	60.54	-2.05	58.00	-4.03	56.01	-5.64	56.01	-6.13	58.01	-5.40
SD	8.132	7.204	8.576	9.333	8.786	9.849	8.462	9.171	8.661	7.558
Minimum	37.1	-23.3	32.3	-34.8	16.9	-35.3	39.5	-41.4	40.0	-28.1
Q1	55.20	-5.50	52.40	-10.30	50.60	-10.40	50.70	-12.10	51.20	-9.90
Median	61.40	-1.50	57.60	-2.40	57.00	-5.25	55.10	-5.30	59.15	-3.90
Q3	66.40	2.40	63.50	2.20	61.90	1.10	62.00	-0.90	64.30	-0.50
Maximum	76.6	13.7	82.4	14.6	76.1	17.0	82.3	17.9	79.9	10.5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	61.83	-0.84	58.56	-3.44	57.42	-4.69	56.40	-5.74	56.57	-6.90
SD	8.452	7.232	8.632	8.625	7.471	10.009	8.558	10.181	8.815	9.190
Minimum	37.6	-20.2	39.6	-34.0	38.1	-34.1	31.8	-46.7	33.8	-30.4
Q1	55.60	-5.60	52.80	-7.80	51.80	-10.90	50.30	-10.70	51.60	-12.10
Median	62.50	-0.70	58.70	-3.00	58.15	-4.00	55.50	-4.40	56.00	-5.70
Q3	68.10	3.80	64.80	2.40	62.35	1.75	62.80	0.00	60.90	-0.30
Maximum	78.1	17.1	88.0	14.0	74.6	16.9	84.1	21.2	83.3	13.7
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	61.41	-0.46	61.00	-1.13	59.13	-1.60	63.04	0.32	57.42	-6.11
SD	9.684	6.140	7.964	7.120	11.068	10.521	7.503	9.283	8.450	7.619
Minimum	46.0	-8.5	47.7	-15.8	26.2	-27.4	51.2	-18.4	44.3	-14.0
Q1	53.40	-5.10	56.80	-4.60	53.70	-9.60	59.10	-5.00	54.70	-11.70
Median	61.35	-1.65	59.50	-1.40	62.25	-2.05	63.80	2.60	56.80	-8.75
Q3	65.50	2.50	66.20	5.40	67.30	5.10	66.60	6.20	63.90	-3.70
Maximum	84.4	15.1	76.9	7.4	73.2	19.7	77.2	11.8	68.3	10.3

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	2.90		2.71		2.84		3.17		2.73	
SD	1.796		1.860		1.952		2.352		1.626	
Minimum	0.6		0.3		0.4		0.5		0.7	
Q1	1.60		1.30		1.40		1.60		1.55	
Median	2.60		2.10		2.25		2.60		2.30	
Q3	3.70		3.80		3.60		3.90		3.65	
Maximum	8.8		9.9		9.7		14.0		9.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	3.28	0.37	2.96	0.25	3.16	0.32	3.45	0.28	3.32	0.59
SD	2.420	1.268	2.019	1.130	2.179	1.376	2.360	1.539	1.888	1.419
Minimum	0.2	-1.6	0.0	-2.6	0.3	-2.7	0.6	-4.3	0.3	-3.7
Q1	1.60	-0.40	1.40	-0.60	1.70	-0.50	1.80	-0.40	2.10	-0.20
Median	2.50	0.00	2.30	0.30	2.40	0.20	2.90	0.20	2.80	0.60
Q3	4.50	1.10	4.10	0.80	4.30	1.00	4.40	1.00	4.80	1.35
Maximum	12.3	4.1	8.2	3.5	9.8	4.9	15.9	5.2	7.8	4.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	3.12	0.19	2.86	0.15	3.10	0.21	3.21	0.02	3.22	0.45
SD	2.207	1.312	1.970	1.331	2.238	1.642	2.033	1.518	1.753	1.244
Minimum	0.4	-3.5	0.0	-3.5	0.3	-4.6	0.5	-5.9	0.4	-4.3
Q1	1.70	-0.60	1.50	-0.70	1.60	-0.50	1.70	-0.60	1.80	-0.30
Median	2.30	0.10	2.30	0.10	2.60	0.00	2.70	0.00	3.10	0.25
Q3	3.80	0.60	3.70	0.90	4.05	0.95	4.50	0.70	4.50	1.20
Maximum	14.4	5.6	10.1	3.8	11.0	7.2	11.4	4.6	8.4	5.1
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	2.92	-0.01	2.84	0.10	3.01	0.11	3.43	0.24	3.00	0.26
SD	2.093	1.498	1.950	1.332	1.959	1.533	2.227	1.644	1.562	1.449
Minimum	0.5	-4.2	0.0	-3.8	0.3	-4.9	0.5	-5.2	0.4	-5.5
Q1	1.30	-0.80	1.40	-0.40	1.75	-0.70	1.70	-0.60	1.90	-0.50
Median	2.50	-0.20	2.40	0.00	2.40	0.10	3.00	0.20	2.70	0.30
Q3	4.00	0.60	3.70	0.70	4.10	0.85	4.70	0.90	4.10	1.10
Maximum	12.8	5.5	9.8	6.2	10.1	4.5	10.3	5.0	7.3	3.1
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	2.68	0.04	2.94	0.08	2.33	-0.07	2.37	-0.71	3.35	0.41
SD	1.855	1.165	3.292	1.226	1.762	0.928	2.431	1.769	2.012	1.341
Minimum	0.5	-1.5	0.5	-0.8	0.3	-1.8	0.6	-4.8	1.1	-2.0
Q1	1.60	-0.70	1.00	-0.60	1.10	-0.70	0.80	-0.70	1.90	-0.10
Median	2.10	-0.20	1.70	-0.20	1.50	0.00	1.80	-0.20	3.15	0.35
Q3	3.40	0.70	4.40	0.10	3.00	0.40	2.50	-0.10	3.70	0.80
Maximum	7.4	3.7	14.7	4.8	6.5	1.5	9.2	1.6	8.0	3.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	0.62		0.62		0.56		0.60		0.63	
SD	0.392		0.424		0.348		0.385		0.416	
Minimum	0.1		0.0		0.2		0.0		0.1	
Q1	0.30		0.30		0.30		0.30		0.40	
Median	0.50		0.50		0.50		0.50		0.50	
Q3	0.80		0.80		0.70		0.80		0.80	
Maximum	1.8		2.3		2.7		2.2		2.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	0.74	0.12	0.69	0.07	0.65	0.09	0.72	0.12	0.80	0.17
SD	0.532	0.450	0.448	0.347	0.410	0.358	0.379	0.380	0.496	0.385
Minimum	0.2	-0.9	0.1	-0.7	0.1	-1.2	0.0	-1.2	0.2	-0.6
Q1	0.40	-0.10	0.40	-0.20	0.40	-0.10	0.50	-0.10	0.40	-0.10
Median	0.60	0.10	0.60	0.00	0.50	0.05	0.60	0.10	0.80	0.00
Q3	0.80	0.20	0.90	0.20	0.90	0.30	0.90	0.30	0.95	0.40
Maximum	3.4	2.2	2.3	1.5	2.1	1.2	2.2	1.3	2.3	1.5
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	0.67	0.05	0.70	0.09	0.62	0.09	0.68	0.08	0.66	0.03
SD	0.407	0.320	0.450	0.372	0.397	0.326	0.327	0.379	0.486	0.297
Minimum	0.1	-0.6	0.0	-1.2	0.1	-0.7	0.2	-1.3	0.1	-0.6
Q1	0.40	-0.10	0.30	-0.20	0.40	-0.10	0.50	-0.10	0.40	-0.10
Median	0.60	0.00	0.60	0.00	0.60	0.00	0.60	0.10	0.50	0.00
Q3	1.00	0.30	0.90	0.40	0.70	0.30	0.90	0.30	0.80	0.20
Maximum	2.3	1.0	2.6	1.1	2.0	1.4	1.7	1.1	3.3	1.0
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	0.62	0.01	0.63	0.01	0.61	0.07	0.69	0.09	0.65	0.04
SD	0.392	0.268	0.354	0.307	0.371	0.319	0.317	0.381	0.465	0.335
Minimum	0.1	-0.8	0.1	-1.0	0.0	-0.7	0.2	-1.5	0.2	-0.6
Q1	0.30	-0.10	0.30	-0.10	0.40	-0.10	0.50	-0.10	0.40	-0.20
Median	0.50	0.00	0.60	0.00	0.60	0.10	0.70	0.10	0.50	0.00
Q3	0.80	0.20	0.80	0.10	0.70	0.30	0.90	0.30	0.80	0.20
Maximum	1.8	0.7	2.2	0.9	2.1	1.2	1.9	0.9	3.0	1.3
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	0.68	0.08	0.66	0.03	0.55	-0.16	0.48	-0.06	0.80	-0.05
SD	0.526	0.294	0.570	0.311	0.263	0.492	0.251	0.284	0.693	0.344
Minimum	0.2	-0.5	0.2	-0.4	0.2	-1.8	0.2	-0.5	0.2	-0.6
Q1	0.30	-0.20	0.20	-0.10	0.40	-0.30	0.30	-0.20	0.20	-0.20
Median	0.55	0.10	0.50	0.00	0.55	0.00	0.40	-0.10	0.60	-0.05
Q3	1.00	0.30	0.70	0.10	0.80	0.10	0.70	0.00	1.30	0.30
Maximum	2.3	0.6	2.0	1.1	1.0	0.5	1.0	0.5	2.3	0.3

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	28.47		29.34		29.08		28.31		27.76	
SD	7.801		8.216		7.363		7.618		7.232	
Minimum	10.6		11.5		15.4		10.6		10.4	
Q1	22.90		23.90		24.10		23.70		22.85	
Median	27.80		28.50		28.05		28.50		27.70	
Q3	34.20		34.90		33.30		32.60		33.75	
Maximum	52.2		54.3		54.3		49.6		42.8	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	30.15	1.69	31.87	2.53	34.57	5.49	34.20	5.89	33.67	5.91
SD	7.330	7.299	7.766	8.331	7.267	8.645	7.969	8.924	7.381	7.538
Minimum	16.2	-18.4	13.3	-18.2	16.5	-14.4	15.7	-16.1	13.1	-15.6
Q1	24.70	-2.70	27.00	-3.70	29.60	-0.25	29.00	0.00	28.50	1.05
Median	29.50	2.10	31.10	2.10	34.70	3.95	34.90	4.70	34.05	5.10
Q3	34.50	5.80	38.30	8.00	39.00	9.40	39.40	12.10	39.80	10.70
Maximum	54.1	29.1	50.0	21.0	50.5	31.3	57.3	45.3	46.2	26.1
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	30.29	1.66	32.78	3.44	34.52	5.31	34.67	6.18	32.87	5.06
SD	6.666	6.241	7.956	8.054	7.751	8.458	8.332	7.841	7.624	6.665
Minimum	17.3	-14.5	11.5	-12.4	15.8	-14.6	9.1	-13.3	12.3	-7.6
Q1	25.70	-2.00	26.70	-1.80	29.30	-0.60	28.90	2.40	27.20	0.50
Median	29.70	1.60	32.00	3.10	34.60	4.40	35.30	4.90	32.85	3.90
Q3	34.60	5.70	38.70	8.20	39.05	9.25	40.60	11.10	38.20	8.70
Maximum	50.6	18.9	56.4	30.0	61.0	32.7	55.1	34.0	50.3	23.5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	29.42	0.84	32.49	3.15	33.67	4.84	34.17	5.67	34.44	6.64
SD	7.508	6.512	7.821	7.395	7.307	9.097	7.809	8.718	8.303	7.763
Minimum	15.3	-15.2	8.8	-12.7	14.5	-14.0	11.1	-18.3	8.5	-10.8
Q1	24.50	-2.60	27.40	-1.80	28.80	-1.20	29.10	0.20	28.90	1.20
Median	28.90	0.60	31.80	3.00	32.75	4.60	35.30	5.20	35.40	5.80
Q3	34.00	5.70	37.80	6.30	38.50	10.25	39.20	10.20	39.20	11.40
Maximum	51.6	17.1	52.5	30.8	53.7	33.1	55.4	39.2	56.1	23.8
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	30.48	0.76	30.05	0.90	31.09	2.19	28.45	-0.03	33.26	6.13
SD	8.124	5.111	7.686	7.065	8.401	9.411	7.295	8.096	7.750	5.859
Minimum	13.3	-11.8	14.8	-9.1	19.3	-14.0	13.5	-10.2	22.6	-4.7
Q1	25.50	-2.60	24.30	-4.20	25.30	-2.50	24.90	-5.80	27.50	2.90
Median	30.45	1.35	28.60	0.70	27.90	2.10	26.80	-2.70	32.50	8.55
Q3	37.20	4.20	36.30	6.30	36.70	8.90	33.90	3.90	36.00	10.10
Maximum	41.3	7.6	43.1	15.8	51.4	26.7	41.4	15.8	46.3	12.3

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	5.20		5.31		5.79		5.56		5.39	
SD	1.364		1.373		1.779		1.388		1.543	
Minimum	2.4		2.3		2.3		2.3		2.7	
Q1	4.30		4.30		4.50		4.60		4.05	
Median	5.10		5.20		5.70		5.50		5.30	
Q3	5.90		6.30		6.55		6.40		6.30	
Maximum	10.2		10.8		13.4		10.3		9.1	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	5.51	0.31	5.52	0.21	5.97	0.18	5.39	-0.17	5.21	-0.18
SD	1.491	1.293	1.168	1.245	1.740	1.659	1.328	1.451	1.530	1.291
Minimum	2.7	-3.0	3.1	-4.1	3.0	-8.1	3.2	-3.4	1.9	-3.3
Q1	4.30	-0.40	4.70	-0.50	4.75	-0.55	4.30	-1.20	4.20	-1.05
Median	5.60	0.30	5.30	0.20	5.80	0.10	5.40	-0.30	5.00	-0.40
Q3	6.40	1.00	6.20	0.90	6.90	1.00	6.20	0.80	6.00	0.75
Maximum	10.8	4.6	9.9	5.1	12.3	6.0	10.6	3.6	11.2	3.6
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	5.38	0.15	5.66	0.35	5.75	0.04	5.43	-0.14	5.25	-0.14
SD	1.527	1.248	1.666	1.638	1.543	1.729	1.424	1.581	1.408	1.390
Minimum	2.8	-4.8	3.1	-3.5	3.3	-8.4	1.9	-4.5	2.8	-4.4
Q1	4.30	-0.60	4.40	-0.60	4.75	-0.95	4.60	-1.10	4.10	-1.00
Median	5.30	-0.10	5.20	0.20	5.50	0.10	5.10	-0.20	5.30	-0.20
Q3	6.20	0.90	6.60	1.10	6.50	1.25	6.50	0.80	6.10	0.70
Maximum	12.5	3.6	10.7	5.6	14.1	4.4	10.7	6.0	11.2	4.0
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	5.21	0.00	5.49	0.18	5.29	-0.34	5.32	-0.25	5.35	-0.04
SD	1.546	1.317	1.515	1.484	1.380	1.640	1.443	1.557	1.663	1.870
Minimum	2.3	-3.3	2.3	-4.3	2.5	-9.1	2.4	-4.4	3.0	-3.7
Q1	4.10	-1.00	4.60	-0.70	4.35	-1.10	4.30	-1.10	4.30	-1.20
Median	5.00	0.00	5.30	0.10	5.00	-0.30	5.20	-0.20	5.10	-0.20
Q3	6.10	0.60	6.00	1.00	6.15	0.40	6.30	0.70	6.00	0.90
Maximum	9.9	5.0	11.5	5.2	8.4	4.4	10.2	4.9	15.0	9.8
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	4.75	-0.42	5.35	0.11	6.90	-0.36	5.65	0.48	5.17	-0.38
SD	1.492	0.967	1.300	1.223	2.708	2.413	1.388	1.129	0.987	1.194
Minimum	1.6	-2.2	3.3	-2.5	4.3	-8.6	3.8	-0.5	3.4	-3.0
Q1	4.00	-1.00	4.50	-0.30	5.00	-1.00	4.80	-0.20	5.00	-0.60
Median	4.80	-0.60	5.10	0.20	6.25	0.00	5.30	0.00	5.40	0.00
Q3	5.90	0.60	6.00	0.90	7.10	0.50	6.50	0.70	5.90	0.30
Maximum	7.1	1.0	8.3	2.7	15.4	3.0	8.3	3.6	6.3	0.9

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	12.38		12.37		12.18		12.12		12.20	
SD	1.116		1.162		1.139		1.199		1.236	
Minimum	9.4		8.7		8.9		9.3		8.0	
Q1	11.80		11.90		11.40		11.20		11.40	
Median	12.40		12.50		12.30		12.30		12.30	
Q3	13.10		13.10		13.05		13.00		12.90	
Maximum	14.5		14.7		14.4		14.5		15.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	12.46	0.08	12.69	0.32	12.74	0.56	12.79	0.67	12.65	0.45
SD	1.040	0.677	1.120	0.599	1.061	0.697	1.235	0.692	1.140	0.675
Minimum	9.1	-1.5	8.4	-1.5	9.9	-1.3	8.9	-1.0	8.5	-1.1
Q1	11.80	-0.30	12.10	-0.10	12.10	0.10	12.00	0.20	11.90	0.00
Median	12.50	0.00	12.70	0.40	12.80	0.50	13.00	0.60	12.85	0.40
Q3	13.30	0.50	13.30	0.70	13.60	1.00	13.60	1.00	13.35	0.80
Maximum	14.0	2.1	15.3	2.5	14.9	2.4	15.4	3.2	15.5	3.8
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	12.62	0.24	12.77	0.40	12.78	0.60	12.94	0.85	12.85	0.66
SD	1.138	0.769	1.133	0.748	1.026	0.710	1.120	0.887	0.979	0.715
Minimum	9.2	-1.8	8.3	-1.8	10.0	-1.2	9.0	-1.1	9.7	-0.7
Q1	12.00	-0.30	12.30	0.00	12.15	0.10	12.50	0.20	12.20	0.20
Median	12.70	0.20	12.90	0.50	12.80	0.60	13.00	0.80	13.00	0.70
Q3	13.40	0.60	13.60	0.80	13.60	1.10	13.60	1.40	13.50	1.00
Maximum	15.0	3.1	15.1	3.6	14.7	2.6	15.7	4.0	15.3	3.8
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	12.50	0.11	12.76	0.40	12.79	0.59	12.94	0.84	12.95	0.77
SD	1.323	0.987	1.102	0.704	0.953	0.754	1.057	0.951	0.882	0.886
Minimum	8.5	-5.2	8.8	-1.3	10.7	-2.0	9.6	-1.0	10.2	-1.6
Q1	11.70	-0.30	12.10	-0.10	12.15	0.10	12.50	0.20	12.50	0.30
Median	12.70	0.10	12.90	0.40	12.75	0.60	13.00	0.70	13.00	0.70
Q3	13.40	0.60	13.40	0.80	13.40	1.05	13.60	1.30	13.60	1.30
Maximum	14.9	3.4	15.6	2.5	15.0	2.6	15.1	4.5	14.6	4.5
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	12.88	0.39	12.68	0.12	12.56	0.11	13.08	0.69	12.62	0.94
SD	0.833	0.572	1.349	0.840	1.048	0.670	1.034	1.008	0.763	0.731
Minimum	10.6	-0.6	9.7	-1.4	10.6	-1.2	11.1	-1.3	11.7	-0.3
Q1	12.40	0.00	12.10	-0.30	12.10	-0.30	12.50	0.20	11.90	0.60
Median	13.00	0.35	13.00	0.00	12.70	-0.05	13.00	0.60	12.65	0.90
Q3	13.50	1.00	13.80	0.60	13.20	0.70	13.70	1.40	13.00	1.40
Maximum	14.1	1.4	14.6	1.7	14.3	1.3	14.8	2.7	14.2	2.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	38.53		38.43		38.02		37.85		38.07	
SD	2.854		2.997		2.972		3.059		3.119	
Minimum	30.4		29.5		31.5		30.3		28.9	
Q1	36.80		37.00		36.15		35.60		36.20	
Median	38.60		38.40		38.40		38.10		38.10	
Q3	40.70		40.30		40.15		40.00		39.90	
Maximum	44.8		44.3		44.2		45.2		47.7	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	38.69	0.16	39.51	1.07	39.72	1.70	39.91	2.05	39.70	1.63
SD	2.690	2.057	2.977	1.750	2.784	2.224	3.014	2.088	2.845	2.030
Minimum	29.4	-4.2	28.9	-3.5	32.5	-5.0	30.5	-3.0	30.7	-2.1
Q1	37.00	-1.00	37.80	-0.30	37.60	0.20	38.10	0.70	37.95	0.20
Median	38.80	0.00	39.70	1.00	39.80	1.70	40.10	2.10	40.10	1.60
Q3	40.70	1.10	41.20	2.10	41.70	3.20	42.00	3.20	41.10	2.75
Maximum	44.1	6.6	46.3	7.3	45.7	7.8	46.4	8.1	47.5	12.0
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	39.12	0.60	39.72	1.28	39.73	1.70	40.26	2.49	40.20	2.15
SD	2.964	2.207	3.020	2.155	2.707	2.111	2.818	2.577	2.510	2.053
Minimum	30.7	-4.6	28.8	-4.4	32.3	-4.2	32.0	-3.2	34.6	-1.5
Q1	37.40	-0.70	37.80	-0.10	37.85	0.60	38.90	0.70	38.70	0.90
Median	39.00	0.50	39.60	1.30	39.80	1.40	40.40	2.40	40.10	2.10
Q3	40.90	1.70	42.10	2.60	41.80	3.05	42.10	4.00	41.80	3.40
Maximum	45.3	7.7	45.5	9.8	45.6	8.3	47.5	10.0	48.1	10.4
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	38.68	0.18	39.56	1.16	39.63	1.55	40.15	2.37	40.31	2.24
SD	3.342	2.852	2.953	2.156	2.559	2.151	2.602	2.505	2.314	2.536
Minimum	26.9	-15.6	30.0	-4.9	33.8	-5.6	33.7	-2.6	34.3	-4.1
Q1	36.80	-1.20	37.30	-0.40	37.70	-0.05	39.00	0.70	39.00	0.70
Median	38.80	0.00	39.80	1.30	39.65	1.55	40.00	2.00	40.20	2.20
Q3	41.00	1.90	41.60	2.70	41.45	3.20	42.00	4.00	41.80	3.50
Maximum	45.7	7.4	45.9	7.4	45.7	7.0	45.5	10.4	45.2	11.3
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	39.81	1.02	39.23	0.12	38.75	0.07	40.14	1.44	39.18	2.59
SD	2.219	2.174	3.474	2.478	2.668	1.860	2.859	3.158	2.010	2.027
Minimum	35.3	-3.3	31.5	-4.4	34.5	-3.5	35.9	-4.5	36.9	-1.0
Q1	38.50	0.00	36.80	-1.30	36.70	-1.80	38.40	-0.30	37.30	1.80
Median	39.65	0.90	40.30	0.00	39.20	-0.05	39.80	1.50	38.85	2.20
Q3	42.20	2.50	41.80	1.30	40.80	1.10	41.20	3.10	40.80	3.70
Maximum	43.1	4.8	43.7	4.9	43.4	3.5	46.0	8.6	42.7	6.5

