表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
C Reactive Protein (mg/dL)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	0 053	0 074	-	0 079	0 089	0 081	0 089	0 104	0 064
			SD	0 1112	0 1485	-	0 1311	0 1534	0 1126	0 1430	0 1974	0 1678
			Min	0 01	0 01	-	0 01	0 01	0 01	0 01	0 01	0 01
			Q1	0 010	0 010	-	0 020	0 020	0 020	0 020	0 020	0 010
			Median	0 020	0 030	-	0 030	0 040	0 040	0 040	0 040	0 020
			Q3	0 050	0 070	-	0 090	0 090	0 090	0 100	0 090	0 050
			Max	0 93	1 41	-	1 03	1 24	0 76	1 22	1 55	1 77
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	0 054	0 074	0 064	0 080	0 089	0 081	0 089	0 128	0 068
			SD	0 1164	0 1485	0 0774	0 1302	0 1445	0 1126	0 1430	0 4068	0 1592
			Min	0 01	0 01	0 01	0 01	0 01	0 01	0 01	0 01	0 01
			Q1	0 010	0 010	0 020	0 020	0 020	0 020	0 020	0 020	0 010
			Median	0 020	0 030	0 030	0 040	0 040	0 040	0 040	0 040	0 020
			Q3	0 050	0 070	0 080	0 090	0 090	0 090	0 100	0 100	0 050
			Max	1 10	1 41	0 42	1 03	1 24	0 76	1 22	6 15	1 77

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
C Reactive Protein (mg/dL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 020	-	0 026	0 035	0 026	0 033	0 050	0 010
			SD	-	0 1683	-	0 1608	0 1728	0 1431	0 1713	0 1695	0 1961
			Min	-	-0 89	-	-0 83	-0 87	-0 89	-0 86	-0 77	-0 90
			Q1	-	0 000	-	0 000	0 000	0 000	0 000	0 000	-0 010
			Median	-	0 010	-	0 010	0 010	0 010	0 010	0 020	0 000
			Q3	-	0 030	-	0 040	0 050	0 050	0 050	0 050	0 010
			Max	-	1 39	-	1 01	1 01	0 73	1 21	1 05	1 69
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 020	0 008	0 025	0 033	0 026	0 033	0 073	0 013
			SD	-	0 1683	0 1340	0 1654	0 1655	0 1431	0 1713	0 4077	0 1897
			Min	-	-0 89	-1 08	-1 06	-0 87	-0 89	-0 86	-1 05	-0 92
			Q1	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	-0 010
			Median	-	0 010	0 010	0 010	0 010	0 010	0 010	0 020	0 000
			Q3	-	0 030	0 040	0 040	0 040	0 050	0 050	0 060	0 010
			Max	-	1 39	0 35	1 01	1 01	0 73	1 21	6 12	1 69

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[e)] (Visit 17/ Discontinuation)	Follow-up[e)] (Visit 19)
Cancer Antigen 125 (U/mL)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	26 76	21 54	-	17 60	17 25	17 95	17 48	16 00	19 98
			SD	25 448	22 495	-	17 212	17 932	20 972	25 607	21 075	30 492
			Min	5 4	4 5	-	3 4	3 8	3 6	3 2	3 3	4 1
			Q1	12 55	10 90	-	9 20	8 80	9 30	8 50	8 30	10 00
			Median	19 00	15 60	-	12 90	12 50	12 20	12 20	12 00	14 30
			Q3	28 30	21 40	-	18 00	16 70	16 80	16 10	16 40	20 10
			Max	174 0	211 0	-	132 0	130 0	167 0	225 0	224 0	358 0
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	27 67	21 54	22 51	18 86	16 43	17 95	17 48	16 75	21 71
			SD	28 546	22 495	26 555	19 956	16 663	20 972	25 607	19 453	27 716
			Min	5 4	4 5	4 7	3 4	3 8	3 6	3 2	3 3	4 1
			Q1	12 60	10 90	9 90	9 60	8 70	9 30	8 50	8 60	10 50
			Median	18 20	15 60	13 20	12 80	11 95	12 20	12 20	12 00	14 40
			Q3	29 00	21 40	21 80	18 65	16 40	16 80	16 10	16 70	21 00
			Max	237 0	211 0	185 0	144 0	130 0	167 0	225 0	224 0	358 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Cancer Antigen 125 (U/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-4 97	-	-8 84	-9 60	-8 61	-8 79	-10 52	-6 48
			SD	-	13 743	-	18 119	21 455	21 011	27 025	23 905	30 680
			Min	-	-76 3	-	-100 7	-133 9	-102 9	-145 3	-125 3	-136 0
			Q1	-	-7 90	-	-11 60	-12 10	-12 30	-11 90	-12 60	-9 10
			Median	-	-3 05	-	-4 80	-5 30	-5 00	-5 10	-5 70	-3 70
			Q3	-	-0 40	-	-2 10	-2 40	-1 90	-2 50	-3 00	-1 50
			Max	-	57 0	-	76 3	105 5	115 3	173 3	172 3	306 3
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-4 97	-6 39	-8 67	-9 10	-8 61	-8 79	-10 86	-5 93
			SD	-	13 743	16 205	17 468	19 522	21 011	27 025	22 809	25 575
			Min	-	-76 3	-70 5	-100 7	-133 9	-102 9	-145 3	-160 7	-139 2
			Q1	-	-7 90	-9 30	-10 05	-11 10	-12 30	-11 90	-12 70	-8 20
			Median	-	-3 05	-4 50	-4 85	-5 30	-5 00	-5 10	-6 10	-3 20
			Q3	-	-0 40	-1 20	-2 00	-2 40	-1 90	-2 50	-2 90	-0 60
			Max	-	57 0	86 0	76 3	105 5	115 3	173 3	172 3	306 3

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
LDH Isoenzyme 1/LDH (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	24 24	24 21	-	24 21	24 46	24 94	24 99	24 67	24 20
			SD	2 773	2 862	-	2 906	2 891	3 054	3 058	3 164	3 146
			Min	18 8	17 0	-	16 5	16 9	18 6	17 2	13 5	15 8
			Q1	22 35	22 20	-	22 40	22 50	22 80	22 90	22 60	22 00
			Median	23 95	24 00	-	24 10	24 10	24 40	24 90	24 20	23 75
			Q3	25 95	26 20	-	25 70	26 20	27 10	27 20	27 10	26 20
			Max	30 2	32 7	-	31 9	34 9	34 1	32 7	32 4	33 2
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	24 12	24 21	24 80	24 56	24 55	24 94	24 99	24 43	24 26
			SD	2 772	2 862	2 915	2 959	2 752	3 054	3 058	2 931	3 206
			Min	16 2	17 0	18 6	16 5	16 9	18 6	17 2	13 5	15 8
			Q1	22 30	22 20	22 60	22 70	22 60	22 80	22 90	22 60	22 10
			Median	23 80	24 00	24 60	24 20	24 25	24 40	24 90	24 10	23 80
			Q3	25 80	26 20	27 00	26 65	26 50	27 10	27 20	26 20	26 40
			Max	30 7	32 7	37 2	34 5	34 9	34 1	32 7	32 4	33 2

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
LDH Isoenzyme 1/LDH (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 03	-	-0 03	0 24	0 70	0 72	0 42	-0 02
			SD	-	2 166	-	2 211	2 158	2 201	2 077	2 352	2 399
			Min	-	-6 6	-	-4 7	-6 7	-4 5	-4 5	-6 0	-6 9
			Q1	-	-1 30	-	-1 60	-1 00	-0 50	-0 60	-1 10	-1 50
			Median	-	-0 20	-	-0 20	0 10	0 50	0 70	0 50	0 10
			Q3	-	1 00	-	1 20	1 50	1 90	1 80	2 10	1 40
			Max	-	11 1	-	8 3	7 3	8 8	8 1	8 4	7 3
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-0 03	0 87	0 48	0 40	0 70	0 72	0 33	0 16
			SD	-	2 166	2 467	2 272	2 214	2 201	2 077	2 240	2 430
			Min	-	-6 6	-6 0	-4 7	-7 7	-4 5	-4 5	-6 0	-6 9
			Q1	-	-1 30	-0 70	-0 95	-0 90	-0 50	-0 60	-1 10	-1 40
			Median	-	-0 20	0 90	0 40	0 30	0 50	0 70	0 40	0 20
			Q3	-	1 00	2 20	1 70	1 60	1 90	1 80	1 80	1 80
			Max	-	11 1	14 4	11 7	7 3	8 8	8 1	8 4	8 2

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
LDH Isoenzyme 2/LDH (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	35 20	35 61	-	35 85	35 89	36 11	36 47	35 79	34 87
			SD	2 018	1 920	-	2 186	2 170	2 081	2 002	2 378	2 046
			Min	28 4	30 0	-	29 8	28 4	31 6	31 5	23 0	27 5
			Q1	33 85	34 50	-	34 30	34 60	34 80	35 10	34 30	33 60
			Median	35 00	35 65	-	35 80	35 90	36 10	36 50	35 80	35 00
			Q3	36 30	36 90	-	37 50	37 40	37 70	37 80	37 40	36 10
			Max	42 5	40 3	-	42 3	41 9	40 7	41 9	41 0	39 6
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	35 33	35 61	36 08	36 18	36 12	36 11	36 47	35 98	34 86
			SD	1 939	1 920	1 865	2 099	2 283	2 081	2 002	2 248	2 001
			Min	28 4	30 0	30 4	29 8	28 4	31 6	31 5	23 0	26 2
			Q1	34 10	34 50	34 80	34 70	34 80	34 80	35 10	34 40	33 60
			Median	35 40	35 65	36 20	36 40	36 00	36 10	36 50	36 10	35 00
			Q3	36 50	36 90	37 30	37 80	37 50	37 70	37 80	37 50	36 30
			Max	42 5	40 3	40 3	42 3	44 3	40 7	41 9	41 0	39 8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 2.sas / Output: t 4 4 2 1 2.rtf
Date of Table Generation: 2023-09-22 20:52
Data Source: adlb

表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
LDH Isoenzyme 2/LDH (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 41	-	0 67	0 72	0 97	1 35	0 64	-0 28
			SD	-	1 909	-	2 117	2 254	1 818	1 983	2 560	2 290
			Min	-	-5 6	-	-6 1	-7 4	-5 0	-4 7	-12 9	-11 9
			Q1	-	-0 90	-	-0 60	-0 70	-0 20	-0 10	-0 70	-1 70
			Median	-	0 30	-	0 80	0 90	0 80	1 30	0 50	-0 10
			Q3	-	1 70	-	2 10	2 20	2 20	2 50	2 20	1 00
			Max	-	4 6	-	6 2	5 7	6 0	6 5	6 0	5 5
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 41	0 62	0 87	0 88	0 97	1 35	0 69	-0 43
			SD	-	1 909	1 962	2 075	2 338	1 818	1 983	2 374	2 214
			Min	-	-5 6	-4 7	-6 1	-8 2	-5 0	-4 7	-12 9	-11 9
			Q1	-	-0 90	-0 70	-0 50	-0 50	-0 20	-0 10	-0 60	-1 80
			Median	-	0 30	0 50	0 95	1 00	0 80	1 30	0 60	-0 30
			Q3	-	1 70	2 00	2 20	2 30	2 20	2 50	2 00	0 90
			Max	-	4 6	6 0	6 7	10 3	6 0	6 5	6 7	5 5

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 2.sas / Output: t 4 4 2 1 2.rtf
Date of Table Generation: 2023-09-22 20:52
Data Source: adlb

表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Troponin I (pg/mL)	Value	Primary FSN-013 Pooled	n	159	157	-	159	155	149	146	153	154
			Mean	4 16	4 13	-	4 12	4 10	4 14	4 13	4 09	4 12
			SD	1 514	1 080	-	1 229	1 064	1 663	1 491	1 067	1 515
			Min	4 0	4 0	-	4 0	4 0	4 0	4 0	4 0	4 0
			Q1	4 00	4 00	-	4 00	4 00	4 00	4 00	4 00	4 00
			Median	4 00	4 00	-	4 00	4 00	4 00	4 00	4 00	4 00
			Q3	4 00	4 00	-	4 00	4 00	4 00	4 00	4 00	4 00
			Max	22 4	16 0	-	19 2	17 1	24 3	22 0	17 2	22 8
		Secondary FSN-013 Pooled	n	310	157	149	304	222	149	146	301	303
			Mean	4 13	4 13	4 03	4 06	4 08	4 14	4 13	4 05	4 07
			SD	1 246	1 080	0 360	0 890	0 902	1 663	1 491	0 763	1 089
			Min	4 0	4 0	4 0	4 0	4 0	4 0	4 0	4 0	4 0
			Q1	4 00	4 00	4 00	4 00	4 00	4 00	4 00	4 00	4 00
			Median	4 00	4 00	4 00	4 00	4 00	4 00	4 00	4 00	4 00
			Q3	4 00	4 00	4 00	4 00	4 00	4 00	4 00	4 00	4 00
			Max	22 4	16 0	8 4	19 2	17 1	24 3	22 0	17 2	22 8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only subjects in the FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 2.sas / Output: t 4 4 2 1 2.rtf
Date of Table Generation: 2023-09-22 20:52
Data Source: adlb

表 2.7.4-130 血液生化学的検査の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.2 Summary of Serum Chemistry Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Troponin I (pg/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	156	-	158	155	149	146	153	153
			Mean	-	-0 04	-	-0 05	-0 06	-0 03	-0 04	-0 08	-0 04
			SD	-	0 808	-	0 464	0 574	0 460	0 443	0 594	0 428
			Min	-	-6 4	-	-4 8	-5 3	-4 8	-4 8	-5 2	-4 8
			Q1	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	6 1	-	0 9	0 4	1 9	0 8	0 2	0 4
		Secondary FSN-013 Pooled	n	-	156	149	303	222	149	146	301	302
			Mean	-	-0 04	-0 06	-0 07	-0 08	-0 03	-0 04	-0 08	-0 06
			SD	-	0 808	0 891	0 701	0 733	0 460	0 443	0 747	0 683
			Min	-	-6 4	-10 6	-10 6	-8 3	-4 8	-4 8	-10 6	-10 6
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	6 1	2 2	0 9	0 4	1 9	0 8	0 2	0 4

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only subjects in the FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

Program Name: t 4 4 2 1 2.sas / Output: t 4 4 2 1 2.rtf
Date of Table Generation: 2023-09-22 20:52
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-64 を引用

表 2.7.4-131 血液生化学的検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.2.2 Frequency of Serum Chemistry Tests Above or Below the Reference Limits (SAS)

Parameter	Primary FSN-013 Pooled N=160		Secondary FSN-013 Pooled N=311	
	Above Upper Limit n(%)	Below Lower Limit n(%)	Above Upper Limit n(%)	Below Lower Limit n(%)
Protein (g/dL)	2 (1.3)	74 (46.3)	3 (1.0)	149 (47.9)
Albumin (g/dL)	3 (1.9)	23 (14.4)	3 (1.0)	39 (12.5)
Bilirubin (mg/dL)	15 (9.4)	0 (0.0)	34 (10.9)	0 (0.0)
Aspartate Aminotransferase (U/L)	5 (3.1)	4 (2.5)	10 (3.2)	10 (3.2)
Alanine Aminotransferase (U/L)	9 (5.6)	6 (3.8)	15 (4.8)	9 (2.9)
Alkaline Phosphatase (U/L)	0 (0.0)	43 (26.9)	0 (0.0)	78 (25.1)
Gamma Glutamyl Transferase (U/L)	22 (13.8)	-	33 (10.6)	-
Lactate Dehydrogenase (U/L)	12 (7.5)	14 (8.8)	18 (5.8)	27 (8.7)
Glomerular Filtration Rate, Estimated (mL/min/1.73m^2)	-	-	-	-
Amylase (U/L)	13 (8.1)	5 (3.1)	21 (6.8)	9 (2.9)
Creatine Kinase (U/L)	36 (22.5)	17 (10.6)	59 (19.0)	31 (10.0)
Urea Nitrogen (mg/dL)	11 (6.9)	38 (23.8)	15 (4.8)	68 (21.9)
Creatinine (mg/dL)	31 (19.4)	7 (4.4)	57 (18.3)	18 (5.8)
Urate (mg/dL)	1 (0.6)	7 (4.4)	4 (1.3)	11 (3.5)
Sodium (mEq/L)	0 (0.0)	6 (3.8)	0 (0.0)	9 (2.9)
Potassium (mEq/L)	1 (0.6)	15 (9.4)	8 (2.6)	23 (7.4)
Chloride (mEq/L)	19 (11.9)	1 (0.6)	36 (11.6)	1 (0.3)
Cholesterol (mg/dL)	48 (30.0)	1 (0.6)	91 (29.3)	4 (1.3)
Triglycerides (mg/dL)	49 (30.6)	5 (3.1)	81 (26.0)	12 (3.9)
HDL Cholesterol (mg/dL)	20 (12.5)	4 (2.5)	36 (11.6)	4 (1.3)
LDL Cholesterol (mg/dL)	35 (21.9)	16 (10.0)	63 (20.3)	25 (8.0)
Glucose (mg/dL)	63 (39.4)	8 (5.0)	118 (37.9)	17 (5.5)
Hemoglobin A1C/Hemoglobin (%)	3 (1.9)	2 (1.3)	3 (1.0)	5 (1.6)

Program Name: t 4 4 2 2 2.sas / Output: t 4 4 2 2 2.rtf
Date of Table Generation: 2023-09-22 21:01
Data Source: adlb

表 2.7.4-131 血液生化学的検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.2.2 Frequency of Serum Chemistry Tests Above or Below the Reference Limits (SAS)

Parameter	Primary FSN-013 Pooled N=160		Secondary FSN-013 Pooled N=311	
	Above Upper Limit n(%)	Below Lower Limit n(%)	Above Upper Limit n(%)	Below Lower Limit n(%)
Iron (ug/dL)	28 (17.5)	50 (31.3)	39 (12.5)	88 (28.3)
Calcium (mg/dL)	0 (0.0)	16 (10.0)	0 (0.0)	26 (8.4)
Phosphate (mg/dL)	21 (13.1)	8 (5.0)	35 (11.3)	10 (3.2)
C Reactive Protein (mg/dL)	29 (18.1)	-	53 (17.0)	-
Cancer Antigen 125 (U/mL)	25 (15.6)	-	56 (18.0)	-
LDH Isoenzyme 1/LDH (%)	13 (8.1)	22 (13.8)	20 (6.4)	40 (12.9)
LDH Isoenzyme 2/LDH (%)	109 (68.1)	3 (1.9)	209 (67.2)	4 (1.3)
Troponin I (pg/mL)	0 (0.0)	-	0 (0.0)	-

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Program Name: t 4 4 2 2 2.sas / Output: t 4 4 2 2 2.rtf
Date of Table Generation: 2023-09-22 21:01
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-72 を引用

2.7.4.3.1.2.5.4 FSN-013P-02 試験

血液生化学的検査値の要約を表 2.7.4-132～表 2.7.4-140 に、血液生化学的検査値の臨床検査値異常変動を表 2.7.4-141～表 2.7.4-143 に示す。

血液生化学的検査値には周期投与群、連続投与群とも、試験期間を通じて特記すべき変動は認められなかった。

表 2.7.4-132 臨床検査値の要約 血液生化学的検査（1）全体（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
総蛋白 (g/dL)	スクリーニング	42	7.13	0.423	5.9	6.2	7.10	7.9
	投薬期1	42	6.87	0.371	5.4	6.1	6.90	8.0
	投薬期2	42	6.91	0.400	5.8	6.2	6.90	8.1
	投薬期3	40	6.90	0.343	5.0	6.2	6.90	7.8
	後観察期	42	6.73	0.444	6.6	5.9	6.60	8.2
アルブミン (g/dL)	スクリーニング	42	4.45	0.255	5.7	3.8	4.50	4.9
	投薬期1	42	4.24	0.212	5.0	3.8	4.20	4.7
	投薬期2	42	4.22	0.255	6.0	3.8	4.20	4.8
	投薬期3	40	4.20	0.316	7.5	3.4	4.20	4.8
	後観察期	42	4.12	0.302	7.3	3.6	4.10	4.9
総ビリルビン (mg/dL)	スクリーニング	42	0.73	0.211	28.8	0.4	0.70	1.4
	投薬期1	42	0.63	0.159	25.4	0.4	0.60	0.9
	投薬期2	42	0.65	0.197	30.0	0.3	0.60	1.1
	投薬期3	40	0.66	0.215	32.8	0.3	0.60	1.3
	後観察期	42	0.59	0.179	30.3	0.3	0.50	1.2
AST (U/L)	スクリーニング	42	16.3	2.94	18.0	11	17.0	24
	投薬期1	42	16.1	4.56	28.3	10	16.0	37
	投薬期2	42	15.1	2.55	16.9	11	15.0	24
	投薬期3	40	15.2	2.03	13.3	10	15 5	20
	後観察期	42	16.0	4.39	27.5	10	15.0	35
ALT (U/L)	スクリーニング	42	12.2	5.04	41.4	5	11.0	25
	投薬期1	42	12.6	9.13	72.3	5	10.0	64
	投薬期2	42	10.8	4.57	42.3	5	10.0	28
	投薬期3	40	10.3	3.07	29.9	4	10.0	18
	後観察期	42	10.8	3.88	35.9	5	10.0	22
ALP (U/L)	スクリーニング	42	159.8	51.96	32.5	57	149.5	320
	投薬期1	42	154.0	44.24	28.7	56	142.0	291
	投薬期2	42	136.5	39.26	28.8	52	130.0	279
	投薬期3	40	135.6	34.99	25.8	83	131.5	253
	後観察期	42	144.0	42.97	29.8	49	134.5	286
γ-GTP (U/L)	スクリーニング	42	14.3	5.77	40.4	8	13.0	35
	投薬期1	42	13.8	5.03	36.6	8	13.0	32
	投薬期2	42	12.3	4.07	33.2	8	11 5	26
	投薬期3	40	12.1	3.77	31.1	7	11.0	27
	後観察期	42	11.4	3.24	28.5	7	11.0	21
LDH (U/L)	スクリーニング	42	140.0	18.74	13.4	71	141.0	182
	投薬期1	42	134.0	21.27	15.9	70	136.5	177
	投薬期2	42	134.5	21.67	16.1	61	134.5	178
	投薬期3	40	136.2	22.29	16.4	64	141.0	173
	後観察期	42	139.6	25.73	18.4	55	138.5	196

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-20 を引用

表 2.7.4-133 臨床検査値の要約 血液生化学的検査（1）周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
総蛋白 (g/dL)	スクリーニング	20	7 30	0.390	5.3	6.4	7 25	7.9
	投薬期1	20	7.01	0.355	5.1	6.5	7.00	8.0
	投薬期2	20	7.04	0.444	6.3	6.4	7.00	8.1
	投薬期3	19	7.02	0.341	4.9	6.4	7.00	7.8
	後観察期	20	6.87	0.485	7.1	6.3	6.85	8.2
アルブミン (g/dL)	スクリーニング	20	4 54	0.206	4.5	4.1	4.60	4.9
	投薬期1	20	4 27	0.213	5.0	3.8	4 25	4.7
	投薬期2	20	4 27	0.223	5.2	3.8	4 20	4.7
	投薬期3	19	4 23	0.311	7.3	3.5	4 30	4.8
	後観察期	20	4 17	0.306	7.3	3.7	4 10	4.9
総ビリルビン (mg/dL)	スクリーニング	20	0.76	0.216	28.4	0.5	0.75	1.4
	投薬期1	20	0.63	0.148	23.7	0.4	0.60	0.9
	投薬期2	20	0.64	0.150	23.6	0.4	0.60	1.1
	投薬期3	19	0.66	0.241	36.3	0.3	0.60	1.3
	後観察期	20	0.66	0.193	29.5	0.4	0.65	1.2
AST (U/L)	スクリーニング	20	15.9	2.83	17.9	11	15.5	22
	投薬期1	20	16.2	5.91	36.6	11	15.0	37
	投薬期2	20	15.1	2.89	19.2	11	15.0	24
	投薬期3	19	15.1	1.91	12.7	10	16.0	18
	後観察期	20	15.1	2.45	16.2	11	14.5	20
ALT (U/L)	スクリーニング	20	11.6	5.82	50.1	5	9.5	25
	投薬期1	20	12.8	12.69	99.1	5	9.0	64
	投薬期2	20	10.9	5.90	54.3	5	9.5	28
	投薬期3	19	10.1	3.85	38.3	4	10.0	18
	後観察期	20	10.0	3.55	35.6	5	9.0	16
ALP (U/L)	スクリーニング	20	158.8	55.56	35.0	57	153.5	320
	投薬期1	20	152.2	48.04	31.6	56	142.0	291
	投薬期2	20	141.1	44.29	31.4	52	134.5	279
	投薬期3	19	144.6	36.64	25.3	99	138.0	253
	後観察期	20	147.9	51.00	34.5	49	135.0	286
γ-GTP (U/L)	スクリーニング	20	14.9	7.13	48.0	8	13.0	35
	投薬期1	20	14.5	6.44	44.6	8	13.5	32
	投薬期2	20	13.0	4.57	35.3	8	12.0	26
	投薬期3	19	12.9	4.38	34.0	8	12.0	27
	後観察期	20	12.1	3.43	28.4	8	12.0	21
LDH (U/L)	スクリーニング	20	140.2	20.27	14.5	71	143.0	171
	投薬期1	20	136.0	24.62	18.1	70	141.0	177
	投薬期2	20	134.4	21.87	16.3	61	136.5	170
	投薬期3	19	138.4	25.12	18.2	64	146.0	173
	後観察期	20	138.0	28.75	20.8	55	137.5	185