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	25.69		25.49		26.01		25.52		26.26	
SD	5.422		6.011		5.909		7.337		6.921	
Minimum	12.8		15.7		15.2		12.6		16.2	
Q1	21.60		21.70		21.65		21.20		21.95	
Median	24.50		24.30		25.05		25.30		25.10	
Q3	28.80		28.20		29.45		29.80		28.70	
Maximum	39.9		41.6		44.4		54.5		59.9	
Week 4										
N	97	97	101	101	100	100	103	103	80	80
Mean	26.11	0.42	24.79	-0.66	25.41	-0.60	24.35	-1.17	26.22	-0.05
SD	5.599	2.461	5.719	3.219	5.688	2.898	6.536	2.796	6.121	3.688
Minimum	15.6	-8.5	14.9	-8.1	9.5	-7.9	11.3	-8.6	15.0	-12.9
Q1	22.20	-1.00	21.00	-2.50	21.70	-2.45	20.20	-2.60	22.30	-1.50
Median	25.00	0.30	23.10	-0.50	24.70	-0.35	24.40	-0.90	25.80	0.20
Q3	29.50	1.90	26.90	0.50	28.60	1.20	28.10	0.40	29.80	1.80
Maximum	38.9	7.0	44.2	17.8	46.6	8.7	55.1	5.9	47.8	8.5
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	26.04	0.26	25.22	-0.27	25.21	-0.95	25.27	-0.43	24.39	-1.93
SD	5.500	2.919	5.876	3.165	5.410	3.511	6.802	3.872	5.884	3.544
Minimum	14.5	-8.9	14.6	-8.0	11.0	-17.1	12.1	-9.7	14.0	-13.6
Q1	21.80	-1.80	21.10	-2.00	21.55	-2.80	21.20	-2.70	20.40	-3.30
Median	25.60	0.70	24.00	-0.40	24.30	-0.60	24.50	-0.40	23.75	-1.80
Q3	29.40	2.10	27.70	1.40	28.05	1.30	28.60	1.50	27.10	0.70
Maximum	40.8	9.6	43.6	12.7	41.9	6.7	59.7	18.1	48.8	5.6
Week 12										
N	92	92	101	101	92	92	101	101	75	75
Mean	26.36	0.52	25.03	-0.48	25.26	-0.98	25.07	-0.63	24.50	-1.91
SD	5.797	3.521	5.430	3.520	5.672	3.928	6.925	4.136	6.142	3.632
Minimum	14.9	-8.1	14.3	-10.9	12.9	-17.0	9.3	-8.7	15.8	-13.9
Q1	22.60	-1.75	21.40	-2.60	22.25	-2.95	21.00	-3.00	20.70	-3.60
Median	25.10	0.30	24.40	-0.60	24.10	-0.90	24.80	-0.70	23.20	-1.10
Q3	28.80	2.70	27.30	1.10	27.95	0.70	29.20	1.40	26.80	0.30
Maximum	40.3	11.3	39.8	13.4	44.0	12.9	57.3	23.7	50.3	4.6
Follow-up										
N	18	18	18	18	22	22	13	13	10	10
Mean	26.91	1.60	26.91	-0.06	25.06	0.28	23.58	-0.35	23.68	-2.06
SD	4.405	2.413	6.224	2.651	4.247	2.913	5.566	2.710	3.188	3.314
Minimum	20.6	-2.1	18.4	-4.5	17.0	-2.7	15.1	-5.8	19.3	-7.4
Q1	24.30	-0.40	21.80	-2.20	20.90	-2.00	19.50	-1.80	21.30	-4.10
Median	26.25	1.55	25.40	-0.10	26.15	-0.60	26.30	0.00	22.95	-0.95
Q3	28.40	3.50	32.10	2.00	28.40	1.40	27.90	1.50	25.60	0.40
Maximum	40.0	5.5	39.2	4.2	32.4	7.8	30.7	3.0	29.0	2.4

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCH (pg)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	29.06		28.98		28.96		28.52		28.62	
SD	2.525		2.248		2.580		2.626		2.788	
Minimum	20.3		21.3		18.6		20.8		19.0	
Q1	28.10		28.00		27.60		26.70		27.70	
Median	29.80		29.30		29.65		28.90		29.30	
Q3	30.60		30.40		30.75		30.50		30.45	
Maximum	32.6		33.6		33.2		33.3		32.3	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	29.08	0.02	28.83	-0.16	28.90	-0.06	28.39	-0.13	28.49	-0.14
SD	2.468	0.674	2.236	0.584	2.446	0.498	2.531	0.711	2.747	0.634
Minimum	20.9	-1.9	20.8	-1.9	20.2	-1.1	20.1	-2.0	19.2	-1.3
Q1	27.70	-0.30	27.70	-0.60	27.65	-0.40	26.60	-0.60	27.40	-0.50
Median	29.60	0.00	29.20	-0.10	29.65	-0.10	28.90	-0.20	29.00	-0.10
Q3	30.90	0.30	30.20	0.20	30.50	0.20	30.10	0.10	30.30	0.10
Maximum	32.6	3.8	33.2	2.0	33.2	1.6	33.0	3.3	32.3	3.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	29.04	-0.02	28.78	-0.20	28.86	-0.06	28.41	-0.09	28.36	-0.22
SD	2.565	0.908	2.268	0.782	2.366	0.771	2.399	1.075	2.571	0.831
Minimum	20.7	-2.7	20.1	-2.9	22.5	-1.6	20.0	-3.6	19.6	-2.2
Q1	27.80	-0.50	28.00	-0.60	27.75	-0.45	27.10	-0.60	27.40	-0.60
Median	29.70	-0.10	29.10	-0.20	29.55	-0.10	28.60	-0.20	28.70	-0.20
Q3	30.90	0.30	30.20	0.20	30.40	0.30	29.90	0.20	30.00	0.00
Maximum	33.3	5.3	32.9	3.6	32.6	3.9	32.8	4.9	32.7	4.7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	28.93	-0.16	28.82	-0.15	28.92	-0.02	28.55	0.04	28.36	-0.11
SD	2.584	1.164	2.229	0.964	2.197	0.968	2.307	1.319	2.367	1.097
Minimum	20.4	-3.7	21.6	-4.3	23.5	-1.9	19.7	-3.7	20.9	-3.0
Q1	27.70	-0.60	28.00	-0.60	27.70	-0.55	27.70	-0.60	27.70	-0.60
Median	29.80	-0.20	29.10	-0.30	29.55	-0.20	28.80	-0.20	28.80	-0.20
Q3	30.70	0.20	30.30	0.20	30.40	0.35	29.90	0.30	29.90	0.20
Maximum	32.8	7.3	32.9	4.4	32.8	4.9	32.4	5.2	32.2	6.6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	30.23	-0.09	28.61	-0.02	29.30	-0.11	29.22	0.50	29.33	0.25
SD	2.273	0.682	2.086	0.644	2.099	0.761	1.668	1.577	2.392	1.010
Minimum	22.9	-1.5	23.1	-1.3	24.4	-1.3	25.2	-0.8	24.9	-1.2
Q1	29.40	-0.60	27.70	-0.40	29.10	-0.70	28.70	-0.40	27.70	-0.30
Median	30.90	-0.10	28.90	-0.20	29.95	-0.25	29.10	-0.20	29.95	-0.05
Q3	31.60	0.40	29.90	0.50	30.60	0.30	30.50	0.70	31.20	0.70
Maximum	32.5	1.0	31.7	1.0	32.1	1.5	31.6	4.8	32.1	2.2

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCHC (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	32.10		32.16		32.02		31.98		32.00	
SD	0.929		0.946		0.992		1.172		1.181	
Minimum	29.4		29.5		27.5		28.3		27.7	
Q1	31.70		31.60		31.40		31.20		31.70	
Median	32.10		32.20		32.10		32.10		32.20	
Q3	32.80		32.80		32.70		32.80		32.70	
Maximum	33.7		34.0		34.2		34.1		34.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	32.19	0.08	32.10	-0.05	32.06	0.04	32.01	0.02	31.84	-0.16
SD	0.893	0.550	0.882	0.562	0.952	0.522	1.144	0.635	1.159	0.567
Minimum	29.2	-1.3	29.1	-1.4	28.4	-1.1	27.6	-1.4	27.7	-1.7
Q1	31.70	-0.30	31.60	-0.40	31.55	-0.30	31.30	-0.30	31.40	-0.50
Median	32.20	0.10	32.10	0.00	32.20	0.00	32.00	0.00	32.00	-0.20
Q3	32.80	0.50	32.70	0.30	32.60	0.40	32.80	0.30	32.70	0.20
Maximum	34.2	1.5	34.2	1.2	34.2	1.7	34.0	2.3	33.7	1.3
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	32.24	0.13	32.13	-0.02	32.17	0.16	32.12	0.13	31.95	-0.04
SD	0.942	0.642	0.938	0.650	0.964	0.659	1.105	0.759	1.066	0.565
Minimum	29.3	-1.8	28.8	-1.5	29.8	-1.5	27.4	-1.9	28.0	-1.8
Q1	31.80	-0.30	31.50	-0.40	31.60	-0.20	31.60	-0.30	31.50	-0.30
Median	32.30	0.10	32.30	0.00	32.40	0.10	32.20	0.20	32.15	0.00
Q3	32.90	0.50	32.90	0.30	32.80	0.60	32.80	0.40	32.70	0.30
Maximum	34.8	2.0	34.2	1.5	33.8	2.4	34.4	3.2	33.8	2.3
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	32.26	0.13	32.23	0.08	32.25	0.26	32.20	0.21	32.11	0.15
SD	1.000	0.708	0.973	0.663	0.810	0.725	1.069	0.807	0.969	0.743
Minimum	29.3	-1.9	29.3	-1.8	30.3	-1.1	28.1	-1.5	29.7	-1.4
Q1	31.80	-0.40	31.60	-0.30	31.90	-0.25	31.80	-0.30	31.70	-0.30
Median	32.40	0.20	32.40	0.00	32.30	0.20	32.30	0.20	32.20	0.10
Q3	33.00	0.60	32.90	0.50	32.70	0.80	32.90	0.50	32.70	0.60
Maximum	34.0	2.9	34.7	1.9	34.2	3.2	34.4	3.3	34.4	3.4
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	32.36	0.16	32.29	0.19	32.41	0.23	32.59	0.58	32.22	0.34
SD	0.751	0.590	1.028	0.656	0.875	0.548	0.903	1.113	0.897	0.608
Minimum	30.0	-1.2	30.1	-1.0	30.2	-0.9	30.9	-0.7	30.6	-0.4
Q1	32.00	0.00	31.50	-0.30	32.10	-0.20	31.90	0.00	31.50	-0.10
Median	32.25	0.20	32.30	0.20	32.45	0.10	32.90	0.40	32.30	0.25
Q3	32.80	0.30	33.20	0.60	33.00	0.60	33.30	1.00	32.80	0.60
Maximum	33.5	1.2	33.9	1.3	33.6	1.6	33.8	3.7	33.4	1.4

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCV (fL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	90.44		90.06		90.31		89.06		89.29	
SD	6.170		5.381		6.190		5.819		6.346	
Minimum	69.3		72.3		67.6		72.0		68.6	
Q1	88.10		87.90		87.10		85.50		86.85	
Median	92.00		90.80		91.70		90.00		90.00	
Q3	94.30		93.30		94.90		93.00		92.95	
Maximum	100.2		101.3		102.3		99.5		99.5	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	90.26	-0.18	89.73	-0.33	90.02	-0.28	88.58	-0.48	89.32	0.03
SD	6.109	1.581	5.519	1.344	5.882	1.334	5.534	1.551	6.347	1.789
Minimum	71.4	-4.5	71.7	-4.9	71.1	-3.3	71.1	-5.7	69.5	-3.8
Q1	86.60	-1.10	87.80	-1.10	86.90	-1.20	85.00	-1.40	87.05	-1.20
Median	91.80	-0.30	90.10	-0.10	91.45	-0.30	89.20	-0.60	90.20	-0.20
Q3	94.30	0.40	93.50	0.30	94.20	0.20	92.60	0.40	93.00	0.65
Maximum	99.5	8.4	101.8	4.3	100.8	4.7	99.6	5.3	101.0	9.2
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	89.96	-0.44	89.50	-0.57	89.63	-0.58	88.35	-0.62	88.62	-0.57
SD	6.343	2.119	5.488	1.659	5.508	1.942	5.360	2.426	5.942	2.186
Minimum	70.7	-7.1	69.9	-5.8	75.3	-4.5	68.5	-8.4	69.9	-6.8
Q1	86.80	-1.70	87.40	-1.40	87.00	-1.85	85.20	-2.00	86.30	-1.50
Median	91.00	-0.50	90.10	-0.60	90.50	-0.90	88.80	-0.60	89.25	-0.65
Q3	94.70	0.40	93.00	0.30	93.55	0.45	91.70	0.20	92.90	0.10
Maximum	101.0	12.0	99.5	7.2	100.5	8.1	98.3	9.5	99.1	10.5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	89.57	-0.88	89.39	-0.67	89.59	-0.71	88.56	-0.42	88.17	-0.74
SD	6.170	2.616	5.296	2.324	5.537	2.367	5.204	2.831	5.598	2.695
Minimum	69.7	-7.5	71.2	-8.4	76.5	-6.1	68.1	-8.8	69.7	-7.0
Q1	86.70	-2.20	87.50	-1.70	87.20	-1.90	85.80	-1.90	86.00	-2.20
Median	90.80	-0.70	90.30	-0.60	91.00	-1.00	88.90	-0.90	88.90	-0.80
Q3	94.30	-0.10	92.80	0.40	93.50	0.35	91.50	0.50	91.90	0.50
Maximum	98.3	15.6	98.5	8.6	100.5	11.3	98.6	8.9	97.7	13.6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	93.37	-0.76	88.53	-0.55	90.35	-0.97	89.66	0.02	90.95	-0.09
SD	5.712	1.867	4.642	1.749	4.876	2.193	4.345	3.092	5.901	2.455
Minimum	76.2	-5.7	76.7	-3.0	78.9	-5.8	81.6	-2.8	81.4	-2.6
Q1	89.30	-1.60	87.20	-1.90	88.00	-2.20	86.90	-2.50	87.00	-1.70
Median	94.85	-0.70	88.80	-1.10	91.55	-0.95	89.70	-1.10	92.35	-0.35
Q3	96.40	0.50	90.80	1.20	94.00	0.10	93.10	0.70	96.40	0.20
Maximum	101.2	2.7	96.5	2.3	96.1	3.3	96.4	5.7	98.0	5.7

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-24　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（CCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Reticulocytes (permil)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	10.5		10.4		10.6		10.5		10.3	
SD	3.64		3.56		3.04		3.23		3.46	
Minimum	4		4		5		5		4	
Q1	8.0		8.0		9.0		8.0		8.0	
Median	10.0		10.0		10.0		10.0		10.0	
Q3	13.0		13.0		12.0		12.0		12.0	
Maximum	27		25		19		20		21	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	11.0	0.5	10.6	0.2	9.7	-1.0	9.7	-0.8	9.2	-1.1
SD	3.79	2.50	4.16	2.75	2.78	2.29	3.29	2.65	3.32	2.24
Minimum	5	-6	5	-6	4	-7	4	-6	4	-7
Q1	8.0	-1.0	8.0	-1.0	8.0	-2.0	7.0	-2.0	7.0	-2.0
Median	11.0	0.0	10.0	0.0	9.0	-1.0	9.0	-1.0	8.0	-1.0
Q3	13.0	2.0	12.0	1.0	12.0	1.0	12.0	0.0	11.0	0.0
Maximum	22	10	33	17	19	7	26	13	20	7
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	10.9	0.4	10.6	0.2	10.2	-0.5	9.8	-0.7	9.5	-0.7
SD	3.44	2.12	3.68	1.93	3.36	2.23	3.04	2.23	3.14	2.43
Minimum	5	-7	4	-4	2	-7	4	-6	4	-7
Q1	9.0	-1.0	8.0	-1.0	7.5	-2.0	8.0	-2.0	7.0	-2.0
Median	10.0	1.0	10.0	0.0	10.0	-0.5	9.0	-1.0	9.0	-1.0
Q3	13.0	2.0	12.0	1.0	12.0	1.0	11.0	1.0	11.0	1.0
Maximum	25	5	28	5	20	5	19	8	18	7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	11.6	1.2	11.0	0.6	10.6	0.0	11.0	0.6	10.3	0.0
SD	4.83	3.62	3.61	2.20	3.52	2.81	3.39	2.56	3.67	2.37
Minimum	5	-9	5	-5	6	-9	5	-5	3	-5
Q1	9.0	-1.0	8.0	-1.0	8.0	-2.0	8.0	-1.0	8.0	-1.0
Median	11.0	1.0	10.0	1.0	10.0	0.0	11.0	1.0	10.0	0.0
Q3	14.0	2.0	13.0	2.0	12.0	2.0	14.0	2.0	13.0	2.0
Maximum	42	24	26	8	24	8	22	9	22	6
Follow-up										
N	18	18	19	19	22	22	13	13	10	10
Mean	12.1	0.0	11.7	1.2	12.8	2.3	15.6	4.8	10.4	1.2
SD	4.49	2.99	4.12	2.36	4.00	3.25	5.08	5.23	4.35	3.19
Minimum	5	-5	6	-4	6	-3	8	-3	4	-3
Q1	10.0	-1.0	9.0	0.0	10.0	0.0	13.0	0.0	7.0	0.0
Median	11.5	0.0	10.0	2.0	11.5	1.0	16.0	5.0	11.0	0.5
Q3	13.0	3.0	15.0	3.0	16.0	5.0	19.0	7.0	12.0	2.0
Maximum	23	5	22	6	19	9	26	17	19	9

治験総括報告書 Table 3.3.1.1.1（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	426.9		427.1		421.9		425.7		427.1	
SD	29.71		27.82		32.13		30.66		30.17	
Minimum	364		355		333		355		361	
Q1	405.0		408.0		401.5		404.0		407.5	
Median	426.0		426.0		418.0		424.0		427.0	
Q3	447.0		446.0		446.5		445.0		444.5	
Maximum	499		484		516		511		500	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	429.6	2.6	441.0	13.8	442.4	20.5	450.9	25.3	445.6	18.4
SD	29.48	20.93	31.56	20.44	33.49	23.64	27.12	22.27	31.58	21.09
Minimum	368	-54	373	-37	343	-61	375	-32	385	-27
Q1	408.0	-11.0	418.0	-3.0	422.0	3.0	432.0	11.0	428.5	4.0
Median	428.0	2.0	439.0	14.0	445.5	21.5	452.0	26.0	442.0	19.0
Q3	448.0	16.0	459.0	29.0	463.0	38.0	471.0	38.0	461.5	28.5
Maximum	521	59	533	67	521	85	503	88	537	105
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	435.9	8.9	444.4	17.3	444.4	21.8	456.3	31.1	454.9	27.6
SD	32.49	23.18	31.26	23.49	33.01	22.89	28.91	26.39	32.04	21.11
Minimum	383	-55	380	-59	354	-56	373	-31	374	-17
Q1	409.0	-8.0	422.0	4.0	421.5	8.0	439.0	13.0	434.0	9.0
Median	436.0	12.0	445.0	16.0	445.0	21.5	456.0	28.0	451.0	28.0
Q3	455.0	26.0	467.0	32.0	466.0	37.0	478.0	52.0	471.0	41.0
Maximum	519	60	528	81	521	74	522	96	549	87
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	432.6	6.1	443.2	16.4	443.4	20.6	454.2	29.0	458.4	29.6
SD	33.02	28.82	30.25	22.59	30.84	23.03	30.12	25.91	31.07	26.04
Minimum	296	-160	373	-38	361	-53	387	-45	364	-50
Q1	415.0	-7.0	421.0	2.0	422.0	2.5	435.0	12.0	438.0	12.0
Median	435.0	5.0	446.0	17.0	446.0	21.0	456.0	25.0	454.0	31.0
Q3	451.0	24.0	466.0	32.0	464.5	38.0	474.0	47.0	477.0	45.0
Maximum	514	65	520	72	536	79	527	92	567	89
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	437.7	9.7	442.4	18.1	440.7	19.4	451.0	26.2	456.1	25.2
SD	32.78	21.33	31.12	23.75	34.77	22.19	28.90	26.33	32.13	27.94
Minimum	377	-31	352	-33	363	-37	377	-36	380	-47
Q1	415.0	-3.0	423.5	1.0	417.0	6.0	431.0	7.0	440.0	9.0
Median	439.0	7.0	439.5	21.0	437.0	22.0	450.0	29.0	452.0	24.0
Q3	457.0	21.0	460.0	33.5	464.0	35.0	470.0	44.0	472.0	41.0
Maximum	545	96	549	98	525	76	527	95	557	112

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: RBC (10^4 /μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	438.0	10.0	445.2	20.4	440.8	19.3	451.4	26.3	456.0	25.4
SD	29.40	23.81	28.80	26.79	31.20	19.65	29.52	27.23	32.15	26.85
Minimum	379	-37	374	-29	352	-31	392	-45	396	-53
Q1	416.0	-6.0	428.0	6.0	424.0	8.0	433.0	6.0	433.0	7.0
Median	440.0	5.0	447.0	20.0	436.0	18.0	448.0	27.0	455.0	23.0
Q3	453.0	29.0	462.0	36.0	467.0	35.0	468.0	45.0	474.0	40.0
Maximum	532	83	548	116	516	59	538	117	543	109
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	431.2	4.3	442.1	17.2	441.8	20.0	451.8	27.0	458.6	27.8
SD	29.30	26.31	30.81	24.07	31.78	20.92	30.75	27.02	31.15	24.64
Minimum	380	-53	368	-55	345	-33	376	-30	381	-31
Q1	404.0	-14.0	419.0	1.0	418.5	6.0	431.5	6.5	435.0	14.0
Median	429.0	6.0	439.0	14.0	443.0	19.5	449.5	26.5	462.0	26.0
Q3	453.0	21.0	465.0	31.0	461.0	35.0	470.0	43.5	479.0	43.0
Maximum	503	89	518	84	537	84	533	116	534	88
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	436.0	7.3	435.2	11.2	432.3	10.7	444.0	19.2	455.5	24.6
SD	29.39	26.68	28.55	22.97	31.81	19.41	27.80	26.29	30.43	24.84
Minimum	383	-55	369	-46	344	-41	390	-49	371	-45
Q1	413.0	-9.0	413.0	-3.0	412.0	-3.0	427.0	4.0	434.0	11.0
Median	437.0	2.0	434.0	10.0	432.0	12.0	441.0	22.0	454.0	25.0
Q3	455.0	25.0	455.0	25.0	460.0	25.0	462.0	39.0	475.0	38.0
Maximum	505	78	488	100	508	57	538	73	538	96

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	5783.5		5574.8		5285.0		5451.5		5798.8	
SD	1518.75		1667.67		1443.09		1697.97		2076.42	
Minimum	2800		2700		2400		2000		2600	
Q1	4700.0		4500.0		4300.0		4300.0		4500.0	
Median	5500.0		5200.0		5200.0		5100.0		5300.0	
Q3	6800.0		6400.0		6250.0		6500.0		6550.0	
Maximum	10700		12400		9200		9800		15900	
Week 4										
N	96	96	103	103	100	100	103	103	80	80
Mean	5457.3	-310.4	5272.8	-301.9	4797.0	-488.0	4762.1	-689.3	5032.5	-766.3
SD	1510.86	1421.60	1461.28	1506.06	1256.86	1258.77	1200.25	1458.98	1570.28	1802.10
Minimum	2700	-4300	3000	-5500	2000	-4800	2300	-4900	2300	-8200
Q1	4300.0	-1050.0	4200.0	-1200.0	4050.0	-1100.0	3900.0	-1400.0	3900.0	-1500.0
Median	5150.0	-200.0	5100.0	-200.0	4700.0	-300.0	4700.0	-400.0	4850.0	-500.0
Q3	6300.0	500.0	6100.0	700.0	5500.0	300.0	5600.0	300.0	5700.0	100.0
Maximum	9500	3700	10400	3900	8300	1800	7900	2000	11800	4300
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	5567.4	-204.2	5137.9	-436.9	4888.5	-439.6	4758.4	-643.6	5161.5	-600.0
SD	1444.69	1246.09	1452.19	1483.37	1274.93	1535.92	1230.63	1368.31	1459.78	1599.11
Minimum	2800	-4500	2400	-5300	2700	-4600	2100	-4600	2800	-8000
Q1	4600.0	-1000.0	4000.0	-1100.0	4100.0	-1450.0	3900.0	-1200.0	4100.0	-1000.0
Median	5400.0	0.0	4900.0	-200.0	4700.0	-250.0	4700.0	-400.0	5050.0	-250.0
Q3	6500.0	600.0	6000.0	500.0	5400.0	500.0	5500.0	100.0	5900.0	300.0
Maximum	9800	2900	9600	2800	8200	4700	8500	2400	8400	2200
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	5679.6	-121.5	5023.8	-543.6	4990.2	-344.6	4928.7	-473.3	4970.7	-801.3
SD	1569.38	1502.02	1417.40	1417.00	1207.86	1400.81	1294.48	1523.94	1324.18	1838.22
Minimum	2900	-5200	2600	-6700	2400	-4200	2300	-4800	2900	-9300
Q1	4500.0	-900.0	4000.0	-1200.0	4200.0	-1250.0	4100.0	-1000.0	3900.0	-1400.0
Median	5500.0	-100.0	4700.0	-500.0	4900.0	-400.0	4800.0	-300.0	4700.0	-500.0
Q3	6400.0	700.0	5800.0	400.0	5600.0	500.0	5500.0	500.0	5600.0	0.0
Maximum	10400	4900	10800	3300	9200	3800	10000	3900	10500	3500
Week 16										
N	74	74	84	84	78	78	89	89	69	69
Mean	5795.9	-24.3	4890.5	-609.5	4952.6	-409.0	4776.4	-650.6	5111.6	-731.9
SD	1615.54	1258.59	1202.47	1293.13	1313.64	1466.61	1294.04	1505.53	1435.53	1820.83
Minimum	3000	-3300	2900	-6400	2400	-4700	2400	-4300	2900	-9200
Q1	4700.0	-800.0	4050.0	-1200.0	4000.0	-1400.0	4000.0	-1300.0	4300.0	-1200.0
Median	5400.0	100.0	4700.0	-500.0	4750.0	-300.0	4500.0	-400.0	4800.0	-500.0
Q3	7000.0	700.0	5500.0	200.0	5700.0	600.0	5400.0	200.0	5500.0	100.0
Maximum	9300	2700	8500	2200	8800	3300	8800	2700	10300	3800

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: WBC (/μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	76	76	87	87	65	65
Mean	5622.7	-162.7	4971.6	-492.6	4878.9	-476.3	4905.7	-506.9	5023.1	-726.2
SD	1653.38	1367.26	1285.32	1472.73	1244.11	1397.13	1496.22	1689.28	1380.64	1744.39
Minimum	3100	-3400	2800	-7000	2500	-4800	2000	-4700	2100	-9000
Q1	4500.0	-900.0	4100.0	-1500.0	4100.0	-1450.0	3900.0	-1300.0	4100.0	-1600.0
Median	5400.0	-100.0	4900.0	-300.0	4650.0	-200.0	4600.0	-300.0	5000.0	-600.0
Q3	6200.0	600.0	5500.0	400.0	5600.0	400.0	5500.0	300.0	5700.0	400.0
Maximum	12800	4200	10300	5600	8400	2800	11700	5600	8700	3900
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	5635.3	-76.5	5058.2	-392.4	4865.8	-509.2	4797.7	-637.5	4924.2	-880.6
SD	1706.86	1445.64	1351.22	1473.25	1355.24	1438.07	1305.78	1749.90	1215.70	1640.16
Minimum	2900	-4100	2700	-5900	2500	-3700	2200	-5800	2100	-10200
Q1	4600.0	-900.0	4000.0	-1100.0	4000.0	-1550.0	3800.0	-1300.0	4100.0	-1400.0
Median	5350.0	-250.0	5000.0	-500.0	4600.0	-350.0	4650.0	-400.0	4650.0	-700.0
Q3	6600.0	700.0	5700.0	300.0	5400.0	450.0	5600.0	450.0	5600.0	0.0
Maximum	13000	5100	8900	4200	8800	2900	8900	3900	8800	1700
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	5458.4	-403.9	5351.8	-126.5	5253.2	-76.6	5423.6	-3.4	5004.3	-839.1
SD	1285.69	1386.16	1478.82	1397.83	1324.03	1364.87	1297.46	1450.11	1201.77	1825.73
Minimum	3300	-4300	3100	-5600	2900	-3600	3000	-4000	2800	-9700
Q1	4500.0	-1200.0	4200.0	-900.0	4300.0	-1000.0	4600.0	-700.0	4300.0	-1200.0
Median	5300.0	0.0	5100.0	0.0	5100.0	0.0	5200.0	200.0	4900.0	-600.0
Q3	6200.0	500.0	6200.0	700.0	5900.0	700.0	6100.0	800.0	5600.0	200.0
Maximum	9300	2600	11300	4000	9300	2900	9300	4300	8300	1600

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	62.81		62.03		61.73		62.37		63.49	
SD	8.847		9.107		8.724		8.753		8.314	
Minimum	39.9		39.7		25.5		40.7		42.3	
Q1	56.70		55.60		56.70		57.10		57.10	
Median	62.90		62.80		62.75		61.20		63.95	
Q3	68.60		68.90		67.45		68.40		69.10	
Maximum	83.3		83.0		77.1		84.5		82.9	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	60.33	-2.48	58.96	-3.07	55.65	-6.08	56.25	-6.12	57.00	-6.49
SD	9.106	8.592	8.385	9.315	7.890	9.783	8.848	10.376	8.473	8.941
Minimum	27.5	-35.9	40.7	-24.5	38.3	-34.4	33.8	-50.7	43.9	-28.7
Q1	55.90	-8.40	52.10	-10.00	50.30	-11.50	51.10	-12.30	50.25	-11.20
Median	62.70	-2.30	59.50	-1.90	55.60	-4.45	56.10	-5.90	55.75	-5.15
Q3	66.80	2.50	64.00	3.30	61.60	0.70	61.70	0.70	63.80	-0.90
Maximum	77.7	19.5	80.2	18.7	71.5	16.9	76.4	17.2	81.7	17.1
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	60.54	-2.05	58.00	-4.03	56.01	-5.64	56.01	-6.13	58.01	-5.40
SD	8.132	7.204	8.576	9.333	8.786	9.849	8.462	9.171	8.661	7.558
Minimum	37.1	-23.3	32.3	-34.8	16.9	-35.3	39.5	-41.4	40.0	-28.1
Q1	55.20	-5.50	52.40	-10.30	50.60	-10.40	50.70	-12.10	51.20	-9.90
Median	61.40	-1.50	57.60	-2.40	57.00	-5.25	55.10	-5.30	59.15	-3.90
Q3	66.40	2.40	63.50	2.20	61.90	1.10	62.00	-0.90	64.30	-0.50
Maximum	76.6	13.7	82.4	14.6	76.1	17.0	82.3	17.9	79.9	10.5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	61.83	-0.84	58.56	-3.44	57.42	-4.69	56.40	-5.74	56.57	-6.90
SD	8.452	7.232	8.632	8.625	7.471	10.009	8.558	10.181	8.815	9.190
Minimum	37.6	-20.2	39.6	-34.0	38.1	-34.1	31.8	-46.7	33.8	-30.4
Q1	55.60	-5.60	52.80	-7.80	51.80	-10.90	50.30	-10.70	51.60	-12.10
Median	62.50	-0.70	58.70	-3.00	58.15	-4.00	55.50	-4.40	56.00	-5.70
Q3	68.10	3.80	64.80	2.40	62.35	1.75	62.80	0.00	60.90	-0.30
Maximum	78.1	17.1	88.0	14.0	74.6	16.9	84.1	21.2	83.3	13.7
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	61.03	-1.57	56.67	-5.33	56.81	-5.19	55.21	-7.20	56.78	-6.69
SD	9.153	8.409	8.178	9.076	8.134	10.271	8.914	11.513	7.260	8.758
Minimum	39.8	-22.6	38.5	-34.6	42.6	-30.2	34.8	-49.7	42.1	-27.0
Q1	55.40	-6.20	50.25	-9.50	50.40	-10.90	48.00	-12.80	51.10	-12.30
Median	61.70	-1.20	57.15	-5.55	56.05	-4.50	55.30	-5.60	56.00	-6.10
Q3	67.70	3.30	62.90	0.30	62.00	0.50	60.70	0.70	61.90	-2.60
Maximum	81.0	21.3	81.8	18.6	81.4	17.0	80.2	17.7	76.1	14.5

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Neutrophils (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	60.58	-2.03	58.57	-3.51	55.59	-6.33	56.17	-6.12	56.70	-6.54
SD	8.883	7.957	8.442	8.782	8.843	9.078	9.085	10.227	8.356	9.798
Minimum	40.2	-23.7	43.2	-26.9	39.0	-34.0	37.6	-39.2	40.3	-32.1
Q1	54.20	-6.80	52.30	-8.50	49.20	-9.70	49.60	-12.20	50.90	-12.50
Median	61.40	-1.20	58.50	-3.10	55.40	-5.70	55.00	-5.10	56.30	-5.20
Q3	66.80	3.80	62.90	2.80	60.80	-1.40	62.20	0.30	60.10	-0.70
Maximum	83.2	22.4	77.5	14.7	76.9	14.1	87.9	16.9	80.3	17.2
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	60.23	-1.61	57.96	-4.12	55.80	-6.14	54.72	-7.78	55.80	-7.33
SD	9.454	9.042	9.533	9.509	8.395	10.555	8.966	10.829	8.189	8.485
Minimum	29.1	-29.1	29.8	-25.4	37.0	-34.6	36.4	-48.1	37.5	-30.2
Q1	53.00	-6.90	51.60	-10.50	49.55	-12.50	48.75	-13.55	49.80	-12.50
Median	60.10	-1.80	58.40	-3.50	55.40	-4.60	52.85	-7.00	56.75	-6.75
Q3	67.40	3.60	63.00	2.50	61.35	0.70	59.70	-1.15	63.60	-1.60
Maximum	78.6	20.7	83.3	24.0	75.4	20.0	76.8	21.5	71.0	8.2
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	60.47	-2.48	60.64	-1.30	59.70	-2.14	60.40	-2.02	55.24	-8.24
SD	7.654	7.901	8.703	9.559	7.555	9.447	7.082	8.706	7.267	8.286
Minimum	37.6	-23.1	33.7	-25.3	35.4	-26.6	42.0	-27.5	41.2	-28.4
Q1	55.60	-7.50	54.50	-7.30	56.30	-7.50	56.60	-6.40	50.20	-13.70
Median	61.00	-2.40	60.10	-1.80	60.30	-1.60	60.00	-1.50	55.20	-8.30
Q3	65.00	1.90	66.10	3.80	64.60	2.30	65.30	3.10	59.70	-1.80
Maximum	76.6	18.2	79.5	30.2	74.2	22.9	79.5	19.8	72.3	8.6

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	2.90		2.71		2.84		3.17		2.73	
SD	1.796		1.860		1.952		2.352		1.626	
Minimum	0.6		0.3		0.4		0.5		0.7	
Q1	1.60		1.30		1.40		1.60		1.55	
Median	2.60		2.10		2.25		2.60		2.30	
Q3	3.70		3.80		3.60		3.90		3.65	
Maximum	8.8		9.9		9.7		14.0		9.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	3.28	0.37	2.96	0.25	3.16	0.32	3.45	0.28	3.32	0.59
SD	2.420	1.268	2.019	1.130	2.179	1.376	2.360	1.539	1.888	1.419
Minimum	0.2	-1.6	0.0	-2.6	0.3	-2.7	0.6	-4.3	0.3	-3.7
Q1	1.60	-0.40	1.40	-0.60	1.70	-0.50	1.80	-0.40	2.10	-0.20
Median	2.50	0.00	2.30	0.30	2.40	0.20	2.90	0.20	2.80	0.60
Q3	4.50	1.10	4.10	0.80	4.30	1.00	4.40	1.00	4.80	1.35
Maximum	12.3	4.1	8.2	3.5	9.8	4.9	15.9	5.2	7.8	4.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	3.12	0.19	2.86	0.15	3.10	0.21	3.21	0.02	3.22	0.45
SD	2.207	1.312	1.970	1.331	2.238	1.642	2.033	1.518	1.753	1.244
Minimum	0.4	-3.5	0.0	-3.5	0.3	-4.6	0.5	-5.9	0.4	-4.3
Q1	1.70	-0.60	1.50	-0.70	1.60	-0.50	1.70	-0.60	1.80	-0.30
Median	2.30	0.10	2.30	0.10	2.60	0.00	2.70	0.00	3.10	0.25
Q3	3.80	0.60	3.70	0.90	4.05	0.95	4.50	0.70	4.50	1.20
Maximum	14.4	5.6	10.1	3.8	11.0	7.2	11.4	4.6	8.4	5.1
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	2.92	-0.01	2.84	0.10	3.01	0.11	3.43	0.24	3.00	0.26
SD	2.093	1.498	1.950	1.332	1.959	1.533	2.227	1.644	1.562	1.449
Minimum	0.5	-4.2	0.0	-3.8	0.3	-4.9	0.5	-5.2	0.4	-5.5
Q1	1.30	-0.80	1.40	-0.40	1.75	-0.70	1.70	-0.60	1.90	-0.50
Median	2.50	-0.20	2.40	0.00	2.40	0.10	3.00	0.20	2.70	0.30
Q3	4.00	0.60	3.70	0.70	4.10	0.85	4.70	0.90	4.10	1.10
Maximum	12.8	5.5	9.8	6.2	10.1	4.5	10.3	5.0	7.3	3.1
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	2.99	-0.01	2.97	0.29	2.90	-0.06	3.41	0.26	3.23	0.51
SD	2.600	1.838	1.949	1.331	2.343	1.664	2.052	1.702	1.617	1.342
Minimum	0.2	-5.0	0.2	-5.2	0.0	-6.8	0.7	-3.9	0.5	-4.7
Q1	1.40	-0.90	1.45	-0.55	1.70	-0.90	1.90	-0.70	2.00	-0.20
Median	2.00	-0.10	2.60	0.35	2.35	-0.10	3.10	0.30	2.90	0.40
Q3	4.20	1.00	4.05	1.10	3.40	0.60	4.30	1.30	4.60	1.10
Maximum	16.6	7.8	9.4	3.8	13.5	5.4	11.8	8.0	7.9	3.8

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Eosinophils (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	3.26	0.26	2.72	0.06	3.21	0.23	3.38	0.23	3.21	0.47
SD	2.678	1.770	1.700	1.180	2.625	1.623	2.082	1.669	2.053	1.716
Minimum	0.5	-4.5	0.0	-2.9	0.3	-4.5	0.6	-3.3	0.5	-6.4
Q1	1.20	-0.70	1.40	-0.70	1.70	-0.60	1.80	-0.70	2.10	-0.40
Median	2.30	0.00	2.50	-0.10	2.30	0.20	2.90	0.10	2.80	0.30
Q3	4.70	0.70	3.60	0.80	4.20	0.70	4.50	1.10	3.90	1.20
Maximum	12.8	5.2	8.3	2.9	13.7	5.4	11.9	8.1	12.2	7.7
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	3.12	0.11	2.83	0.15	3.02	0.02	3.43	0.31	3.05	0.35
SD	2.329	1.611	1.757	1.380	2.095	1.366	2.093	2.029	2.035	1.565
Minimum	0.3	-4.1	0.0	-3.9	0.2	-4.4	0.5	-4.7	0.4	-4.7
Q1	1.50	-0.80	1.60	-0.50	1.50	-0.40	1.90	-1.00	1.70	-0.50
Median	2.40	-0.10	2.50	0.10	2.50	-0.05	3.10	0.20	2.65	0.20
Q3	4.10	0.70	3.60	1.00	3.85	0.60	4.30	1.20	4.00	1.00
Maximum	13.4	6.6	9.6	4.0	10.9	4.4	12.5	8.7	11.9	5.8
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	3.07	0.08	2.45	-0.22	2.71	-0.28	2.91	-0.24	3.23	0.51
SD	2.166	1.721	1.785	1.106	1.970	1.630	1.734	1.676	1.874	1.581
Minimum	0.5	-5.1	0.0	-3.7	0.2	-6.1	0.5	-4.7	0.7	-6.6
Q1	1.60	-0.90	1.10	-0.80	1.50	-0.80	1.70	-1.20	1.90	-0.10
Median	2.50	0.00	1.90	-0.10	2.10	-0.20	2.60	-0.10	2.60	0.40
Q3	3.90	1.00	3.30	0.50	3.00	0.50	3.80	0.60	4.10	1.30
Maximum	12.4	5.5	10.1	3.0	9.9	3.8	8.1	4.2	10.3	4.1

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	0.62		0.62		0.56		0.60		0.63	
SD	0.392		0.424		0.348		0.385		0.416	
Minimum	0.1		0.0		0.2		0.0		0.1	
Q1	0.30		0.30		0.30		0.30		0.40	
Median	0.50		0.50		0.50		0.50		0.50	
Q3	0.80		0.80		0.70		0.80		0.80	
Maximum	1.8		2.3		2.7		2.2		2.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	0.74	0.12	0.69	0.07	0.65	0.09	0.72	0.12	0.80	0.17
SD	0.532	0.450	0.448	0.347	0.410	0.358	0.379	0.380	0.496	0.385
Minimum	0.2	-0.9	0.1	-0.7	0.1	-1.2	0.0	-1.2	0.2	-0.6
Q1	0.40	-0.10	0.40	-0.20	0.40	-0.10	0.50	-0.10	0.40	-0.10
Median	0.60	0.10	0.60	0.00	0.50	0.05	0.60	0.10	0.80	0.00
Q3	0.80	0.20	0.90	0.20	0.90	0.30	0.90	0.30	0.95	0.40
Maximum	3.4	2.2	2.3	1.5	2.1	1.2	2.2	1.3	2.3	1.5
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	0.67	0.05	0.70	0.09	0.62	0.09	0.68	0.08	0.66	0.03
SD	0.407	0.320	0.450	0.372	0.397	0.326	0.327	0.379	0.486	0.297
Minimum	0.1	-0.6	0.0	-1.2	0.1	-0.7	0.2	-1.3	0.1	-0.6
Q1	0.40	-0.10	0.30	-0.20	0.40	-0.10	0.50	-0.10	0.40	-0.10
Median	0.60	0.00	0.60	0.00	0.60	0.00	0.60	0.10	0.50	0.00
Q3	1.00	0.30	0.90	0.40	0.70	0.30	0.90	0.30	0.80	0.20
Maximum	2.3	1.0	2.6	1.1	2.0	1.4	1.7	1.1	3.3	1.0
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	0.62	0.01	0.63	0.01	0.61	0.07	0.69	0.09	0.65	0.04
SD	0.392	0.268	0.354	0.307	0.371	0.319	0.317	0.381	0.465	0.335
Minimum	0.1	-0.8	0.1	-1.0	0.0	-0.7	0.2	-1.5	0.2	-0.6
Q1	0.30	-0.10	0.30	-0.10	0.40	-0.10	0.50	-0.10	0.40	-0.20
Median	0.50	0.00	0.60	0.00	0.60	0.10	0.70	0.10	0.50	0.00
Q3	0.80	0.20	0.80	0.10	0.70	0.30	0.90	0.30	0.80	0.20
Maximum	1.8	0.7	2.2	0.9	2.1	1.2	1.9	0.9	3.0	1.3
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	0.67	0.05	0.70	0.09	0.57	0.05	0.71	0.10	0.61	0.02
SD	0.446	0.301	0.404	0.353	0.309	0.287	0.345	0.403	0.328	0.272
Minimum	0.1	-0.8	0.0	-1.1	0.1	-0.7	0.1	-1.5	0.2	-0.5
Q1	0.40	-0.10	0.40	-0.10	0.30	-0.10	0.50	-0.10	0.40	-0.20
Median	0.50	0.10	0.60	0.10	0.50	0.00	0.70	0.10	0.60	0.00
Q3	0.80	0.20	0.95	0.30	0.70	0.20	0.90	0.30	0.80	0.20
Maximum	2.1	0.9	1.8	0.8	1.5	0.7	1.7	1.2	1.9	1.0

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Basophils (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	0.67	0.05	0.70	0.09	0.58	0.06	0.68	0.07	0.61	0.00
SD	0.345	0.303	0.423	0.383	0.331	0.286	0.363	0.367	0.335	0.329
Minimum	0.1	-0.8	0.0	-1.0	0.0	-0.5	0.1	-1.5	0.2	-0.9
Q1	0.40	-0.10	0.40	-0.20	0.30	-0.10	0.40	-0.10	0.40	-0.20
Median	0.60	0.10	0.60	0.10	0.50	0.00	0.60	0.10	0.60	0.00
Q3	0.90	0.20	0.90	0.30	0.70	0.20	0.90	0.30	0.80	0.20
Maximum	1.7	1.0	1.9	1.0	1.7	0.9	2.1	1.0	2.3	0.7
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	0.70	0.07	0.66	0.05	0.59	0.08	0.69	0.09	0.64	0.03
SD	0.413	0.412	0.352	0.380	0.395	0.367	0.380	0.419	0.358	0.330
Minimum	0.1	-1.2	0.0	-1.1	0.0	-0.8	0.0	-1.3	0.2	-1.0
Q1	0.40	-0.15	0.40	-0.10	0.30	-0.10	0.45	-0.10	0.30	-0.20
Median	0.60	0.10	0.60	0.00	0.50	0.00	0.70	0.00	0.60	0.00
Q3	0.90	0.25	0.90	0.30	0.80	0.25	0.90	0.30	0.90	0.30
Maximum	1.8	1.1	1.9	1.2	2.6	1.7	2.3	1.6	1.6	0.8
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	0.72	0.10	0.60	-0.01	0.51	0.00	0.55	-0.06	0.64	0.05
SD	0.425	0.345	0.408	0.348	0.367	0.321	0.243	0.363	0.357	0.301
Minimum	0.2	-1.1	0.0	-0.7	0.1	-0.8	0.1	-1.4	0.2	-0.7
Q1	0.40	-0.10	0.30	-0.20	0.30	-0.10	0.40	-0.20	0.40	-0.20
Median	0.60	0.10	0.50	0.00	0.40	0.00	0.50	0.00	0.60	0.00
Q3	0.90	0.30	0.80	0.20	0.60	0.10	0.70	0.20	0.70	0.20
Maximum	2.1	1.2	1.9	1.1	2.1	1.2	1.2	0.7	2.1	0.9