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-21 を引用

表 2.7.4-134 臨床検査値の要約 血液生化学的検査（1）連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
総蛋白 (g/dL)	スクリーニング	22	6.98	0.401	5.7	6.2	6.90	7.8
	投薬期1	22	6.75	0.349	5 2	6.1	6.70	7.3
	投薬期2	22	6.80	0.327	4.8	6.2	6.85	7.4
	投薬期3	21	6.80	0.315	4.6	6.2	6.80	7.2
	後観察期	22	6.61	0.375	5.7	5.9	6.60	7.5
アルブミン (g/dL)	スクリーニング	22	4.38	0.277	6 3	3.8	4.40	4.9
	投薬期1	22	4.21	0.211	5.0	3.9	4.20	4.7
	投薬期2	22	4.18	0.281	6.7	3.8	4.15	4.8
	投薬期3	21	4.17	0.326	7.8	3.4	4.20	4.7
	後観察期	22	4.08	0.299	7 3	3.6	4.05	4.6
総ビリルビン (mg/dL)	スクリーニング	22	0.71	0.209	29.5	0.4	0.70	1.2
	投薬期1	22	0.63	0.172	27.5	0.4	0.60	0.9
	投薬期2	22	0.67	0.233	34.7	0.3	0.60	1.1
	投薬期3	21	0.65	0.194	29.9	0.3	0.70	1.1
	後観察期	22	0.53	0.146	27.5	0.3	0.50	0.8
AST (U/L)	スクリーニング	22	16.7	3.04	18.2	11	17.0	24
	投薬期1	22	16.1	3.00	18.6	10	16.0	22
	投薬期2	22	15.2	2.27	14.9	11	15.0	19
	投薬期3	21	15.3	2.18	14.2	11	15.0	20
	後観察期	22	16.8	5.55	33.1	10	15.0	35
ALT (U/L)	スクリーニング	22	12.7	4.29	33.7	6	12.5	24
	投薬期1	22	12.5	4.10	32.9	7	12.0	21
	投薬期2	22	10.8	3.05	28.3	6	10.0	19
	投薬期3	21	10.5	2.23	21.3	7	11.0	14
	後観察期	22	11.6	4.09	35.3	6	10.0	22
ALP (U/L)	スクリーニング	22	160.7	49.77	31.0	103	145.0	256
	投薬期1	22	155.7	41.56	26.7	95	141.0	222
	投薬期2	22	132.4	34.60	26.1	87	124.5	196
	投薬期3	21	127.4	32.11	25.2	83	129.0	208
	後観察期	22	140.5	35.00	24.9	91	132.5	205
γ-GTP (U/L)	スクリーニング	22	13.8	4.30	31.2	9	13.0	25
	投薬期1	22	13.1	3.31	25.2	8	13.0	18
	投薬期2	22	11.7	3.56	30.5	8	11.0	24
	投薬期3	21	11.4	3.04	26.7	7	11.0	20
	後観察期	22	10.7	2.99	27.9	7	10.5	20
LDH (U/L)	スクリーニング	22	139.8	17.71	12.7	103	138.5	182
	投薬期1	22	132.2	18.10	13.7	93	132.5	164
	投薬期2	22	134.5	22.01	16.4	78	133.0	178
	投薬期3	21	134.2	19.80	14.8	90	133.0	169
	後観察期	22	141.1	23.24	16.5	87	138.5	196

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-22 を引用

表 2.7.4-135 臨床検査値の要約 血液生化学的検査（2）全体（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
eGFR (mL/min/1.73m^2)	スクリーニング	42	106.61	16.262	15.3	73.0	105.40	137.9
	投薬期1	42	101.76	16.144	15.9	68.4	100.15	138.2
	投薬期2	42	96.77	15.862	16.4	65.6	98.00	130.6
	投薬期3	40	95.52	15.679	16.4	66.0	95.65	138.6
	後観察期	42	104.26	18.487	17.7	69.4	105.60	138.6
アミラーゼ (U/L)	スクリーニング	42	69.4	17.00	24.5	42	66.5	120
	投薬期1	42	73.6	18.75	25.5	44	70.0	119
	投薬期2	42	77.4	17.77	23.0	46	71.5	117
	投薬期3	40	81.5	41.64	51.1	52	71.0	313
	後観察期	42	76.8	16.51	21.5	50	76.0	136
CK (U/L)	スクリーニング	42	76.8	28.89	37.6	39	73.0	162
	投薬期1	42	68.8	23.46	34.1	35	68.5	148
	投薬期2	42	73.3	28.76	39.2	36	67.0	153
	投薬期3	40	72.9	23.57	32.3	33	69.0	145
	後観察期	42	81.0	61.45	75.8	38	67.5	429
BUN (mg/dL)	スクリーニング	42	8.65	2.307	26.7	4.4	8.35	13.3
	投薬期1	42	10.05	2.589	25.8	5.1	9.65	16.6
	投薬期2	42	10.62	2.910	27.4	5.4	9.90	18.0
	投薬期3	40	11.10	2.728	24.6	7.5	10.80	19.0
	後観察期	42	9.63	3.419	35.5	4.1	9.25	17.9
クレアチニン (mg/dL)	スクリーニング	42	0 563	0.0749	13.3	0.43	0.560	0.78
	投薬期1	42	0 587	0.0779	13.3	0.44	0.590	0.78
	投薬期2	42	0.617	0.0889	14.4	0.49	0.595	0.82
	投薬期3	40	0.623	0.0868	13.9	0.47	0.610	0.86
	後観察期	42	0 578	0.0894	15.5	0.44	0.560	0.77
尿酸 (mg/dL)	スクリーニング	42	4.23	0.731	17.3	2.1	4.30	5.7
	投薬期1	42	4.22	0.910	21.5	2.2	3.95	6.6
	投薬期2	42	4.04	0.900	22.3	1.8	4.10	5.9
	投薬期3	40	4.04	0.786	19.5	2.3	3.90	5.7
	後観察期	42	3.87	0.719	18.6	2.2	3.85	5.9
Na (mEq/L)	スクリーニング	42	138.6	1.29	0 9	135	139.0	141
	投薬期1	42	138.5	1.21	0 9	136	138.0	141
	投薬期2	42	138.9	1.44	1.0	136	139.0	142
	投薬期3	40	138.8	1.49	1 1	135	139.0	142
	後観察期	42	139.1	1.34	1.0	137	139.0	141
K (mEq/L)	スクリーニング	42	3.78	0.243	6.4	3.4	3.70	4.5
	投薬期1	42	3.81	0.262	6 9	3.2	3.80	4.5
	投薬期2	42	3.78	0.246	6 5	3.4	3.75	4.7
	投薬期3	40	3.77	0.214	5.7	3.3	3.80	4.4
	後観察期	42	3.73	0.215	5.8	3.2	3.70	4.2
Cl (mEq/L)	スクリーニング	42	103.4	1.96	1 9	98	103 5	106
	投薬期1	42	104.5	1.70	1.6	101	105.0	108
	投薬期2	42	104.8	2.00	1 9	100	105.0	108
	投薬期3	40	104.4	1.88	1.8	99	105.0	107
	後観察期	42	104.5	1.82	1.7	100	104.0	108

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-23 を引用

表 2.7.4-136 臨床検査値の要約 血液生化学的検査（2）周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
eGFR (mL/min/1.73m^2)	スクリーニング	20	105 97	16.835	15.9	73.0	104.45	137.3
	投薬期1	20	99.31	14.563	14.7	80.8	98.35	138.2
	投薬期2	20	97.12	18.342	18.9	65.6	96.55	130.6
	投薬期3	19	96.57	16.713	17.3	66.0	95.40	138.6
	後観察期	20	106.00	18.918	17.8	74.6	106.55	138.6
アミラーゼ (U/L)	スクリーニング	20	68.7	18.51	26.9	42	65.5	105
	投薬期1	20	72.8	17.38	23.9	50	71.0	108
	投薬期2	20	75.7	13.81	18.3	56	73.5	106
	投薬期3	19	74 2	14.00	18.9	52	70.0	99
	後観察期	20	72.7	15.11	20.8	50	73.5	95
CK (U/L)	スクリーニング	20	73 1	27.05	37.0	39	66.0	162
	投薬期1	20	65 2	12.66	19.4	42	66.5	87
	投薬期2	20	72.0	23.47	32.6	36	73.0	127
	投薬期3	19	75.8	19.71	26.0	44	73.0	126
	後観察期	20	72 1	17.95	24.9	47	71.0	114
BUN (mg/dL)	スクリーニング	20	8.75	2.516	28.8	4.4	8.25	13.3
	投薬期1	20	9.78	2.083	21.3	6.2	9.65	13.7
	投薬期2	20	10.63	3.004	28.3	5.4	10.00	16.9
	投薬期3	19	10.80	2.505	23.2	7.5	10.80	16.2
	後観察期	20	8.63	2.870	33.3	4.3	8.55	15.2
クレアチニン (mg/dL)	スクリーニング	20	0.569	0.0825	14.5	0.43	0.570	0.78
	投薬期1	20	0.601	0.0759	12.6	0.44	0.600	0.77
	投薬期2	20	0.621	0.1053	17.0	0.49	0.595	0.82
	投薬期3	19	0.618	0.0916	14.8	0.47	0.610	0.86
	後観察期	20	0.572	0.0933	16.3	0.44	0.545	0.76
尿酸 (mg/dL)	スクリーニング	20	4.27	0.632	14.8	3.4	4.30	5.4
	投薬期1	20	4.24	0.692	16.3	3.4	4.20	5.8
	投薬期2	20	3.91	0.766	19.6	2.6	4.05	5.6
	投薬期3	19	4.17	0.733	17.6	3.1	3.90	5.5
	後観察期	20	3.78	0.599	15.9	2.7	3.80	4.7
Na (mEq/L)	スクリーニング	20	138.7	1.42	1.0	135	139.0	141
	投薬期1	20	138.7	0.98	0.7	137	139.0	140
	投薬期2	20	139.1	1.37	1.0	136	139.0	141
	投薬期3	19	139.1	1.47	1.1	136	139.0	142
	後観察期	20	139.1	1.39	1.0	137	139.0	141
K (mEq/L)	スクリーニング	20	3.75	0.244	6.5	3.4	3.70	4.5
	投薬期1	20	3.78	0.212	5.6	3.3	3.80	4.1
	投薬期2	20	3.73	0.205	5.5	3.4	3.70	4.1
	投薬期3	19	3.72	0.178	4.8	3.4	3.70	4.1
	後観察期	20	3.71	0.157	4.2	3.5	3.70	4.0
Cl (mEq/L)	スクリーニング	20	103.4	1.90	1.8	98	103.5	106
	投薬期1	20	104.7	1.69	1.6	102	105.0	108
	投薬期2	20	104.8	1.94	1.9	100	105.0	108
	投薬期3	19	104.5	1.98	1.9	99	105.0	107
	後観察期	20	104.3	1.84	1.8	100	104.5	107

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-24 を引用

表 2.7.4-137 臨床検査値の要約 血液生化学的検査（2）連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
eGFR (mL/min/1.73m^2)	スクリーニング	22	107 20	16.097	15.0	78.2	111.30	137.9
	投薬期1	22	103 98	17.495	16.8	68.4	105.15	133.6
	投薬期2	22	96.46	13.660	14.2	68.4	99.85	117.8
	投薬期3	21	94.56	15.031	15.9	68.4	95.90	118.3
	後観察期	22	102.69	18.386	17.9	69.4	105.30	136.7
アミラーゼ (U/L)	スクリーニング	22	70 1	15.91	22.7	48	67.0	120
	投薬期1	22	74.4	20.29	27.3	44	69.0	119
	投薬期2	22	79.0	20.93	26.5	46	70.5	117
	投薬期3	21	88 1	55.75	63.3	54	72.0	313
	後観察期	22	80.6	17.15	21.3	57	80.5	136
CK (U/L)	スクリーニング	22	80 2	30.70	38.3	39	77.5	143
	投薬期1	22	72 1	30.10	41.7	35	69.0	148
	投薬期2	22	74 5	33.37	44.8	39	65.0	153
	投薬期3	21	70 2	26.79	38.1	33	65.0	145
	後観察期	22	89 2	83.27	93.3	38	64.0	429
BUN (mg/dL)	スクリーニング	22	8.55	2.155	25.2	5.3	8.35	13.1
	投薬期1	22	10.30	3.005	29.2	5.1	10.45	16.6
	投薬期2	22	10.61	2.893	27.3	5.8	9.90	18.0
	投薬期3	21	11.38	2.949	25.9	7.9	10.80	19.0
	後観察期	22	10.55	3.678	34.9	4.1	9.85	17.9
クレアチニン (mg/dL)	スクリーニング	22	0.557	0.0688	12.3	0.45	0.545	0.69
	投薬期1	22	0.575	0.0795	13.8	0.48	0.555	0.78
	投薬期2	22	0.613	0.0734	12.0	0.52	0.595	0.78
	投薬期3	21	0.627	0.0842	13.4	0.50	0.610	0.78
	後観察期	22	0.584	0.0876	15.0	0.47	0.560	0.77
尿酸 (mg/dL)	スクリーニング	22	4.20	0.824	19.6	2.1	4.30	5.7
	投薬期1	22	4.20	1.087	25.9	2.2	3.85	6.6
	投薬期2	22	4.16	1.010	24.3	1.8	4.20	5.9
	投薬期3	21	3.92	0.831	21.2	2.3	3.90	5.7
	後観察期	22	3.96	0.817	20.6	2.2	4.00	5.9
Na (mEq/L)	スクリーニング	22	138.6	1.18	0.9	136	139.0	141
	投薬期1	22	138.3	1.39	1.0	136	138.0	141
	投薬期2	22	138.6	1.50	1.1	136	139.0	142
	投薬期3	21	138.5	1.50	1.1	135	139.0	142
	後観察期	22	139.2	1.31	0.9	137	139.0	141
K (mEq/L)	スクリーニング	22	3.81	0.245	6.4	3.5	3.75	4.5
	投薬期1	22	3.84	0.303	7.9	3.2	3.85	4.5
	投薬期2	22	3.83	0.275	7.2	3.4	3.80	4.7
	投薬期3	21	3.81	0.239	6.3	3.3	3.90	4.4
	後観察期	22	3.76	0.258	6.9	3.2	3.75	4.2
Cl (mEq/L)	スクリーニング	22	103.3	2.06	2.0	100	103.5	106
	投薬期1	22	104.3	1.73	1.7	101	104.5	107
	投薬期2	22	104.8	2.09	2.0	101	104.5	108
	投薬期3	21	104.3	1.83	1.7	101	104.0	107
	後観察期	22	104.6	1.84	1.8	100	104.0	108

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-25 を引用

表 2.7.4-138 臨床検査値の要約 血液生化学的検査（3）全体（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
総コレステロール (mg/dL)	スクリーニング	42	185.4	27.07	14.6	131	181.5	244
	投薬期1	42	174.6	28.35	16.2	128	169.5	248
	投薬期2	42	183.4	33.06	18.0	140	177.5	313
	投薬期3	40	183.6	24.56	13.4	148	177.5	256
	後観察期	42	181.0	23.26	12.8	148	181.0	267
中性脂肪 (mg/dL)	スクリーニング	42	56.8	19.69	34.7	28	52.0	121
	投薬期1	42	57.9	21.74	37.6	23	52.0	117
	投薬期2	42	61.8	22.74	36.8	27	58.5	132
	投薬期3	40	61.7	21.46	34.8	27	58.0	138
	後観察期	42	70.7	43.29	61.3	25	60.5	302
HDL-C (mg/dL)	スクリーニング	42	72.5	14.15	19.5	53	68.5	107
	投薬期1	42	68.4	12.11	17.7	47	68.5	97
	投薬期2	42	71.7	13.28	18.5	48	70.0	95
	投薬期3	40	73.9	12.25	16.6	49	72.5	105
	後観察期	42	71.5	13.76	19.2	45	71.0	104
LDL-C (mg/dL)	スクリーニング	42	107.7	23.66	22.0	67	104.0	163
	投薬期1	42	100.8	24.20	24.0	65	97.5	177
	投薬期2	42	104.6	25.01	23.9	67	99.0	188
	投薬期3	40	102.8	20.42	19.9	66	98.0	160
	後観察期	42	102.3	16.86	16.5	65	99.0	150
グルコース (mg/dL)	スクリーニング	42	92.0	8.61	9.4	72	92.0	112
	投薬期1	42	92.3	7.27	7.9	65	93.0	108
	投薬期2	42	91.7	5.40	5.9	78	91.0	103
	投薬期3	40	91.8	8.38	9.1	57	92.0	105
	後観察期	42	91.4	7.26	7.9	77	91.0	111
HbA1c (%)	スクリーニング	42	5 24	0.193	3.7	4.9	5 25	5.7
	投薬期1	42	5 17	0.173	3.3	4.8	5 20	5.6
	投薬期2	42	5 19	0.221	4.3	4.8	5 20	5.6
	投薬期3	40	5 24	0.199	3.8	4.8	5 20	5.6
	後観察期	42	5 28	0.229	4.3	4.8	5 25	5.9
重炭酸イオン (mmol/L)	スクリーニング	42	26.15	2.646	10.1	21.7	26.25	31.1
	投薬期1	41	24.90	2.258	9.1	19.6	25.10	31.0
	投薬期2	42	25.47	2.167	8.5	22.0	25.25	30.5
	投薬期3	40	24.92	2.533	10.2	14.8	25.10	29.6
	後観察期	42	26.85	2.551	9.5	21.5	26.80	31.1
Fe (μg/dL)	スクリーニング	42	89.5	29.11	32.5	42	88.0	176
	投薬期1	42	79.0	29.10	36.8	18	76.5	152
	投薬期2	42	84.0	44.10	52.5	20	78.5	194
	投薬期3	40	76.7	32.36	42.2	22	78.5	153
	後観察期	42	69.7	31.05	44.5	12	69.0	168
Ca (mg/dL)	スクリーニング	42	9 30	0.243	2.6	8.8	9 35	9.7
	投薬期1	42	8 93	0.361	4.0	8.2	8 90	9.7
	投薬期2	42	8 97	0.284	3.2	8.3	8 90	9.5
	投薬期3	40	8 95	0.308	3.4	8.4	8 90	9.6
	後観察期	42	8.83	0.307	3.5	8.1	8 90	9.4
P (mg/dL)	スクリーニング	42	3.66	0.359	9.8	2.8	3.60	4.5
	投薬期1	42	3.60	0.423	11.7	2.7	3.60	4.5
	投薬期2	42	3 59	0.342	9.5	2.8	3.60	4.5
	投薬期3	40	3.67	0.459	12.5	2.7	3.70	4.7
	後観察期	42	3 58	0.406	11.4	2.7	3 55	4.6
CRP (mg/dL)	スクリーニング	42	0.035	0.0614	175.5	0.01	0.010	0.29
	投薬期1	42	0.040	0.0607	151.0	0.01	0.020	0.31
	投薬期2	42	0.083	0.2817	338.1	0.01	0.025	1.83
	投薬期3	40	0.101	0.3078	304.0	0.01	0.020	1.45
	後観察期	42	0.061	0.1493	244.9	0.01	0.015	0.83

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-26 を引用

表 2.7.4-139 臨床検査値の要約 血液生化学的検査（3）周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
総コレステロール (mg/dL)	スクリーニング	20	179.9	20.62	11.5	142	179.0	219
	投薬期1	20	170.3	19.78	11.6	128	168.0	210
	投薬期2	20	181.9	23.11	12.7	149	179.0	241
	投薬期3	19	181.5	17.75	9.8	154	178.0	218
	後観察期	20	180.0	15.58	8.7	151	183.0	204
中性脂肪 (mg/dL)	スクリーニング	20	55 1	18.75	34.1	28	54.0	111
	投薬期1	20	52.6	20.28	38.6	23	46.5	105
	投薬期2	20	60 5	25.59	42.3	30	51.0	132
	投薬期3	19	59.6	22.75	38.2	34	55.0	138
	後観察期	20	69.6	57.66	82.9	31	57.5	302
HDL-C (mg/dL)	スクリーニング	20	72.4	13.89	19.2	53	70.5	99
	投薬期1	20	69.6	11.19	16.1	52	70.0	94
	投薬期2	20	72 9	10.75	14.8	52	74.5	87
	投薬期3	19	75 9	10.36	13.6	59	74.0	105
	後観察期	20	73.4	13.80	18.8	45	75.0	93
LDL-C (mg/dL)	スクリーニング	20	102.8	20.14	19.6	67	102 5	145
	投薬期1	20	96.7	17.36	18.0	71	96.5	133
	投薬期2	20	103.2	19.71	19.1	67	102 5	147
	投薬期3	19	99 5	17.32	17.4	66	98.0	134
	後観察期	20	100.2	12.17	12.2	65	99.5	121
グルコース (mg/dL)	スクリーニング	20	91.0	7.55	8.3	76	91.0	110
	投薬期1	20	93 9	5.37	5.7	85	94.0	108
	投薬期2	20	91.8	3.61	3.9	85	91.5	100
	投薬期3	19	91 9	10.26	11.2	57	93.0	105
	後観察期	20	90.4	7.47	8.3	77	91.5	107
HbA1c (%)	スクリーニング	20	5.27	0.184	3.5	5.0	5.30	5.6
	投薬期1	20	5.19	0.139	2.7	4.9	5.20	5.4
	投薬期2	20	5.24	0.228	4.4	4.8	5.20	5.6
	投薬期3	19	5.28	0.190	3.6	4.9	5.30	5.6
	後観察期	20	5.31	0.240	4.5	4.8	5.30	5.8
重炭酸イオン (mmol/L)	スクリーニング	20	26.25	2.675	10.2	22.1	26.15	31.1
	投薬期1	19	24.50	1.520	6.2	22.0	25.10	26.6
	投薬期2	20	25.88	2.184	8.4	22.3	26.25	29.6
	投薬期3	19	25.05	3.251	13.0	14.8	25.00	29.6
	後観察期	20	27.03	2.423	9.0	23.7	26.55	31.1
Fe (μg/dL)	スクリーニング	20	93.7	28.15	30.0	42	94.0	162
	投薬期1	20	71.6	26.53	37.1	18	67.5	124
	投薬期2	20	73.8	38.05	51.6	20	75.0	160
	投薬期3	19	67 5	30.62	45.4	22	69.0	123
	後観察期	20	72.8	37.60	51.7	22	67.5	168
Ca (mg/dL)	スクリーニング	20	9.37	0.220	2.4	8.9	9.40	9.7
	投薬期1	20	8.90	0.410	4.6	8.2	8.85	9.7
	投薬期2	20	9.00	0.275	3.1	8.5	9.00	9.5
	投薬期3	19	8.96	0.329	3.7	8.4	8.90	9.5
	後観察期	20	8.86	0.289	3.3	8.3	8.90	9.4
P (mg/dL)	スクリーニング	20	3.71	0.373	10.0	2.8	3.75	4.5
	投薬期1	20	3.65	0.412	11.3	2.9	3.60	4.4
	投薬期2	20	3.64	0.322	8.8	3.0	3.70	4.5
	投薬期3	19	3.78	0.451	11.9	2.7	3.80	4.5
	後観察期	20	3.59	0.450	12.5	2.8	3.60	4.6
CRP (mg/dL)	スクリーニング	20	0.022	0.0267	121.3	0.01	0.010	0.11
	投薬期1	20	0.042	0.0556	132.4	0.01	0.020	0.23
	投薬期2	20	0.124	0.4027	326.1	0.01	0.030	1.83
	投薬期3	19	0.112	0.3258	292.0	0.01	0.030	1.45
	後観察期	20	0.085	0.2099	246.9	0.01	0.010	0.83