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	28.47		29.34		29.08		28.31		27.76	
SD	7.801		8.216		7.363		7.618		7.232	
Minimum	10.6		11.5		15.4		10.6		10.4	
Q1	22.90		23.90		24.10		23.70		22.85	
Median	27.80		28.50		28.05		28.50		27.70	
Q3	34.20		34.90		33.30		32.60		33.75	
Maximum	52.2		54.3		54.3		49.6		42.8	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	30.15	1.69	31.87	2.53	34.57	5.49	34.20	5.89	33.67	5.91
SD	7.330	7.299	7.766	8.331	7.267	8.645	7.969	8.924	7.381	7.538
Minimum	16.2	-18.4	13.3	-18.2	16.5	-14.4	15.7	-16.1	13.1	-15.6
Q1	24.70	-2.70	27.00	-3.70	29.60	-0.25	29.00	0.00	28.50	1.05
Median	29.50	2.10	31.10	2.10	34.70	3.95	34.90	4.70	34.05	5.10
Q3	34.50	5.80	38.30	8.00	39.00	9.40	39.40	12.10	39.80	10.70
Maximum	54.1	29.1	50.0	21.0	50.5	31.3	57.3	45.3	46.2	26.1
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	30.29	1.66	32.78	3.44	34.52	5.31	34.67	6.18	32.87	5.06
SD	6.666	6.241	7.956	8.054	7.751	8.458	8.332	7.841	7.624	6.665
Minimum	17.3	-14.5	11.5	-12.4	15.8	-14.6	9.1	-13.3	12.3	-7.6
Q1	25.70	-2.00	26.70	-1.80	29.30	-0.60	28.90	2.40	27.20	0.50
Median	29.70	1.60	32.00	3.10	34.60	4.40	35.30	4.90	32.85	3.90
Q3	34.60	5.70	38.70	8.20	39.05	9.25	40.60	11.10	38.20	8.70
Maximum	50.6	18.9	56.4	30.0	61.0	32.7	55.1	34.0	50.3	23.5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	29.42	0.84	32.49	3.15	33.67	4.84	34.17	5.67	34.44	6.64
SD	7.508	6.512	7.821	7.395	7.307	9.097	7.809	8.718	8.303	7.763
Minimum	15.3	-15.2	8.8	-12.7	14.5	-14.0	11.1	-18.3	8.5	-10.8
Q1	24.50	-2.60	27.40	-1.80	28.80	-1.20	29.10	0.20	28.90	1.20
Median	28.90	0.60	31.80	3.00	32.75	4.60	35.30	5.20	35.40	5.80
Q3	34.00	5.70	37.80	6.30	38.50	10.25	39.20	10.20	39.20	11.40
Maximum	51.6	17.1	52.5	30.8	53.7	33.1	55.4	39.2	56.1	23.8
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	29.90	1.33	34.24	4.86	34.30	5.16	35.31	7.08	34.15	6.31
SD	7.799	7.478	7.259	8.111	7.494	8.781	8.412	9.993	6.609	7.476
Minimum	9.8	-18.4	15.0	-18.9	13.5	-13.8	12.8	-14.0	13.0	-12.0
Q1	24.70	-2.70	29.05	0.35	29.20	-0.20	28.60	0.40	29.80	2.60
Median	29.50	1.50	33.75	4.10	34.35	4.30	34.50	6.50	34.40	5.50
Q3	35.90	5.80	39.35	9.60	40.10	10.30	41.20	11.90	38.10	11.10
Maximum	50.5	18.7	49.3	31.0	48.9	26.9	55.4	43.4	47.0	21.9

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Lymphocytes (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	29.99	1.42	32.46	3.16	35.09	5.90	34.41	6.07	34.20	6.18
SD	7.296	7.039	7.791	8.029	7.977	8.063	8.530	8.790	7.391	8.444
Minimum	11.1	-18.0	16.9	-12.0	15.6	-13.3	8.1	-16.6	13.5	-11.9
Q1	25.10	-3.30	27.00	-2.20	29.30	1.00	29.20	0.70	31.30	1.10
Median	29.10	1.60	32.60	3.80	35.10	5.40	34.80	5.40	34.00	5.40
Q3	34.70	6.00	38.10	8.20	40.50	9.30	40.90	11.40	39.50	11.10
Maximum	51.3	21.4	49.1	23.7	52.0	27.2	53.9	32.0	48.8	26.1
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	30.57	1.27	33.11	3.84	35.26	6.12	35.77	7.58	35.25	7.03
SD	8.494	8.177	8.630	8.589	7.796	9.553	8.338	9.121	7.031	7.593
Minimum	14.2	-18.6	11.3	-20.9	18.1	-17.6	16.4	-18.2	18.6	-10.5
Q1	24.50	-3.10	27.70	-0.90	30.10	0.00	31.60	1.70	29.50	1.30
Median	31.40	1.60	32.50	2.80	34.30	4.95	35.65	6.65	35.10	7.05
Q3	36.20	5.95	39.60	9.20	39.60	11.00	41.40	13.80	40.00	11.40
Maximum	63.5	25.3	55.7	24.3	53.7	34.5	53.7	40.1	51.1	26.6
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	30.35	2.09	30.66	1.21	31.53	2.26	30.69	2.46	35.64	7.80
SD	6.944	6.716	7.965	9.005	6.987	8.120	6.861	7.557	6.515	7.220
Minimum	17.1	-15.4	14.6	-32.5	18.3	-19.9	12.1	-17.8	18.1	-7.7
Q1	24.80	-1.20	25.00	-3.80	27.40	-2.10	26.00	-1.90	32.60	2.70
Median	30.80	2.50	31.20	1.80	30.60	1.50	31.00	2.50	35.60	7.80
Q3	34.40	6.00	36.40	6.80	35.30	6.60	34.80	7.20	39.90	12.50
Maximum	54.3	19.2	48.8	23.8	54.1	22.1	47.8	21.6	47.8	24.5

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	5.20		5.31		5.79		5.56		5.39	
SD	1.364		1.373		1.779		1.388		1.543	
Minimum	2.4		2.3		2.3		2.3		2.7	
Q1	4.30		4.30		4.50		4.60		4.05	
Median	5.10		5.20		5.70		5.50		5.30	
Q3	5.90		6.30		6.55		6.40		6.30	
Maximum	10.2		10.8		13.4		10.3		9.1	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	5.51	0.31	5.52	0.21	5.97	0.18	5.39	-0.17	5.21	-0.18
SD	1.491	1.293	1.168	1.245	1.740	1.659	1.328	1.451	1.530	1.291
Minimum	2.7	-3.0	3.1	-4.1	3.0	-8.1	3.2	-3.4	1.9	-3.3
Q1	4.30	-0.40	4.70	-0.50	4.75	-0.55	4.30	-1.20	4.20	-1.05
Median	5.60	0.30	5.30	0.20	5.80	0.10	5.40	-0.30	5.00	-0.40
Q3	6.40	1.00	6.20	0.90	6.90	1.00	6.20	0.80	6.00	0.75
Maximum	10.8	4.6	9.9	5.1	12.3	6.0	10.6	3.6	11.2	3.6
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	5.38	0.15	5.66	0.35	5.75	0.04	5.43	-0.14	5.25	-0.14
SD	1.527	1.248	1.666	1.638	1.543	1.729	1.424	1.581	1.408	1.390
Minimum	2.8	-4.8	3.1	-3.5	3.3	-8.4	1.9	-4.5	2.8	-4.4
Q1	4.30	-0.60	4.40	-0.60	4.75	-0.95	4.60	-1.10	4.10	-1.00
Median	5.30	-0.10	5.20	0.20	5.50	0.10	5.10	-0.20	5.30	-0.20
Q3	6.20	0.90	6.60	1.10	6.50	1.25	6.50	0.80	6.10	0.70
Maximum	12.5	3.6	10.7	5.6	14.1	4.4	10.7	6.0	11.2	4.0
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	5.21	0.00	5.49	0.18	5.29	-0.34	5.32	-0.25	5.35	-0.04
SD	1.546	1.317	1.515	1.484	1.380	1.640	1.443	1.557	1.663	1.870
Minimum	2.3	-3.3	2.3	-4.3	2.5	-9.1	2.4	-4.4	3.0	-3.7
Q1	4.10	-1.00	4.60	-0.70	4.35	-1.10	4.30	-1.10	4.30	-1.20
Median	5.00	0.00	5.30	0.10	5.00	-0.30	5.20	-0.20	5.10	-0.20
Q3	6.10	0.60	6.00	1.00	6.15	0.40	6.30	0.70	6.00	0.90
Maximum	9.9	5.0	11.5	5.2	8.4	4.4	10.2	4.9	15.0	9.8
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	5.41	0.20	5.42	0.10	5.42	0.04	5.35	-0.24	5.23	-0.13
SD	1.518	1.060	1.334	1.391	1.305	1.345	1.445	1.593	1.236	1.414
Minimum	2.2	-2.4	2.8	-4.3	1.6	-3.5	2.7	-3.7	2.7	-3.5
Q1	4.40	-0.60	4.55	-0.75	4.40	-0.70	4.40	-1.30	4.40	-1.10
Median	5.20	0.30	5.35	0.10	5.45	-0.10	5.10	-0.60	5.10	-0.10
Q3	6.00	0.90	6.35	1.15	6.40	0.80	6.00	0.90	5.70	0.90
Maximum	10.2	2.2	8.7	3.9	8.5	2.5	9.8	4.0	9.0	3.8

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Monocytes (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	5.51	0.30	5.54	0.20	5.54	0.14	5.37	-0.25	5.28	-0.11
SD	1.784	1.540	1.199	1.279	1.327	1.320	1.584	1.703	1.463	1.421
Minimum	2.4	-3.4	3.0	-4.0	2.6	-3.1	2.9	-4.1	2.6	-4.5
Q1	4.00	-0.70	4.70	-0.70	4.80	-0.60	4.30	-1.50	4.30	-1.00
Median	5.20	0.00	5.50	0.30	5.40	0.00	5.00	-0.50	5.00	-0.30
Q3	6.50	1.00	6.20	1.00	6.20	0.80	6.40	0.70	6.00	0.90
Maximum	10.4	4.7	9.0	4.0	9.7	4.4	12.0	7.5	9.0	3.2
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	5.39	0.16	5.45	0.08	5.33	-0.08	5.38	-0.20	5.26	-0.09
SD	1.384	0.966	1.342	1.244	1.239	1.282	1.404	1.505	1.497	1.320
Minimum	2.1	-2.0	0.8	-3.2	2.9	-3.1	2.8	-4.1	2.9	-4.0
Q1	4.50	-0.45	4.60	-0.80	4.45	-0.90	4.50	-1.15	4.30	-1.00
Median	5.35	0.30	5.40	0.10	5.20	-0.30	5.20	-0.30	5.10	-0.10
Q3	6.30	0.70	6.20	0.70	6.10	0.80	6.10	0.50	6.00	0.80
Maximum	8.7	2.7	8.4	3.0	9.0	3.4	10.7	4.4	11.1	3.9
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	5.40	0.22	5.65	0.31	5.55	0.17	5.45	-0.14	5.24	-0.12
SD	1.484	1.154	1.435	1.459	1.182	1.185	1.186	1.378	1.396	1.171
Minimum	2.3	-3.4	2.8	-4.0	3.5	-2.8	2.9	-4.7	3.1	-3.4
Q1	4.30	-0.50	4.60	-0.40	4.60	-0.50	4.70	-1.00	4.30	-0.90
Median	5.40	0.10	5.50	0.20	5.40	0.00	5.40	0.00	5.10	-0.10
Q3	6.30	1.00	6.30	1.10	6.30	1.10	6.10	0.80	6.00	0.60
Maximum	8.8	2.9	11.5	4.8	8.3	3.0	8.3	3.2	9.8	3.0

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	12.38		12.37		12.18		12.12		12.20	
SD	1.116		1.162		1.139		1.199		1.236	
Minimum	9.4		8.7		8.9		9.3		8.0	
Q1	11.80		11.90		11.40		11.20		11.40	
Median	12.40		12.50		12.30		12.30		12.30	
Q3	13.10		13.10		13.05		13.00		12.90	
Maximum	14.5		14.7		14.4		14.5		15.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	12.46	0.08	12.69	0.32	12.74	0.56	12.79	0.67	12.65	0.45
SD	1.040	0.677	1.120	0.599	1.061	0.697	1.235	0.692	1.140	0.675
Minimum	9.1	-1.5	8.4	-1.5	9.9	-1.3	8.9	-1.0	8.5	-1.1
Q1	11.80	-0.30	12.10	-0.10	12.10	0.10	12.00	0.20	11.90	0.00
Median	12.50	0.00	12.70	0.40	12.80	0.50	13.00	0.60	12.85	0.40
Q3	13.30	0.50	13.30	0.70	13.60	1.00	13.60	1.00	13.35	0.80
Maximum	14.0	2.1	15.3	2.5	14.9	2.4	15.4	3.2	15.5	3.8
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	12.62	0.24	12.77	0.40	12.78	0.60	12.94	0.85	12.85	0.66
SD	1.138	0.769	1.133	0.748	1.026	0.710	1.120	0.887	0.979	0.715
Minimum	9.2	-1.8	8.3	-1.8	10.0	-1.2	9.0	-1.1	9.7	-0.7
Q1	12.00	-0.30	12.30	0.00	12.15	0.10	12.50	0.20	12.20	0.20
Median	12.70	0.20	12.90	0.50	12.80	0.60	13.00	0.80	13.00	0.70
Q3	13.40	0.60	13.60	0.80	13.60	1.10	13.60	1.40	13.50	1.00
Maximum	15.0	3.1	15.1	3.6	14.7	2.6	15.7	4.0	15.3	3.8
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	12.50	0.11	12.76	0.40	12.79	0.59	12.94	0.84	12.95	0.77
SD	1.323	0.987	1.102	0.704	0.953	0.754	1.057	0.951	0.882	0.886
Minimum	8.5	-5.2	8.8	-1.3	10.7	-2.0	9.6	-1.0	10.2	-1.6
Q1	11.70	-0.30	12.10	-0.10	12.15	0.10	12.50	0.20	12.50	0.30
Median	12.70	0.10	12.90	0.40	12.75	0.60	13.00	0.70	13.00	0.70
Q3	13.40	0.60	13.40	0.80	13.40	1.05	13.60	1.30	13.60	1.30
Maximum	14.9	3.4	15.6	2.5	15.0	2.6	15.1	4.5	14.6	4.5
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	12.46	0.13	12.73	0.41	12.70	0.59	12.95	0.86	13.01	0.73
SD	1.302	0.895	1.075	0.852	0.943	0.769	1.020	1.028	0.852	1.017
Minimum	9.0	-1.9	8.3	-1.2	10.3	-0.8	9.9	-1.2	10.6	-2.0
Q1	11.60	-0.30	12.30	-0.10	12.10	0.10	12.50	0.20	12.60	0.10
Median	12.60	0.00	12.75	0.35	12.70	0.60	13.00	0.90	13.00	0.60
Q3	13.30	0.50	13.45	0.85	13.30	1.00	13.50	1.30	13.50	1.30
Maximum	15.7	3.9	14.9	4.3	14.9	3.4	15.3	5.3	15.5	5.5

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hemoglobin (g/dL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	12.43	0.11	12.85	0.50	12.74	0.63	13.03	0.94	13.07	0.84
SD	1.256	0.887	0.888	0.968	0.947	0.837	0.968	1.009	0.836	0.998
Minimum	9.0	-2.0	10.5	-1.3	10.0	-1.0	10.4	-1.6	11.0	-2.1
Q1	11.60	-0.40	12.40	0.00	12.30	0.00	12.60	0.30	12.60	0.20
Median	12.60	0.10	12.90	0.40	12.80	0.60	13.10	0.80	13.10	0.70
Q3	13.40	0.60	13.40	0.80	13.30	1.00	13.50	1.50	13.50	1.40
Maximum	15.1	3.3	15.1	4.7	14.7	3.3	15.2	4.0	15.2	3.9
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	12.22	-0.11	12.84	0.46	12.74	0.64	13.09	1.01	13.25	1.06
SD	1.203	0.859	0.914	0.958	0.981	0.972	0.987	1.117	0.844	0.994
Minimum	8.8	-2.2	10.0	-2.0	10.4	-1.3	11.0	-1.4	11.6	-0.9
Q1	11.70	-0.60	12.30	-0.10	12.20	0.00	12.60	0.25	12.70	0.30
Median	12.40	-0.20	12.80	0.30	12.95	0.55	13.00	0.90	13.25	0.90
Q3	13.00	0.45	13.50	0.80	13.50	1.05	13.75	1.70	13.80	1.70
Maximum	14.1	2.1	14.9	4.8	14.6	4.0	15.1	5.0	15.8	4.6
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	12.36	0.00	12.63	0.30	12.49	0.38	12.91	0.82	13.27	1.00
SD	1.353	0.912	0.906	0.888	1.014	0.844	0.963	1.113	0.805	1.101
Minimum	8.2	-2.8	9.6	-1.7	9.9	-1.9	10.3	-1.7	11.4	-1.8
Q1	11.60	-0.70	12.10	-0.30	12.10	-0.10	12.30	0.10	12.70	0.20
Median	12.30	-0.10	12.60	0.20	12.60	0.30	13.00	0.80	13.30	0.90
Q3	13.30	0.60	13.30	0.70	13.10	0.80	13.50	1.50	13.70	1.60
Maximum	14.8	2.1	14.3	4.0	14.5	3.2	14.9	4.3	15.8	4.9

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	38.53		38.43		38.02		37.85		38.07	
SD	2.854		2.997		2.972		3.059		3.119	
Minimum	30.4		29.5		31.5		30.3		28.9	
Q1	36.80		37.00		36.15		35.60		36.20	
Median	38.60		38.40		38.40		38.10		38.10	
Q3	40.70		40.30		40.15		40.00		39.90	
Maximum	44.8		44.3		44.2		45.2		47.7	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	38.69	0.16	39.51	1.07	39.72	1.70	39.91	2.05	39.70	1.63
SD	2.690	2.057	2.977	1.750	2.784	2.224	3.014	2.088	2.845	2.030
Minimum	29.4	-4.2	28.9	-3.5	32.5	-5.0	30.5	-3.0	30.7	-2.1
Q1	37.00	-1.00	37.80	-0.30	37.60	0.20	38.10	0.70	37.95	0.20
Median	38.80	0.00	39.70	1.00	39.80	1.70	40.10	2.10	40.10	1.60
Q3	40.70	1.10	41.20	2.10	41.70	3.20	42.00	3.20	41.10	2.75
Maximum	44.1	6.6	46.3	7.3	45.7	7.8	46.4	8.1	47.5	12.0
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	39.12	0.60	39.72	1.28	39.73	1.70	40.26	2.49	40.20	2.15
SD	2.964	2.207	3.020	2.155	2.707	2.111	2.818	2.577	2.510	2.053
Minimum	30.7	-4.6	28.8	-4.4	32.3	-4.2	32.0	-3.2	34.6	-1.5
Q1	37.40	-0.70	37.80	-0.10	37.85	0.60	38.90	0.70	38.70	0.90
Median	39.00	0.50	39.60	1.30	39.80	1.40	40.40	2.40	40.10	2.10
Q3	40.90	1.70	42.10	2.60	41.80	3.05	42.10	4.00	41.80	3.40
Maximum	45.3	7.7	45.5	9.8	45.6	8.3	47.5	10.0	48.1	10.4
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	38.68	0.18	39.56	1.16	39.63	1.55	40.15	2.37	40.31	2.24
SD	3.342	2.852	2.953	2.156	2.559	2.151	2.602	2.505	2.314	2.536
Minimum	26.9	-15.6	30.0	-4.9	33.8	-5.6	33.7	-2.6	34.3	-4.1
Q1	36.80	-1.20	37.30	-0.40	37.70	-0.05	39.00	0.70	39.00	0.70
Median	38.80	0.00	39.80	1.30	39.65	1.55	40.00	2.00	40.20	2.20
Q3	41.00	1.90	41.60	2.70	41.45	3.20	42.00	4.00	41.80	3.50
Maximum	45.7	7.4	45.9	7.4	45.7	7.0	45.5	10.4	45.2	11.3
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	38.78	0.43	39.82	1.53	39.49	1.66	40.16	2.40	40.44	2.13
SD	3.326	2.392	3.001	2.431	2.612	2.141	2.656	2.687	2.444	2.866
Minimum	30.5	-4.1	29.4	-3.1	33.9	-2.5	33.9	-3.9	35.2	-6.8
Q1	36.70	-1.20	38.10	-0.10	37.90	0.20	38.50	0.60	38.70	0.50
Median	39.10	0.10	40.20	1.50	39.10	1.75	40.10	2.50	40.60	1.70
Q3	41.00	1.60	41.90	3.10	41.00	3.10	42.20	3.60	41.40	3.60
Maximum	47.6	8.9	45.0	11.7	45.4	7.7	47.3	12.4	47.0	14.6

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Hematocrit (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	38.65	0.30	40.08	1.73	39.54	1.71	40.36	2.61	40.59	2.44
SD	3.110	2.449	2.382	2.733	2.603	2.251	2.626	2.716	2.331	2.722
Minimum	30.8	-4.5	34.7	-3.3	32.4	-2.8	33.0	-4.3	36.2	-7.3
Q1	37.00	-1.40	38.50	0.20	38.30	0.00	38.80	0.80	39.10	0.30
Median	39.10	0.20	40.00	1.50	39.60	1.60	40.60	2.80	40.20	1.90
Q3	40.80	1.60	41.40	2.90	40.90	3.10	42.30	4.30	41.90	4.10
Maximum	46.7	8.7	45.9	11.9	46.4	7.8	46.7	9.1	46.6	9.3
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	38.12	-0.22	39.92	1.50	39.54	1.72	40.43	2.69	41.04	2.96
SD	3.051	2.372	2.543	2.695	2.625	2.543	2.743	2.905	2.361	2.574
Minimum	30.6	-4.9	33.8	-5.7	33.5	-3.0	33.9	-3.2	36.1	-3.1
Q1	36.55	-1.65	38.30	0.10	37.90	0.00	38.45	0.80	39.20	1.30
Median	38.30	-0.45	39.60	1.30	40.25	1.55	40.25	2.50	40.80	2.90
Q3	40.20	1.35	41.90	2.90	41.25	2.80	42.20	4.45	42.50	4.60
Maximum	43.6	5.5	46.0	12.9	45.7	9.0	46.5	10.6	47.7	9.8
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	38.55	0.12	39.36	1.09	38.78	0.93	39.82	2.06	40.94	2.63
SD	3.496	2.525	2.546	2.494	2.703	2.167	2.679	2.985	2.440	2.846
Minimum	28.7	-6.6	31.1	-4.8	32.0	-3.8	33.5	-5.0	36.2	-5.6
Q1	36.30	-1.30	37.70	-0.10	37.10	-0.40	37.60	0.40	39.20	0.90
Median	38.50	-0.20	39.20	0.70	39.00	1.10	39.60	2.10	41.00	2.30
Q3	41.00	1.90	41.20	2.10	40.60	2.10	41.50	3.80	42.40	4.30
Maximum	47.3	7.0	44.7	10.4	43.9	7.9	45.5	10.7	49.7	10.4