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-27 を引用

表 2.7.4-140 臨床検査値の要約 血液生化学的検査（3）連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
総コレステロール (mg/dL)	スクリーニング	22	190.4	31.48	16.5	131	190.0	244
	投薬期1	22	178.6	34.35	19.2	140	171.0	248
	投薬期2	22	184.8	40.57	22.0	140	171.5	313
	投薬期3	21	185.5	29.74	16.0	148	177.0	256
	後観察期	22	182.0	28.89	15.9	148	179.5	267
中性脂肪 (mg/dL)	スクリーニング	22	58.4	20.82	35.6	40	51.0	121
	投薬期1	22	62.7	22.35	35.7	29	58.0	117
	投薬期2	22	63.0	20.34	32.3	27	62.0	104
	投薬期3	21	63 5	20.61	32.5	27	60.0	107
	後観察期	22	71.7	25.46	35.5	25	72.0	119
HDL-C (mg/dL)	スクリーニング	22	72.7	14.70	20.2	53	68.5	107
	投薬期1	22	67 3	13.05	19.4	47	65.5	97
	投薬期2	22	70.6	15.40	21.8	48	70.0	95
	投薬期3	21	72.0	13.71	19.1	49	69.0	99
	後観察期	22	69 9	13.85	19.8	46	69.5	104
LDL-C (mg/dL)	スクリーニング	22	112.3	26.09	23.2	72	106.5	163
	投薬期1	22	104.5	28.99	27.7	65	97.5	177
	投薬期2	22	106.0	29.43	27.8	72	93.5	188
	投薬期3	21	105.8	22.89	21.6	80	97.0	160
	後観察期	22	104.2	20.32	19.5	79	97.5	150
グルコース (mg/dL)	スクリーニング	22	92.8	9.57	10.3	72	92.0	112
	投薬期1	22	90.8	8.51	9.4	65	91.5	102
	投薬期2	22	91.6	6.72	7.3	78	90.5	103
	投薬期3	21	91.6	6.48	7.1	81	91.0	103
	後観察期	22	92.4	7.10	7.7	83	90.5	111
HbA1c (%)	スクリーニング	22	5.22	0.202	3.9	4.9	5.20	5.7
	投薬期1	22	5.16	0.201	3.9	4.8	5.10	5.6
	投薬期2	22	5.15	0.213	4.1	4.8	5.10	5.6
	投薬期3	21	5.20	0.204	3.9	4.8	5.20	5.6
	後観察期	22	5.26	0.222	4.2	5.0	5.20	5.9
重炭酸イオン (mmol/L)	スクリーニング	22	26.07	2.680	10.3	21.7	26.25	31.0
	投薬期1	22	25.25	2.732	10.8	19.6	25.25	31.0
	投薬期2	22	25.10	2.134	8.5	22.0	25.10	30.5
	投薬期3	21	24.80	1.724	7.0	20.1	25.20	27.8
	後観察期	22	26.70	2.709	10.1	21.5	26.95	31.0
Fe (μg/dL)	スクリーニング	22	85.8	30.10	35.1	44	84.0	176
	投薬期1	22	85.8	30.26	35.3	24	85.5	152
	投薬期2	22	93 2	47.93	51.4	23	78.5	194
	投薬期3	21	85.0	32.33	38.0	29	83.0	153
	後観察期	22	66 9	24.20	36.2	12	69.0	97
Ca (mg/dL)	スクリーニング	22	9.23	0.247	2.7	8.8	9.25	9.7
	投薬期1	22	8.96	0.316	3.5	8.4	8.95	9.5
	投薬期2	22	8.95	0.296	3.3	8.3	8.90	9.5
	投薬期3	21	8.94	0.296	3.3	8.4	8.90	9.6
	後観察期	22	8.81	0.328	3.7	8.1	8.85	9.4
P (mg/dL)	スクリーニング	22	3.61	0.348	9.6	2.9	3.60	4.4
	投薬期1	22	3.56	0.437	12.3	2.7	3.60	4.5
	投薬期2	22	3.55	0.361	10.2	2.8	3.60	4.3
	投薬期3	21	3.57	0.452	12.7	2.8	3.60	4.7
	後観察期	22	3.57	0.373	10.4	2.7	3.55	4.5
CRP (mg/dL)	スクリーニング	22	0.047	0.0801	171.0	0.01	0.010	0.29
	投薬期1	22	0.039	0.0664	171.7	0.01	0.020	0.31
	投薬期2	22	0.047	0.0729	155.8	0.01	0.025	0.35
	投薬期3	21	0.092	0.2983	324.5	0.01	0.020	1.39
	後観察期	22	0.039	0.0509	130.2	0.01	0.020	0.24

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-28 を引用

表 2.7.4-141 臨床検査値異常変動 血液生化学的検査（1）（FSN-013P-02 試験）（安全性解析対象集団）

		全体			周期投与群			連続投与群		
			異常変動			異常変動			異常変動	
	観察時点	例数	例数	割合 (%)	例数	例数	割合 (%)	例数	例数	割合 (%)
総蛋白 (g/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
アルブミン (g/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
総ビリルビン (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
AST (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
ALT (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	1	2 4	20	1	5 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
ALP (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
γ-GTP (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
LDH (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-43 を引用

表 2.7.4-142 臨床検査値異常変動 血液生化学的検査（2）（FSN-013P-02 試験）（安全性解析対象集団）

		全体			周期投与群			連続投与群		
			異常変動			異常変動			異常変動	
	観察時点	例数	例数	割合 (%)	例数	例数	割合 (%)	例数	例数	割合 (%)
eGFR (mL/min/1 73m^2)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
アミラーゼ (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	2	5 0	19	0	0 0	21	2	9 5
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
CK (U/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
BUN (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
クレアチニン (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
尿酸 (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
Na (mEq/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
K (mEq/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
Cl (mEq/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-44 を引用

表 2.7.4-143 臨床検査値異常変動 血液生化学的検査（3）（FSN-013P-02 試験）（安全性解析対象集団）

		全体			周期投与群			連続投与群		
			異常変動			異常変動			異常変動	
	観察時点	例数	例数	割合 (%)	例数	例数	割合 (%)	例数	例数	割合 (%)
総コレステロール (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
中性脂肪 (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	1	2 4	20	1	5 0	22	0	0 0
HDL-C (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
LDL-C (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
グルコース (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	1	2 5	19	1	5 3	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
HbA1c (%)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
重炭酸イオン (mmol/L)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	41	0	0 0	19	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	1	2 5	19	1	5 3	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
Fe (µg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	2	4 8	20	1	5 0	22	1	4 5
	投薬期2	42	3	7 1	20	2	10 0	22	1	4 5
	投薬期3	40	2	5 0	19	2	10 5	21	0	0 0
	後観察期	42	4	9 5	20	1	5 0	22	3	13 6
Ca (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
P (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
CRP (mg/dL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	1	2 4	20	0	0 0	22	1	4 5
	投薬期2	42	1	2 4	20	1	5 0	22	0	0 0
	投薬期3	40	2	5 0	19	1	5 3	21	1	4 8
	後観察期	42	2	4 8	20	2	10 0	22	0	0 0

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-45 を引用

2.7.4.3.1.2.5.5 FSN-013P-05 試験

血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量を表 2.7.4-144 に示す。

血液生化学的検査値には、FSN-013 群、EE/DRSP フレックス投与群とも、治験期間を通じて特記すべき変動は認められなかった。

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
総蛋白 (g/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	7.06 (0.450)	7.22 (0.556)		
		CV	6.4	7.7		
		中央値	6.90	7.10		
		Q1 - Q3	6.70 - 7.40	6.80 - 7.50		
		最小値 - 最大値	6.5 - 8.3	6.4 - 9.3		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	7.13 (0.348)	7.24 (0.486)	0.09 (0.442)	0.00 (0.515)
		CV	4.9	6.7	512.1	20605.9
		中央値	7.10	7.10	0.10	-0.05
		Q1 - Q3	6.90 - 7.35	7.00 - 7.50	-0.20 - 0.45	-0.30 - 0.35
		最小値 - 最大値	6.4 - 7.8	6.4 - 9.2	-0.7 - 0.9	-1.3 - 1.0
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	7.14 (0.465)	7.19 (0.544)	0.09 (0.514)	-0.05 (0.553)
		CV	6.5	7.6	578.7	-1228.5
		中央値	7.20	7.10	0.10	-0.10
		Q1 - Q3	6.80 - 7.40	6.95 - 7.45	-0.10 - 0.40	-0.40 - 0.30
		最小値 - 最大値	6.2 - 8.3	5.9 - 8.7	-1.0 - 1.2	-1.5 - 1.3
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	7.01 (0.423)	7.01 (0.552)	-0.04 (0.538)	-0.21 (0.630)
		CV	6.0	7.9	-1210.3	-293.5
		中央値	7.00	7.00	0.00	-0.20
		Q1 - Q3	6.70 - 7.20	6.70 - 7.40	-0.40 - 0.30	-0.70 - 0.20
		最小値 - 最大値	6.3 - 8.5	5.4 - 8.1	-1.5 - 1.3	-1.5 - 1.1

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
アルブミン (g/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	4.35 (0.305)	4.40 (0.312)		
		CV	7.0	7.1		
		中央値	4.30	4.40		
		Q1 - Q3	4.10 - 4.50	4.20 - 4.60		
		最小値 - 最大値	3.8 - 5.2	3.8 - 5.1		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	4.36 (0.276)	4.26 (0.270)	0.00 (0.277)	-0.16 (0.338)
		CV	6.3	6.3	6093.8	-218.1
		中央値	4.30	4.20	0.00	-0.10
		Q1 - Q3	4.15 - 4.55	4.00 - 4.40	-0.20 - 0.20	-0.40 - 0.10
		最小値 - 最大値	3.7 - 4.8	3.9 - 5.0	-0.6 - 0.5	-0.8 - 0.5
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	4.35 (0.273)	4.15 (0.346)	0.00 (0.311)	-0.26 (0.350)
		CV	6.3	8.4	630595329189195520.0	-133.3
		中央値	4.40	4.10	0.00	-0.30
		Q1 - Q3	4.20 - 4.50	3.90 - 4.30	-0.20 - 0.20	-0.50 - -0.05
		最小値 - 最大値	3.7 - 4.9	3.7 - 5.2	-0.5 - 0.7	-0.9 - 0.6
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	4.28 (0.289)	4.12 (0.294)	-0.07 (0.317)	-0.29 (0.371)
		CV	6.8	7.1	-459.9	-129.8
		中央値	4.30	4.10	0.00	-0.30
		Q1 - Q3	4.10 - 4.50	3.90 - 4.30	-0.30 - 0.10	-0.50 - 0.00
		最小値 - 最大値	3.6 - 5.0	3.6 - 4.7	-0.9 - 0.5	-1.0 - 0.6

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
総ビリルビン (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	0.72 (0.239)	0.78 (0.322)		
		CV	33.4	41.6		
		中央値	0.70	0.70		
		Q1 - Q3	0.60 - 0.80	0.60 - 0.90		
		最小値 - 最大値	0.3 - 1.5	0.4 - 2.0		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	0.76 (0.362)	0.65 (0.247)	0.05 (0.250)	-0.13 (0.270)
		CV	47.5	38.1	550.2	-203.9
		中央値	0.70	0.60	0.00	-0.10
		Q1 - Q3	0.60 - 0.90	0.50 - 0.75	-0.10 - 0.20	-0.20 - 0.00
		最小値 - 最大値	0.2 - 2.3	0.3 - 1.4	-0.4 - 0.8	-0.9 - 0.7
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	0.76 (0.273)	0.60 (0.191)	0.04 (0.171)	-0.18 (0.252)
		CV	35.9	32.1	385.4	-138.1
		中央値	0.70	0.60	0.00	-0.10
		Q1 - Q3	0.60 - 0.80	0.50 - 0.70	0.00 - 0.10	-0.20 - 0.00
		最小値 - 最大値	0.2 - 1.4	0.3 - 1.1	-0.3 - 0.5	-1.0 - 0.2
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	0.71 (0.275)	0.60 (0.232)	-0.01 (0.217)	-0.18 (0.269)
		CV	38.9	38.8	-2443.9	-151.0
		中央値	0.60	0.50	0.00	-0.10
		Q1 - Q3	0.50 - 0.90	0.50 - 0.70	-0.10 - 0.10	-0.30 - -0.10
		最小値 - 最大値	0.4 - 1.5	0.3 - 1.7	-0.6 - 0.5	-1.1 - 0.5

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
AST (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	15.3 (4.05)	17.0 (4.75)		
		CV	26.4	28.0		
		中央値	15.0	16.0		
		Q1 - Q3	13.0 - 17.0	14.0 - 18.0		
		最小値 - 最大値	6 - 28	11 - 37		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	15.4 (3.82)	16.0 (4.22)	0.1 (3.79)	-0.5 (5.14)
		CV	24.9	26.4	3331.9	-1143.1
		中央値	14.0	15.0	0.0	-1.0
		Q1 - Q3	13.0 - 17.5	14.0 - 17.0	-2.0 - 2.0	-3.0 - 1.0
		最小値 - 最大値	8 - 28	10 - 36	-12 - 12	-8 - 24
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	15.4 (3.10)	15.7 (3.25)	0.1 (3.72)	-1.0 (3.42)
		CV	20.1	20.7	5579.6	-334.0
		中央値	15.0	15.0	0.0	-1.0
		Q1 - Q3	14.0 - 16.0	13.5 - 17.0	-2.0 - 3.0	-3.0 - 1.0
		最小値 - 最大値	10 - 24	9 - 26	-12 - 8	-11 - 8
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	16.2 (3.22)	16.2 (3.60)	0.9 (3.79)	-0.8 (4.47)
		CV	19.9	22.2	437.0	-590.6
		中央値	16.0	16.0	1.0	0.0
		Q1 - Q3	14.0 - 18.0	14.0 - 18.0	-1.0 - 4.0	-2.0 - 1.0
		最小値 - 最大値	10 - 26	9 - 27	-14 - 6	-15 - 9

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
ALT (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	12.7 (5.70)	13.4 (7.71)		
		CV	45.0	57.4		
		中央値	11.0	11.0		
		Q1 - Q3	9.0 - 13.0	9.0 - 16.0		
		最小値 - 最大値	6 - 35	5 - 43		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	11.4 (4.54)	13.0 (8.53)	-1.0 (4.67)	0.3 (10.15)
		CV	39.9	65.5	-488.7	3121.9
		中央値	10.0	10.0	-1.0	0.0
		Q1 - Q3	8.5 - 12.0	8.5 - 15.0	-3.5 - 1.0	-3.0 - 3.0
		最小値 - 最大値	6 - 24	5 - 51	-15 - 11	-23 - 44
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	11.4 (5.18)	11.2 (4.85)	-1.3 (6.04)	-2.2 (6.44)
		CV	45.6	43.4	-468.3	-299.7
		中央値	10.0	10.0	-1.0	-1.0
		Q1 - Q3	9.0 - 12.0	8.0 - 13.0	-4.0 - 1.0	-4.5 - 1.0
		最小値 - 最大値	5 - 35	4 - 27	-16 - 25	-22 - 13
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	11.7 (3.66)	11.9 (5.66)	-1.0 (4.66)	-1.6 (6.16)
		CV	31.3	47.7	-466.1	-394.4
		中央値	11.0	11.0	-1.0	0.0
		Q1 - Q3	9.0 - 14.0	8.0 - 14.0	-3.0 - 2.0	-3.0 - 1.0
		最小値 - 最大値	5 - 21	5 - 32	-17 - 6	-22 - 11

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
ALP (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	166.9 (48.65)	165.8 (41.71)		
		CV	29.1	25.2		
		中央値	159.0	163.0		
		Q1 - Q3	136.0 - 195.0	140.0 - 192.0		
		最小値 - 最大値	68 - 300	73 - 300		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	145.0 (40.12)	132.8 (38.52)	-21.2 (21.35)	-33.2 (23.04)
		CV	27.7	29.0	-100.9	-69.4
		中央値	146.0	127.0	-19.5	-33.5
		Q1 - Q3	111.0 - 172.0	101.0 - 152.0	-31.0 - -8.5	-44.0 - -23.0
		最小値 - 最大値	57 - 227	70 - 227	-74 - 26	-87 - 30
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	140.0 (37.05)	128.2 (30.17)	-26.9 (27.32)	-39.1 (29.66)
		CV	26.5	23.5	-101.4	-75.8
		中央値	142.0	127.0	-24.0	-35.5
		Q1 - Q3	109.0 - 171.0	106.0 - 143.0	-38.0 - -14.0	-55.5 - -24.0
		最小値 - 最大値	54 - 201	72 - 216	-109 - 48	-136 - 30
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	152.3 (45.22)	152.2 (39.92)	-14.6 (21.97)	-13.6 (26.80)
		CV	29.7	26.2	-150.5	-196.9
		中央値	151.0	150.0	-16.0	-15.0
		Q1 - Q3	118.0 - 177.0	126.0 - 178.0	-27.0 - -6.0	-26.0 - 5.0
		最小値 - 最大値	54 - 273	81 - 260	-71 - 38	-73 - 51

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
γ-GT (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	14.2 (5.75)	15.3 (9.61)		
		CV	40.4	62.9		
		中央値	14.0	13.0		
		Q1 - Q3	11.0 - 16.0	10.0 - 16.0		
		最小値 - 最大値	7 - 46	6 - 60		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	13.5 (3.76)	14.1 (6.78)	-0.1 (2.58)	-0.5 (4.24)
		CV	27.9	48.2	-3787.8	-893.2
		中央値	12.0	13.0	0.0	-1.0
		Q1 - Q3	11.0 - 16.5	9.0 - 15.5	-2.0 - 1.0	-2.0 - 1.5
		最小値 - 最大値	7 - 23	6 - 41	-6 - 7	-19 - 9
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	13.2 (4.42)	14.2 (7.83)	-1.0 (3.51)	-1.1 (7.12)
		CV	33.3	55.3	-351.0	-647.0
		中央値	13.0	11.0	-1.0	-1.0
		Q1 - Q3	10.0 - 14.0	10.0 - 15.5	-3.0 - 1.0	-2.0 - 0.0
		最小値 - 最大値	6 - 31	6 - 37	-15 - 6	-32 - 18
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	13.2 (3.80)	14.7 (7.61)	-1.0 (3.73)	-0.5 (4.72)
		CV	28.8	51.6	-357.1	-880.2
		中央値	13.0	13.0	-1.0	0.0
		Q1 - Q3	10.0 - 16.0	9.0 - 16.0	-3.0 - 1.0	-2.0 - 3.0
		最小値 - 最大値	6 - 26	6 - 44	-20 - 5	-16 - 9

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
LDH (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	145.6 (23.46)	143.8 (25.26)		
		CV	16.1	17.6		
		中央値	141.0	140.0		
		Q1 - Q3	134.0 - 160.0	133.0 - 153.0		
		最小値 - 最大値	61 - 208	100 - 221		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	147.1 (21.51)	139.4 (21.76)	1.5 (17.11)	-2.5 (13.60)
		CV	14.6	15.6	1176.2	-544.0
		中央値	149.5	138.5	0.0	-1.0
		Q1 - Q3	136.5 - 163.0	124.0 - 151.0	-7.5 - 12.0	-10.0 - 5.0
		最小値 - 最大値	60 - 185	99 - 209	-37 - 51	-35 - 29
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	147.4 (20.79)	145.2 (29.14)	1.8 (16.03)	2.2 (20.15)
		CV	14.1	20.1	901.7	916.0
		中央値	146.0	140.0	0.0	-1.5
		Q1 - Q3	138.0 - 160.0	128.5 - 154.5	-8.0 - 11.0	-8.0 - 10.0
		最小値 - 最大値	69 - 194	99 - 260	-37 - 40	-51 - 66
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	147.9 (22.66)	141.0 (22.11)	2.3 (16.61)	-2.8 (12.98)
		CV	15.3	15.7	732.7	-458.9
		中央値	148.0	140.0	0.0	0.0
		Q1 - Q3	136.0 - 160.0	125.0 - 152.0	-8.0 - 16.0	-10.0 - 6.0
		最小値 - 最大値	69 - 205	98 - 207	-38 - 40	-33 - 25

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
アミラーゼ (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	68.8 (19.88)	82.3 (32.67)		
		CV	28.9	39.7		
		中央値	67.0	78.0		
		Q1 - Q3	55.0 - 83.0	66.0 - 93.0		
		最小値 - 最大値	31 - 115	37 - 219		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	74.0 (19.11)	92.5 (31.55)	5.8 (9.19)	10.0 (17.40)
		CV	25.8	34.1	157.3	174.4
		中央値	73.5	88.5	5.0	9.5
		Q1 - Q3	58.5 - 84.5	73.5 - 110.0	1.0 - 9.5	0.5 - 17.5
		最小値 - 最大値	37 - 119	44 - 214	-22 - 39	-40 - 64
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	74.2 (20.63)	90.1 (33.26)	5.3 (10.80)	8.2 (15.14)
		CV	27.8	36.9	202.5	184.6
		中央値	76.0	86.5	5.0	9.5
		Q1 - Q3	56.0 - 91.0	77.0 - 103.5	-1.0 - 10.0	1.0 - 17.0
		最小値 - 最大値	37 - 111	39 - 245	-25 - 50	-46 - 41
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	72.2 (20.33)	84.2 (25.89)	3.4 (11.35)	2.0 (17.34)
		CV	28.2	30.7	338.2	888.9
		中央値	73.0	81.0	3.0	3.0
		Q1 - Q3	56.0 - 88.0	72.0 - 104.0	-3.0 - 9.0	-4.0 - 11.0
		最小値 - 最大値	38 - 130	42 - 169	-26 - 44	-50 - 39

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
CK (U/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	74.5 (32.88)	71.1 (36.71)		
		CV	44.1	51.7		
		中央値	68.0	65.0		
		Q1 - Q3	54.0 - 85.0	50.0 - 80.0		
		最小値 - 最大値	30 - 232	26 - 207		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	74.5 (22.67)	68.5 (27.31)	-0.5 (23.08)	-2.8 (27.39)
		CV	30.4	39.9	-5076.6	-987.0
		中央値	70.0	62.0	4.0	3.0
		Q1 - Q3	59.5 - 91.0	49.0 - 82.5	-9.0 - 9.5	-6.0 - 8.0
		最小値 - 最大値	35 - 133	30 - 146	-125 - 41	-146 - 30
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	74.7 (27.26)	74.3 (37.02)	0.2 (24.76)	3.2 (33.77)
		CV	36.5	49.8	13928.0	1047.0
		中央値	72.0	63.0	0.0	3.0
		Q1 - Q3	57.0 - 85.0	47.5 - 89.0	-10.0 - 9.0	-5.0 - 12.5
		最小値 - 最大値	32 - 174	29 - 222	-119 - 48	-145 - 79
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	74.8 (24.46)	72.4 (38.33)	0.2 (28.32)	1.3 (37.62)
		CV	32.7	52.9	11583.7	2804.3
		中央値	72.0	66.0	2.0	-1.0
		Q1 - Q3	60.0 - 90.0	44.0 - 78.0	-10.0 - 11.0	-7.0 - 7.0
		最小値 - 最大値	39 - 165	27 - 191	-138 - 59	-133 - 136

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
BUN (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	10.75 (2.672)	11.12 (2.826)		
		CV	24.9	25.4		
		中央値	11.00	10.70		
		Q1 - Q3	8.70 - 12.50	9.40 - 12.10		
		最小値 - 最大値	6.1 - 17.1	6.9 - 19.4		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	12.04 (2.336)	12.02 (3.298)	1.25 (2.649)	0.82 (2.832)
		CV	19.4	27.4	211.5	347.5
		中央値	11.70	10.60	1.70	1.05
		Q1 - Q3	10.25 - 13.65	9.65 - 13.40	-0.55 - 2.60	-0.75 - 2.75
		最小値 - 最大値	7.1 - 17.6	7.8 - 22.6	-5.1 - 8.9	-5.5 - 6.1
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	12.16 (2.788)	11.47 (2.867)	1.41 (3.022)	0.40 (2.512)
		CV	22.9	25.0	214.5	628.1
		中央値	12.10	11.20	1.50	0.95
		Q1 - Q3	9.90 - 14.40	9.60 - 13.55	-0.60 - 3.50	-1.10 - 1.90
		最小値 - 最大値	5.5 - 17.8	7.1 - 21.2	-4.9 - 7.3	-6.6 - 5.6
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	11.16 (2.960)	11.24 (3.104)	0.41 (2.725)	0.11 (2.656)
		CV	26.5	27.6	662.9	2317.3
		中央値	10.80	10.70	0.40	-0.20
		Q1 - Q3	9.30 - 12.20	9.20 - 12.60	-1.80 - 1.90	-1.40 - 1.50
		最小値 - 最大値	4.3 - 21.0	6.6 - 24.5	-4.3 - 10.1	-4.6 - 6.0

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
クレアチニン (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	0.584 (0.0886)	0.598 (0.0808)		
		CV	15.2	13.5		
		中央値	0.580	0.590		
		Q1 - Q3	0.540 - 0.650	0.560 - 0.650		
		最小値 - 最大値	0.41 - 0.76	0.42 - 0.79		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	0.640 (0.0871)	0.652 (0.0902)	0.058 (0.0576)	0.054 (0.0650)
		CV	13.6	13.8	99.4	119.8
		中央値	0.635	0.650	0.055	0.055
		Q1 - Q3	0.570 - 0.705	0.595 - 0.720	0.020 - 0.090	0.015 - 0.080
		最小値 - 最大値	0.45 - 0.85	0.47 - 0.84	-0.08 - 0.18	-0.08 - 0.24
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	0.640 (0.0831)	0.646 (0.0860)	0.056 (0.0603)	0.050 (0.0502)
		CV	13.0	13.3	107.6	101.4
		中央値	0.640	0.640	0.060	0.050
		Q1 - Q3	0.590 - 0.690	0.600 - 0.710	0.010 - 0.100	0.030 - 0.075
		最小値 - 最大値	0.48 - 0.82	0.44 - 0.85	-0.08 - 0.19	-0.08 - 0.16
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	0.592 (0.0843)	0.591 (0.0910)	0.009 (0.0570)	-0.007 (0.0608)
		CV	14.2	15.4	641.4	-859.5
		中央値	0.600	0.590	0.010	-0.010
		Q1 - Q3	0.510 - 0.660	0.530 - 0.670	-0.020 - 0.040	-0.050 - 0.020
		最小値 - 最大値	0.41 - 0.73	0.39 - 0.77	-0.16 - 0.14	-0.13 - 0.12

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
尿酸 (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	3.98 (0.898)	3.94 (0.933)		
		CV	22.6	23.7		
		中央値	3.90	3.80		
		Q1 - Q3	3.40 - 4.40	3.30 - 4.70		
		最小値 - 最大値	2.3 - 6.1	2.0 - 5.9		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	3.99 (0.759)	3.85 (0.851)	-0.02 (0.654)	-0.06 (0.548)
		CV	19.0	22.1	-4113.9	-912.7
		中央値	4.00	3.95	0.10	0.00
		Q1 - Q3	3.45 - 4.45	3.30 - 4.55	-0.55 - 0.45	-0.45 - 0.35
		最小値 - 最大値	2.5 - 5.9	1.9 - 5.2	-1.3 - 1.5	-1.3 - 1.1
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	4.02 (0.862)	3.74 (0.782)	0.04 (0.697)	-0.17 (0.574)
		CV	21.4	20.9	1743.0	-337.8
		中央値	4.00	3.65	0.00	-0.10
		Q1 - Q3	3.50 - 4.70	3.15 - 4.30	-0.40 - 0.50	-0.50 - 0.20
		最小値 - 最大値	2.1 - 5.9	2.3 - 5.4	-1.4 - 2.0	-1.6 - 0.8
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	3.83 (0.789)	3.62 (0.783)	-0.15 (0.577)	-0.31 (0.574)
		CV	20.6	21.6	-381.6	-183.8
		中央値	3.80	3.70	-0.10	-0.30
		Q1 - Q3	3.20 - 4.40	3.20 - 4.20	-0.50 - 0.20	-0.50 - 0.00
		最小値 - 最大値	2.1 - 5.4	2.0 - 5.0	-1.6 - 1.2	-1.9 - 1.2

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
Na (mEq/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	139.8 (1.85)	139.7 (1.60)		
		CV	1.3	1.1		
		中央値	140.0	140.0		
		Q1 - Q3	139.0 - 141.0	139.0 - 141.0		
		最小値 - 最大値	135 - 144	135 - 143		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	139.9 (1.95)	138.8 (1.63)	0.0 (2.26)	-1.0 (2.25)
		CV	1.4	1.2	-	-230.5
		中央値	140.0	139.0	0.0	-1.0
		Q1 - Q3	139.0 - 141.0	137.5 - 140.0	-2.0 - 2.0	-2.5 - 1.0
		最小値 - 最大値	136 - 146	136 - 142	-6 - 4	-6 - 3
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	139.9 (1.39)	138.8 (1.68)	0.1 (2.02)	-0.8 (1.70)
		CV	1.0	1.2	3023.8	-212.2
		中央値	140.0	139.0	0.0	-1.0
		Q1 - Q3	139.0 - 141.0	138.0 - 140.0	-1.0 - 1.0	-2.0 - 0.0
		最小値 - 最大値	137 - 143	135 - 143	-5 - 4	-5 - 4
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	140.2 (1.47)	139.7 (1.94)	0.4 (1.98)	0.0 (1.92)
		CV	1.0	1.4	524.2	-3942.0
		中央値	140.0	139.0	0.0	0.0
		Q1 - Q3	139.0 - 141.0	139.0 - 141.0	-1.0 - 2.0	-1.0 - 1.0
		最小値 - 最大値	137 - 144	137 - 146	-5 - 4	-5 - 5

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
K (mEq/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	3.87 (0.245)	3.87 (0.215)		
		CV	6.3	5.5		
		中央値	3.80	3.90		
		Q1 - Q3	3.70 - 4.10	3.70 - 4.00		
		最小値 - 最大値	3.4 - 4.4	3.5 - 4.8		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	3.92 (0.247)	3.99 (0.324)	0.04 (0.229)	0.12 (0.253)
		CV	6.3	8.1	529.5	215.4
		中央値	3.90	4.00	0.10	0.10
		Q1 - Q3	3.75 - 4.10	3.80 - 4.20	-0.05 - 0.20	0.00 - 0.30
		最小値 - 最大値	3.3 - 4.5	3.5 - 5.3	-0.5 - 0.5	-0.4 - 0.6
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	3.89 (0.248)	3.93 (0.278)	0.02 (0.207)	0.06 (0.281)
		CV	6.4	7.1	929.6	488.6
		中央値	3.90	3.80	0.00	0.00
		Q1 - Q3	3.70 - 4.00	3.70 - 4.15	-0.10 - 0.10	-0.10 - 0.20
		最小値 - 最大値	3.4 - 4.6	3.6 - 4.6	-0.4 - 0.5	-0.4 - 0.8
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	3.83 (0.276)	3.83 (0.263)	-0.04 (0.251)	-0.04 (0.221)
		CV	7.2	6.9	-663.7	-566.9
		中央値	3.80	3.80	0.00	0.00
		Q1 - Q3	3.60 - 4.00	3.70 - 3.90	-0.20 - 0.10	-0.20 - 0.10
		最小値 - 最大値	3.2 - 4.7	3.4 - 4.6	-0.7 - 0.4	-0.5 - 0.5

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
Cl (mEq/L)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	104.5 (2.32)	103.9 (1.77)		
		CV	2.2	1.7		
		中央値	105.0	104.0		
		Q1 - Q3	103.0 - 106.0	103.0 - 105.0		
		最小値 - 最大値	101 - 110	101 - 108		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	105.4 (2.09)	104.5 (2.01)	0.8 (2.73)	0.6 (2.50)
		CV	2.0	1.9	343.6	416.5
		中央値	105.0	104.0	0.5	1.0
		Q1 - Q3	104.0 - 107.0	103.5 - 106.0	-1.0 - 2.5	-1.5 - 3.0
		最小値 - 最大値	101 - 110	99 - 109	-5 - 7	-4 - 5
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	105.3 (1.84)	104.2 (2.07)	0.8 (2.59)	0.4 (2.26)
		CV	1.7	2.0	342.3	645.6
		中央値	105.0	104.0	1.0	0.0
		Q1 - Q3	104.0 - 106.0	103.0 - 105.0	-1.0 - 3.0	-1.0 - 2.0
		最小値 - 最大値	101 - 109	100 - 110	-6 - 6	-4 - 5
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	104.2 (2.05)	103.9 (2.57)	-0.3 (2.51)	0.0 (2.56)
		CV	2.0	2.5	-940.6	-
		中央値	104.0	104.0	0.0	0.0
		Q1 - Q3	103.0 - 105.0	102.0 - 105.0	-2.0 - 2.0	-2.0 - 1.0
		最小値 - 最大値	100 - 109	100 - 111	-5 - 5	-5 - 7

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
総コレステロール (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	189.9 (27.51)	193.1 (27.86)		
		CV	14.5	14.4		
		中央値	187.0	187.0		
		Q1 - Q3	174.0 - 206.0	172.0 - 211.0		
		最小値 - 最大値	118 - 256	146 - 256		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	181.3 (24.13)	177.6 (25.39)	-7.6 (22.12)	-14.7 (21.31)
		CV	13.3	14.3	-290.5	-145.4
		中央値	178.0	179.0	-6.0	-17.0
		Q1 - Q3	169.0 - 193.5	155.0 - 192.0	-21.0 - 9.5	-27.5 - -2.0
		最小値 - 最大値	130 - 264	138 - 231	-56 - 57	-66 - 27
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	184.6 (27.80)	191.7 (31.72)	-5.4 (26.10)	-1.8 (27.33)
		CV	15.1	16.6	-487.4	-1561.7
		中央値	180.0	189.0	-10.0	-3.0
		Q1 - Q3	169.0 - 199.0	166.5 - 219.0	-22.0 - 6.0	-12.5 - 11.5
		最小値 - 最大値	124 - 280	128 - 254	-47 - 73	-84 - 69
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	194.0 (27.43)	202.0 (29.83)	4.1 (20.89)	8.9 (23.32)
		CV	14.1	14.8	513.6	262.7
		中央値	192.0	198.0	3.0	4.0
		Q1 - Q3	179.0 - 209.0	184.0 - 220.0	-7.0 - 15.0	-10.0 - 31.0
		最小値 - 最大値	133 - 263	140 - 273	-47 - 75	-35 - 52

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
中性脂肪 (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	69.1 (38.22)	67.0 (29.81)		
		CV	55.3	44.5		
		中央値	59.0	57.0		
		Q1 - Q3	43.0 - 77.0	47.0 - 77.0		
		最小値 - 最大値	32 - 217	31 - 158		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	80.5 (39.77)	92.7 (31.22)	11.2 (42.65)	26.3 (29.49)
		CV	49.4	33.7	382.2	112.3
		中央値	69.5	85.0	8.0	26.5
		Q1 - Q3	53.5 - 90.0	71.0 - 104.0	-8.0 - 23.0	10.0 - 38.5
		最小値 - 最大値	38 - 201	57 - 189	-98 - 145	-45 - 114
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	85.6 (45.89)	101.8 (32.07)	16.5 (49.19)	33.8 (29.23)
		CV	53.6	31.5	298.3	86.5
		中央値	69.0	99.0	8.0	30.0
		Q1 - Q3	58.0 - 103.0	75.0 - 119.5	-2.0 - 37.0	12.0 - 55.5
		最小値 - 最大値	28 - 302	55 - 180	-92 - 215	-37 - 108
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	73.0 (34.62)	83.7 (33.47)	3.8 (34.74)	16.6 (30.70)
		CV	47.5	40.0	903.7	184.8
		中央値	68.0	76.0	7.0	13.0
		Q1 - Q3	50.0 - 85.0	63.0 - 93.0	-6.0 - 19.0	-6.0 - 30.0
		最小値 - 最大値	34 - 222	37 - 194	-105 - 115	-30 - 119

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
HDL-C (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	70.6 (15.46)	69.6 (13.23)		
		CV	21.9	19.0		
		中央値	72.0	67.0		
		Q1 - Q3	59.0 - 77.0	61.0 - 76.0		
		最小値 - 最大値	43 - 113	50 - 109		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	69.1 (12.97)	72.9 (13.80)	-1.4 (9.27)	3.1 (8.34)
		CV	18.8	18.9	-658.2	267.0
		中央値	68.5	71.5	-2.0	4.0
		Q1 - Q3	58.0 - 75.5	63.5 - 80.0	-7.0 - 5.0	-1.0 - 9.0
		最小値 - 最大値	47 - 99	49 - 113	-27 - 24	-21 - 18
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	70.0 (12.17)	74.1 (15.50)	-0.6 (10.10)	5.1 (9.32)
		CV	17.4	20.9	-1683.0	181.8
		中央値	69.0	71.0	-1.0	4.5
		Q1 - Q3	63.0 - 75.0	64.0 - 83.0	-7.0 - 7.0	-0.5 - 9.5
		最小値 - 最大値	49 - 103	52 - 115	-27 - 28	-12 - 36
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	71.4 (14.25)	71.8 (14.18)	0.8 (8.81)	2.1 (7.74)
		CV	20.0	19.8	1043.1	360.8
		中央値	70.0	68.0	2.0	2.0
		Q1 - Q3	62.0 - 78.0	63.0 - 82.0	-5.0 - 7.0	-4.0 - 5.0
		最小値 - 最大値	48 - 125	41 - 108	-25 - 16	-13 - 20

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
LDL-C (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	105.6 (21.17)	109.0 (22.51)		
		CV	20.0	20.7		
		中央値	106.0	104.0		
		Q1 - Q3	93.0 - 115.0	97.0 - 128.0		
		最小値 - 最大値	46 - 150	65 - 159		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	96.8 (19.20)	87.1 (20.84)	-7.8 (15.85)	-21.0 (18.96)
		CV	19.8	23.9	-202.1	-90.2
		中央値	95.5	87.0	-9.0	-22.0
		Q1 - Q3	84.0 - 108.5	70.0 - 102.5	-17.5 - 3.0	-31.0 - -9.0
		最小値 - 最大値	62 - 170	52 - 133	-41 - 37	-71 - 27
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	99.4 (22.80)	98.3 (25.12)	-6.2 (20.50)	-11.4 (22.40)
		CV	22.9	25.6	-329.4	-196.1
		中央値	96.0	98.5	-9.0	-12.0
		Q1 - Q3	84.0 - 113.0	84.5 - 112.5	-19.0 - 5.0	-21.0 - 0.0
		最小値 - 最大値	55 - 184	49 - 158	-42 - 54	-82 - 56
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	109.8 (22.22)	114.0 (24.53)	4.2 (17.11)	5.0 (18.55)
		CV	20.2	21.5	403.2	372.8
		中央値	104.0	116.0	5.0	5.0
		Q1 - Q3	96.0 - 130.0	101.0 - 129.0	-5.0 - 10.0	-5.0 - 17.0
		最小値 - 最大値	55 - 167	59 - 169	-33 - 82	-40 - 40

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
グルコース (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	91.5 (10.17)	93.3 (11.78)		
		CV	11.1	12.6		
		中央値	89.0	90.0		
		Q1 - Q3	87.0 - 97.0	86.0 - 97.0		
		最小値 - 最大値	69 - 127	74 - 139		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	93.1 (11.99)	94.2 (9.75)	1.5 (13.52)	1.2 (8.79)
		CV	12.9	10.3	929.3	732.9
		中央値	90.5	91.5	1.5	0.5
		Q1 - Q3	86.0 - 96.5	86.5 - 101.5	-4.5 - 5.5	-4.0 - 8.5
		最小値 - 最大値	72 - 136	79 - 120	-39 - 50	-28 - 19
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	87.9 (7.68)	92.8 (11.68)	-3.6 (9.95)	-0.7 (9.33)
		CV	8.7	12.6	-274.6	-1287.5
		中央値	88.0	90.5	-1.0	0.5
		Q1 - Q3	83.0 - 92.0	85.5 - 98.5	-7.0 - 1.0	-5.5 - 4.0
		最小値 - 最大値	64 - 108	77 - 144	-28 - 19	-37 - 19
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	91.4 (10.62)	92.7 (9.55)	-0.1 (12.36)	-0.5 (12.36)
		CV	11.6	10.3	-13906.8	-2303.3
		中央値	90.0	90.0	-1.0	0.0
		Q1 - Q3	87.0 - 93.0	86.0 - 97.0	-6.0 - 7.0	-4.0 - 3.0
		最小値 - 最大値	79 - 141	80 - 128	-35 - 42	-55 - 41

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
HbA1c (%)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	5.21 (0.219)	5.20 (0.289)		
		CV	4.2	5.6		
		中央値	5.30	5.20		
		Q1 - Q3	5.00 - 5.40	5.10 - 5.40		
		最小値 - 最大値	4.7 - 5.6	4.4 - 5.8		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	5.23 (0.213)	5.22 (0.291)	0.02 (0.158)	0.02 (0.153)
		CV	4.1	5.6	696.4	876.6
		中央値	5.20	5.20	0.00	0.00
		Q1 - Q3	5.10 - 5.40	5.10 - 5.40	-0.10 - 0.10	-0.10 - 0.10
		最小値 - 最大値	4.8 - 5.6	4.3 - 5.9	-0.4 - 0.4	-0.4 - 0.5
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	5.32 (0.217)	5.30 (0.315)	0.10 (0.186)	0.10 (0.187)
		CV	4.1	5.9	177.9	186.7
		中央値	5.30	5.30	0.10	0.10
		Q1 - Q3	5.10 - 5.50	5.10 - 5.50	0.00 - 0.20	0.00 - 0.20
		最小値 - 最大値	4.8 - 5.8	4.3 - 5.9	-0.4 - 0.6	-0.4 - 0.5
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	5.33 (0.222)	5.37 (0.314)	0.12 (0.188)	0.16 (0.180)
		CV	4.2	5.8	156.5	110.1
		中央値	5.40	5.40	0.10	0.20
		Q1 - Q3	5.20 - 5.50	5.20 - 5.50	0.00 - 0.20	0.10 - 0.30
		最小値 - 最大値	4.9 - 5.7	4.3 - 6.0	-0.3 - 0.7	-0.5 - 0.5

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
Fe (ug/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	72.2 (27.55)	85.0 (49.01)		
		CV	38.2	57.7		
		中央値	71.0	80.0		
		Q1 - Q3	52.0 - 94.0	42.0 - 119.0		
		最小値 - 最大値	16 - 123	14 - 184		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	91.2 (46.45)	87.1 (46.84)	19.4 (37.43)	1.0 (49.60)
		CV	51.0	53.8	192.6	5221.3
		中央値	97.0	87.5	18.0	-2.5
		Q1 - Q3	48.0 - 124.5	47.5 - 115.5	-10.5 - 48.0	-23.5 - 38.5
		最小値 - 最大値	20 - 227	13 - 178	-39 - 124	-117 - 97
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	92.4 (40.49)	98.4 (49.72)	20.3 (38.98)	13.4 (48.47)
		CV	43.8	50.5	192.3	361.7
		中央値	90.0	108.5	21.0	10.5
		Q1 - Q3	66.0 - 124.0	60.0 - 130.0	-2.0 - 44.0	-10.5 - 33.0
		最小値 - 最大値	23 - 188	15 - 213	-65 - 109	-115 - 162
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	73.5 (35.75)	71.3 (37.10)	1.3 (37.65)	-13.7 (41.48)
		CV	48.7	52.1	2921.1	-303.1
		中央値	61.0	67.0	0.0	-6.0
		Q1 - Q3	52.0 - 101.0	41.0 - 97.0	-24.0 - 22.0	-26.0 - 16.0
		最小値 - 最大値	14 - 159	16 - 153	-76 - 107	-128 - 38

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
Ca (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	9.21 (0.287)	9.23 (0.327)		
		CV	3.1	3.5		
		中央値	9.20	9.30		
		Q1 - Q3	9.10 - 9.40	9.00 - 9.50		
		最小値 - 最大値	8.6 - 9.9	8.6 - 10.1		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	9.20 (0.248)	9.14 (0.283)	-0.02 (0.331)	-0.10 (0.357)
		CV	2.7	3.1	-2082.3	-356.6
		中央値	9.15	9.10	-0.10	-0.10
		Q1 - Q3	9.00 - 9.40	8.90 - 9.30	-0.30 - 0.20	-0.30 - 0.15
		最小値 - 最大値	8.7 - 9.7	8.5 - 9.8	-0.9 - 0.8	-0.7 - 0.7
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	9.20 (0.286)	9.15 (0.395)	-0.02 (0.378)	-0.09 (0.404)
		CV	3.1	4.3	-2126.1	-475.5
		中央値	9.20	9.10	-0.10	-0.20
		Q1 - Q3	9.00 - 9.40	8.95 - 9.30	-0.30 - 0.30	-0.40 - 0.15
		最小値 - 最大値	8.4 - 9.8	8.4 - 10.5	-0.8 - 0.8	-0.9 - 1.2
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	9.16 (0.303)	9.13 (0.329)	-0.06 (0.344)	-0.10 (0.397)
		CV	3.3	3.6	-595.6	-387.7
		中央値	9.20	9.10	0.00	-0.10
		Q1 - Q3	8.90 - 9.40	8.90 - 9.40	-0.30 - 0.20	-0.30 - 0.10
		最小値 - 最大値	8.4 - 9.8	8.2 - 9.7	-1.0 - 1.0	-1.3 - 0.6

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目	評価期間	測定値		変化量	
		FSN-013群	ヤーズフレックス配合錠群	FSN-013群	ヤーズフレックス配合錠群

表 2.7.4-144 血液生化学的検査値の測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
CRP (mg/dL)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	0.060 (0.1646)	0.057 (0.0826)		
		CV	272.3	145.3		
		中央値	0.020	0.020		
		Q1 - Q3	0.010 - 0.030	0.010 - 0.060		
		最小値 - 最大値	0.01 - 1.01	0.01 - 0.35		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	0.092 (0.2324)	0.102 (0.1563)	0.030 (0.1651)	0.044 (0.1229)
		CV	253.7	153.3	546.1	277.7
		中央値	0.020	0.050	0.000	0.020
		Q1 - Q3	0.010 - 0.050	0.020 - 0.110	0.000 - 0.030	0.000 - 0.070
		最小値 - 最大値	0.01 - 1.15	0.01 - 0.84	-0.48 - 0.93	-0.28 - 0.49
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	0.094 (0.2393)	0.115 (0.1546)	0.033 (0.1293)	0.058 (0.1542)
		CV	255.2	134.1	387.9	265.9
		中央値	0.020	0.085	0.010	0.035
		Q1 - Q3	0.020 - 0.050	0.025 - 0.155	0.000 - 0.030	0.005 - 0.085
		最小値 - 最大値	0.01 - 1.53	0.01 - 0.94	-0.45 - 0.52	-0.24 - 0.85
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	0.066 (0.2166)	0.053 (0.0600)	0.005 (0.1066)	-0.004 (0.0815)
		CV	329.2	113.4	1999.0	-2087.2
		中央値	0.020	0.040	0.000	0.010
		Q1 - Q3	0.010 - 0.040	0.020 - 0.060	0.000 - 0.020	0.000 - 0.020
		最小値 - 最大値	0.01 - 1.46	0.01 - 0.33	-0.49 - 0.45	-0.30 - 0.15