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	25.69		25.49		26.01		25.52		26.26	
SD	5.422		6.011		5.909		7.337		6.921	
Minimum	12.8		15.7		15.2		12.6		16.2	
Q1	21.60		21.70		21.65		21.20		21.95	
Median	24.50		24.30		25.05		25.30		25.10	
Q3	28.80		28.20		29.45		29.80		28.70	
Maximum	39.9		41.6		44.4		54.5		59.9	
Week 4										
N	97	97	101	101	100	100	103	103	80	80
Mean	26.11	0.42	24.79	-0.66	25.41	-0.60	24.35	-1.17	26.22	-0.05
SD	5.599	2.461	5.719	3.219	5.688	2.898	6.536	2.796	6.121	3.688
Minimum	15.6	-8.5	14.9	-8.1	9.5	-7.9	11.3	-8.6	15.0	-12.9
Q1	22.20	-1.00	21.00	-2.50	21.70	-2.45	20.20	-2.60	22.30	-1.50
Median	25.00	0.30	23.10	-0.50	24.70	-0.35	24.40	-0.90	25.80	0.20
Q3	29.50	1.90	26.90	0.50	28.60	1.20	28.10	0.40	29.80	1.80
Maximum	38.9	7.0	44.2	17.8	46.6	8.7	55.1	5.9	47.8	8.5
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	26.04	0.26	25.22	-0.27	25.21	-0.95	25.27	-0.43	24.39	-1.93
SD	5.500	2.919	5.876	3.165	5.410	3.511	6.802	3.872	5.884	3.544
Minimum	14.5	-8.9	14.6	-8.0	11.0	-17.1	12.1	-9.7	14.0	-13.6
Q1	21.80	-1.80	21.10	-2.00	21.55	-2.80	21.20	-2.70	20.40	-3.30
Median	25.60	0.70	24.00	-0.40	24.30	-0.60	24.50	-0.40	23.75	-1.80
Q3	29.40	2.10	27.70	1.40	28.05	1.30	28.60	1.50	27.10	0.70
Maximum	40.8	9.6	43.6	12.7	41.9	6.7	59.7	18.1	48.8	5.6
Week 12										
N	92	92	101	101	92	92	101	101	75	75
Mean	26.36	0.52	25.03	-0.48	25.26	-0.98	25.07	-0.63	24.50	-1.91
SD	5.797	3.521	5.430	3.520	5.672	3.928	6.925	4.136	6.142	3.632
Minimum	14.9	-8.1	14.3	-10.9	12.9	-17.0	9.3	-8.7	15.8	-13.9
Q1	22.60	-1.75	21.40	-2.60	22.25	-2.95	21.00	-3.00	20.70	-3.60
Median	25.10	0.30	24.40	-0.60	24.10	-0.90	24.80	-0.70	23.20	-1.10
Q3	28.80	2.70	27.30	1.10	27.95	0.70	29.20	1.40	26.80	0.30
Maximum	40.3	11.3	39.8	13.4	44.0	12.9	57.3	23.7	50.3	4.6
Week 16										
N	74	74	84	84	78	78	88	88	69	69
Mean	26.69	0.80	25.48	0.21	25.11	-1.25	25.09	-0.72	24.76	-1.69
SD	6.306	3.904	5.234	3.521	5.916	3.262	6.399	3.793	6.102	3.788
Minimum	14.8	-8.3	14.3	-7.3	12.5	-14.4	10.2	-8.4	14.3	-14.6
Q1	22.70	-1.50	21.45	-2.10	22.00	-3.10	20.80	-2.65	20.70	-2.70
Median	25.95	0.10	25.25	-0.10	24.45	-1.30	24.20	-0.45	24.30	-1.20
Q3	30.50	2.70	27.90	2.00	27.30	0.80	29.15	1.00	27.80	0.30
Maximum	43.9	11.1	39.1	10.4	44.7	5.5	49.5	15.0	46.4	4.7

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Platelets (10^4 /μL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	27.06	1.20	25.59	0.27	25.58	-0.64	24.98	-0.82	24.42	-1.93
SD	6.148	3.658	6.201	3.256	5.974	3.629	6.727	4.548	5.693	4.059
Minimum	14.3	-6.8	14.6	-6.3	11.3	-14.6	9.7	-8.6	14.3	-14.0
Q1	23.20	-1.10	21.70	-1.60	21.60	-2.80	20.20	-3.70	19.60	-3.30
Median	26.00	0.70	24.50	0.10	24.30	-0.40	24.30	-0.80	24.60	-1.00
Q3	31.90	3.60	28.30	2.00	29.20	1.90	28.00	1.80	27.40	0.30
Maximum	42.6	10.2	45.9	10.6	42.7	8.0	46.4	26.1	46.2	6.4
Week 24										
N	68	68	78	78	76	76	88	88	62	62
Mean	26.98	0.68	25.29	-0.08	25.63	-0.74	25.11	-0.70	24.25	-2.00
SD	5.897	3.267	5.655	3.552	5.977	3.958	6.570	4.210	5.383	4.172
Minimum	16.3	-7.0	14.4	-10.0	11.5	-14.4	9.6	-14.4	15.7	-18.0
Q1	23.30	-1.25	21.70	-2.40	21.35	-2.70	21.75	-3.40	20.20	-3.00
Median	26.35	0.70	23.80	-0.05	24.50	-0.75	24.15	-0.45	24.20	-1.05
Q3	30.35	2.60	28.60	1.90	29.90	1.90	28.05	1.60	27.10	0.60
Maximum	40.8	11.5	40.2	10.9	43.5	11.1	49.7	18.4	43.0	4.2
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	26.88	1.13	25.50	0.20	26.32	-0.06	25.28	-0.49	24.06	-2.39
SD	5.676	3.769	5.792	3.739	5.300	3.855	6.104	3.826	5.549	4.201
Minimum	17.1	-7.8	16.3	-8.8	14.9	-12.5	11.9	-14.8	12.6	-18.6
Q1	23.20	-1.50	21.60	-1.80	22.50	-1.70	21.50	-2.80	19.70	-3.40
Median	26.60	1.20	24.20	-0.20	25.70	0.30	24.40	-0.20	23.60	-1.30
Q3	29.50	3.90	28.20	2.10	29.60	2.00	28.50	1.80	26.60	-0.30
Maximum	41.0	11.0	43.7	17.3	43.7	8.4	48.9	6.5	42.3	10.3

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCH (pg)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	29.06		28.98		28.96		28.52		28.62	
SD	2.525		2.248		2.580		2.626		2.788	
Minimum	20.3		21.3		18.6		20.8		19.0	
Q1	28.10		28.00		27.60		26.70		27.70	
Median	29.80		29.30		29.65		28.90		29.30	
Q3	30.60		30.40		30.75		30.50		30.45	
Maximum	32.6		33.6		33.2		33.3		32.3	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	29.08	0.02	28.83	-0.16	28.90	-0.06	28.39	-0.13	28.49	-0.14
SD	2.468	0.674	2.236	0.584	2.446	0.498	2.531	0.711	2.747	0.634
Minimum	20.9	-1.9	20.8	-1.9	20.2	-1.1	20.1	-2.0	19.2	-1.3
Q1	27.70	-0.30	27.70	-0.60	27.65	-0.40	26.60	-0.60	27.40	-0.50
Median	29.60	0.00	29.20	-0.10	29.65	-0.10	28.90	-0.20	29.00	-0.10
Q3	30.90	0.30	30.20	0.20	30.50	0.20	30.10	0.10	30.30	0.10
Maximum	32.6	3.8	33.2	2.0	33.2	1.6	33.0	3.3	32.3	3.4
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	29.04	-0.02	28.78	-0.20	28.86	-0.06	28.41	-0.09	28.36	-0.22
SD	2.565	0.908	2.268	0.782	2.366	0.771	2.399	1.075	2.571	0.831
Minimum	20.7	-2.7	20.1	-2.9	22.5	-1.6	20.0	-3.6	19.6	-2.2
Q1	27.80	-0.50	28.00	-0.60	27.75	-0.45	27.10	-0.60	27.40	-0.60
Median	29.70	-0.10	29.10	-0.20	29.55	-0.10	28.60	-0.20	28.70	-0.20
Q3	30.90	0.30	30.20	0.20	30.40	0.30	29.90	0.20	30.00	0.00
Maximum	33.3	5.3	32.9	3.6	32.6	3.9	32.8	4.9	32.7	4.7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	28.93	-0.16	28.82	-0.15	28.92	-0.02	28.55	0.04	28.36	-0.11
SD	2.584	1.164	2.229	0.964	2.197	0.968	2.307	1.319	2.367	1.097
Minimum	20.4	-3.7	21.6	-4.3	23.5	-1.9	19.7	-3.7	20.9	-3.0
Q1	27.70	-0.60	28.00	-0.60	27.70	-0.55	27.70	-0.60	27.70	-0.60
Median	29.80	-0.20	29.10	-0.30	29.55	-0.20	28.80	-0.20	28.80	-0.20
Q3	30.70	0.20	30.30	0.20	30.40	0.35	29.90	0.30	29.90	0.20
Maximum	32.8	7.3	32.9	4.4	32.8	4.9	32.4	5.2	32.2	6.6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	28.53	-0.31	28.83	-0.23	28.92	0.09	28.77	0.26	28.61	0.07
SD	2.714	1.517	2.189	1.263	2.210	1.139	2.212	1.526	2.160	1.313
Minimum	19.7	-5.1	20.5	-5.5	23.0	-2.6	20.5	-3.5	21.5	-2.8
Q1	26.90	-0.80	27.95	-0.70	27.70	-0.50	27.80	-0.60	27.80	-0.50
Median	29.20	-0.20	29.20	-0.30	29.50	-0.10	29.10	-0.10	29.10	-0.20
Q3	30.60	0.20	30.45	0.10	30.30	0.30	30.10	0.80	29.80	0.40
Maximum	32.8	8.3	32.7	4.6	33.1	5.7	32.8	5.9	31.9	8.3

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCH (pg)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	28.45	-0.39	28.93	-0.16	28.97	0.15	28.92	0.44	28.74	0.29
SD	2.840	1.681	1.998	1.411	2.216	1.298	2.105	1.697	1.979	1.500
Minimum	19.7	-5.6	22.2	-6.5	22.9	-2.7	21.2	-3.1	22.5	-1.6
Q1	26.80	-0.90	28.00	-0.70	27.90	-0.50	28.30	-0.70	28.40	-0.50
Median	29.30	-0.40	29.10	-0.40	29.50	-0.10	29.20	-0.10	29.00	0.00
Q3	30.60	0.20	30.50	0.20	30.20	0.40	30.30	1.30	29.90	0.70
Maximum	33.1	8.6	32.1	6.6	33.5	6.3	32.6	6.3	31.9	9.4
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	28.41	-0.51	29.11	-0.05	28.92	0.14	29.05	0.55	28.98	0.60
SD	2.896	1.633	1.957	1.478	2.215	1.521	2.027	1.817	1.845	1.689
Minimum	20.2	-5.7	22.0	-7.2	22.9	-3.6	21.6	-3.6	23.2	-1.6
Q1	26.55	-1.20	28.20	-0.60	27.70	-0.60	28.35	-0.60	28.20	-0.30
Median	29.40	-0.40	29.40	-0.20	29.50	-0.10	29.40	0.15	29.20	0.30
Q3	30.75	0.10	30.50	0.30	30.10	0.40	30.25	1.25	30.10	1.10
Maximum	33.3	8.4	32.4	6.1	33.5	7.0	33.1	7.2	31.7	10.0
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	28.38	-0.49	29.07	0.00	28.97	0.16	29.13	0.62	29.19	0.65
SD	2.808	1.608	1.902	1.368	2.271	1.594	1.924	1.819	1.528	1.772
Minimum	19.9	-6.0	21.9	-4.7	22.4	-4.2	22.0	-2.3	23.7	-2.0
Q1	26.50	-1.00	28.00	-0.70	27.90	-0.60	28.40	-0.50	28.50	-0.40
Median	29.40	-0.30	29.40	-0.30	29.50	-0.10	29.50	0.00	29.50	0.20
Q3	30.40	0.30	30.40	0.40	30.20	0.50	30.20	1.40	30.10	1.30
Maximum	32.2	7.6	32.4	6.4	33.7	5.9	33.4	6.3	31.6	9.8

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCHC (%)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	32.10		32.16		32.02		31.98		32.00	
SD	0.929		0.946		0.992		1.172		1.181	
Minimum	29.4		29.5		27.5		28.3		27.7	
Q1	31.70		31.60		31.40		31.20		31.70	
Median	32.10		32.20		32.10		32.10		32.20	
Q3	32.80		32.80		32.70		32.80		32.70	
Maximum	33.7		34.0		34.2		34.1		34.4	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	32.19	0.08	32.10	-0.05	32.06	0.04	32.01	0.02	31.84	-0.16
SD	0.893	0.550	0.882	0.562	0.952	0.522	1.144	0.635	1.159	0.567
Minimum	29.2	-1.3	29.1	-1.4	28.4	-1.1	27.6	-1.4	27.7	-1.7
Q1	31.70	-0.30	31.60	-0.40	31.55	-0.30	31.30	-0.30	31.40	-0.50
Median	32.20	0.10	32.10	0.00	32.20	0.00	32.00	0.00	32.00	-0.20
Q3	32.80	0.50	32.70	0.30	32.60	0.40	32.80	0.30	32.70	0.20
Maximum	34.2	1.5	34.2	1.2	34.2	1.7	34.0	2.3	33.7	1.3
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	32.24	0.13	32.13	-0.02	32.17	0.16	32.12	0.13	31.95	-0.04
SD	0.942	0.642	0.938	0.650	0.964	0.659	1.105	0.759	1.066	0.565
Minimum	29.3	-1.8	28.8	-1.5	29.8	-1.5	27.4	-1.9	28.0	-1.8
Q1	31.80	-0.30	31.50	-0.40	31.60	-0.20	31.60	-0.30	31.50	-0.30
Median	32.30	0.10	32.30	0.00	32.40	0.10	32.20	0.20	32.15	0.00
Q3	32.90	0.50	32.90	0.30	32.80	0.60	32.80	0.40	32.70	0.30
Maximum	34.8	2.0	34.2	1.5	33.8	2.4	34.4	3.2	33.8	2.3
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	32.26	0.13	32.23	0.08	32.25	0.26	32.20	0.21	32.11	0.15
SD	1.000	0.708	0.973	0.663	0.810	0.725	1.069	0.807	0.969	0.743
Minimum	29.3	-1.9	29.3	-1.8	30.3	-1.1	28.1	-1.5	29.7	-1.4
Q1	31.80	-0.40	31.60	-0.30	31.90	-0.25	31.80	-0.30	31.70	-0.30
Median	32.40	0.20	32.40	0.00	32.30	0.20	32.30	0.20	32.20	0.10
Q3	33.00	0.60	32.90	0.50	32.70	0.80	32.90	0.50	32.70	0.60
Maximum	34.0	2.9	34.7	1.9	34.2	3.2	34.4	3.3	34.4	3.4
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	32.09	-0.01	31.96	-0.20	32.15	0.18	32.23	0.24	32.16	0.15
SD	1.070	0.793	0.926	0.759	0.751	0.843	0.982	0.915	0.909	0.767
Minimum	28.1	-2.0	28.2	-2.2	30.4	-1.4	27.9	-1.7	30.0	-1.3
Q1	31.50	-0.50	31.45	-0.60	31.80	-0.40	31.80	-0.40	31.60	-0.40
Median	32.10	0.00	32.00	-0.30	32.20	0.20	32.30	0.10	32.20	0.20
Q3	32.80	0.40	32.60	0.30	32.60	0.60	32.70	0.80	32.80	0.60
Maximum	34.2	2.9	34.3	2.1	33.9	3.9	34.2	3.6	33.9	3.3

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCHC (%)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	32.12	0.02	32.06	-0.11	32.19	0.22	32.27	0.30	32.20	0.20
SD	1.113	0.853	0.929	0.859	0.741	0.908	0.949	0.911	0.861	0.873
Minimum	28.7	-2.0	28.5	-2.6	29.9	-1.7	28.7	-1.8	29.7	-1.3
Q1	31.50	-0.50	31.60	-0.60	31.70	-0.50	31.80	-0.40	31.50	-0.30
Median	32.20	-0.10	32.20	-0.20	32.20	0.10	32.30	0.20	32.40	0.10
Q3	33.00	0.60	32.60	0.30	32.60	0.80	32.80	0.90	32.80	0.60
Maximum	34.2	3.1	34.0	2.9	33.8	3.7	34.1	3.2	34.0	4.3
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	32.01	-0.11	32.16	-0.04	32.21	0.25	32.39	0.40	32.30	0.31
SD	1.074	0.834	0.911	0.792	0.760	0.949	0.946	0.955	0.866	0.947
Minimum	28.8	-2.4	29.2	-2.7	29.8	-1.4	28.8	-1.9	29.8	-1.4
Q1	31.40	-0.70	31.70	-0.50	31.90	-0.40	32.00	-0.10	31.80	-0.20
Median	32.25	-0.20	32.10	0.00	32.20	0.20	32.40	0.25	32.30	0.20
Q3	32.75	0.40	32.80	0.50	32.70	0.70	33.00	1.00	32.90	0.70
Maximum	34.2	2.9	34.0	2.3	33.7	4.6	34.2	4.3	34.1	4.9
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	32.00	-0.11	32.08	-0.09	32.19	0.24	32.42	0.44	32.42	0.41
SD	1.111	0.857	0.800	0.777	0.783	0.885	0.907	0.901	0.747	0.994
Minimum	28.6	-2.6	29.6	-2.0	29.4	-2.0	29.4	-1.5	30.5	-1.9
Q1	31.40	-0.60	31.50	-0.60	31.80	-0.30	31.90	-0.20	31.90	-0.10
Median	32.20	-0.20	32.10	-0.10	32.40	0.10	32.40	0.30	32.50	0.40
Q3	32.90	0.50	32.60	0.40	32.80	0.60	33.00	1.00	32.90	0.90
Maximum	34.1	2.3	33.8	2.3	33.7	3.5	34.4	3.3	34.0	5.1

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCV (fL)

Visit / Statistics	Placebo (N=97) Observed Value at Visit	Placebo (N=97) Change from Baseline	TAK-385 10mg (N=103) Observed Value at Visit	TAK-385 10mg (N=103) Change from Baseline	TAK-385 20mg (N=100) Observed Value at Visit	TAK-385 20mg (N=100) Change from Baseline	TAK-385 40mg (N=103) Observed Value at Visit	TAK-385 40mg (N=103) Change from Baseline	Leuprorelin (N=80) Observed Value at Visit	Leuprorelin (N=80) Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	90.44		90.06		90.31		89.06		89.29	
SD	6.170		5.381		6.190		5.819		6.346	
Minimum	69.3		72.3		67.6		72.0		68.6	
Q1	88.10		87.90		87.10		85.50		86.85	
Median	92.00		90.80		91.70		90.00		90.00	
Q3	94.30		93.30		94.90		93.00		92.95	
Maximum	100.2		101.3		102.3		99.5		99.5	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	90.26	-0.18	89.73	-0.33	90.02	-0.28	88.58	-0.48	89.32	0.03
SD	6.109	1.581	5.519	1.344	5.882	1.334	5.534	1.551	6.347	1.789
Minimum	71.4	-4.5	71.7	-4.9	71.1	-3.3	71.1	-5.7	69.5	-3.8
Q1	86.60	-1.10	87.80	-1.10	86.90	-1.20	85.00	-1.40	87.05	-1.20
Median	91.80	-0.30	90.10	-0.10	91.45	-0.30	89.20	-0.60	90.20	-0.20
Q3	94.30	0.40	93.50	0.30	94.20	0.20	92.60	0.40	93.00	0.65
Maximum	99.5	8.4	101.8	4.3	100.8	4.7	99.6	5.3	101.0	9.2
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	89.96	-0.44	89.50	-0.57	89.63	-0.58	88.35	-0.62	88.62	-0.57
SD	6.343	2.119	5.488	1.659	5.508	1.942	5.360	2.426	5.942	2.186
Minimum	70.7	-7.1	69.9	-5.8	75.3	-4.5	68.5	-8.4	69.9	-6.8
Q1	86.80	-1.70	87.40	-1.40	87.00	-1.85	85.20	-2.00	86.30	-1.50
Median	91.00	-0.50	90.10	-0.60	90.50	-0.90	88.80	-0.60	89.25	-0.65
Q3	94.70	0.40	93.00	0.30	93.55	0.45	91.70	0.20	92.90	0.10
Maximum	101.0	12.0	99.5	7.2	100.5	8.1	98.3	9.5	99.1	10.5
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	89.57	-0.88	89.39	-0.67	89.59	-0.71	88.56	-0.42	88.17	-0.74
SD	6.170	2.616	5.296	2.324	5.537	2.367	5.204	2.831	5.598	2.695
Minimum	69.7	-7.5	71.2	-8.4	76.5	-6.1	68.1	-8.8	69.7	-7.0
Q1	86.70	-2.20	87.50	-1.70	87.20	-1.90	85.80	-1.90	86.00	-2.20
Median	90.80	-0.70	90.30	-0.60	91.00	-1.00	88.90	-0.90	88.90	-0.80
Q3	94.30	-0.10	92.80	0.40	93.50	0.35	91.50	0.50	91.90	0.50
Maximum	98.3	15.6	98.5	8.6	100.5	11.3	98.6	8.9	97.7	13.6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	88.74	-0.99	90.12	-0.16	89.87	-0.15	89.20	0.20	88.87	-0.16
SD	6.463	3.601	5.420	3.215	5.712	2.798	5.292	3.269	5.163	3.280
Minimum	70.0	-11.7	71.9	-13.0	75.7	-6.4	69.9	-7.6	71.5	-6.2
Q1	85.00	-2.40	88.30	-1.45	86.70	-1.60	85.90	-1.70	87.30	-1.70
Median	90.30	-0.70	90.50	-0.25	91.70	-0.40	89.80	-0.50	89.80	-0.40
Q3	93.80	0.10	93.25	1.60	93.60	0.70	92.90	1.30	92.00	1.20
Maximum	97.1	18.5	101.7	9.8	101.4	12.7	99.3	11.9	98.2	19.3

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: MCV (fL)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	88.42	-1.31	90.19	-0.15	89.91	-0.07	89.55	0.62	89.20	0.47
SD	6.865	4.074	4.983	3.299	5.762	3.217	5.123	3.745	4.746	3.353
Minimum	68.8	-13.5	73.1	-13.4	74.8	-7.5	71.2	-6.6	74.0	-5.0
Q1	84.60	-3.40	87.60	-1.80	87.20	-1.80	87.30	-1.70	87.50	-1.40
Median	89.70	-1.10	90.60	-0.30	91.00	-0.30	89.30	-0.30	89.80	0.00
Q3	93.80	0.50	93.30	0.90	93.10	0.70	92.50	2.00	92.30	1.50
Maximum	99.2	18.9	100.5	14.0	100.7	12.4	99.3	12.4	97.5	20.2
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	88.59	-1.35	90.47	-0.04	89.74	-0.18	89.61	0.65	89.65	1.11
SD	6.970	3.942	4.804	3.543	5.774	3.532	4.813	4.015	4.416	3.797
Minimum	69.7	-12.9	74.4	-15.3	74.8	-10.0	73.6	-6.4	76.6	-6.0
Q1	84.40	-3.10	87.80	-1.40	86.45	-2.05	87.30	-1.80	87.30	-1.30
Median	90.80	-1.00	90.90	-0.20	90.80	-0.65	90.10	-0.05	89.90	0.35
Q3	94.00	0.55	93.70	1.00	93.20	1.15	93.00	2.25	92.20	3.10
Maximum	99.0	19.0	100.0	13.9	102.3	12.3	99.0	12.4	97.9	20.4
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	88.54	-1.25	90.57	0.24	89.92	-0.09	89.79	0.79	90.01	0.98
SD	6.880	4.074	4.649	3.290	5.661	3.571	4.817	4.177	4.041	3.698
Minimum	69.7	-13.4	74.1	-9.1	74.9	-11.2	74.8	-5.8	77.2	-3.5
Q1	84.70	-3.00	88.10	-1.50	86.80	-1.70	87.10	-1.80	87.90	-1.30
Median	89.90	-1.40	91.20	-0.10	91.40	-0.70	90.50	0.10	89.80	0.10
Q3	93.80	0.50	93.20	1.20	93.50	1.10	93.00	2.10	92.80	1.90
Maximum	99.5	18.2	100.3	14.8	102.1	11.5	98.8	14.3	99.3	19.1

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Reticulocytes (permil)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Baseline										
N	97		103		100		103		80	
Mean	10.5		10.4		10.6		10.5		10.3	
SD	3.64		3.56		3.04		3.23		3.46	
Minimum	4		4		5		5		4	
Q1	8.0		8.0		9.0		8.0		8.0	
Median	10.0		10.0		10.0		10.0		10.0	
Q3	13.0		13.0		12.0		12.0		12.0	
Maximum	27		25		19		20		21	
Week 4										
N	97	97	103	103	100	100	103	103	80	80
Mean	11.0	0.5	10.6	0.2	9.7	-1.0	9.7	-0.8	9.2	-1.1
SD	3.79	2.50	4.16	2.75	2.78	2.29	3.29	2.65	3.32	2.24
Minimum	5	-6	5	-6	4	-7	4	-6	4	-7
Q1	8.0	-1.0	8.0	-1.0	8.0	-2.0	7.0	-2.0	7.0	-2.0
Median	11.0	0.0	10.0	0.0	9.0	-1.0	9.0	-1.0	8.0	-1.0
Q3	13.0	2.0	12.0	1.0	12.0	1.0	12.0	0.0	11.0	0.0
Maximum	22	10	33	17	19	7	26	13	20	7
Week 8										
N	95	95	103	103	96	96	101	101	78	78
Mean	10.9	0.4	10.6	0.2	10.2	-0.5	9.8	-0.7	9.5	-0.7
SD	3.44	2.12	3.68	1.93	3.36	2.23	3.04	2.23	3.14	2.43
Minimum	5	-7	4	-4	2	-7	4	-6	4	-7
Q1	9.0	-1.0	8.0	-1.0	7.5	-2.0	8.0	-2.0	7.0	-2.0
Median	10.0	1.0	10.0	0.0	10.0	-0.5	9.0	-1.0	9.0	-1.0
Q3	13.0	2.0	12.0	1.0	12.0	1.0	11.0	1.0	11.0	1.0
Maximum	25	5	28	5	20	5	19	8	18	7
Week 12										
N	93	93	101	101	92	92	101	101	75	75
Mean	11.6	1.2	11.0	0.6	10.6	0.0	11.0	0.6	10.3	0.0
SD	4.83	3.62	3.61	2.20	3.52	2.81	3.39	2.56	3.67	2.37
Minimum	5	-9	5	-5	6	-9	5	-5	3	-5
Q1	9.0	-1.0	8.0	-1.0	8.0	-2.0	8.0	-1.0	8.0	-1.0
Median	11.0	1.0	10.0	1.0	10.0	0.0	11.0	1.0	10.0	0.0
Q3	14.0	2.0	13.0	2.0	12.0	2.0	14.0	2.0	13.0	2.0
Maximum	42	24	26	8	24	8	22	9	22	6
Week 16										
N	75	75	84	84	78	78	89	89	69	69
Mean	10.7	0.6	11.3	0.9	11.4	0.7	11.5	1.1	10.8	0.4
SD	3.28	2.15	3.96	3.09	3.66	2.39	3.71	2.56	3.81	2.61
Minimum	4	-6	5	-9	5	-5	5	-4	5	-6
Q1	8.0	0.0	8.5	-1.0	9.0	-1.0	9.0	-1.0	8.0	-1.0
Median	10.0	1.0	10.5	0.5	11.0	1.0	11.0	1.0	10.0	0.0
Q3	13.0	2.0	14.0	2.0	13.0	2.0	14.0	3.0	13.0	2.0
Maximum	21	5	24	13	22	7	21	9	23	8

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-25　血液学的検査値の要約統計量の経時的推移（安全性データの解析対象集団）（OCT-101 試験）（続き）

Laboratory Group: Hematology
Laboratory Test: Reticulocytes (permil)

Visit / Statistics	Placebo (N=97)		TAK-385 10mg (N=103)		TAK-385 20mg (N=100)		TAK-385 40mg (N=103)		Leuprorelin (N=80)	
	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline	Observed Value at Visit	Change from Baseline
Week 20										
N	75	75	81	81	77	77	87	87	65	65
Mean	10.9	0.7	11.5	1.1	11.5	0.9	11.6	1.2	11.5	0.9
SD	3.26	2.24	3.73	2.55	3.28	2.29	4.38	2.89	4.12	2.74
Minimum	5	-5	5	-4	5	-4	3	-5	5	-4
Q1	8.0	-1.0	9.0	-1.0	9.0	-1.0	8.0	-1.0	9.0	-1.0
Median	11.0	1.0	11.0	1.0	11.0	1.0	12.0	1.0	11.0	1.0
Q3	13.0	2.0	14.0	2.0	14.0	3.0	14.0	3.0	14.0	3.0
Maximum	19	7	22	10	19	6	24	10	25	9
Week 24										
N	68	68	79	79	76	76	88	88	62	62
Mean	11.4	1.2	11.8	1.4	11.3	0.8	11.7	1.3	10.8	0.3
SD	3.21	2.29	3.80	2.72	3.23	2.66	3.78	2.59	4.00	2.90
Minimum	5	-5	6	-3	5	-9	5	-6	5	-6
Q1	9.0	0.0	9.0	-1.0	9.0	-1.0	9.0	-1.0	8.0	-2.0
Median	11.0	1.0	12.0	1.0	11.0	1.0	11.5	1.0	10.0	0.0
Q3	14.0	3.0	14.0	3.0	13.0	2.0	14.0	3.0	13.0	2.0
Maximum	19	6	26	14	20	8	22	8	25	9
Follow-up										
N	77	77	83	83	77	77	89	89	69	69
Mean	11.6	1.4	12.5	2.1	13.1	2.4	14.5	4.1	11.7	1.2
SD	3.77	2.72	4.05	3.00	3.65	2.67	4.40	3.04	3.96	2.83
Minimum	6	-5	7	-5	7	-5	7	-3	5	-4
Q1	9.0	0.0	10.0	0.0	10.0	1.0	11.0	2.0	9.0	-1.0
Median	11.0	1.0	11.0	2.0	12.0	2.0	14.0	4.0	11.0	1.0
Q3	14.0	3.0	15.0	3.0	16.0	4.0	17.0	6.0	14.0	3.0
Maximum	31	13	25	16	25	9	26	12	27	11

治験総括報告書 Table 3.2.1.1.1（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）

RBC (10^4/uL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	2	-	-	2	12	1	-	13
Normal	18	106	-	124	16	107	-	123
High	-	11	1	12	-	5	1	6
Total	20	117	1	138	28	113	1	142
Week 8								
Low	-	1	-	1	1	-	-	1
Normal	19	102	-	121	27	99	1	127
High	-	12	1	13	-	14	-	14
Total	19	115	1	135	28	113	1	142
Week 12								
Low	1	-	-	1	2	-	-	2
Normal	15	100	-	115	26	94	1	121
High	3	10	1	14	-	18	-	18
Total	19	110	1	130	28	112	1	141
Week 16								
Low	-	1	-	1	2	-	-	2
Normal	16	101	-	117	24	96	1	121
High	3	7	1	11	1	12	-	13
Total	19	109	1	129	27	108	1	136
Week 20								
Low	1	-	-	1	3	-	-	3
Normal	15	99	-	114	22	96	-	118
High	2	8	1	11	-	10	1	11
Total	18	107	1	126	25	106	1	132
Week 24								
Low	-	1	-	1	3	1	-	4
Normal	17	95	-	112	22	96	1	119
High	-	8	1	9	-	8	-	8
Total	17	104	1	122	25	105	1	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

RBC (10^4/uL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	2	3	-	5	3	-	-	3
Normal	16	110	-	126	25	103	-	128
High	-	3	1	4	-	9	1	10
Total	18	116	1	135	28	112	1	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Platelets (10^4/uL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	122	4	126	-	116	4	120
High	-	2	10	12	-	6	15	21
Total	-	124	14	138	-	122	19	141
Week 8								
Low	-	1	-	1	-	-	-	-
Normal	-	119	6	125	-	120	10	130
High	-	1	8	9	-	3	9	12
Total	-	121	14	135	-	123	19	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	113	6	119	-	118	10	128
High	-	3	8	11	-	2	9	11
Total	-	116	14	130	-	120	19	139
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	110	7	117	-	116	15	131
High	-	4	7	11	-	2	3	5
Total	-	114	14	128	-	118	18	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	109	8	117	-	111	12	123
High	-	3	5	8	-	2	5	7
Total	-	112	13	125	-	113	17	130
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	105	6	111	-	111	12	123
High	-	2	6	8	-	1	5	6
Total	-	107	12	119	-	112	17	129

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Platelets (10^4/uL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	118	6	124	-	119	16	135
High	-	3	7	10	-	2	3	5
Total	-	121	13	134	-	121	19	140

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

WBC (/uL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	2	7	-	9	2	7	-	9
Normal	3	121	2	126	1	126	2	129
High	-	1	2	3	-	1	3	4
Total	5	129	4	138	3	134	5	142
Week 8								
Low	-	1	-	1	1	1	-	2
Normal	5	124	3	132	2	131	3	136
High	-	1	1	2	-	2	2	4
Total	5	126	4	135	3	134	5	142
Week 12								
Low	1	3	-	4	2	3	-	5
Normal	4	117	3	124	1	126	4	131
High	-	1	1	2	-	4	1	5
Total	5	121	4	130	3	133	5	141
Week 16								
Low	-	2	-	2	2	1	-	3
Normal	5	117	4	126	1	127	2	130
High	-	1	-	1	-	1	2	3
Total	5	120	4	129	3	129	4	136
Week 20								
Low	1	3	-	4	-	1	-	1
Normal	4	113	4	121	3	122	2	127
High	-	1	-	1	-	2	2	4
Total	5	117	4	126	3	125	4	132
Week 24								
Low	-	7	-	7	1	1	-	2
Normal	5	104	3	112	2	120	3	125
High	-	2	1	3	-	3	1	4
Total	5	113	4	122	3	124	4	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

WBC (/uL)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	1	3	-	4	1	1	-	2
Normal	4	122	4	130	2	129	4	135
High	-	1	-	1	-	3	1	4
Total	5	126	4	135	3	133	5	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Neutrophils (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	1	-	2	-	4	-	4
Normal	1	133	1	135	1	134	2	137
High	-	1	-	1	-	1	-	1
Total	2	135	1	138	1	139	2	142
Week 8								
Low	1	2	-	3	-	3	-	3
Normal	1	128	1	130	1	134	1	136
High	-	2	-	2	-	2	1	3
Total	2	132	1	135	1	139	2	142
Week 12								
Low	1	2	-	3	-	3	-	3
Normal	1	124	1	126	1	133	2	136
High	-	1	-	1	-	2	-	2
Total	2	127	1	130	1	138	2	141
Week 16								
Low	2	3	-	5	-	4	-	4
Normal	-	123	1	124	1	128	2	131
High	-	-	-	-	-	1	-	1
Total	2	126	1	129	1	133	2	136
Week 20								
Low	1	-	-	1	-	3	-	3
Normal	1	122	1	124	1	120	-	121
High	-	1	-	1	-	5	2	7
Total	2	123	1	126	1	128	2	131
Week 24								
Low	1	1	-	2	-	5	-	5
Normal	-	116	1	117	1	121	1	123
High	-	3	-	3	-	2	1	3
Total	1	120	1	122	1	128	2	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Neutrophils (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	1	1	-	2	-	2	-	2
Normal	1	131	1	133	1	135	2	138
High	-	-	-	-	-	1	-	1
Total	2	132	1	135	1	138	2	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Eosinophils (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	128	2	130	-	132	-	132
High	-	3	5	8	-	7	3	10
Total	-	131	7	138	-	139	3	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	124	3	127	-	134	1	135
High	-	4	4	8	-	5	2	7
Total	-	128	7	135	-	139	3	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	120	3	123	-	133	2	135
High	-	4	3	7	-	5	1	6
Total	-	124	6	130	-	138	3	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	116	3	119	-	131	1	132
High	-	7	3	10	-	3	1	4
Total	-	123	6	129	-	134	2	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	114	3	117	-	120	1	121
High	-	6	3	9	-	9	1	10
Total	-	120	6	126	-	129	2	131
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	112	3	115	-	123	2	125
High	-	5	2	7	-	6	-	6
Total	-	117	5	122	-	129	2	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Eosinophils (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	126	4	130	-	131	1	132
High	-	2	3	5	-	7	2	9
Total	-	128	7	135	-	138	3	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Basophils (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	136	1	137	-	139	-	139
High	-	1	-	1	-	3	-	3
Total	-	137	1	138	-	142	-	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	134	1	135	-	142	-	142
High	-	-	-	-	-	-	-	-
Total	-	134	1	135	-	142	-	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	128	1	129	-	140	-	140
High	-	1	-	1	-	1	-	1
Total	-	129	1	130	-	141	-	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	127	-	127	-	136	-	136
High	-	1	1	2	-	-	-	-
Total	-	128	1	129	-	136	-	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	125	1	126	-	130	-	130
High	-	-	-	-	-	1	-	1
Total	-	125	1	126	-	131	-	131
Week 24								
Low	-	-	-	-	-	-	-	-
Normal	-	122	-	122	-	130	-	130
High	-	-	-	-	-	1	-	1
Total	-	122	-	122	-	131	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Basophils (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	134	1	135	-	140	-	140
High	-	-	-	-	-	1	-	1
Total	-	134	1	135	-	141	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Lymphocytes (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	1	-	2	1	1	-	2
Normal	3	128	1	132	3	135	-	138
High	-	3	1	4	-	2	-	2
Total	4	132	2	138	4	138	-	142
Week 8								
Low	-	2	-	2	2	1	-	3
Normal	4	127	1	132	2	134	-	136
High	-	-	1	1	-	3	-	3
Total	4	129	2	135	4	138	-	142
Week 12								
Low	-	1	-	1	2	2	-	4
Normal	4	120	-	124	2	132	-	134
High	-	3	2	5	-	3	-	3
Total	4	124	2	130	4	137	-	141
Week 16								
Low	-	1	-	1	1	2	-	3
Normal	4	117	-	121	3	127	-	130
High	-	5	2	7	-	3	-	3
Total	4	123	2	129	4	132	-	136
Week 20								
Low	1	5	-	6	3	4	-	7
Normal	3	114	1	118	1	122	-	123
High	-	1	1	2	-	1	-	1
Total	4	120	2	126	4	127	-	131
Week 24								
Low	-	4	-	4	1	2	-	3
Normal	4	110	1	115	3	122	-	125
High	-	2	1	3	-	3	-	3
Total	4	116	2	122	4	127	-	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Lymphocytes (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	1	-	1	1	-	-	1
Normal	4	127	1	132	3	135	-	138
High	-	1	1	2	-	2	-	2
Total	4	129	2	135	4	137	-	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Monocytes (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	1	-	1	-	-	-	-
Normal	-	129	2	131	-	134	6	140
High	-	6	-	6	-	2	-	2
Total	-	136	2	138	-	136	6	142
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	128	1	129	-	134	5	139
High	-	5	1	6	-	2	1	3
Total	-	133	2	135	-	136	6	142
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	125	2	127	-	129	4	133
High	-	3	-	3	-	6	2	8
Total	-	128	2	130	-	135	6	141
Week 16								
Low	-	-	-	-	-	-	-	-
Normal	-	124	2	126	-	126	5	131
High	-	3	-	3	-	4	1	5
Total	-	127	2	129	-	130	6	136
Week 20								
Low	-	-	-	-	-	-	-	-
Normal	-	117	2	119	-	121	4	125
High	-	7	-	7	-	4	2	6
Total	-	124	2	126	-	125	6	131
Week 24								
Low	-	-	-	-	-	1	-	1
Normal	-	115	2	117	-	118	5	123
High	-	5	-	5	-	6	1	7
Total	-	120	2	122	-	125	6	131

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-26　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-002 試験）（続き）

Monocytes (%)

	Baseline							
	TAK-385 40mg (N=138)				Leuprorelin (N=142)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Follow-up								
Low	-	1	-	1	-	-	-	-
Normal	-	125	2	127	-	130	5	135
High	-	7	-	7	-	5	1	6
Total	-	133	2	135	-	135	6	141

治験総括報告書 Table 15.3.2.1.3.1（5.3.5.1-2）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）

RBC (10^4/uL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	2	-	-	2	3	2	-	5
Normal	2	23	-	25	2	24	-	26
High	-	3	3	6	-	1	-	1
Total	4	26	3	33	5	27	-	32
Week 8								
Low	1	-	-	1	2	3	-	5
Normal	3	21	2	26	3	21	-	24
High	-	4	1	5	-	2	-	2
Total	4	25	3	32	5	26	-	31
Week 12								
Low	1	-	-	1	3	2	-	5
Normal	3	22	2	27	2	23	-	25
High	-	3	1	4	-	1	-	1
Total	4	25	3	32	5	26	-	31
Follow-up								
Low	2	-	-	2	2	1	-	3
Normal	2	24	2	28	3	25	-	28
High	-	2	1	3	-	1	-	1
Total	4	26	3	33	5	27	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

WBC (/uL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	1	-	2	-	-	-	-
Normal	-	30	1	31	1	28	-	29
High	-	-	-	-	-	1	2	3
Total	1	31	1	33	1	29	2	32
Week 8								
Low	-	1	-	1	-	1	-	1
Normal	1	30	-	31	1	26	-	27
High	-	-	-	-	-	1	2	3
Total	1	31	-	32	1	28	2	31
Week 12								
Low	1	1	-	2	-	2	-	2
Normal	-	30	-	30	1	24	-	25
High	-	-	-	-	-	2	2	4
Total	1	31	-	32	1	28	2	31
Follow-up								
Low	-	1	-	1	-	2	-	2
Normal	1	29	-	30	1	25	-	26
High	-	1	1	2	-	2	2	4
Total	1	31	1	33	1	29	2	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Neutrophils (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	2	-	2	-	-	-	-
Normal	-	29	1	30	-	31	1	32
High	-	-	1	1	-	-	-	-
Total	-	31	2	33	-	31	1	32
Week 8								
Low	-	1	-	1	-	-	-	-
Normal	-	29	1	30	-	28	1	29
High	-	-	1	1	-	2	-	2
Total	-	30	2	32	-	30	1	31
Week 12								
Low	-	1	-	1	-	-	-	-
Normal	-	28	2	30	-	30	1	31
High	-	1	-	1	-	-	-	-
Total	-	30	2	32	-	30	1	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	30	1	31	-	31	1	32
High	-	1	1	2	-	-	-	-
Total	-	31	2	33	-	31	1	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Eosinophils (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	32	1	33	-	31	1	32
High	-	-	-	-	-	-	-	-
Total	-	32	1	33	-	31	1	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	31	1	32	-	30	1	31
High	-	-	-	-	-	-	-	-
Total	-	31	1	32	-	30	1	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	30	1	31	-	29	1	30
High	-	1	-	1	-	1	-	1
Total	-	31	1	32	-	30	1	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	32	1	33	-	31	1	32
High	-	-	-	-	-	-	-	-
Total	-	32	1	33	-	31	1	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Basophils (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	31	-	31	-	30	-	30
High	-	1	-	1	-	1	-	1
Total	-	32	-	32	-	31	-	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	-	32	-	32	-	31	-	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	-	32	-	32
High	-	-	-	-	-	-	-	-
Total	-	33	-	33	-	32	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Lymphocytes (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	1	-	-	1	1	-	-	1
Normal	1	29	-	30	-	31	-	31
High	-	2	-	2	-	-	-	-
Total	2	31	-	33	1	31	-	32
Week 8								
Low	1	-	-	1	-	2	-	2
Normal	1	30	-	31	1	28	-	29
High	-	-	-	-	-	-	-	-
Total	2	30	-	32	1	30	-	31
Week 12								
Low	-	1	-	1	-	1	-	1
Normal	2	28	-	30	1	29	-	30
High	-	1	-	1	-	-	-	-
Total	2	30	-	32	1	30	-	31
Follow-up								
Low	-	-	-	-	1	-	-	1
Normal	2	31	-	33	-	31	-	31
High	-	-	-	-	-	-	-	-
Total	2	31	-	33	1	31	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Monocytes (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	32	-	32	-	27	2	29
High	-	1	-	1	-	2	1	3
Total	-	33	-	33	-	29	3	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	30	-	30	-	29	2	31
High	-	2	-	2	-	-	-	-
Total	-	32	-	32	-	29	2	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	30	-	30	-	28	2	30
High	-	2	-	2	-	1	-	1
Total	-	32	-	32	-	29	2	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	33	-	33	-	28	3	31
High	-	-	-	-	-	1	-	1
Total	-	33	-	33	-	29	3	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