引用元：FSN-013P-05（資料番号 5.3.4.2-01）表 15.4-7 を引用

2.7.4.3.1.2.5.6 海外 ISS

第 III 相試験のみの統合データでの、血液生化学検査のベースラインから試験終了までのシフトテーブルを表 2.7.4-145 に示す。

ベースラインから試験終了までにあるカテゴリー（低値、正常値又は高値）から別のカテゴリーへのシフトが認められた割合が比較的大きかった検査項目は重炭酸塩及び LDH2 濃度であった。

重炭酸塩については、ベースライン時に正常値カテゴリーに属していた 1227 例のうち、495 例（全体集団の 16.9%、ベースライン時に正常値カテゴリーに属していた被験者の 40.3%）が試験終了時に低値カテゴリーへシフトした。同時に、ベースライン時に低値カテゴリーに属していた 1705 例のうち、687 例（全体集団の 23.4%、ベースライン時に低値カテゴリーに属していた被験者の 40.3%）が正常値カテゴリーにシフトした。

表 2.7.4-145 血液生化学検査のベースラインから試験終了までのシフトテーブル（海外 ISS、第 III 相試験のみ）（安全性解析対象集団）

	Phase 3 Studies E4/DRSP 15/3 mg (N=3632)*		
Lab Parameter Time Point Post-Baseline Value [n (%)]	Low	Normal	High
EoS	Baseline Value		
Alanine Aminotransferase			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	2819 (96.2)	36 (1.2)
High	0 (0.0)	67 (2.3)	7 (0.2)
Albumin			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	2929 (99.7)	6 (0.2)
High	0 (0.0)	2 (0.1)	0 (0.0)
Aspartate Aminotransferase			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	2824 (97.1)	31 (1.1)
High	0 (0.0)	50 (1.7)	4 (0.1)
Bicarbonate			
Low	1018 (34.7)	495 (16.9)	0 (0.0)
Normal	687 (23.4)	732 (25.0)	0 (0.0)
High	0 (0.0)	0 (0.0)	0 (0.0)
Blood Urea Nitrogen			
Low	3 (0.1)	36 (1.2)	0 (0.0)
Normal	21 (0.7)	2877 (97.9)	1 (0.0)
High	0 (0.0)	1 (0.0)	0 (0.0)
Calcium			
Low	1 (0.0)	23 (0.8)	0 (0.0)
Normal	9 (0.3)	2892 (98.4)	7 (0.2)
High	0 (0.0)	6 (0.2)	1 (0.0)
Chloride			
Low	16 (0.5)	49 (1.7)	0 (0.0)
Normal	125 (4.3)	2746 (93.4)	3 (0.1)
High	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-145 血液生化学検査のベースラインから試験終了までのシフトテーブル（海外 ISS、第 III 相試験のみ）（安全性解析対象集団）（続き）

	Phase 3 Studies E4/DRSP 15/3 mg (N=3,632)*		
Lab Parameter Time Point Post-Baseline Value [n (%)]	Low	Normal	High
EoS	Baseline Value		
Creatinine			
Low	2 (0.1)	12 (0.4)	0 (0.0)
Normal	11 (0.4)	2531 (86.1)	142 (4.8)
High	0 (0.0)	140 (4.8)	100 (3.4)
Glomerular Filtration Rate			
Low	0 (0.0)	10 (0.3)	0 (0.0)
Normal	1 (0.0)	2624 (89.4)	110 (3.7)
High	0 (0.0)	95 (3.2)	96 (3.3)
Gamma Glutamyl Transferase			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	2889 (98.4)	19 (0.6)
High	0 (0.0)	19 (0.6)	9 (0.3)
LDH Isoenzyme 1			
Low	11 (0.4)	30 (1.0)	0 (0.0)
Normal	19 (0.6)	2827 (96.5)	17 (0.6)
High	0 (0.0)	14 (0.5)	11 (0.4)
LDH Isoenzyme 2			
Low	523 (17.9)	357 (12.2)	0 (0.0)
Normal	497 (17.0)	1551 (53.0)	0 (0.0)
High	0 (0.0)	1 (0.0)	0 (0.0)
Phosphate			
Low	25 (0.9)	91 (3.1)	0 (0.0)
Normal	65 (2.2)	2709 (92.3)	23 (0.8)
High	0 (0.0)	23 (0.8)	0 (0.0)

表 2.7.4-145 血液生化学検査のベースラインから試験終了までのシフトテーブル（海外 ISS、第 III 相試験のみ）（安全性解析対象集団）（続き）

	Phase 3 Studies E4/DRSP 15/3 mg (N=3632)*		
Lab Parameter Time Point Post-Baseline Value [n (%)]	Low	Normal	High
EoS	Baseline Value		
Potassium			
Low	1 (0.0)	9 (0.3)	0 (0.0)
Normal	5 (0.2)	2793 (95.2)	68 (2.3)
High	0 (0.0)	41 (1.4)	16 (0.5)
Sodium			
Low	0 (0.0)	2 (0.1)	0 (0.0)
Normal	1 (0.0)	2927 (99.6)	6 (0.2)
High	0 (0.0)	3 (0.1)	0 (0.0)
Bilirubin			
Low	0 (0.0)	0 (0.0)	0 (0.0)
Normal	0 (0.0)	2858 (97.4)	35 (1.2)
High	0 (0.0)	30 (1.0)	12 (0.4)
Protein			
Low	1 (0.0)	8 (0.3)	0 (0.0)
Normal	4 (0.1)	2918 (99.4)	5 (0.2)
High	0 (0.0)	0 (0.0)	1 (0.0)

DRSP = drospirenone, EoS = end of study, E4 = estetrol, LDH = lactate dehydrogenase, n = number of subjects in the Safety Population with a value at baseline and at EoS

* The ISS Safety Population from Phase 3 studies only includes 3,632 subjects, from which 3,417 had a confirmed exposure to E4/DRSP 15/3 mg and 215 subjects for whom neither exposure nor non-exposure could be confirmed.

Integrated Summary of Safety（資料番号 5.3.5.3-int02）Table 14.2.2.1.2 より作成

第 III 相試験及び第 II 相試験の統合データでの、血液生化学検査のベースラインから試験終了までのシフトテーブルを表 2.7.4-146 に示す。

第 III 相試験で得られた結果と同様、ベースラインから試験終了までに低値、正常値又は高値から別のカテゴリーへのシフトが認められた割合が比較的大きかった検査項目は、重炭酸塩及び LDH2 であった。

表 2.7.4-146 血液生化学検査のベースラインから試験終了までのシフトテーブル（海外 ISS、第 III 相試験及び第 II 相試験）（安全性解析対象集団）

	Phase 3 and 2 Studies E4/DRSP 15/3 mg (N=3790)*		
Lab Parameter Time Point Post-Baseline Value [n (%)]	Low	Normal	High
Cycle 7/EoS	Baseline Value		
Bicarbonate			
Low	888 (32.9)	408 (15.1)	0 (0.0)
Normal	650 (24.1)	750 (27.8)	0 (0.0)
High	0 (0.0)	0 (0.0)	0 (0.0)
Blood Urea Nitrogen			
Low	3 (0.1)	13 (0.5)	0 (0.0)
Normal	17 (0.6)	2693 (98.4)	4 (0.1)
High	0 (0.0)	8 (0.3)	0 (0.0)
Calcium			
Low	1 (0.0)	6 (0.2)	0 (0.0)
Normal	9 (0.3)	2669 (98.7)	8 (0.3)
High	0 (0.0)	8 (0.3)	3 (0.1)
Chloride			
Low	9 (0.3)	34 (1.3)	0 (0.0)
Normal	116 (4.3)	2541 (94.0)	3 (0.1)
High	0 (0.0)	1 (0.0)	0 (0.0)
Creatinine			
Low	0 (0.0)	6 (0.2)	2 (0.1)
Normal	9 (0.3)	2359 (85.0)	106 (3.8)
High	0 (0.0)	181 (6.5)	112 (4.0)
LDH Isoenzyme 1			
Low	6 (0.2)	16 (0.6)	0 (0.0)
Normal	27 (1.0)	2552 (96.2)	21 (0.8)
High	0 (0.0)	22 (0.8)	9 (0.3)

表 2.7.4-146 血液生化学検査のベースラインから試験終了までのシフトテーブル（海外 ISS、第 III 相試験及び第 II 相試験）（安全性解析対象集団）（続き）

	Phase 3 and 2 Studies E4/DRSP 15/3 mg (N=3790)*		
Lab Parameter Time Point Post-Baseline Value [n (%)]	Low	Normal	High
Cycle 7/EoS	Baseline Value		
LDH Isoenzyme 2			
Low	411 (15.5)	365 (13.8)	0 (0.0)
Normal	502 (18.9)	1373 (51.8)	0 (0.0)
High	0 (0.0)	2 (0.1)	0 (0.0)
Phosphate			
Low	11 (0.4)	59 (2.2)	0 (0.0)
Normal	78 (2.9)	2509 (92.8)	18 (0.7)
High	0 (0.0)	27 (1.0)	2 (0.1)
Potassium			
Low	2 (0.1)	1 (0.0)	0 (0.0)
Normal	6 (0.2)	2642 (95.2)	56 (2.0)
High	0 (0.0)	53 (1.9)	15 (0.5)
Sodium			
Low	0 (0.0)	2 (0.1)	0 (0.0)
Normal	5 (0.2)	2760 (99.4)	5 (0.2)
High	0 (0.0)	5 (0.2)	0 (0.0)

DRSP = drospirenone, EOS = end of study, E4 = estetrol, LDH = lactate dehydrogenase, n = number of subjects in the Safety Population with a baseline value and a value at Cycle 7/EOS.

* The ISS Safety Population includes 3,575 subjects with confirmed exposure to E4/DRSP 15/3 mg and 215 subjects for whom neither exposure or non-exposure could be confirmed. All 215 subjects were included in Phase 3 studies.

Integrated Summary of Safety（資料番号 5.3.5.3-int02）Table 14.2.2.1.3 より作成

2.7.4.3.1.3 血液凝固線溶系検査

検証試験である FSN-013P-03 試験及び FSN-013P-04 試験では、凝固系活性化により変動するトロンビン・アンチトロンビン III 複合体及び可溶性フィブリンモノマー複合体、抗凝固因子であるプロテイン C 及びその補助因子であるプロテイン S、並びに凝固線溶状態を示す D-ダイマーについて特記する。

2.7.4.3.1.3.1 FSN-013P-03 試験

2.7.4.3.1.3.1.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、血液凝固系検査の測定値、ベースラインからの変化量及び変化率を表 2.7.4-147～表 2.7.4-149 に、血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度を表 2.7.4-150 に示す。

トロンビン・アンチトロンビン III 複合体、可溶性フィブリンモノマー複合体、プロテイン C、プロテイン S 及び D-ダイマーに関する投与前後の平均変化量に特記すべき異常変動はみられなかった。また、D-ダイマーの基準値上限を逸脱した被験者の割合は、FSN-013 群では 3.7%（3/81 例）、プラセボ群では 6.3%（5/79 例）であり、両群間で同様であった。その他のいずれの項目も経時的推移は FSN-013 群、プラセボ群（投与 5 周期目以降に FSN-013 投与に切替え）で同様であり、FSN-013 群及びプラセボ群の基準値上限超、基準値下限未満の頻度に大差は認められなかった。

なお、投与 4 周期（16 週）終了時点までの安全性解析対象集団を対象とした、FSN-013 群及びプラセボ群の基準値上限超、基準値下限未満の頻度に大差は認められなかった。（5.3.5.2-dys01 表 14-36）。

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Time (sec)	Value	FSN-013	n	81	80	81	77
			Mean	11 27	11 30	11 33	11 38
			SD	0 802	0 665	0 679	0 718
			Min	9 7	9 7	9 6	9 5
			Q1	10 70	10 80	10 90	10 80
			Median	11 20	11 30	11 30	11 30
			Q3	11 70	11 70	11 80	11 90
			Max	13 6	12 8	13 1	13 1
		Placebo	n	79	78	79	74
			Mean	11 23	11 44	11 46	11 35
			SD	0 789	0 714	0 654	0 741
			Min	9 3	10 2	9 9	9 4
			Q1	10 60	10 90	11 00	11 00
			Median	11 20	11 40	11 40	11 30
			Q3	11 70	11 90	12 00	11 80
			Max	13 4	13 2	13 2	13 7
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0 01	0 06	0 07
			SD	-	0 640	0 633	0 670
			Min	-	-1 6	-1 3	-1 6
			Q1	-	-0 40	-0 30	-0 40
			Median	-	0 05	0 00	0 20
			Q3	-	0 50	0 50	0 50
			Max	-	1 7	1 8	1 3
		Placebo	n	-	78	79	74
			Mean	-	0 22	0 23	0 14
			SD	-	0 737	0 724	0 712
			Min	-	-2 1	-1 8	-1 5
			Q1	-	-0 20	-0 20	-0 30
			Median	-	0 25	0 20	0 10
			Q3	-	0 70	0 80	0 70
			Max	-	2 0	1 7	1 5

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Time (sec)	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.31	0.72	0.88
			SD	-	5.666	5.649	5.873
			Min	-	-13.2	-11.3	-12.4
			Q1	-	-3.64	-2.80	-3.28
			Median	-	0.45	0.00	1.64
			Q3	-	4.22	4.50	4.76
			Max	-	16.8	17.8	12.7
		Placebo	n	-	78	79	74
			Mean	-	2.26	2.37	1.53
			SD	-	6.528	6.498	6.494
			Min	-	-16.4	-14.1	-13.8
			Q1	-	-1.61	-1.82	-2.63
			Median	-	2.25	1.80	0.90
			Q3	-	5.94	7.55	6.60
			Max	-	21.5	18.3	16.1

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Control (sec)	Value	FSN-013	n	81	80	81	77
			Mean	11.50	11.50	11.50	11.50
			SD	0.000	0.000	0.000	0.000
			Min	11.5	11.5	11.5	11.5
			Q1	11.50	11.50	11.50	11.50
			Median	11.50	11.50	11.50	11.50
			Q3	11.50	11.50	11.50	11.50
			Max	11.5	11.5	11.5	11.5
		Placebo	n	79	78	79	74
			Mean	11.50	11.50	11.50	11.50
			SD	0.000	0.000	0.000	0.000
			Min	11.5	11.5	11.5	11.5
			Q1	11.50	11.50	11.50	11.50
			Median	11.50	11.50	11.50	11.50
			Q3	11.50	11.50	11.50	11.50
			Max	11.5	11.5	11.5	11.5

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Control (sec)	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0
		Placebo	n	-	78	79	74
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0
		Placebo	n	-	78	79	74
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Activity (%)	Value	FSN-013	n	81	80	81	77
			Mean	96.5	97.0	97.1	96.7
			SD	6.25	5.30	5.46	5.78
			Min	75	81	78	81
			Q1	94.0	94.0	94.0	92.0
			Median	100.0	99.5	100.0	100.0
			Q3	101.0	101.0	101.0	101.0
			Max	101	101	101	101
		Placebo	n	79	78	79	74
			Mean	96.9	95.8	96.4	97.1
			SD	5.77	6.37	5.82	5.80
			Min	78	77	80	76
			Q1	94.0	92.0	92.0	94.0
			Median	101.0	98.0	99.0	100.0
			Q3	101.0	101.0	101.0	101.0
			Max	101	101	101	101
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.6	0.6	0.4
			SD	-	4.94	5.20	5.73
			Min	-	-11	-16	-12
			Q1	-	-2.5	-1.0	-2.0
			Median	-	0.0	0.0	0.0
			Q3	-	2.0	2.0	2.0
			Max	-	12	14	18
		Placebo	n	-	78	79	74
			Mean	-	-1.1	-0.5	0.1
			SD	-	6.41	6.46	5.81
			Min	-	-16	-16	-14
			Q1	-	-5.0	-4.0	-3.0
			Median	-	0.0	0.0	0.0
			Q3	-	1.0	3.0	3.0
			Max	-	18	18	15

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Activity (%)	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.78	0.87	0.67
			SD	-	5.474	5.714	6.394
			Min	-	-10.9	-16.2	-12.8
			Q1	-	-2.60	-0.99	-2.15
			Median	-	0.00	0.00	0.00
			Q3	-	2.19	2.27	2.02
			Max	-	13.8	17.1	22.5
		Placebo	n	-	78	79	74
			Mean	-	-0.97	-0.26	0.26
			SD	-	6.979	6.947	6.238
			Min	-	-16.3	-16.0	-13.9
			Q1	-	-4.95	-4.08	-2.97
			Median	-	0.00	0.00	0.00
			Q3	-	1.03	3.06	3.57
			Max	-	21.7	21.7	18.1
Prothrombin Intl. Normalized Ratio	Value	FSN-013	n	81	80	81	77
			Mean	0.981	0.983	0.985	0.990
			SD	0.0680	0.0566	0.0575	0.0618
			Min	0.85	0.85	0.84	0.83
			Q1	0.930	0.940	0.950	0.940
			Median	0.970	0.980	0.980	0.980
			Q3	1.020	1.020	1.030	1.030
			Max	1.17	1.11	1.14	1.14
		Placebo	n	79	78	79	74
			Mean	0.977	0.995	0.996	0.988
			SD	0.0662	0.0607	0.0570	0.0633
			Min	0.82	0.89	0.86	0.82
			Q1	0.920	0.950	0.960	0.960
			Median	0.970	0.990	0.990	0.980
			Q3	1.020	1.030	1.040	1.030
			Max	1.16	1.15	1.15	1.19

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Intl. Normalized Ratio	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.001	0.004	0.006
			SD	-	0.0544	0.0530	0.0564
			Min	-	-0.13	-0.11	-0.14
			Q1	-	-0.035	-0.030	-0.040
			Median	-	0.000	0.000	0.010
			Q3	-	0.040	0.040	0.050
			Max	-	0.15	0.15	0.11
		Placebo	n	-	78	79	74
			Mean	-	0.018	0.019	0.012
			SD	-	0.0621	0.0619	0.0607
			Min	-	-0.18	-0.15	-0.13
			Q1	-	-0.020	-0.020	-0.030
			Median	-	0.020	0.020	0.005
			Q3	-	0.060	0.070	0.060
			Max	-	0.16	0.14	0.13
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.28	0.65	0.81
			SD	-	5.553	5.436	5.690
			Min	-	-12.4	-11.0	-12.5
			Q1	-	-3.71	-2.94	-3.67
			Median	-	0.00	0.00	1.03
			Q3	-	3.94	4.30	4.81
			Max	-	17.0	17.0	12.4
		Placebo	n	-	78	79	74
			Mean	-	2.13	2.21	1.48
			SD	-	6.290	6.376	6.346
			Min	-	-16.2	-13.5	-13.7
			Q1	-	-1.85	-2.02	-2.83
			Median	-	2.11	1.94	0.52
			Q3	-	5.83	7.07	6.52
			Max	-	19.5	17.1	14.6

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Time (sec)	Value	FSN-013	n	81	80	81	77
			Mean	32.86	31.31	31.19	31.31
			SD	5.464	2.751	2.688	2.834
			Min	25.5	26.7	25.5	25.1
			Q1	30.70	29.45	29.50	29.40
			Median	32.40	30.70	30.80	30.90
			Q3	34.20	33.00	32.60	32.30
			Max	74.6	39.8	38.8	41.7
		Placebo	n	79	78	79	74
			Mean	32.63	32.44	32.03	30.73
			SD	3.808	3.098	3.014	2.898
			Min	25.1	25.6	25.5	23.9
			Q1	30.60	30.10	30.00	28.90
			Median	32.10	32.15	31.90	30.65
			Q3	34.20	34.60	33.70	32.30
			Max	52.9	43.3	40.9	38.7
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-1.60	-1.66	-1.65
			SD	-	5.130	5.280	5.447
			Min	-	-45.2	-46.4	-45.7
			Q1	-	-2.20	-2.20	-2.30
			Median	-	-1.05	-1.40	-1.10
			Q3	-	-0.10	-0.10	0.10
			Max	-	1.9	2.7	4.3
		Placebo	n	-	78	79	74
			Mean	-	-0.21	-0.60	-1.96
			SD	-	2.843	3.216	3.395
			Min	-	-18.2	-23.4	-23.7
			Q1	-	-1.40	-1.60	-2.80
			Median	-	-0.15	-0.30	-1.35
			Q3	-	1.20	0.80	-0.30
			Max	-	6.7	4.8	2.7

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Time (sec)	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-3.85	-4.00	-3.88
			SD	-	7.707	8.154	8.871
			Min	-	-60.6	-62.2	-61.3
			Q1	-	-6.77	-7.17	-7.17
			Median	-	-3.11	-4.18	-3.75
			Q3	-	-0.30	-0.31	0.31
			Max	-	5.2	8.8	15.1
		Placebo	n	-	78	79	74
			Mean	-	-0.18	-1.32	-5.45
			SD	-	7.300	7.434	7.954
			Min	-	-34.4	-44.2	-44.8
			Q1	-	-4.14	-4.68	-8.54
			Median	-	-0.51	-0.88	-4.14
			Q3	-	4.06	2.50	-0.89
			Max	-	25.0	13.4	9.8
Activated Partial Thromboplastin Control (sec)	Value	FSN-013	n	81	80	81	77
			Mean	28.70	28.70	28.70	28.70
			SD	0.000	0.000	0.000	0.000
			Min	28.7	28.7	28.7	28.7
			Q1	28.70	28.70	28.70	28.70
			Median	28.70	28.70	28.70	28.70
			Q3	28.70	28.70	28.70	28.70
			Max	28.7	28.7	28.7	28.7
		Placebo	n	79	78	79	74
			Mean	28.70	28.70	28.70	28.70
			SD	0.000	0.000	0.000	0.000
			Min	28.7	28.7	28.7	28.7
			Q1	28.70	28.70	28.70	28.70
			Median	28.70	28.70	28.70	28.70
			Q3	28.70	28.70	28.70	28.70
			Max	28.7	28.7	28.7	28.7

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Control (sec)	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0
		Placebo	n	-	78	79	74
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0
		Placebo	n	-	78	79	74
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Fibrinogen (mg/dL)	Value	FSN-013	n	81	80	81	77
			Mean	251.6	262.5	275.4	273.2
			SD	46.37	39.64	48.79	54.05
			Min	173	185	182	126
			Q1	221.0	233.5	237.0	229.0
			Median	244.0	256.0	274.0	271.0
			Q3	272.0	290.5	305.0	311.0
			Max	403	353	432	421
		Placebo	n	79	78	79	74
			Mean	264.3	269.2	276.4	288.2
			SD	36.33	40.48	47.43	41.15
			Min	168	187	197	214
			Q1	238.0	245.0	243.0	261.0
			Median	261.0	262.0	268.0	284.0
			Q3	293.0	286.0	295.0	318.0
			Max	364	375	409	405
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	10.2	23.7	21.7
			SD	-	38.81	47.00	52.57
			Min	-	-124	-97	-106
			Q1	-	-8.0	0.0	-8.0
			Median	-	11.0	17.0	22.0
			Q3	-	37.5	44.0	50.0
			Max	-	86	189	206
		Placebo	n	-	78	79	74
			Mean	-	4.8	12.1	22.6
			SD	-	37.36	44.65	37.52
			Min	-	-86	-106	-98
			Q1	-	-22.0	-18.0	-8.0
			Median	-	5.5	11.0	22.5
			Q3	-	30.0	42.0	46.0
			Max	-	83	109	107