HGB (g/dL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	4	-	-	4	9	1	-	10
Normal	3	24	-	27	1	21	-	22
High	-	1	1	2	-	-	-	-
Total	7	25	1	33	10	22	-	32
Week 8								
Low	4	-	-	4	7	-	-	7
Normal	3	24	1	28	3	20	-	23
High	-	-	-	-	-	1	-	1
Total	7	24	1	32	10	21	-	31
Week 12								
Low	3	-	-	3	9	-	-	9
Normal	4	22	1	27	1	20	-	21
High	-	2	-	2	-	1	-	1
Total	7	24	1	32	10	21	-	31
Follow-up								
Low	3	-	-	3	4	-	-	4
Normal	4	25	1	30	6	22	-	28
High	-	-	-	-	-	-	-	-
Total	7	25	1	33	10	22	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Hematocrit (HCT) (%)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	6	-	-	6	9	2	-	11
Normal	5	21	-	26	2	19	-	21
High	-	1	-	1	-	-	-	-
Total	11	22	-	33	11	21	-	32
Week 8								
Low	5	-	-	5	9	1	-	10
Normal	6	21	-	27	2	18	-	20
High	-	-	-	-	-	1	-	1
Total	11	21	-	32	11	20	-	31
Week 12								
Low	4	-	-	4	9	2	-	11
Normal	7	21	-	28	2	18	-	20
High	-	-	-	-	-	-	-	-
Total	11	21	-	32	11	20	-	31
Follow-up								
Low	4	2	-	6	6	1	-	7
Normal	7	20	-	27	5	20	-	25
High	-	-	-	-	-	-	-	-
Total	11	22	-	33	11	21	-	32

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-27　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（3008 試験）（続き）

Platelets (10^4/uL)

	Baseline							
	TAK-385 40mg (N=33)				Placebo (N=32)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total
Week 4								
Low	-	-	-	-	-	-	-	-
Normal	-	26	4	30	-	27	-	27
High	-	-	1	1	-	1	4	5
Total	-	26	5	31	-	28	4	32
Week 8								
Low	-	-	-	-	-	-	-	-
Normal	-	27	3	30	-	27	-	27
High	-	-	1	1	-	-	4	4
Total	-	27	4	31	-	27	4	31
Week 12								
Low	-	-	-	-	-	-	-	-
Normal	-	27	1	28	-	27	-	27
High	-	1	3	4	-	-	4	4
Total	-	28	4	32	-	27	4	31
Follow-up								
Low	-	-	-	-	-	-	-	-
Normal	-	28	2	30	-	25	-	25
High	-	-	3	3	-	3	3	6
Total	-	28	5	33	-	28	3	31

治験総括報告書 Table 15.3.2.1.3（5.3.5.1-3）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）

RBC

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	1	1	-	2	1	-	-	1	3	-	-	3	1	-	-	1	-	-	-	-
Normal	3	91	-	94	4	93	-	97	3	89	1	93	3	95	-	98	3	71	-	74
High	-	1	-	1	-	5	-	5	-	3	1	4	-	2	2	4	-	6	-	6
Total	4	93	-	97	5	98	-	103	6	92	2	100	4	97	2	103	3	77	-	80
Week 8																				
Low	-	-	-	-	-	-	-	-	2	-	-	2	-	1	-	1	1	-	-	1
Normal	4	86	-	90	5	95	-	100	4	85	1	90	4	91	1	96	2	69	-	71
High	-	5	-	5	-	3	-	3	-	3	1	4	-	3	1	4	-	6	-	6
Total	4	91	-	95	5	98	-	103	6	88	2	96	4	95	2	101	3	75	-	78
Week 12																				
Low	-	2	-	2	-	1	-	1	1	-	-	1	-	-	-	-	-	1	-	1
Normal	4	86	-	90	5	93	-	98	5	83	1	89	4	92	-	96	3	67	-	70
High	-	1	-	1	-	2	-	2	-	1	1	2	-	3	2	5	-	4	-	4
Total	4	89	-	93	5	96	-	101	6	84	2	92	4	95	2	101	3	72	-	75
Follow-up																				
Low	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	17	-	18	-	18	-	18	-	21	1	22	-	12	1	13	1	8	-	9
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	1	17	-	18	1	18	-	19	-	21	1	22	-	12	1	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

WBC

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	2	4	-	6	3	5	-	8	7	7	-	14	5	8	-	13	4	4	-	8
Normal	2	83	4	89	1	88	3	92	1	84	1	86	4	82	4	90	-	66	4	70
High	-	1	-	1	-	3	-	3	-	-	-	-	-	-	-	-	-	1	1	2
Total	4	88	4	96	4	96	3	103	8	91	1	100	9	90	4	103	4	71	5	80
Week 8																				
Low	2	2	-	4	3	8	-	11	3	7	-	10	4	7	-	11	2	5	-	7
Normal	2	85	3	90	1	87	3	91	4	81	1	86	5	81	4	90	2	65	4	71
High	-	-	1	1	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	87	4	95	4	96	3	103	7	88	1	96	9	88	4	101	4	70	4	78
Week 12																				
Low	1	3	-	4	3	6	-	9	3	6	-	9	4	4	-	8	1	3	-	4
Normal	3	79	4	86	1	87	3	91	3	78	1	82	5	83	4	92	3	64	3	70
High	-	3	-	3	-	1	-	1	-	1	-	1	-	1	-	1	-	-	1	1
Total	4	85	4	93	4	94	3	101	6	85	1	92	9	88	4	101	4	67	4	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	1	3	-	4	-	-	-	-	-	-	-	-
Normal	-	15	-	15	-	18	1	19	1	17	-	18	-	13	-	13	-	9	1	10
High	-	2	1	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	17	1	18	-	18	1	19	2	20	-	22	-	13	-	13	-	9	1	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Neutrophils

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	1	2	-	3	-	-	-	-	-	3	1	4	-	4	1	5	-	-	-	-
Normal	-	84	9	93	1	89	10	100	1	90	5	96	-	88	9	97	-	70	6	76
High	-	1	-	1	-	3	-	3	-	-	-	-	-	1	-	1	-	3	1	4
Total	1	87	9	97	1	92	10	103	1	93	6	100	-	93	10	103	-	73	7	80
Week 8																				
Low	1	1	-	2	-	3	-	3	1	2	1	4	-	1	-	1	-	-	-	-
Normal	-	84	7	91	1	87	10	98	-	86	5	91	-	90	8	98	-	70	6	76
High	-	1	1	2	-	2	-	2	-	1	-	1	-	1	1	2	-	1	1	2
Total	1	86	8	95	1	92	10	103	1	89	6	96	-	92	9	101	-	71	7	78
Week 12																				
Low	1	1	-	2	-	1	-	1	-	3	-	3	-	2	1	3	-	1	-	1
Normal	-	77	6	83	1	88	9	98	-	82	6	88	-	88	7	95	-	66	6	72
High	-	6	2	8	-	1	1	2	-	1	-	1	-	2	1	3	-	1	1	2
Total	1	84	8	93	1	90	10	101	-	86	6	92	-	92	9	101	-	68	7	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-
Normal	-	16	-	16	-	16	2	18	-	21	-	21	-	11	1	12	-	9	1	10
High	-	1	1	2	-	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	17	1	18	-	17	2	19	1	21	-	22	-	12	1	13	-	9	1	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Eosinophils

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	83	1	84	-	91	2	93	-	86	2	88	-	86	4	90	-	68	2	70
High	-	5	8	13	-	8	2	10	-	6	6	12	-	8	5	13	-	8	2	10
Total	-	88	9	97	-	99	4	103	-	92	8	100	-	94	9	103	-	76	4	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	82	2	84	-	92	2	94	-	83	3	86	-	87	4	91	-	72	2	74
High	-	4	7	11	-	7	2	9	-	5	5	10	-	5	5	10	-	2	2	4
Total	-	86	9	95	-	99	4	103	-	88	8	96	-	92	9	101	-	74	4	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	79	6	85	-	91	1	92	-	82	2	84	-	83	3	86	-	70	2	72
High	-	5	3	8	-	6	3	9	-	3	5	8	-	9	6	15	-	2	1	3
Total	-	84	9	93	-	97	4	101	-	85	7	92	-	92	9	101	-	72	3	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	16	-	16	-	17	-	17	-	21	-	21	-	11	1	12	-	9	-	9
High	-	1	1	2	-	1	1	2	-	-	1	1	-	-	1	1	-	-	1	1
Total	-	17	1	18	-	18	1	19	-	21	1	22	-	11	2	13	-	9	1	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Basophils

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	94	-	94	-	100	2	102	-	98	1	99	-	101	1	102	-	76	-	76
High	-	3	-	3	-	1	-	1	-	1	-	1	-	1	-	1	-	3	1	4
Total	-	97	-	97	-	101	2	103	-	99	1	100	-	102	1	103	-	79	1	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	94	-	94	-	100	1	101	-	96	-	96	-	100	1	101	-	77	-	77
High	-	1	-	1	-	1	1	2	-	-	-	-	-	-	-	-	-	-	1	1
Total	-	95	-	95	-	101	2	103	-	96	-	96	-	100	1	101	-	77	1	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	93	-	93	-	99	1	100	-	91	-	91	-	100	1	101	-	73	-	73
High	-	-	-	-	-	-	1	1	-	1	-	1	-	-	-	-	-	1	1	2
Total	-	93	-	93	-	99	2	101	-	92	-	92	-	100	1	101	-	74	1	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	17	-	17	-	19	-	19	-	21	1	22	-	13	-	13	-	9	-	9
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	-	18	-	18	-	19	-	19	-	21	1	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Lymphocytes

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	2	-	2	-	4	-	4	1	-	-	1	-	1	-	1	1	2	-	3
Normal	6	89	-	95	7	92	-	99	4	95	-	99	10	92	-	102	8	69	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	6	91	-	97	7	96	-	103	5	95	-	100	10	93	-	103	9	71	-	80
Week 8																				
Low	-	1	-	1	-	1	-	1	-	1	-	1	2	-	-	2	1	1	-	2
Normal	5	89	-	94	7	95	-	102	4	90	-	94	7	92	-	99	8	68	-	76
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	5	90	-	95	7	96	-	103	4	92	-	96	9	92	-	101	9	69	-	78
Week 12																				
Low	-	6	-	6	1	-	-	1	-	2	-	2	1	2	-	3	1	2	-	3
Normal	5	82	-	87	6	94	-	100	4	86	-	90	8	90	-	98	8	64	-	72
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	88	-	93	7	94	-	101	4	88	-	92	9	92	-	101	9	66	-	75
Follow-up																				
Low	1	1	-	2	-	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-
Normal	-	16	-	16	1	17	-	18	2	20	-	22	1	11	-	12	1	9	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	17	-	18	1	18	-	19	2	20	-	22	1	12	-	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Monocytes

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	88	2	90	-	97	4	101	-	89	5	94	-	97	2	99	-	72	4	76
High	-	6	1	7	-	1	1	2	-	3	3	6	-	2	2	4	-	3	1	4
Total	-	94	3	97	-	98	5	103	-	92	8	100	-	99	4	103	-	75	5	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	91	1	92	-	88	5	93	-	84	5	89	-	96	4	100	-	72	4	76
High	-	1	2	3	-	10	-	10	-	6	1	7	-	1	-	1	-	1	1	2
Total	-	92	3	95	-	98	5	103	-	90	6	96	-	97	4	101	-	73	5	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	86	2	88	-	91	3	94	-	82	4	86	-	94	4	98	-	67	4	71
High	-	4	1	5	-	5	2	7	-	5	1	6	-	3	-	3	-	3	1	4
Total	-	90	3	93	-	96	5	101	-	87	5	92	-	97	4	101	-	70	5	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	18	-	18	-	15	2	17	-	12	-	12	-	9	1	10
High	-	-	-	-	-	-	1	1	-	1	4	5	-	1	-	1	-	-	-	-
Total	-	18	-	18	-	18	1	19	-	16	6	22	-	13	-	13	-	9	1	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Hemoglobin

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	10	2	-	12	8	-	-	8	9	2	-	11	12	1	-	13	6	1	-	7
Normal	3	82	-	85	5	89	-	94	11	78	-	89	14	74	-	88	9	62	1	72
High	-	-	-	-	-	1	-	1	-	-	-	-	-	2	-	2	-	1	-	1
Total	13	84	-	97	13	90	-	103	20	80	-	100	26	77	-	103	15	64	1	80
Week 8																				
Low	9	3	-	12	8	2	-	10	9	-	-	9	7	1	-	8	4	-	-	4
Normal	4	79	-	83	5	88	-	93	10	77	-	87	19	73	-	92	11	61	1	73
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1
Total	13	82	-	95	13	90	-	103	19	77	-	96	26	75	-	101	15	62	1	78
Week 12																				
Low	9	3	-	12	8	-	-	8	4	-	-	4	6	2	-	8	2	1	-	3
Normal	4	77	-	81	5	87	-	92	13	75	-	88	20	73	-	93	13	58	1	72
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	13	80	-	93	13	88	-	101	17	75	-	92	26	75	-	101	15	59	1	75
Follow-up																				
Low	1	-	-	1	3	-	-	3	2	1	-	3	1	-	-	1	-	-	-	-
Normal	-	17	-	17	-	16	-	16	2	17	-	19	1	11	-	12	4	6	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	17	-	18	3	16	-	19	4	18	-	22	2	11	-	13	4	6	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Hematocrit

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	2	-	-	2	4	-	-	4	-	1	-	1	1	1	-	2	3	-	-	3
Normal	2	93	-	95	3	92	-	95	8	88	-	96	8	89	1	98	2	72	-	74
High	-	-	-	-	-	4	-	4	-	3	-	3	-	3	-	3	-	2	1	3
Total	4	93	-	97	7	96	-	103	8	92	-	100	9	93	1	103	5	74	1	80
Week 8																				
Low	2	1	-	3	3	-	-	3	1	-	-	1	2	1	-	3	-	-	-	-
Normal	2	87	-	89	4	93	-	97	7	87	-	94	7	88	1	96	5	70	-	75
High	-	3	-	3	-	3	-	3	-	1	-	1	-	2	-	2	-	2	1	3
Total	4	91	-	95	7	96	-	103	8	88	-	96	9	91	1	101	5	72	1	78
Week 12																				
Low	2	3	-	5	2	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Normal	2	84	-	86	5	93	-	98	7	84	-	91	9	87	1	97	5	67	1	73
High	-	2	-	2	-	1	-	1	-	1	-	1	-	4	-	4	-	2	-	2
Total	4	89	-	93	7	94	-	101	7	85	-	92	9	91	1	101	5	69	1	75
Follow-up																				
Low	-	-	-	-	1	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	18	-	18	-	18	-	18	2	20	-	22	1	11	-	12	1	9	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-
Total	-	18	-	18	1	18	-	19	2	20	-	22	1	12	-	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Platelets

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2	-	-	-	-
Normal	1	92	-	93	-	93	4	97	-	93	1	94	1	95	3	99	-	74	2	76
High	-	2	2	4	-	2	2	4	-	-	5	5	-	-	2	2	-	1	3	4
Total	1	94	2	97	-	95	6	101	-	94	6	100	1	97	5	103	-	75	5	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	1	90	2	93	-	95	4	99	-	89	2	91	-	93	3	96	-	73	3	76
High	-	2	-	2	-	1	3	4	-	-	4	4	-	2	2	4	-	-	2	2
Total	1	92	2	95	-	96	7	103	-	90	6	96	-	96	5	101	-	73	5	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	1	85	-	86	-	91	7	98	-	84	4	88	-	93	3	96	-	69	3	72
High	-	4	2	6	-	3	-	3	-	1	2	3	-	2	2	4	-	1	2	3
Total	1	89	2	92	-	94	7	101	-	86	6	92	-	96	5	101	-	70	5	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	17	-	17	-	14	2	16	-	22	-	22	1	12	-	13	-	10	-	10
High	-	1	-	1	-	-	2	2	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	18	-	18	-	14	4	18	-	22	-	22	1	12	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

MCH

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	13	1	-	14	9	1	-	10	14	1	-	15	19	2	-	21	13	-	-	13
Normal	1	82	-	83	2	91	-	93	1	84	-	85	3	79	-	82	1	66	-	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	14	83	-	97	11	92	-	103	15	85	-	100	22	81	-	103	14	66	-	80
Week 8																				
Low	13	1	-	14	8	-	-	8	13	1	-	14	14	1	-	15	12	2	-	14
Normal	1	80	-	81	3	92	-	95	2	80	-	82	8	78	-	86	2	62	-	64
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	14	81	-	95	11	92	-	103	15	81	-	96	22	79	-	101	14	64	-	78
Week 12																				
Low	12	1	-	13	9	1	-	10	11	2	-	13	11	-	-	11	12	1	-	13
Normal	1	79	-	80	2	89	-	91	3	76	-	79	11	79	-	90	2	60	-	62
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	13	80	-	93	11	90	-	101	14	78	-	92	22	79	-	101	14	61	-	75
Follow-up																				
Low	1	-	-	1	2	-	-	2	3	-	-	3	1	-	-	1	1	1	-	2
Normal	-	17	-	17	-	17	-	17	-	19	-	19	2	10	-	12	1	7	-	8
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	17	-	18	2	17	-	19	3	19	-	22	3	10	-	13	2	8	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

MCHC

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	4	-	-	4	5	2	-	7	6	2	-	8	7	1	-	8	10	2	-	12
Normal	3	90	-	93	3	93	-	96	1	91	-	92	7	88	-	95	1	67	-	68
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	7	90	-	97	8	95	-	103	7	93	-	100	14	89	-	103	11	69	-	80
Week 8																				
Low	3	2	-	5	4	5	-	9	6	2	-	8	6	1	-	7	9	-	-	9
Normal	4	86	-	90	4	90	-	94	1	87	-	88	8	86	-	94	2	67	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	7	88	-	95	8	95	-	103	7	89	-	96	14	87	-	101	11	67	-	78
Week 12																				
Low	3	5	-	8	4	2	-	6	2	2	-	4	6	-	-	6	7	-	-	7
Normal	3	82	-	85	4	91	-	95	5	83	-	88	8	87	-	95	4	64	-	68
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	6	87	-	93	8	93	-	101	7	85	-	92	14	87	-	101	11	64	-	75
Follow-up																				
Low	1	-	-	1	1	-	-	1	1	1	-	2	-	-	-	-	1	-	-	1
Normal	-	17	-	17	1	17	-	18	-	20	-	20	2	11	-	13	-	9	-	9
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	1	17	-	18	2	17	-	19	1	21	-	22	2	11	-	13	1	9	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

MCV

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	5	2	-	7	6	-	-	6	6	1	-	7	4	2	-	6	5	2	-	7
Normal	1	88	1	90	-	96	-	96	1	91	-	92	1	96	-	97	-	71	-	71
High	-	-	-	-	-	-	1	1	-	-	1	1	-	-	-	-	-	2	-	2
Total	6	90	1	97	6	96	1	103	7	92	1	100	5	98	-	103	5	75	-	80
Week 8																				
Low	4	4	-	8	5	-	-	5	7	1	-	8	4	1	-	5	4	1	-	5
Normal	2	84	-	86	1	96	1	98	-	87	-	87	1	95	-	96	1	72	-	73
High	-	-	1	1	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-
Total	6	88	1	95	6	96	1	103	7	88	1	96	5	96	-	101	5	73	-	78
Week 12																				
Low	4	4	-	8	4	2	-	6	7	1	-	8	4	1	-	5	4	1	-	5
Normal	1	84	-	85	2	92	1	95	-	83	-	83	1	95	-	96	1	69	-	70
High	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-
Total	5	88	-	93	6	94	1	101	7	84	1	92	5	96	-	101	5	70	-	75
Follow-up																				
Low	-	1	-	1	1	-	-	1	1	-	-	1	-	-	-	-	-	-	-	-
Normal	-	16	-	16	-	18	-	18	-	21	-	21	-	13	-	13	-	10	-	10
High	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	17	1	18	1	18	-	19	1	21	-	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-28　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（CCT-101 試験）（続き）

Reticulocytes

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	96	1	97	-	102	-	102	-	100	-	100	-	103	-	103	-	80	-	80
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	96	1	97	-	103	-	103	-	100	-	100	-	103	-	103	-	80	-	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	94	1	95	-	102	-	102	-	96	-	96	-	101	-	101	-	78	-	78
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	94	1	95	-	103	-	103	-	96	-	96	-	101	-	101	-	78	-	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	91	1	92	-	101	-	101	-	92	-	92	-	101	-	101	-	75	-	75
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	92	1	93	-	101	-	101	-	92	-	92	-	101	-	101	-	75	-	75
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	17	1	18	-	19	-	19	-	22	-	22	-	13	-	13	-	10	-	10
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	17	1	18	-	19	-	19	-	22	-	22	-	13	-	13	-	10	-	10

治験総括報告書 Table 3.3.1.1.3（Section 15.1）（5.3.5.4-1）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）

RBC

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	1	1	-	2	1	-	-	1	3	-	-	3	1	-	-	1	-	-	-	-
Normal	3	91	-	94	4	93	-	97	3	89	1	93	3	95	-	98	3	71	-	74
High	-	1	-	1	-	5	-	5	-	3	1	4	-	2	2	4	-	6	-	6
Total	4	93	-	97	5	98	-	103	6	92	2	100	4	97	2	103	3	77	-	80
Week 8																				
Low	-	-	-	-	-	-	-	-	2	-	-	2	-	1	-	1	1	-	-	1
Normal	4	86	-	90	5	95	-	100	4	85	1	90	4	91	1	96	2	69	-	71
High	-	5	-	5	-	3	-	3	-	3	1	4	-	3	1	4	-	6	-	6
Total	4	91	-	95	5	98	-	103	6	88	2	96	4	95	2	101	3	75	-	78
Week 12																				
Low	-	2	-	2	-	1	-	1	1	-	-	1	-	-	-	-	-	1	-	1
Normal	4	86	-	90	5	93	-	98	5	83	1	89	4	92	-	96	3	67	-	70
High	-	1	-	1	-	2	-	2	-	1	1	2	-	3	2	5	-	4	-	4
Total	4	89	-	93	5	96	-	101	6	84	2	92	4	95	2	101	3	72	-	75
Week 16																				
Low	-	-	-	-	1	-	-	1	2	1	-	3	-	-	-	-	-	-	-	-
Normal	3	69	-	72	3	78	-	81	4	67	-	71	4	80	-	84	2	62	-	64
High	-	3	-	3	-	2	-	2	-	3	1	4	-	4	1	5	-	5	-	5
Total	3	72	-	75	4	80	-	84	6	71	1	78	4	84	1	89	2	67	-	69
Week 20																				
Low	-	-	-	-	-	1	-	1	2	-	-	2	-	-	-	-	-	-	-	-
Normal	3	70	-	73	4	74	-	78	4	70	-	74	4	77	-	81	2	57	-	59
High	-	2	-	2	-	2	-	2	-	-	1	1	-	5	1	6	-	6	-	6
Total	3	72	-	75	4	77	-	81	6	70	1	77	4	82	1	87	2	63	-	65
Week 24																				
Low	-	-	-	-	-	1	-	1	1	-	-	1	-	-	-	-	-	-	-	-
Normal	3	64	-	67	4	73	-	77	5	68	-	73	4	78	-	82	2	56	-	58
High	-	1	-	1	-	1	-	1	-	1	1	2	-	5	1	6	-	4	-	4
Total	3	65	-	68	4	75	-	79	6	69	1	76	4	83	1	88	2	60	-	62
Follow-up																				
Low	-	-	-	-	-	2	-	2	2	1	-	3	-	-	-	-	1	-	-	1
Normal	3	73	-	76	4	77	-	81	4	69	-	73	4	82	-	86	1	63	-	64
High	-	1	-	1	-	-	-	-	-	-	1	1	-	2	1	3	-	4	-	4
Total	3	74	-	77	4	79	-	83	6	70	1	77	4	84	1	89	2	67	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