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Fibrinogen (mg/dL)	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	5.52	11.06	10.15
			SD	-	14.759	20.057	21.465
			Min	-	-33.6	-24.9	-32.3
			Q1	-	-3.27	0.00	-2.83
			Median	-	4.95	6.97	8.92
			Q3	-	16.87	18.22	22.62
			Max	-	41.6	86.0	95.8
		Placebo	n	-	78	79	74
			Mean	-	2.69	5.48	9.46
			SD	-	14.415	17.031	14.505
			Min	-	-26.3	-32.4	-30.0
			Q1	-	-8.73	-6.91	-2.96
			Median	-	2.06	4.74	8.92
			Q3	-	13.43	14.71	18.43
			Max	-	47.0	63.7	42.3
Antithrombin Activity (%)	Value	FSN-013	n	81	80	81	77
			Mean	112.4	107.9	107.6	107.8
			SD	11.17	10.68	11.30	10.88
			Min	87	84	86	82
			Q1	105.0	101.5	99.0	102.0
			Median	112.0	107.0	106.0	108.0
			Q3	121.0	115.0	116.0	116.0
			Max	138	132	140	128
		Placebo	n	79	78	79	74
			Mean	113.9	110.8	111.0	110.3
			SD	11.17	11.07	10.31	10.33
			Min	86	90	89	86
			Q1	107.0	103.0	105.0	103.0
			Median	114.0	110.0	110.0	111.0
			Q3	120.0	117.0	117.0	116.0
			Max	140	144	148	143

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Antithrombin Activity (%)	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-4.6	-4.8	-4.4
			SD	-	8.88	9.70	9.32
			Min	-	-31	-30	-25
			Q1	-	-11.0	-12.0	-10.0
			Median	-	-5.5	-5.0	-3.0
			Q3	-	1.0	2.0	3.0
			Max	-	16	22	18
		Placebo	n	-	78	79	74
			Mean	-	-3.1	-2.9	-3.7
			SD	-	8.44	9.70	8.66
			Min	-	-26	-26	-22
			Q1	-	-8.0	-9.0	-11.0
			Median	-	-4.0	-2.0	-4.0
			Q3	-	2.0	2.0	3.0
			Max	-	17	22	20
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-3.72	-3.98	-3.57
			SD	-	7.912	8.560	8.219
			Min	-	-26.3	-23.3	-20.7
			Q1	-	-9.30	-9.82	-9.01
			Median	-	-4.90	-4.03	-2.70
			Q3	-	0.92	1.65	2.40
			Max	-	16.8	21.1	16.8
		Placebo	n	-	78	79	74
			Mean	-	-2.45	-2.15	-2.89
			SD	-	7.267	8.639	7.575
			Min	-	-22.0	-20.8	-16.7
			Q1	-	-7.20	-7.89	-8.94
			Median	-	-3.51	-1.69	-3.28
			Q3	-	1.87	1.60	2.68
			Max	-	13.4	23.7	21.5

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Plasminogen (%)	Value	FSN-013	n	81	80	81	77
			Mean	97.3	106.4	109.6	108.5
			SD	14.01	14.97	15.47	16.41
			Min	50	55	51	52
			Q1	91.0	98.5	101.0	101.0
			Median	98.0	106.5	111.0	108.0
			Q3	106.0	115.0	120.0	118.0
			Max	123	138	139	138
		Placebo	n	79	78	79	74
			Mean	98.1	97.8	97.9	107.0
			SD	15.18	14.99	14.79	15.39
			Min	57	53	50	60
			Q1	90.0	90.0	90.0	100.0
			Median	99.0	98.5	98.0	109.0
			Q3	107.0	104.0	105.0	118.0
			Max	135	135	128	133
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	9.0	12.3	11.3
			SD	-	10.33	10.09	10.21
			Min	-	-12	-18	-16
			Q1	-	4.0	6.0	5.0
			Median	-	7.5	11.0	13.0
			Q3	-	14.0	18.0	17.0
			Max	-	39	37	39
		Placebo	n	-	78	79	74
			Mean	-	-0.2	-0.1	8.9
			SD	-	7.94	7.84	8.28
			Min	-	-19	-16	-10
			Q1	-	-5.0	-6.0	3.0
			Median	-	-1.0	0.0	10.0
			Q3	-	5.0	5.0	15.0
			Max	-	20	23	27

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Plasminogen (%)	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	9.90	13.23	12.06
			SD	-	11.204	10.927	10.793
			Min	-	-10.6	-15.9	-13.3
			Q1	-	3.41	6.36	5.61
			Median	-	7.79	11.63	13.21
			Q3	-	15.46	19.63	17.44
			Max	-	43.7	42.0	40.7
		Placebo	n	-	78	79	74
			Mean	-	0.14	0.20	9.62
			SD	-	8.430	8.919	8.883
			Min	-	-15.4	-20.6	-9.8
			Q1	-	-5.88	-5.19	3.30
			Median	-	-0.99	0.00	9.50
			Q3	-	5.45	4.72	15.94
			Max	-	29.0	33.3	31.8
Factor XIV Activity (%)	Value	FSN-013	n	81	80	81	77
			Mean	110.2	107.7	108.6	108.0
			SD	14.59	14.43	15.12	16.16
			Min	72	81	80	79
			Q1	101.0	95.5	99.0	95.0
			Median	110.0	108.0	108.0	105.0
			Q3	121.0	117.5	119.0	117.0
			Max	151	142	148	151
		Placebo	n	79	78	79	74
			Mean	113.7	108.4	106.8	109.4
			SD	16.81	17.43	16.50	15.30
			Min	80	76	79	78
			Q1	102.0	95.0	95.0	98.0
			Median	112.0	107.0	103.0	108.0
			Q3	125.0	119.0	117.0	117.0
			Max	151	151	151	151

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Factor XIV Activity (%)	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-2.5	-1.6	-2.2
			SD	-	9.06	10.48	10.69
			Min	-	-20	-22	-28
			Q1	-	-8.0	-9.0	-8.0
			Median	-	-4.0	-2.0	-3.0
			Q3	-	3.0	6.0	5.0
			Max	-	28	21	20
		Placebo	n	-	78	79	74
			Mean	-	-5.3	-6.9	-4.4
			SD	-	9.90	10.53	10.75
			Min	-	-39	-33	-32
			Q1	-	-12.0	-15.0	-11.0
			Median	-	-5.5	-5.0	-3.5
			Q3	-	0.0	0.0	3.0
			Max	-	21	21	17
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-1.95	-1.11	-1.66
			SD	-	8.245	9.576	9.941
			Min	-	-16.7	-19.1	-22.0
			Q1	-	-8.12	-7.02	-7.45
			Median	-	-3.36	-1.60	-2.33
			Q3	-	3.05	5.41	4.55
			Max	-	24.6	19.4	27.8
		Placebo	n	-	78	79	74
			Mean	-	-4.44	-5.70	-3.29
			SD	-	8.587	8.957	9.103
			Min	-	-31.7	-23.7	-25.2
			Q1	-	-10.19	-13.22	-9.80
			Median	-	-5.07	-4.72	-3.12
			Q3	-	0.00	0.00	2.88
			Max	-	17.2	20.6	17.4

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Activity Actual/Control	Value	FSN-013	n	81	80	81	77
			Mean	1.091	1.102	1.023	1.041
			SD	0.1283	0.1355	0.1245	0.1013
			Min	0.59	0.51	0.60	0.61
			Q1	1.010	1.045	0.930	0.980
			Median	1.100	1.105	1.030	1.040
			Q3	1.170	1.170	1.110	1.110
			Max	1.41	1.43	1.38	1.29
		Placebo	n	79	78	79	74
			Mean	1.080	1.125	1.063	1.045
			SD	0.0939	0.1169	0.1193	0.1093
			Min	0.71	0.82	0.63	0.66
			Q1	1.020	1.070	1.000	0.960
			Median	1.070	1.120	1.060	1.060
			Q3	1.150	1.180	1.150	1.130
			Max	1.29	1.48	1.34	1.37
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.011	-0.069	-0.050
			SD	-	0.0973	0.1259	0.0959
			Min	-	-0.25	-0.44	-0.25
			Q1	-	-0.050	-0.130	-0.120
			Median	-	0.010	-0.060	-0.050
			Q3	-	0.090	0.010	0.010
			Max	-	0.17	0.25	0.16
		Placebo	n	-	78	79	74
			Mean	-	0.048	-0.017	-0.032
			SD	-	0.1136	0.1143	0.1014
			Min	-	-0.18	-0.28	-0.25
			Q1	-	-0.030	-0.100	-0.090
			Median	-	0.050	0.000	-0.030
			Q3	-	0.120	0.060	0.040
			Max	-	0.34	0.22	0.26

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Activity Actual/Control	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	1.33	-5.65	-4.12
			SD	-	9.191	11.185	8.460
			Min	-	-27.1	-36.1	-19.0
			Q1	-	-4.60	-12.15	-10.71
			Median	-	0.97	-5.94	-4.39
			Q3	-	9.26	0.99	1.04
			Max	-	17.2	22.1	16.5
		Placebo	n	-	78	79	74
			Mean	-	4.79	-1.33	-2.72
			SD	-	10.485	10.494	9.229
			Min	-	-14.6	-24.1	-20.3
			Q1	-	-3.06	-8.94	-8.11
			Median	-	4.65	0.00	-2.62
			Q3	-	12.12	5.66	3.64
			Max	-	29.8	23.2	23.4
Protein S Total Activity (IU/mL)	Value	FSN-013	n	81	80	81	77
			Mean	1.032	1.022	0.939	0.961
			SD	0.1630	0.1908	0.1875	0.2113
			Min	0.64	0.45	0.53	0.54
			Q1	0.930	0.905	0.790	0.810
			Median	1.060	1.050	0.950	0.940
			Q3	1.130	1.145	1.060	1.050
			Max	1.54	1.56	1.39	1.62
		Placebo	n	79	78	79	74
			Mean	1.081	1.103	1.030	1.002
			SD	0.1328	0.1392	0.1692	0.1676
			Min	0.75	0.79	0.68	0.56
			Q1	0.980	1.000	0.900	0.880
			Median	1.090	1.110	1.040	0.985
			Q3	1.170	1.170	1.140	1.100
			Max	1.43	1.41	1.43	1.37

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Total Activity (IU/mL)	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-0.013	-0.093	-0.072
			SD	-	0.1154	0.1558	0.1652
			Min	-	-0.32	-0.64	-0.42
			Q1	-	-0.090	-0.170	-0.190
			Median	-	-0.010	-0.110	-0.080
			Q3	-	0.065	-0.020	0.030
			Max	-	0.25	0.35	0.39
		Placebo	n	-	78	79	74
			Mean	-	0.023	-0.051	-0.079
			SD	-	0.0993	0.1393	0.1268
			Min	-	-0.22	-0.41	-0.39
			Q1	-	-0.040	-0.160	-0.160
			Median	-	0.020	-0.050	-0.070
			Q3	-	0.090	0.060	0.020
			Max	-	0.25	0.21	0.19
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-1.19	-8.59	-6.87
			SD	-	11.590	14.182	15.382
			Min	-	-35.7	-41.6	-34.4
			Q1	-	-7.86	-15.45	-19.00
			Median	-	-1.04	-9.88	-8.43
			Q3	-	6.25	-1.94	3.23
			Max	-	27.8	33.7	36.9
		Placebo	n	-	78	79	74
			Mean	-	2.51	-4.36	-7.16
			SD	-	9.312	13.105	11.917
			Min	-	-17.7	-37.6	-34.1
			Q1	-	-3.70	-14.88	-14.61
			Median	-	2.01	-4.67	-6.84
			Q3	-	8.25	5.50	1.50
			Max	-	30.7	20.6	17.4

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S, Free (%)	Value	FSN-013	n	81	80	81	77
			Mean	91.7	93.6	92.6	91.4
			SD	17.14	16.60	16.54	16.95
			Min	38	55	53	52
			Q1	80.0	81.5	82.0	79.0
			Median	93.0	92.0	93.0	94.0
			Q3	102.0	106.0	100.0	102.0
			Max	134	134	134	141
		Placebo	n	79	78	79	74
			Mean	93.2	91.9	91.9	95.6
			SD	15.79	16.65	17.88	16.28
			Min	47	37	29	45
			Q1	83.0	81.0	81.0	88.0
			Median	92.0	90.5	90.0	92.5
			Q3	102.0	100.0	99.0	106.0
			Max	138	132	144	144
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	1.7	1.0	0.3
			SD	-	8.11	8.60	10.13
			Min	-	-20	-22	-26
			Q1	-	-2.0	-3.0	-6.0
			Median	-	2.0	2.0	1.0
			Q3	-	6.5	7.0	5.0
			Max	-	26	18	40
		Placebo	n	-	78	79	74
			Mean	-	-1.3	-1.3	2.3
			SD	-	7.85	8.85	9.03
			Min	-	-15	-26	-19
			Q1	-	-7.0	-9.0	-4.0
			Median	-	-3.0	-1.0	1.0
			Q3	-	2.0	5.0	9.0
			Max	-	25	20	23

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S, Free (%)	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	2.65	1.79	1.12
			SD	-	11.183	10.180	13.241
			Min	-	-23.8	-22.3	-25.7
			Q1	-	-2.35	-4.90	-6.82
			Median	-	1.95	1.67	0.82
			Q3	-	7.35	7.53	6.02
			Max	-	68.4	47.4	65.8
		Placebo	n	-	78	79	74
			Mean	-	-1.33	-1.47	2.91
			SD	-	8.531	10.144	10.036
			Min	-	-21.3	-38.3	-23.5
			Q1	-	-7.77	-8.04	-4.26
			Median	-	-2.77	-1.15	1.33
			Q3	-	2.53	5.26	9.90
			Max	-	28.4	21.5	26.4
Protein S (IU/mL)	Value	FSN-013	n	81	80	81	77
			Mean	0.952	0.931	0.923	0.924
			SD	0.1420	0.1529	0.1664	0.1777
			Min	0.67	0.65	0.60	0.55
			Q1	0.870	0.810	0.800	0.790
			Median	0.940	0.930	0.900	0.890
			Q3	1.050	1.040	1.040	1.030
			Max	1.35	1.34	1.28	1.46
		Placebo	n	79	78	79	74
			Mean	1.006	0.987	0.972	0.964
			SD	0.1405	0.1411	0.1379	0.1568
			Min	0.76	0.69	0.71	0.67
			Q1	0.900	0.880	0.860	0.850
			Median	0.980	0.985	0.930	0.955
			Q3	1.100	1.080	1.090	1.070
			Max	1.50	1.26	1.24	1.48

表 2.7.4-147 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S (IU/mL)	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-0 024	-0 029	-0 029
			SD	-	0 1001	0 1274	0 1296
			Min	-	-0 28	-0 33	-0 35
			Q1	-	-0 105	-0 110	-0 100
			Median	-	-0 025	-0 030	-0 020
			Q3	-	0 030	0 040	0 040
			Max	-	0 36	0 42	0 36
		Placebo	n	-	78	79	74
			Mean	-	-0 020	-0 034	-0 045
			SD	-	0 0961	0 1042	0 1147
			Min	-	-0 27	-0 32	-0 28
			Q1	-	-0 070	-0 080	-0 140
			Median	-	-0 020	-0 030	-0 020
			Q3	-	0 040	0 040	0 040
			Max	-	0 19	0 18	0 18
	Percent Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	-2 24	-2 69	-2 94
			SD	-	10 681	13 751	12 877
			Min	-	-25 0	-29 6	-31 3
			Q1	-	-10 83	-12 16	-11 11
			Median	-	-2 40	-3 19	-2 63
			Q3	-	3 97	3 53	5 00
			Max	-	45 0	52 5	36 0
		Placebo	n	-	78	79	74
			Mean	-	-1 65	-2 88	-4 16
			SD	-	9 484	9 934	11 343
			Min	-	-24 5	-29 1	-26 8
			Q1	-	-7 95	-7 87	-13 79
			Median	-	-2 04	-2 68	-1 84
			Q3	-	3 53	3 70	5 26
			Max	-	22 6	19 4	19 1

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-24 を引用

表 2.7.4-148 血液凝固系検査（SHBG）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period	Extension Period
				Visit 3	Visit 8 / Discontinuation	Visit 17 / Discontinuation
Sex Hormone Binding Globulin (nmol/L)	Value	FSN-013	n	81	81	1
			Mean	156.32	235.02	358.90
			SD	62.179	93.772	-
			Min	31.0	34.6	358.9
			Q1	111.30	168.50	358.90
			Median	159.30	226.00	358.90
			Q3	191.90	323.80	358.90
			Max	298.4	393.2	358.9
		Placebo	n	79	79	1
			Mean	150.61	148.40	148.50
			SD	59.465	63.416	-
			Min	37.4	34.5	148.5
			Q1	110.50	102.50	148.50
			Median	143.40	139.40	148.50
			Q3	190.50	179.70	148.50
			Max	292.9	363.9	148.5
	Change from Baseline	FSN-013	n	-	81	1
			Mean	-	78.70	180.20
			SD	-	76.035	-
			Min	-	-161.6	180.2
			Q1	-	29.50	180.20
			Median	-	83.60	180.20
			Q3	-	134.50	180.20
			Max	-	210.2	180.2
		Placebo	n	-	79	1
			Mean	-	-2.20	-35.00
			SD	-	46.598	-
			Min	-	-127.3	-35.0
			Q1	-	-31.50	-35.00
			Median	-	-7.90	-35.00
			Q3	-	25.30	-35.00
			Max	-	151.3	-35.0

表 2.7.4-148 血液凝固系検査（SHBG）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period	Extension Period
				Visit 3	Visit 8 / Discontinuation	Visit 17 / Discontinuation
Sex Hormone Binding Globulin (nmol/L)	Percent Change from Baseline	FSN-013	n	-	81	1
			Mean	-	59.82	100.84
			SD	-	56.129	-
			Min	-	-59.2	100.8
			Q1	-	16.84	100.84
			Median	-	63.03	100.84
			Q3	-	94.58	100.84
			Max	-	210.1	100.8
		Placebo	n	-	79	1
			Mean	-	2.60	-19.07
			SD	-	31.856	-
			Min	-	-45.8	-19.1
			Q1	-	-21.02	-19.07
			Median	-	-7.80	-19.07
			Q3	-	22.54	-19.07
			Max	-	122.0	-19.1

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.

Visit 17 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-25 を引用

表 2.7.4-149 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Thrombin Antithrombin Complex (ng/mL)	Value	FSN-013	n	81	80	79	81	77	77
			Mean	1.30	1.24	1.84	2.56	1.05	1.53
			SD	0.868	0.644	6.929	12.179	0.177	2.174
			Min	1.0	1.0	1.0	1.0	1.0	1.0
			Q1	1.00	1.00	1.00	1.00	1.00	1.00
			Median	1.00	1.00	1.00	1.00	1.00	1.00
			Q3	1.20	1.10	1.00	1.00	1.00	1.00
			Max	7.1	4.8	62.6	110.3	2.2	18.0
		Placebo	n	79	78	76	79	74	74
			Mean	1.17	1.57	1.15	1.60	1.08	3.06
			SD	0.403	3.077	0.418	3.852	0.277	11.324
			Min	1.0	1.0	1.0	1.0	1.0	1.0
			Q1	1.00	1.00	1.00	1.00	1.00	1.00
			Median	1.00	1.00	1.00	1.00	1.00	1.00
			Q3	1.20	1.10	1.00	1.20	1.00	1.20
			Max	3.5	24.8	3.0	35.2	2.7	92.3
	Change from Baseline	FSN-013	n	-	80	79	81	77	77
			Mean	-	-0.07	0.53	1.25	-0.26	0.22
			SD	-	0.952	7.009	12.246	0.916	2.360
			Min	-	-6.1	-5.2	-6.1	-6.1	-6.1
			Q1	-	-0.10	-0.20	-0.20	-0.20	-0.20
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00
			Max	-	2.0	61.6	109.3	1.2	17.0
		Placebo	n	-	78	76	79	74	74
			Mean	-	0.40	-0.03	0.43	-0.09	1.89
			SD	-	3.069	0.468	3.875	0.470	11.361
			Min	-	-2.5	-1.7	-1.7	-2.5	-2.5
			Q1	-	0.00	-0.10	-0.10	-0.10	-0.10
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.10	0.00	0.10	0.00	0.00
			Max	-	23.4	1.7	34.1	1.7	91.3

表 2.7.4-149 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Thrombin Antithrombin Complex (ng/mL)	Percent Change from Baseline	FSN-013	n	-	80	79	81	77	77
			Mean	-	4 75	70 66	142 16	-7 52	36 22
			SD	-	41 034	694 612	1219 660	27 104	216 298
			Min	-	-85 9	-75 6	-85 9	-85 9	-85 9
			Q1	-	-9 09	-16 67	-13 04	-16 67	-16 67
			Median	-	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00
			Max	-	200 0	6160 0	10930 0	120 0	1700 0
		Placebo	n	-	78	76	79	74	74
			Mean	-	33 04	1 73	44 90	-2 71	194 84
			SD	-	217 534	33 235	350 801	29 316	1134 151
			Min	-	-71 4	-63 0	-63 0	-71 4	-71 4
			Q1	-	0 00	-9 09	-9 09	-9 09	-9 09
			Median	-	0 00	0 00	0 00	0 00	0 00
			Q3	-	7 69	0 00	10 00	0 00	0 00
			Max	-	1671 4	170 0	3100 0	170 0	9130 0
D-Dimer (ug/mL)	Value	FSN-013	n	81	80	79	81	77	77
			Mean	0 352	0 359	0 344	0 364	0 363	0 353
			SD	0 1189	0 1461	0 0951	0 1328	0 1446	0 1334
			Min	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300
			Q3	0 350	0 325	0 320	0 360	0 350	0 320
			Max	1 11	1 17	0 74	0 89	1 04	1 14
		Placebo	n	79	78	76	79	74	74
			Mean	0 347	0 375	0 390	0 372	0 368	0 414
			SD	0 1241	0 1168	0 1607	0 1166	0 1430	0 2562
			Min	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300
			Q3	0 340	0 440	0 405	0 450	0 360	0 390
			Max	1 07	0 73	1 03	0 80	1 01	1 77

表 2.7.4-149 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
D-Dimer (ug/mL)	Change from Baseline	FSN-013	n	-	80	79	81	77	77
			Mean	-	0.006	-0.006	0.012	0.012	0.002
			SD	-	0.1436	0.1200	0.1525	0.1639	0.1649
			Min	-	-0.81	-0.81	-0.81	-0.81	-0.81
			Q1	-	0.000	-0.010	0.000	0.000	0.000
			Median	-	0.000	0.000	0.000	0.000	0.000
			Q3	-	0.000	0.000	0.020	0.000	0.000
			Max	-	0.49	0.25	0.59	0.51	0.84
		Placebo	n	-	78	76	79	74	74
			Mean	-	0.027	0.043	0.025	0.019	0.065
			SD	-	0.1379	0.1431	0.1337	0.1472	0.2070
			Min	-	-0.55	-0.24	-0.63	-0.63	-0.23
			Q1	-	0.000	0.000	0.000	0.000	0.000
			Median	-	0.000	0.000	0.000	0.000	0.000
			Q3	-	0.030	0.050	0.080	0.020	0.020
			Max	-	0.40	0.57	0.40	0.71	0.84
	Percent Change from Baseline	FSN-013	n	-	80	79	81	77	77
			Mean	-	3.81	1.53	7.29	7.24	5.19
			SD	-	27.925	22.359	37.165	40.671	43.801
			Min	-	-73.0	-73.0	-73.0	-73.0	-73.0
			Q1	-	0.00	-2.56	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	6.25	0.00	0.00
			Max	-	146.7	76.7	196.7	170.0	280.0
		Placebo	n	-	78	76	79	74	74
			Mean	-	12.43	15.50	11.46	8.92	18.81
			SD	-	36.826	42.544	33.407	39.304	55.203
			Min	-	-59.1	-38.7	-67.7	-67.7	-37.1
			Q1	-	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	10.00	16.67	25.00	5.26	5.88
			Max	-	133.3	190.0	133.3	236.7	260.0

表 2.7.4-149 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Soluble Fibrin Monomer Complex (ug/mL)	Value	FSN-013	n	81	80	79	81	77	77
			Mean	5.32	5.69	6.85	6.03	5.05	6.49
			SD	1.895	5.033	16.426	7.307	0.255	7.413
			Min	5.0	5.0	5.0	5.0	5.0	5.0
			Q1	5.00	5.00	5.00	5.00	5.00	5.00
			Median	5.00	5.00	5.00	5.00	5.00	5.00
			Q3	5.00	5.00	5.00	5.00	5.00	5.00
			Max	18.7	48.7	151.0	68.8	7.0	48.6
		Placebo	n	79	78	76	79	74	74
			Mean	5.07	6.13	5.07	6.45	5.02	6.73
			SD	0.420	7.338	0.406	12.211	0.127	11.626
			Min	5.0	5.0	5.0	5.0	5.0	5.0
			Q1	5.00	5.00	5.00	5.00	5.00	5.00
			Median	5.00	5.00	5.00	5.00	5.00	5.00
			Q3	5.00	5.00	5.00	5.00	5.00	5.00
			Max	7.8	62.1	8.1	113.5	5.9	103.7
	Change from Baseline	FSN-013	n	-	80	79	81	77	77
			Mean	-	0.37	1.53	0.71	-0.28	1.15
			SD	-	4.245	16.574	7.592	1.967	7.071
			Min	-	-13.7	-13.7	-13.7	-13.7	-13.7
			Q1	-	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00
			Max	-	33.4	146.0	63.8	2.0	43.6
		Placebo	n	-	78	76	79	74	74
			Mean	-	1.06	0.00	1.38	-0.05	1.66
			SD	-	7.361	0.495	12.223	0.372	11.645
			Min	-	-2.8	-2.8	-2.8	-2.5	-2.8
			Q1	-	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00
			Max	-	57.1	3.1	108.5	0.5	98.7

表 2.7.4-149 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Soluble Fibrin Monomer Complex (ug/mL)	Percent Change from Baseline	FSN-013	n	-	80	79	81	77	77
			Mean	-	4.42	34.96	18.53	-1.17	21.26
			SD	-	36.251	328.948	146.850	12.668	126.799
			Min	-	-73.3	-73.3	-73.3	-73.3	-73.3
			Q1	-	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00
			Max	-	228.0	2920.0	1276.0	40.0	872.0
		Placebo	n	-	78	76	79	74	74
			Mean	-	21.73	0.34	27.95	-0.61	33.61
			SD	-	147.011	8.454	244.371	5.047	232.733
			Min	-	-35.9	-35.9	-35.9	-33.3	-35.9
			Q1	-	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00
			Max	-	1142.0	62.0	2170.0	10.0	1974.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-26 を引用

表 2.7.4-150 血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	FSN-013		Placebo	
	N = 81		N = 79	
	Above Upper Limit n (%)	Below Lower Limit n (%)	Above Upper Limit n (%)	Below Lower Limit n (%)
Prothrombin Time (sec)	8 (9.9)	0 (0.0)	11 (13.9)	0 (0.0)
Prothrombin Control (sec)	-	-	-	-
Prothrombin Activity (%)	57 (70.4)	0 (0.0)	57 (72.2)	0 (0.0)
Prothrombin Intl. Normalized Ratio	0 (0.0)	1 (1.2)	1 (1.3)	1 (1.3)
Activated Partial Thromboplastin Time (sec)	8 (9.9)	0 (0.0)	9 (11.4)	3 (3.8)
Activated Partial Thromboplastin Control (sec)	-	-	-	-
Fibrinogen (mg/dL)	2 (2.5)	1 (1.2)	0 (0.0)	0 (0.0)
Antithrombin Activity (%)	12 (14.8)	0 (0.0)	12 (15.2)	0 (0.0)
Plasminogen (%)	9 (11.1)	3 (3.7)	5 (6.3)	4 (5.1)
Thrombin Antithrombin Complex (ng/mL)	10 (12.3)	-	8 (10.1)	-
Factor XIV Activity (%)	9 (11.1)	0 (0.0)	9 (11.4)	0 (0.0)
D-Dimer (ug/mL)	3 (3.7)	-	5 (6.3)	-
Soluble Fibrin Monomer Complex (ug/mL)	10 (12.3)	-	9 (11.4)	-
Protein S Activity Actual/Control	19 (23.5)	5 (6.2)	28 (35.4)	3 (3.8)
Protein S Total Activity (IU/mL)	8 (9.9)	17 (21.0)	7 (8.9)	4 (5.1)
Protein S, Free (%)	2 (2.5)	2 (2.5)	5 (6.3)	1 (1.3)
Protein S (IU/mL)	6 (7.4)	13 (16.0)	2 (2.5)	7 (8.9)
Sex Hormone Binding Globulin (nmol/L)	-	-	-	-

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-33 を引用

2.7.4.3.1.3.1.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、血液凝固系検査の測定値、ベースラインからの変化量及び変化率を表 2.7.4-151～表 2.7.4-153 に、血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度を表 2.7.4-154 に示す。

トロンビン・アンチトロンビン III 複合体、可溶性フィブリンモノマー複合体、プロテイン C、プロテイン S 及び D-ダイマーに関する投与前後の平均変化量に特記すべき異常変動はみられなかった。また、D-ダイマーの基準値上限を逸脱した被験者の割合は、FSN-013 群では 4.9%（4/81 例）、プラセボ群では 10.8%（8/74 例）であった。その他のいずれの項目も経時的推移は FSN-013 群及びプラセボ群で特記すべき異常変動はなく、FSN-013 群（52 週投与）の基準値上限超、基準値下限未満の頻度は、FSN-013 群（24 週投与、表 2.7.4-150）と比べて大差は認められなかった。

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Time (sec)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	11.27	11.30	11.33	11.38	11.21	11.34	11.21	11.12
			SD	0.802	0.665	0.679	0.718	0.613	0.711	0.759	0.603
			Min	9.7	9.7	9.6	9.5	9.8	10.1	9.7	9.8
			Q1	10.70	10.80	10.90	10.80	10.80	10.80	10.60	10.80
			Median	11.20	11.30	11.30	11.30	11.20	11.20	11.20	11.10
			Q3	11.70	11.70	11.80	11.90	11.70	11.80	11.60	11.60
			Max	13.6	12.8	13.1	13.1	12.6	14.2	13.4	12.4
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	11.23	11.44	11.46	11.35	11.35	11.38	11.11	11.03
			SD	0.789	0.714	0.654	0.741	0.705	0.638	0.790	0.718
			Min	9.3	10.2	9.9	9.4	9.4	10.3	9.9	9.7
			Q1	10.60	10.90	11.00	11.00	10.80	10.90	10.50	10.60
			Median	11.20	11.40	11.40	11.30	11.30	11.30	11.00	11.00
			Q3	11.70	11.90	12.00	11.80	11.90	11.70	11.60	11.40
			Max	13.4	13.2	13.2	13.7	12.8	13.3	14.2	13.2
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.01	0.06	0.07	-0.07	0.06	-0.09	-0.15
			SD	-	0.640	0.633	0.670	0.736	0.682	0.766	0.677
			Min	-	-1.6	-1.3	-1.6	-1.9	-2.0	-2.0	-1.9
			Q1	-	-0.40	-0.30	-0.40	-0.50	-0.30	-0.40	-0.50
			Median	-	0.05	0.00	0.20	0.00	0.10	-0.10	-0.10
			Q3	-	0.50	0.50	0.50	0.50	0.50	0.40	0.30
			Max	-	1.7	1.8	1.3	1.3	2.6	2.4	1.4
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0.22	0.23	0.14	0.15	0.19	-0.10	-0.18
			SD	-	0.737	0.724	0.712	0.765	0.670	0.693	0.631
			Min	-	-2.1	-1.8	-1.5	-1.9	-2.0	-1.9	-1.9
			Q1	-	-0.20	-0.20	-0.30	-0.30	-0.20	-0.60	-0.50
			Median	-	0.25	0.20	0.10	0.10	0.20	-0.10	-0.20
			Q3	-	0.70	0.80	0.70	0.60	0.70	0.20	0.20
			Max	-	2.0	1.7	1.5	2.0	2.5	1.9	1.1

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Time (sec)	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.31	0.72	0.88	-0.32	0.74	-0.59	-1.04
			SD	-	5.666	5.649	5.873	6.321	5.955	6.790	5.922
			Min	-	-13.2	-11.3	-12.4	-14.7	-15.5	-15.7	-15.7
			Q1	-	-3.64	-2.80	-3.28	-4.42	-2.80	-3.64	-4.31
			Median	-	0.45	0.00	1.64	0.00	0.86	-0.93	-0.95
			Q3	-	4.22	4.50	4.76	4.63	4.59	3.33	2.83
			Max	-	16.8	17.8	12.7	12.0	22.4	22.2	13.9
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	2.26	2.37	1.53	1.64	1.99	-0.72	-1.43
			SD	-	6.528	6.498	6.494	6.905	6.171	6.181	5.488
			Min	-	-16.4	-14.1	-13.8	-14.8	-15.6	-14.8	-14.8
			Q1	-	-1.61	-1.82	-2.63	-2.29	-1.82	-5.22	-4.55
			Median	-	2.25	1.80	0.90	0.89	1.80	-0.90	-1.72
			Q3	-	5.94	7.55	6.60	5.66	6.09	1.94	2.02
			Max	-	21.5	18.3	16.1	19.4	26.9	20.4	10.8
Prothrombin Control (sec)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			SD	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5
			Q1	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			Median	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			Q3	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			Max	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			SD	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5
			Q1	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			Median	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			Q3	11.50	11.50	11.50	11.50	11.50	11.50	11.50	11.50
			Max	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Control (sec)	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Activity (%)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	96.5	97.0	97.1	96.7	98.0	96.9	96.3	96.5
			SD	6.25	5.30	5.46	5.78	4.60	6.13	6.02	4.90
			Min	75	81	78	81	87	72	75	83
			Q1	94.0	94.0	94.0	92.0	95.0	93.0	93.0	93.0
			Median	100.0	99.5	100.0	100.0	101.0	101.0	99.0	98.0
			Q3	101.0	101.0	101.0	101.0	101.0	101.0	101.0	101.0
			Max	101	101	101	101	101	101	101	101
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	96.9	95.8	96.4	97.1	96.6	97.2	97.0	96.8
			SD	5.77	6.37	5.82	5.80	5.64	5.98	6.34	5.74
			Min	78	77	80	76	81	76	70	76
			Q1	94.0	92.0	92.0	94.0	92.0	96.0	95.0	94.0
			Median	101.0	98.0	99.0	100.0	100.0	101.0	101.0	99.0
			Q3	101.0	101.0	101.0	101.0	101.0	101.0	101.0	101.0
			Max	101	101	101	101	101	101	101	101
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.6	0.6	0.4	1.6	0.5	0.0	0.2
			SD	-	4.94	5.20	5.73	5.94	6.03	6.05	4.97
			Min	-	-11	-16	-12	-13	-23	-21	-11
			Q1	-	-2.5	-1.0	-2.0	-1.0	-1.0	-1.0	-2.0
			Median	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
			Q3	-	2.0	2.0	2.0	3.0	3.0	1.0	1.0
			Max	-	12	14	18	21	19	18	12
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-1.1	-0.5	0.1	-0.4	0.1	0.0	-0.2
			SD	-	6.41	6.46	5.81	6.17	5.29	5.48	5.32
			Min	-	-16	-16	-14	-16	-18	-13	-13
			Q1	-	-5.0	-4.0	-3.0	-3.0	-3.0	-1.0	-3.0
			Median	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
			Q3	-	1.0	3.0	3.0	2.0	3.0	1.0	0.0
			Max	-	18	18	15	18	18	18	16

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Activity (%)	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.78	0.87	0.67	1.99	0.77	0.24	0.40
			SD	-	5.474	5.714	6.394	6.819	6.612	6.650	5.541
			Min	-	-10.9	-16.2	-12.8	-12.9	-24.2	-20.8	-11.1
			Q1	-	-2.60	-0.99	-2.15	-0.99	-0.99	-1.16	-2.20
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	2.19	2.27	2.02	3.16	3.45	1.19	1.09
			Max	-	13.8	17.1	22.5	26.3	23.8	24.0	13.8
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-0.97	-0.26	0.26	-0.19	0.21	0.17	-0.01
			SD	-	6.979	6.947	6.238	6.675	5.770	6.158	5.891
			Min	-	-16.3	-16.0	-13.9	-15.8	-19.1	-13.8	-14.6
			Q1	-	-4.95	-4.08	-2.97	-2.97	-2.97	-0.99	-2.97
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	1.03	3.06	3.57	2.06	3.09	1.00	0.00
			Max	-	21.7	21.7	18.1	21.7	21.7	21.7	19.3
Prothrombin Intl. Normalized Ratio	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	0.981	0.983	0.985	0.990	0.975	0.987	0.995	0.997
			SD	0.0680	0.0566	0.0575	0.0618	0.0523	0.0601	0.0621	0.0511
			Min	0.85	0.85	0.84	0.83	0.85	0.88	0.88	0.89
			Q1	0.930	0.940	0.950	0.940	0.940	0.940	0.950	0.960
			Median	0.970	0.980	0.980	0.980	0.970	0.970	1.000	1.000
			Q3	1.020	1.020	1.030	1.030	1.020	1.030	1.040	1.030
			Max	1.17	1.11	1.14	1.14	1.09	1.23	1.16	1.11
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	0.977	0.995	0.996	0.988	0.987	0.990	0.987	0.989
			SD	0.0662	0.0607	0.0570	0.0633	0.0605	0.0542	0.0687	0.0634
			Min	0.82	0.89	0.86	0.82	0.82	0.90	0.87	0.87
			Q1	0.920	0.950	0.960	0.960	0.940	0.950	0.940	0.960
			Median	0.970	0.990	0.990	0.980	0.980	0.980	0.970	0.980
			Q3	1.020	1.030	1.040	1.030	1.030	1.020	1.030	1.030
			Max	1.16	1.15	1.15	1.19	1.11	1.15	1.27	1.18

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Intl. Normalized Ratio	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.001	0.004	0.006	-0.007	0.005	0.012	0.016
			SD	-	0.0544	0.0530	0.0564	0.0620	0.0573	0.0640	0.0558
			Min	-	-0.13	-0.11	-0.14	-0.16	-0.17	-0.13	-0.13
			Q1	-	-0.035	-0.030	-0.040	-0.050	-0.030	-0.030	-0.020
			Median	-	0.000	0.000	0.010	0.000	0.010	0.010	0.020
			Q3	-	0.040	0.040	0.050	0.040	0.040	0.050	0.050
			Max	-	0.15	0.15	0.11	0.11	0.22	0.21	0.15
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0.018	0.019	0.012	0.012	0.016	0.011	0.013
			SD	-	0.0621	0.0619	0.0607	0.0650	0.0565	0.0618	0.0564
			Min	-	-0.18	-0.15	-0.13	-0.16	-0.17	-0.16	-0.13
			Q1	-	-0.020	-0.020	-0.030	-0.020	-0.020	-0.020	-0.020
			Median	-	0.020	0.020	0.005	0.010	0.020	0.020	0.020
			Q3	-	0.060	0.070	0.060	0.050	0.050	0.040	0.050
			Max	-	0.16	0.14	0.13	0.17	0.21	0.19	0.13
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.28	0.65	0.81	-0.44	0.68	1.46	1.91
			SD	-	5.553	5.436	5.690	6.118	5.757	6.621	5.750
			Min	-	-12.4	-11.0	-12.5	-14.3	-15.2	-12.0	-12.4
			Q1	-	-3.71	-2.94	-3.67	-4.90	-3.09	-2.83	-1.83
			Median	-	0.00	0.00	1.03	0.00	0.94	1.03	2.06
			Q3	-	3.94	4.30	4.81	4.30	4.35	5.21	5.10
			Max	-	17.0	17.0	12.4	11.7	21.8	22.3	17.0
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	2.13	2.21	1.48	1.49	1.90	1.33	1.49
			SD	-	6.290	6.376	6.346	6.728	5.951	6.305	5.746
			Min	-	-16.2	-13.5	-13.7	-14.4	-15.3	-14.4	-11.7
			Q1	-	-1.85	-2.02	-2.83	-2.06	-2.02	-1.96	-2.00
			Median	-	2.11	1.94	0.52	0.98	1.94	1.90	1.98
			Q3	-	5.83	7.07	6.52	5.43	5.75	4.35	5.43
			Max	-	19.5	17.1	14.6	18.7	25.6	23.2	13.7

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Activated Partial Thromboplastin Time (sec)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	32.86	31.31	31.19	31.31	31.03	31.04	30.04	30.78
			SD	5.464	2.751	2.688	2.834	2.882	2.750	2.623	2.636
			Min	25.5	26.7	25.5	25.1	23.6	25.5	23.4	24.5
			Q1	30.70	29.45	29.50	29.40	29.20	29.10	28.40	29.30
			Median	32.40	30.70	30.80	30.90	30.90	30.50	29.70	30.60
			Q3	34.20	33.00	32.60	32.30	32.70	32.70	31.50	32.20
			Max	74.6	39.8	38.8	41.7	38.9	38.5	37.0	37.2
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	32.63	32.44	32.03	30.73	30.61	30.71	29.62	30.34
			SD	3.808	3.098	3.014	2.898	2.852	2.704	2.460	2.583
			Min	25.1	25.6	25.5	23.9	24.8	26.1	23.5	23.4
			Q1	30.60	30.10	30.00	28.90	28.80	28.70	27.90	28.40
			Median	32.10	32.15	31.90	30.65	30.50	30.30	29.20	30.10
			Q3	34.20	34.60	33.70	32.30	32.20	31.70	31.20	32.10
			Max	52.9	43.3	40.9	38.7	41.3	41.8	37.2	37.5
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-1.60	-1.66	-1.65	-1.88	-1.88	-2.91	-2.16
			SD	-	5.130	5.280	5.447	5.320	5.317	5.109	5.145
			Min	-	-45.2	-46.4	-45.7	-45.0	-44.5	-44.6	-45.1
			Q1	-	-2.20	-2.20	-2.30	-2.10	-2.70	-3.70	-3.00
			Median	-	-1.05	-1.40	-1.10	-1.30	-1.60	-2.40	-1.40
			Q3	-	-0.10	-0.10	0.10	-0.10	0.00	-1.50	-0.40
			Max	-	1.9	2.7	4.3	1.9	3.2	1.9	2.6
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-0.21	-0.60	-1.96	-2.07	-2.06	-3.08	-2.31
			SD	-	2.843	3.216	3.395	3.244	3.599	3.208	3.088
			Min	-	-18.2	-23.4	-23.7	-24.4	-26.3	-26.4	-24.3
			Q1	-	-1.40	-1.60	-2.80	-3.00	-3.40	-3.80	-2.70
			Median	-	-0.15	-0.30	-1.35	-1.80	-1.90	-2.90	-1.90
			Q3	-	1.20	0.80	-0.30	-0.60	-0.20	-1.90	-1.40
			Max	-	6.7	4.8	2.7	3.0	3.0	1.7	2.5

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Activated Partial Thromboplastin Time (sec)	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-3.85	-4.00	-3.88	-4.68	-4.60	-7.84	-5.54
			SD	-	7.707	8.154	8.871	8.295	8.559	7.849	7.871
			Min	-	-60.6	-62.2	-61.3	-60.3	-59.7	-59.8	-60.5
			Q1	-	-6.77	-7.17	-7.17	-6.75	-7.65	-11.17	-9.12
			Median	-	-3.11	-4.18	-3.75	-3.99	-4.86	-7.65	-4.24
			Q3	-	-0.30	-0.31	0.31	-0.33	0.00	-4.57	-1.23
			Max	-	5.2	8.8	15.1	6.8	9.1	5.4	8.5
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-0.18	-1.32	-5.45	-5.79	-5.65	-8.86	-6.54
			SD	-	7.300	7.434	7.954	7.272	8.098	6.778	6.856
			Min	-	-34.4	-44.2	-44.8	-46.1	-49.7	-49.9	-45.9
			Q1	-	-4.14	-4.68	-8.54	-9.25	-10.14	-11.40	-8.12
			Median	-	-0.51	-0.88	-4.14	-5.71	-5.38	-8.33	-5.88
			Q3	-	4.06	2.50	-0.89	-1.91	-0.66	-6.37	-4.14
			Max	-	25.0	13.4	9.8	11.7	11.7	6.6	9.8
Activated Partial Thromboplastin Control (sec)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			SD	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7
			Q1	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			Median	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			Q3	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			Max	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			SD	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
			Min	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7
			Q1	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			Median	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			Q3	28.70	28.70	28.70	28.70	28.70	28.70	28.70	28.70
			Max	28.7	28.7	28.7	28.7	28.7	28.7	28.7	28.7

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Activated Partial Thromboplastin Control (sec)	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Fibrinogen (mg/dL)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	251.6	262.5	275.4	273.2	274.1	286.7	279.1	253.3
			SD	46.37	39.64	48.79	54.05	46.42	53.38	46.79	38.81
			Min	173	185	182	126	170	195	203	180
			Q1	221.0	233.5	237.0	229.0	239.0	252.0	249.0	229.0
			Median	244.0	256.0	274.0	271.0	274.0	282.0	274.0	247.0
			Q3	272.0	290.5	305.0	311.0	303.0	313.0	303.0	274.0
			Max	403	353	432	421	451	519	489	358
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	264.3	269.2	276.4	288.2	286.2	293.0	290.7	268.2
			SD	36.33	40.48	47.43	41.15	39.80	38.26	44.04	45.18
			Min	168	187	197	214	207	229	195	193
			Q1	238.0	245.0	243.0	261.0	256.0	263.0	261.0	239.0
			Median	261.0	262.0	268.0	284.0	282.0	294.0	285.0	259.0
			Q3	293.0	286.0	295.0	318.0	309.0	318.0	323.0	285.0
			Max	364	375	409	405	400	405	410	421
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	10.2	23.7	21.7	22.4	35.1	27.5	1.2
			SD	-	38.81	47.00	52.57	46.18	46.19	38.92	40.23
			Min	-	-124	-97	-106	-92	-76	-56	-118
			Q1	-	-8.0	0.0	-8.0	-4.0	8.0	0.0	-17.0
			Median	-	11.0	17.0	22.0	24.0	33.0	32.0	-1.0
			Q3	-	37.5	44.0	50.0	40.0	53.0	47.0	24.0
			Max	-	86	189	206	236	268	147	93
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	4.8	12.1	22.6	22.1	28.1	24.9	3.8
			SD	-	37.36	44.65	37.52	36.62	36.93	42.90	45.31
			Min	-	-86	-106	-98	-64	-78	-87	-94
			Q1	-	-22.0	-18.0	-8.0	-3.0	9.0	-2.0	-25.0
			Median	-	5.5	11.0	22.5	21.0	34.0	19.0	0.0
			Q3	-	30.0	42.0	46.0	46.0	52.0	52.0	29.0
			Max	-	83	109	107	149	112	121	180