WBC

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	2	4	-	6	3	5	-	8	7	7	-	14	5	8	-	13	4	4	-	8
Normal	2	83	4	89	1	88	3	92	1	84	1	86	4	82	4	90	-	66	4	70
High	-	1	-	1	-	3	-	3	-	-	-	-	-	-	-	-	-	1	1	2
Total	4	88	4	96	4	96	3	103	8	91	1	100	9	90	4	103	4	71	5	80
Week 8																				
Low	2	2	-	4	3	8	-	11	3	7	-	10	4	7	-	11	2	5	-	7
Normal	2	85	3	90	1	87	3	91	4	81	1	86	5	81	4	90	2	65	4	71
High	-	-	1	1	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	87	4	95	4	96	3	103	7	88	1	96	9	88	4	101	4	70	4	78
Week 12																				
Low	1	3	-	4	3	6	-	9	3	6	-	9	4	4	-	8	1	3	-	4
Normal	3	79	4	86	1	87	3	91	3	78	1	82	5	83	4	92	3	64	3	70
High	-	3	-	3	-	1	-	1	-	1	-	1	-	1	-	1	-	-	1	1
Total	4	85	4	93	4	94	3	101	6	85	1	92	9	88	4	101	4	67	4	75
Week 16																				
Low	-	3	-	3	2	6	-	8	3	4	-	7	6	5	-	11	2	4	-	6
Normal	3	64	2	69	2	72	2	76	3	67	1	71	3	71	4	78	2	56	4	62
High	-	2	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	3	69	2	74	4	78	2	84	6	71	1	78	9	76	4	89	4	61	4	69
Week 20																				
Low	1	1	-	2	4	3	-	7	3	4	-	7	8	5	-	13	2	4	-	6
Normal	3	65	1	69	-	71	2	73	3	65	1	69	1	68	4	73	2	54	3	59
High	-	3	1	4	-	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-
Total	4	69	2	75	4	75	2	81	6	69	1	76	9	74	4	87	4	58	3	65
Week 24																				
Low	1	4	-	5	3	5	-	8	2	4	-	6	5	8	-	13	2	3	-	5
Normal	3	57	1	61	1	68	2	71	3	66	1	70	4	67	4	75	2	52	3	57
High	-	2	-	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	63	1	68	4	73	2	79	5	70	1	76	9	75	4	88	4	55	3	62
Follow-up																				
Low	-	2	-	2	-	2	-	2	2	4	-	6	3	-	-	3	1	6	-	7
Normal	4	68	2	74	4	73	2	79	4	65	1	70	6	75	4	85	3	55	4	62
High	-	-	1	1	-	2	-	2	-	1	-	1	-	1	-	1	-	-	-	-
Total	4	70	3	77	4	77	2	83	6	70	1	77	9	76	4	89	4	61	4	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Neutrophils

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	1	2	-	3	-	-	-	-	-	3	1	4	-	4	1	5	-	-	-	-
Normal	-	84	9	93	1	89	10	100	1	90	5	96	-	88	9	97	-	70	6	76
High	-	1	-	1	-	3	-	3	-	-	-	-	-	1	-	1	-	3	1	4
Total	1	87	9	97	1	92	10	103	1	93	6	100	-	93	10	103	-	73	7	80
Week 8																				
Low	1	1	-	2	-	3	-	3	1	2	1	4	-	1	-	1	-	-	-	-
Normal	-	84	7	91	1	87	10	98	-	86	5	91	-	90	8	98	-	70	6	76
High	-	1	1	2	-	2	-	2	-	1	-	1	-	1	1	2	-	1	1	2
Total	1	86	8	95	1	92	10	103	1	89	6	96	-	92	9	101	-	71	7	78
Week 12																				
Low	1	1	-	2	-	1	-	1	-	3	-	3	-	2	1	3	-	1	-	1
Normal	-	77	6	83	1	88	9	98	-	82	6	88	-	88	7	95	-	66	6	72
High	-	6	2	8	-	1	1	2	-	1	-	1	-	2	1	3	-	1	1	2
Total	1	84	8	93	1	90	10	101	-	86	6	92	-	92	9	101	-	68	7	75
Week 16																				
Low	-	1	-	1	-	1	-	1	-	-	-	-	-	1	2	3	-	-	-	-
Normal	1	61	6	68	1	73	8	82	-	70	6	76	-	79	6	85	-	63	5	68
High	-	5	1	6	-	1	-	1	-	2	-	2	-	-	1	1	-	-	1	1
Total	1	67	7	75	1	75	8	84	-	72	6	78	-	80	9	89	-	63	6	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	1	64	6	71	1	68	8	77	-	68	6	74	-	77	7	84	-	58	5	63
High	-	3	1	4	-	4	-	4	-	2	-	2	-	1	1	2	-	2	-	2
Total	1	67	7	75	1	72	8	81	-	71	6	77	-	79	8	87	-	60	5	65
Week 24																				
Low	1	1	-	2	-	2	-	2	-	2	1	3	-	3	1	4	-	1	-	1
Normal	-	55	5	60	1	63	8	72	-	67	5	72	-	73	7	80	-	56	5	61
High	-	5	1	6	-	5	-	5	-	1	-	1	-	3	1	4	-	-	-	-
Total	1	61	6	68	1	70	8	79	-	70	6	76	-	79	9	88	-	57	5	62
Follow-up																				
Low	1	-	-	1	-	1	-	1	-	2	-	2	-	-	-	-	-	-	-	-
Normal	-	66	8	74	1	65	8	74	-	69	5	74	-	79	8	87	-	63	6	69
High	-	2	-	2	-	8	-	8	-	1	-	1	-	1	1	2	-	-	-	-
Total	1	68	8	77	1	74	8	83	-	72	5	77	-	80	9	89	-	63	6	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Eosinophils

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	83	1	84	-	91	2	93	-	86	2	88	-	86	4	90	-	68	2	70
High	-	5	8	13	-	8	2	10	-	6	6	12	-	8	5	13	-	8	2	10
Total	-	88	9	97	-	99	4	103	-	92	8	100	-	94	9	103	-	76	4	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	82	2	84	-	92	2	94	-	83	3	86	-	87	4	91	-	72	2	74
High	-	4	7	11	-	7	2	9	-	5	5	10	-	5	5	10	-	2	2	4
Total	-	86	9	95	-	99	4	103	-	88	8	96	-	92	9	101	-	74	4	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	79	6	85	-	91	1	92	-	82	2	84	-	83	3	86	-	70	2	72
High	-	5	3	8	-	6	3	9	-	3	5	8	-	9	6	15	-	2	1	3
Total	-	84	9	93	-	97	4	101	-	85	7	92	-	92	9	101	-	72	3	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	4	69	-	75	2	77	-	69	3	72	-	77	4	81	-	65	2	67
High	-	2	4	6	-	6	1	7	-	2	4	6	-	5	3	8	-	1	1	2
Total	-	67	8	75	-	81	3	84	-	71	7	78	-	82	7	89	-	66	3	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	62	3	65	-	78	-	78	-	67	2	69	-	75	4	79	-	59	1	60
High	-	5	5	10	-	1	2	3	-	3	5	8	-	5	3	8	-	3	2	5
Total	-	67	8	75	-	79	2	81	-	70	7	77	-	80	7	87	-	62	3	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	58	5	63	-	75	-	75	-	66	2	68	-	75	5	80	-	57	2	59
High	-	3	2	5	-	2	2	4	-	3	5	8	-	6	2	8	-	2	1	3
Total	-	61	7	68	-	77	2	79	-	69	7	76	-	81	7	88	-	59	3	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	65	4	69	-	78	-	78	-	69	3	72	-	77	5	82	-	61	2	63
High	-	4	4	8	-	2	3	5	-	1	4	5	-	5	2	7	-	5	1	6
Total	-	69	8	77	-	80	3	83	-	70	7	77	-	82	7	89	-	66	3	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Basophils

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	94	-	94	-	100	2	102	-	98	1	99	-	101	1	102	-	76	-	76
High	-	3	-	3	-	1	-	1	-	1	-	1	-	1	-	1	-	3	1	4
Total	-	97	-	97	-	101	2	103	-	99	1	100	-	102	1	103	-	79	1	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	94	-	94	-	100	1	101	-	96	-	96	-	100	1	101	-	77	-	77
High	-	1	-	1	-	1	1	2	-	-	-	-	-	-	-	-	-	-	1	1
Total	-	95	-	95	-	101	2	103	-	96	-	96	-	100	1	101	-	77	1	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	93	-	93	-	99	1	100	-	91	-	91	-	100	1	101	-	73	-	73
High	-	-	-	-	-	-	1	1	-	1	-	1	-	-	-	-	-	1	1	2
Total	-	93	-	93	-	99	2	101	-	92	-	92	-	100	1	101	-	74	1	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	74	-	74	-	82	2	84	-	78	-	78	-	88	1	89	-	68	1	69
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	-	75	-	75	-	82	2	84	-	78	-	78	-	88	1	89	-	68	1	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	75	-	75	-	79	2	81	-	77	-	77	-	86	-	86	-	64	-	64
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	1	1
Total	-	75	-	75	-	79	2	81	-	77	-	77	-	86	1	87	-	64	1	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	68	-	68	-	77	2	79	-	75	-	75	-	86	1	87	-	61	1	62
High	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Total	-	68	-	68	-	77	2	79	-	76	-	76	-	87	1	88	-	61	1	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	76	-	76	-	81	2	83	-	76	-	76	-	88	1	89	-	68	-	68
High	-	1	-	1	-	-	-	-	-	1	-	1	-	-	-	-	-	-	1	1
Total	-	77	-	77	-	81	2	83	-	77	-	77	-	88	1	89	-	68	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Lymphocytes

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	2	-	2	-	4	-	4	1	-	-	1	-	1	-	1	1	2	-	3
Normal	6	89	-	95	7	92	-	99	4	95	-	99	10	92	-	102	8	69	-	77
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	6	91	-	97	7	96	-	103	5	95	-	100	10	93	-	103	9	71	-	80
Week 8																				
Low	-	1	-	1	-	1	-	1	-	1	-	1	2	-	-	2	1	1	-	2
Normal	5	89	-	94	7	95	-	102	4	90	-	94	7	92	-	99	8	68	-	76
High	-	-	-	-	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-
Total	5	90	-	95	7	96	-	103	4	92	-	96	9	92	-	101	9	69	-	78
Week 12																				
Low	-	6	-	6	1	-	-	1	-	2	-	2	1	2	-	3	1	2	-	3
Normal	5	82	-	87	6	94	-	100	4	86	-	90	8	90	-	98	8	64	-	72
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	88	-	93	7	94	-	101	4	88	-	92	9	92	-	101	9	66	-	75
Week 16																				
Low	-	5	-	5	-	1	-	1	-	2	-	2	1	-	-	1	1	-	-	1
Normal	4	66	-	70	6	77	-	83	3	73	-	76	8	80	-	88	7	61	-	68
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	71	-	75	6	78	-	84	3	75	-	78	9	80	-	89	8	61	-	69
Week 20																				
Low	-	4	-	4	-	1	-	1	-	1	-	1	2	1	-	3	1	1	-	2
Normal	4	67	-	71	6	74	-	80	3	73	-	76	6	78	-	84	6	57	-	63
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	4	71	-	75	6	75	-	81	3	74	-	77	8	79	-	87	7	58	-	65
Week 24																				
Low	-	3	-	3	-	5	-	5	-	-	-	-	1	3	-	4	-	-	-	-
Normal	3	61	-	64	6	68	-	74	3	73	-	76	8	76	-	84	7	55	-	62
High	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	3	65	-	68	6	73	-	79	3	73	-	76	9	79	-	88	7	55	-	62
Follow-up																				
Low	-	2	-	2	1	7	-	8	-	-	-	-	1	2	-	3	-	-	-	-
Normal	5	70	-	75	5	70	-	75	3	74	-	77	8	78	-	86	8	61	-	69
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	5	72	-	77	6	77	-	83	3	74	-	77	9	80	-	89	8	61	-	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Monocytes

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	88	2	90	-	97	4	101	-	89	5	94	-	97	2	99	-	72	4	76
High	-	6	1	7	-	1	1	2	-	3	3	6	-	2	2	4	-	3	1	4
Total	-	94	3	97	-	98	5	103	-	92	8	100	-	99	4	103	-	75	5	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	91	1	92	-	88	5	93	-	84	5	89	-	96	4	100	-	72	4	76
High	-	1	2	3	-	10	-	10	-	6	1	7	-	1	-	1	-	1	1	2
Total	-	92	3	95	-	98	5	103	-	90	6	96	-	97	4	101	-	73	5	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	86	2	88	-	91	3	94	-	82	4	86	-	94	4	98	-	67	4	71
High	-	4	1	5	-	5	2	7	-	5	1	6	-	3	-	3	-	3	1	4
Total	-	90	3	93	-	96	5	101	-	87	5	92	-	97	4	101	-	70	5	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	69	-	69	-	78	3	81	-	74	2	76	-	81	3	84	-	64	3	67
High	-	3	3	6	-	2	1	3	-	2	-	2	-	4	1	5	-	1	1	2
Total	-	72	3	75	-	80	4	84	-	76	2	78	-	85	4	89	-	65	4	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	67	1	68	-	76	3	79	-	71	1	72	-	78	3	81	-	58	3	61
High	-	5	2	7	-	1	1	2	-	4	1	5	-	5	1	6	-	3	1	4
Total	-	72	3	75	-	77	4	81	-	75	2	77	-	83	4	87	-	61	4	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	64	2	66	-	72	3	75	-	72	2	74	-	80	3	83	-	56	3	59
High	-	1	1	2	-	3	1	4	-	2	-	2	-	4	1	5	-	2	1	3
Total	-	65	3	68	-	75	4	79	-	74	2	76	-	84	4	88	-	58	4	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	-	71	2	73	-	74	3	77	-	73	2	75	-	81	3	84	-	63	3	66
High	-	3	1	4	-	5	1	6	-	2	-	2	-	4	1	5	-	2	1	3
Total	-	74	3	77	-	79	4	83	-	75	2	77	-	85	4	89	-	65	4	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Hemoglobin

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	10	2	-	12	8	-	-	8	9	2	-	11	12	1	-	13	6	1	-	7
Normal	3	82	-	85	5	89	-	94	11	78	-	89	14	74	-	88	9	62	1	72
High	-	-	-	-	-	1	-	1	-	-	-	-	-	2	-	2	-	1	-	1
Total	13	84	-	97	13	90	-	103	20	80	-	100	26	77	-	103	15	64	1	80
Week 8																				
Low	9	3	-	12	8	2	-	10	9	-	-	9	7	1	-	8	4	-	-	4
Normal	4	79	-	83	5	88	-	93	10	77	-	87	19	73	-	92	11	61	1	73
High	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1
Total	13	82	-	95	13	90	-	103	19	77	-	96	26	75	-	101	15	62	1	78
Week 12																				
Low	9	3	-	12	8	-	-	8	4	-	-	4	6	2	-	8	2	1	-	3
Normal	4	77	-	81	5	87	-	92	13	75	-	88	20	73	-	93	13	58	1	72
High	-	-	-	-	-	1	-	1	-	-	-	-	-	-	-	-	-	-	-	-
Total	13	80	-	93	13	88	-	101	17	75	-	92	26	75	-	101	15	59	1	75
Week 16																				
Low	7	3	-	10	3	1	-	4	4	-	-	4	8	-	-	8	2	-	-	2
Normal	5	59	-	64	7	73	-	80	12	62	-	74	14	66	-	80	9	56	1	66
High	-	1	-	1	-	-	-	-	-	-	-	-	1	-	-	1	-	1	-	1
Total	12	63	-	75	10	74	-	84	16	62	-	78	23	66	-	89	11	57	1	69
Week 20																				
Low	9	3	-	12	2	1	-	3	4	2	-	6	6	1	-	7	2	-	-	2
Normal	3	60	-	63	8	70	-	78	12	59	-	71	17	63	-	80	9	53	1	63
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	12	63	-	75	10	71	-	81	16	61	-	77	23	64	-	87	11	53	1	65
Week 24																				
Low	7	6	-	13	2	2	-	4	5	4	-	9	4	1	-	5	-	-	-	-
Normal	3	52	-	55	7	68	-	75	11	56	-	67	19	64	-	83	11	49	1	61
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Total	10	58	-	68	9	70	-	79	16	60	-	76	23	65	-	88	11	50	1	62
Follow-up																				
Low	8	6	-	14	2	1	-	3	6	4	-	10	5	1	-	6	-	-	-	-
Normal	4	59	-	63	8	72	-	80	10	57	-	67	18	65	-	83	11	55	1	67
High	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	2
Total	12	65	-	77	10	73	-	83	16	61	-	77	23	66	-	89	11	57	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Hematocrit

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	2	-	-	2	4	-	-	4	-	1	-	1	1	1	-	2	3	-	-	3
Normal	2	93	-	95	3	92	-	95	8	88	-	96	8	89	1	98	2	72	-	74
High	-	-	-	-	-	4	-	4	-	3	-	3	-	3	-	3	-	2	1	3
Total	4	93	-	97	7	96	-	103	8	92	-	100	9	93	1	103	5	74	1	80
Week 8																				
Low	2	1	-	3	3	-	-	3	1	-	-	1	2	1	-	3	-	-	-	-
Normal	2	87	-	89	4	93	-	97	7	87	-	94	7	88	1	96	5	70	-	75
High	-	3	-	3	-	3	-	3	-	1	-	1	-	2	-	2	-	2	1	3
Total	4	91	-	95	7	96	-	103	8	88	-	96	9	91	1	101	5	72	1	78
Week 12																				
Low	2	3	-	5	2	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Normal	2	84	-	86	5	93	-	98	7	84	-	91	9	87	1	97	5	67	1	73
High	-	2	-	2	-	1	-	1	-	1	-	1	-	4	-	4	-	2	-	2
Total	4	89	-	93	7	94	-	101	7	85	-	92	9	91	1	101	5	69	1	75
Week 16																				
Low	2	3	-	5	2	-	-	2	-	-	-	-	-	-	-	-	-	-	-	-
Normal	2	65	-	67	4	77	-	81	6	70	-	76	8	78	1	87	4	60	1	65
High	-	3	-	3	-	1	-	1	-	2	-	2	-	2	-	2	-	4	-	4
Total	4	71	-	75	6	78	-	84	6	72	-	78	8	80	1	89	4	64	1	69
Week 20																				
Low	2	4	-	6	-	-	-	-	-	1	-	1	1	-	-	1	-	-	-	-
Normal	2	66	-	68	6	73	-	79	6	68	-	74	7	75	1	83	4	57	1	62
High	-	1	-	1	-	2	-	2	-	2	-	2	-	3	-	3	-	3	-	3
Total	4	71	-	75	6	75	-	81	6	71	-	77	8	78	1	87	4	60	1	65
Week 24																				
Low	2	5	-	7	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Normal	1	60	-	61	5	73	-	78	6	69	-	75	8	74	1	83	4	52	1	57
High	-	-	-	-	-	1	-	1	-	1	-	1	-	5	-	5	-	5	-	5
Total	3	65	-	68	5	74	-	79	6	70	-	76	8	79	1	88	4	57	1	62
Follow-up																				
Low	1	4	-	5	1	-	-	1	2	1	-	3	-	-	-	-	-	-	-	-
Normal	3	68	-	71	5	77	-	82	4	70	-	74	8	75	1	84	4	59	1	64
High	-	1	-	1	-	-	-	-	-	-	-	-	-	5	-	5	-	5	-	5
Total	4	73	-	77	6	77	-	83	6	71	-	77	8	80	1	89	4	64	1	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用

表 2.7.4.8-付録-29　血液学的検査値のシフトテーブル（安全性データの解析対象集団）（OCT-101 試験）（続き）

Platelets

	Baseline																			
	Placebo (N=97)				TAK-385 10mg (N=103)				TAK-385 20mg (N=100)				TAK-385 40mg (N=103)				Leuprorelin (N=80)			
Visit	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total	Low	Normal	High	Total
Week 4																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2	-	-	-	-
Normal	1	92	-	93	-	93	4	97	-	93	1	94	1	95	3	99	-	74	2	76
High	-	2	2	4	-	2	2	4	-	-	5	5	-	-	2	2	-	1	3	4
Total	1	94	2	97	-	95	6	101	-	94	6	100	1	97	5	103	-	75	5	80
Week 8																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	1	90	2	93	-	95	4	99	-	89	2	91	-	93	3	96	-	73	3	76
High	-	2	-	2	-	1	3	4	-	-	4	4	-	2	2	4	-	-	2	2
Total	1	92	2	95	-	96	7	103	-	90	6	96	-	96	5	101	-	73	5	78
Week 12																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	1	85	-	86	-	91	7	98	-	84	4	88	-	93	3	96	-	69	3	72
High	-	4	2	6	-	3	-	3	-	1	2	3	-	2	2	4	-	1	2	3
Total	1	89	2	92	-	94	7	101	-	86	6	92	-	96	5	101	-	70	5	75
Week 16																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1	-	-	-	-
Normal	1	67	-	68	-	79	3	82	-	71	2	73	-	82	3	85	-	64	3	67
High	-	4	2	6	-	2	-	2	-	-	4	4	-	-	2	2	-	-	2	2
Total	1	71	2	74	-	81	3	84	-	72	6	78	-	83	5	88	-	64	5	69
Week 20																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2	-	-	-	-
Normal	1	68	1	70	-	76	1	77	-	70	2	72	-	78	3	81	-	61	2	63
High	-	4	1	5	-	2	2	4	-	-	4	4	-	2	2	4	-	-	2	2
Total	1	72	2	75	-	78	3	81	-	71	6	77	-	82	5	87	-	61	4	65
Week 24																				
Low	-	-	-	-	-	-	-	-	-	1	-	1	-	2	-	2	-	-	-	-
Normal	1	60	1	62	-	73	1	74	-	67	3	70	-	77	3	80	-	58	2	60
High	-	5	1	6	-	2	2	4	-	2	3	5	-	4	2	6	-	-	2	2
Total	1	65	2	68	-	75	3	78	-	70	6	76	-	83	5	88	-	58	4	62
Follow-up																				
Low	-	-	-	-	-	-	-	-	-	-	-	-	-	1	-	1	-	1	-	1
Normal	1	70	1	72	-	79	1	80	-	71	3	74	-	80	3	83	-	63	3	66
High	-	4	1	5	-	1	2	3	-	-	3	3	-	3	2	5	-	-	2	2
Total	1	74	2	77	-	80	3	83	-	71	6	77	-	84	5	89	-	64	5	69

治験総括報告書 Table 3.2.1.1.3（Section 15.1）（5.3.5.4-2）から引用