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Fibrinogen (mg/dL)	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	5.52	11.06	10.15	10.61	15.29	12.49	2.10
			SD	-	14.759	20.057	21.465	19.088	18.625	17.019	15.769
			Min	-	-33.6	-24.9	-32.3	-22.8	-19.5	-19.1	-30.6
			Q1	-	-3.27	0.00	-2.83	-1.41	3.88	0.00	-7.36
			Median	-	4.95	6.97	8.92	9.22	12.64	13.29	-0.41
			Q3	-	16.87	18.22	22.62	17.99	21.54	21.15	10.23
			Max	-	41.6	86.0	95.8	109.8	106.8	69.7	49.2
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	2.69	5.48	9.46	9.34	11.71	10.48	2.42
			SD	-	14.415	17.031	14.505	14.754	14.294	16.987	17.733
			Min	-	-26.3	-32.4	-30.0	-19.6	-24.9	-27.2	-30.0
			Q1	-	-8.73	-6.91	-2.96	-0.97	3.24	-0.70	-10.00
			Median	-	2.06	4.74	8.92	7.69	12.13	7.14	0.00
			Q3	-	13.43	14.71	18.43	16.73	20.75	20.48	11.84
			Max	-	47.0	63.7	42.3	61.8	51.2	55.4	74.7
Antithrombin Activity (%)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	112.4	107.9	107.6	107.8	109.6	111.2	109.7	107.3
			SD	11.17	10.68	11.30	10.88	9.47	10.57	10.63	10.17
			Min	87	84	86	82	89	88	85	82
			Q1	105.0	101.5	99.0	102.0	102.0	104.0	102.0	99.0
			Median	112.0	107.0	106.0	108.0	111.0	111.0	110.0	108.0
			Q3	121.0	115.0	116.0	116.0	116.0	117.0	116.0	114.0
			Max	138	132	140	128	127	141	138	133
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	113.9	110.8	111.0	110.3	108.9	111.7	109.8	108.9
			SD	11.17	11.07	10.31	10.33	10.56	9.49	11.33	10.31
			Min	86	90	89	86	85	92	83	82
			Q1	107.0	103.0	105.0	103.0	102.0	105.0	103.0	101.0
			Median	114.0	110.0	110.0	111.0	109.0	111.0	110.0	108.0
			Q3	120.0	117.0	117.0	116.0	115.0	116.0	117.0	116.0
			Max	140	144	148	143	138	138	136	137

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Antithrombin Activity (%)	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-4.6	-4.8	-4.4	-2.9	-1.3	-2.5	-4.9
			SD	-	8.88	9.70	9.32	8.78	8.13	10.42	9.43
			Min	-	-31	-30	-25	-18	-19	-31	-29
			Q1	-	-11.0	-12.0	-10.0	-11.0	-6.0	-10.0	-11.0
			Median	-	-5.5	-5.0	-3.0	-3.0	-1.0	-1.0	-4.0
			Q3	-	1.0	2.0	3.0	3.0	2.0	5.0	1.0
			Max	-	16	22	18	19	24	18	13
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-3.1	-2.9	-3.7	-4.6	-1.7	-4.0	-4.8
			SD	-	8.44	9.70	8.66	9.91	8.69	9.71	8.51
			Min	-	-26	-26	-22	-23	-20	-25	-23
			Q1	-	-8.0	-9.0	-11.0	-12.0	-8.0	-10.0	-11.0
			Median	-	-4.0	-2.0	-4.0	-6.0	-2.0	-5.0	-5.0
			Q3	-	2.0	2.0	3.0	3.0	4.0	2.0	2.0
			Max	-	17	22	20	30	21	19	16
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-3.72	-3.98	-3.57	-2.15	-0.86	-1.76	-4.00
			SD	-	7.912	8.560	8.219	7.850	7.416	9.309	8.257
			Min	-	-26.3	-23.3	-20.7	-15.2	-16.1	-23.7	-22.6
			Q1	-	-9.30	-9.82	-9.01	-8.94	-5.10	-8.93	-9.71
			Median	-	-4.90	-4.03	-2.70	-2.68	-0.85	-0.98	-3.31
			Q3	-	0.92	1.65	2.40	2.63	2.20	4.46	1.03
			Max	-	16.8	21.1	16.8	17.6	25.3	20.2	14.6
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-2.45	-2.15	-2.89	-3.59	-1.08	-3.14	-3.90
			SD	-	7.267	8.639	7.575	9.107	7.864	8.686	7.402
			Min	-	-22.0	-20.8	-16.7	-18.4	-16.4	-21.1	-20.4
			Q1	-	-7.20	-7.89	-8.94	-10.26	-6.67	-8.20	-8.80
			Median	-	-3.51	-1.69	-3.28	-4.69	-1.79	-4.07	-4.13
			Q3	-	1.87	1.60	2.68	2.50	3.81	1.87	1.85
			Max	-	13.4	23.7	21.5	32.3	22.6	20.4	14.7

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Plasminogen (%)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	97.3	106.4	109.6	108.5	108.5	108.2	107.3	95.6
			SD	14.01	14.97	15.47	16.41	16.18	16.32	15.92	12.61
			Min	50	55	51	52	54	48	56	45
			Q1	91.0	98.5	101.0	101.0	101.0	100.0	99.0	90.0
			Median	98.0	106.5	111.0	108.0	111.0	109.0	107.0	96.0
			Q3	106.0	115.0	120.0	118.0	117.0	118.0	116.0	103.0
			Max	123	138	139	138	141	148	141	126
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	98.1	97.8	97.9	107.0	106.9	107.1	106.6	96.1
			SD	15.18	14.99	14.79	15.39	16.77	15.30	16.60	13.79
			Min	57	53	50	60	53	53	59	51
			Q1	90.0	90.0	90.0	100.0	97.0	101.0	96.0	88.0
			Median	99.0	98.5	98.0	109.0	108.0	107.0	109.0	99.0
			Q3	107.0	104.0	105.0	118.0	118.0	118.0	118.0	105.0
			Max	135	135	128	133	145	135	137	119
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	9.0	12.3	11.3	11.1	10.7	10.1	-2.3
			SD	-	10.33	10.09	10.21	10.49	10.70	12.05	8.20
			Min	-	-12	-18	-16	-12	-14	-27	-25
			Q1	-	4.0	6.0	5.0	4.0	4.0	4.0	-7.0
			Median	-	7.5	11.0	13.0	11.0	8.0	11.0	-1.0
			Q3	-	14.0	18.0	17.0	16.0	17.0	18.0	2.0
			Max	-	39	37	39	42	39	42	24
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-0.2	-0.1	8.9	9.5	9.6	8.9	-1.8
			SD	-	7.94	7.84	8.28	9.45	8.98	9.53	8.01
			Min	-	-19	-16	-10	-11	-6	-17	-23
			Q1	-	-5.0	-6.0	3.0	2.0	3.0	2.0	-5.0
			Median	-	-1.0	0.0	10.0	8.0	9.0	9.0	-2.0
			Q3	-	5.0	5.0	15.0	14.0	14.0	13.0	3.0
			Max	-	20	23	27	40	46	36	15

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Plasminogen (%)	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	9 90	13 23	12 06	11 90	11 48	11 13	-1 96
			SD	-	11 204	10 927	10 793	11 366	11 544	12 507	8 272
			Min	-	-10 6	-15 9	-13 3	-10 0	-11 7	-22 5	-21 1
			Q1	-	3 41	6 36	5 61	3 95	3 77	3 25	-7 02
			Median	-	7 79	11 63	13 21	11 70	9 52	12 00	-1 16
			Q3	-	15 46	19 63	17 44	16 67	19 15	18 42	2 13
			Max	-	43 7	42 0	40 7	48 1	43 2	42 4	29 6
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0 14	0 20	9 62	10 12	10 25	9 48	-1 33
			SD	-	8 430	8 919	8 883	10 158	10 096	10 098	8 045
			Min	-	-15 4	-20 6	-9 8	-10 8	-7 0	-12 6	-18 6
			Q1	-	-5 88	-5 19	3 30	2 20	3 06	3 16	-4 85
			Median	-	-0 99	0 00	9 50	8 42	9 73	9 00	-2 13
			Q3	-	5 45	4 72	15 94	15 48	15 24	14 29	3 09
			Max	-	29 0	33 3	31 8	40 8	54 1	42 4	20 0
Factor XIV Activity (%)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	110 2	107 7	108 6	108 0	109 6	108 9	111 2	111 7
			SD	14 59	14 43	15 12	16 16	15 58	15 57	15 87	15 48
			Min	72	81	80	79	81	71	77	80
			Q1	101 0	95 5	99 0	95 0	98 0	98 0	99 0	102 0
			Median	110 0	108 0	108 0	105 0	107 0	107 0	109 0	111 0
			Q3	121 0	117 5	119 0	117 0	119 0	119 0	121 0	119 0
			Max	151	142	148	151	147	146	151	151
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	113 7	108 4	106 8	109 4	108 4	110 0	113 5	113 1
			SD	16 81	17 43	16 50	15 30	17 62	17 08	19 09	16 89
			Min	80	76	79	78	76	77	79	63
			Q1	102 0	95 0	95 0	98 0	95 0	98 0	98 0	101 0
			Median	112 0	107 0	103 0	108 0	105 0	106 0	110 0	110 0
			Q3	125 0	119 0	117 0	117 0	118 0	120 0	129 0	124 0
			Max	151	151	151	151	151	151	151	151

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Factor XIV Activity (%)	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-2.5	-1.6	-2.2	-0.7	-1.3	1.1	1.3
			SD	-	9.06	10.48	10.69	11.92	10.81	11.65	11.00
			Min	-	-20	-22	-28	-23	-28	-29	-37
			Q1	-	-8.0	-9.0	-8.0	-11.0	-9.0	-5.0	-6.0
			Median	-	-4.0	-2.0	-3.0	0.0	0.0	1.0	2.0
			Q3	-	3.0	6.0	5.0	6.0	6.0	7.0	9.0
			Max	-	28	21	20	29	22	27	27
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-5.3	-6.9	-4.4	-4.7	-3.0	-0.3	-0.7
			SD	-	9.90	10.53	10.75	11.18	13.05	12.68	13.09
			Min	-	-39	-33	-32	-30	-36	-26	-62
			Q1	-	-12.0	-15.0	-11.0	-11.0	-11.0	-6.0	-7.0
			Median	-	-5.5	-5.0	-3.5	-6.0	-4.0	-2.0	1.0
			Q3	-	0.0	0.0	3.0	2.0	3.0	6.0	7.0
			Max	-	21	21	17	23	50	36	33
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-1.95	-1.11	-1.66	-0.07	-0.79	1.41	1.64
			SD	-	8.245	9.576	9.941	11.053	9.901	10.522	9.922
			Min	-	-16.7	-19.1	-22.0	-17.8	-25.9	-22.5	-27.6
			Q1	-	-8.12	-7.02	-7.45	-9.63	-7.02	-4.44	-5.60
			Median	-	-3.36	-1.60	-2.33	0.00	0.00	0.91	1.94
			Q3	-	3.05	5.41	4.55	5.38	6.38	7.69	8.41
			Max	-	24.6	19.4	27.8	30.9	22.2	26.4	23.9
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-4.44	-5.70	-3.29	-3.84	-2.04	0.09	0.08
			SD	-	8.587	8.957	9.103	9.678	11.812	11.225	11.104
			Min	-	-31.7	-23.7	-25.2	-26.8	-24.1	-22.9	-49.6
			Q1	-	-10.19	-13.22	-9.80	-10.69	-8.80	-4.95	-5.04
			Median	-	-5.07	-4.72	-3.12	-4.76	-3.28	-1.85	0.75
			Q3	-	0.00	0.00	2.88	1.82	3.33	7.06	5.88
			Max	-	17.2	20.6	17.4	25.0	54.3	39.1	35.9

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S Activity Actual/Control	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	1.091	1.102	1.023	1.041	1.046	1.054	1.057	1.057
			SD	0.1283	0.1355	0.1245	0.1013	0.0916	0.0900	0.0866	0.0997
			Min	0.59	0.51	0.60	0.61	0.61	0.66	0.64	0.63
			Q1	1.010	1.045	0.930	0.980	1.000	0.990	1.000	1.010
			Median	1.100	1.105	1.030	1.040	1.040	1.060	1.050	1.060
			Q3	1.170	1.170	1.110	1.110	1.120	1.110	1.100	1.120
			Max	1.41	1.43	1.38	1.29	1.24	1.27	1.22	1.23
		Placebo	n	79	78	79	74	70	67	73	75
			Mean	1.080	1.125	1.063	1.045	1.047	1.057	1.049	1.057
			SD	0.0939	0.1169	0.1193	0.1093	0.0857	0.0884	0.0868	0.0898
			Min	0.71	0.82	0.63	0.66	0.68	0.68	0.69	0.68
			Q1	1.020	1.070	1.000	0.960	1.000	1.000	1.010	1.000
			Median	1.070	1.120	1.060	1.060	1.040	1.060	1.060	1.050
			Q3	1.150	1.180	1.150	1.130	1.110	1.110	1.120	1.130
			Max	1.29	1.48	1.34	1.37	1.20	1.22	1.22	1.22
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.011	-0.069	-0.050	-0.046	-0.038	-0.034	-0.029
			SD	-	0.0973	0.1259	0.0959	0.0814	0.1021	0.0868	0.0910
			Min	-	-0.25	-0.44	-0.25	-0.24	-0.33	-0.29	-0.27
			Q1	-	-0.050	-0.130	-0.120	-0.100	-0.120	-0.080	-0.100
			Median	-	0.010	-0.060	-0.050	-0.040	-0.030	-0.030	-0.030
			Q3	-	0.090	0.010	0.010	0.020	0.040	0.020	0.040
			Max	-	0.17	0.25	0.16	0.12	0.16	0.17	0.20
		Placebo	n	-	78	79	74	70	67	73	75
			Mean	-	0.048	-0.017	-0.032	-0.030	-0.025	-0.028	-0.026
			SD	-	0.1136	0.1143	0.1014	0.0829	0.0911	0.0906	0.0974
			Min	-	-0.18	-0.28	-0.25	-0.22	-0.27	-0.29	-0.26
			Q1	-	-0.030	-0.100	-0.090	-0.080	-0.080	-0.090	-0.090
			Median	-	0.050	0.000	-0.030	-0.020	-0.020	-0.010	-0.030
			Q3	-	0.120	0.060	0.040	0.030	0.050	0.030	0.040
			Max	-	0.34	0.22	0.26	0.13	0.13	0.15	0.19

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S Activity Actual/Control	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	1 33	-5 65	-4 12	-3 75	-2 83	-2 59	-2 15
			SD	-	9 191	11 185	8 460	7 026	8 948	7 551	8 131
			Min	-	-27 1	-36 1	-19 0	-18 8	-23 4	-22 7	-19 1
			Q1	-	-4 60	-12 15	-10 71	-9 09	-10 94	-6 78	-9 32
			Median	-	0 97	-5 94	-4 39	-3 92	-2 88	-2 54	-2 46
			Q3	-	9 26	0 99	1 04	1 80	3 64	1 89	3 92
			Max	-	17 2	22 1	16 5	11 8	17 6	17 0	22 0
		Placebo	n	-	78	79	74	70	67	73	75
			Mean	-	4 79	-1 33	-2 72	-2 46	-1 98	-2 29	-1 98
			SD	-	10 485	10 494	9 229	7 400	8 078	8 010	8 797
			Min	-	-14 6	-24 1	-20 3	-17 8	-21 4	-23 0	-20 6
			Q1	-	-3 06	-8 94	-8 11	-7 14	-6 96	-7 76	-8 26
			Median	-	4 65	0 00	-2 62	-2 05	-1 72	-1 06	-2 88
			Q3	-	12 12	5 66	3 64	2 73	4 72	2 94	3 64
			Max	-	29 8	23 2	23 4	12 6	12 9	15 8	19 2
Protein S Total Activity (IU/mL)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	1 032	1 022	0 939	0 961	0 949	0 950	0 933	0 965
			SD	0 1630	0 1908	0 1875	0 2113	0 1699	0 1955	0 1485	0 1684
			Min	0 64	0 45	0 53	0 54	0 58	0 56	0 61	0 64
			Q1	0 930	0 905	0 790	0 810	0 830	0 820	0 840	0 830
			Median	1 060	1 050	0 950	0 940	0 960	0 950	0 910	0 940
			Q3	1 130	1 145	1 060	1 050	1 080	1 090	1 020	1 080
			Max	1 54	1 56	1 39	1 62	1 39	1 47	1 30	1 43
		Placebo	n	79	78	79	74	70	67	73	75
			Mean	1 081	1 103	1 030	1 002	0 987	0 988	0 966	0 995
			SD	0 1328	0 1392	0 1692	0 1676	0 1772	0 1676	0 1807	0 1409
			Min	0 75	0 79	0 68	0 56	0 66	0 67	0 56	0 73
			Q1	0 980	1 000	0 900	0 880	0 870	0 850	0 830	0 890
			Median	1 090	1 110	1 040	0 985	0 935	0 960	0 910	0 980
			Q3	1 170	1 170	1 140	1 100	1 080	1 120	1 130	1 100
			Max	1 43	1 41	1 43	1 37	1 49	1 39	1 32	1 30

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S Total Activity (IU/mL)	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-0.013	-0.093	-0.072	-0.084	-0.083	-0.101	-0.066
			SD	-	0.1154	0.1558	0.1652	0.1229	0.1460	0.1232	0.0977
			Min	-	-0.32	-0.64	-0.42	-0.32	-0.34	-0.36	-0.29
			Q1	-	-0.090	-0.170	-0.190	-0.170	-0.210	-0.190	-0.120
			Median	-	-0.010	-0.110	-0.080	-0.070	-0.070	-0.090	-0.070
			Q3	-	0.065	-0.020	0.030	0.000	0.010	-0.010	0.010
			Max	-	0.25	0.35	0.39	0.29	0.28	0.15	0.18
		Placebo	n	-	78	79	74	70	67	73	75
			Mean	-	0.023	-0.051	-0.079	-0.086	-0.086	-0.116	-0.084
			SD	-	0.0993	0.1393	0.1268	0.1377	0.1311	0.1453	0.1165
			Min	-	-0.22	-0.41	-0.39	-0.42	-0.38	-0.39	-0.36
			Q1	-	-0.040	-0.160	-0.160	-0.180	-0.190	-0.210	-0.170
			Median	-	0.020	-0.050	-0.070	-0.095	-0.090	-0.130	-0.080
			Q3	-	0.090	0.060	0.020	-0.020	0.020	-0.020	0.010
			Max	-	0.25	0.21	0.19	0.35	0.17	0.26	0.15
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-1.19	-8.59	-6.87	-7.90	-7.91	-9.13	-6.19
			SD	-	11.590	14.182	15.382	11.912	14.004	11.628	9.169
			Min	-	-35.7	-41.6	-34.4	-34.1	-34.3	-31.1	-24.6
			Q1	-	-7.86	-15.45	-19.00	-16.82	-18.58	-17.05	-12.12
			Median	-	-1.04	-9.88	-8.43	-7.69	-7.81	-8.26	-7.14
			Q3	-	6.25	-1.94	3.23	0.00	0.90	-1.33	1.08
			Max	-	27.8	33.7	36.9	34.1	24.8	18.7	21.7
		Placebo	n	-	78	79	74	70	67	73	75
			Mean	-	2.51	-4.36	-7.16	-7.97	-7.83	-10.57	-7.39
			SD	-	9.312	13.105	11.917	12.513	11.984	13.821	10.679
			Min	-	-17.7	-37.6	-34.1	-37.5	-33.0	-34.1	-32.1
			Q1	-	-3.70	-14.88	-14.61	-15.29	-16.92	-20.56	-15.08
			Median	-	2.01	-4.67	-6.84	-9.61	-8.60	-11.70	-7.37
			Q3	-	8.25	5.50	1.50	-1.83	1.83	-1.77	0.93
			Max	-	30.7	20.6	17.4	35.0	15.0	28.9	20.0

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S, Free (%)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	91.7	93.6	92.6	91.4	93.9	92.8	94.2	93.1
			SD	17.14	16.60	16.54	16.95	17.08	18.08	18.90	17.23
			Min	38	55	53	52	53	52	54	55
			Q1	80.0	81.5	82.0	79.0	82.0	80.0	81.0	82.0
			Median	93.0	92.0	93.0	94.0	92.0	91.0	94.0	91.0
			Q3	102.0	106.0	100.0	102.0	106.0	104.0	103.0	104.0
			Max	134	134	134	141	134	144	149	139
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	93.2	91.9	91.9	95.6	93.6	94.3	94.9	92.7
			SD	15.79	16.65	17.88	16.28	16.33	15.84	15.94	16.70
			Min	47	37	29	45	50	48	50	36
			Q1	83.0	81.0	81.0	88.0	83.0	85.0	84.0	82.0
			Median	92.0	90.5	90.0	92.5	92.0	91.0	92.0	91.0
			Q3	102.0	100.0	99.0	106.0	101.0	103.0	106.0	103.0
			Max	138	132	144	144	138	142	134	139
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	1.7	1.0	0.3	2.7	1.6	3.1	2.0
			SD	-	8.11	8.60	10.13	8.91	9.10	11.92	10.71
			Min	-	-20	-22	-26	-18	-33	-30	-31
			Q1	-	-2.0	-3.0	-6.0	-3.0	-3.0	-3.0	-6.0
			Median	-	2.0	2.0	1.0	2.0	1.0	3.0	3.0
			Q3	-	6.5	7.0	5.0	8.0	7.0	12.0	10.0
			Max	-	26	18	40	25	21	29	29
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-1.3	-1.3	2.3	1.0	2.3	1.7	-0.4
			SD	-	7.85	8.85	9.03	9.65	8.50	8.98	9.05
			Min	-	-15	-26	-19	-25	-17	-24	-27
			Q1	-	-7.0	-9.0	-4.0	-6.0	-3.0	-4.0	-6.0
			Median	-	-3.0	-1.0	1.0	2.0	2.0	3.0	0.0
			Q3	-	2.0	5.0	9.0	6.0	8.0	7.0	6.0
			Max	-	25	20	23	20	22	23	23

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S, Free (%)	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	2.65	1.79	1.12	3.65	2.21	4.07	3.16
			SD	-	11.183	10.180	13.241	11.785	11.348	13.370	13.924
			Min	-	-23.8	-22.3	-25.7	-19.1	-32.4	-26.5	-30.4
			Q1	-	-2.35	-4.90	-6.82	-3.90	-3.61	-3.00	-6.25
			Median	-	1.95	1.67	0.82	1.90	1.08	4.05	3.17
			Q3	-	7.35	7.53	6.02	9.64	7.62	14.56	11.76
			Max	-	68.4	47.4	65.8	63.2	55.3	42.1	76.3
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-1.33	-1.47	2.91	1.59	2.91	2.32	-0.20
			SD	-	8.531	10.144	10.036	10.610	9.255	9.434	9.933
			Min	-	-21.3	-38.3	-23.5	-24.5	-17.7	-17.4	-29.3
			Q1	-	-7.77	-8.04	-4.26	-6.73	-3.57	-5.00	-5.68
			Median	-	-2.77	-1.15	1.33	2.02	2.13	2.94	0.00
			Q3	-	2.53	5.26	9.90	6.76	7.69	8.33	5.49
			Max	-	28.4	21.5	26.4	25.3	23.7	24.7	22.8
Protein S (IU/mL)	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	0.952	0.931	0.923	0.924	0.909	0.903	0.885	0.914
			SD	0.1420	0.1529	0.1664	0.1777	0.1576	0.1766	0.1350	0.1436
			Min	0.67	0.65	0.60	0.55	0.58	0.57	0.58	0.63
			Q1	0.870	0.810	0.800	0.790	0.780	0.780	0.790	0.790
			Median	0.940	0.930	0.900	0.890	0.900	0.880	0.870	0.910
			Q3	1.050	1.040	1.040	1.030	1.000	1.000	0.960	1.030
			Max	1.35	1.34	1.28	1.46	1.28	1.36	1.23	1.27
		Placebo	n	79	78	79	74	70	67	73	75
			Mean	1.006	0.987	0.972	0.964	0.944	0.939	0.926	0.948
			SD	0.1405	0.1411	0.1379	0.1568	0.1678	0.1630	0.1812	0.1545
			Min	0.76	0.69	0.71	0.67	0.69	0.67	0.55	0.71
			Q1	0.900	0.880	0.860	0.850	0.810	0.800	0.770	0.830
			Median	0.980	0.985	0.930	0.955	0.930	0.900	0.890	0.920
			Q3	1.100	1.080	1.090	1.070	1.050	1.060	1.060	1.050
			Max	1.50	1.26	1.24	1.48	1.44	1.46	1.32	1.55

表 2.7.4-151 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S (IU/mL)	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-0 024	-0 029	-0 029	-0 042	-0 048	-0 068	-0 040
			SD	-	0 1001	0 1274	0 1296	0 1151	0 1322	0 1199	0 1048
			Min	-	-0 28	-0 33	-0 35	-0 27	-0 33	-0 34	-0 39
			Q1	-	-0 105	-0 110	-0 100	-0 110	-0 160	-0 140	-0 110
			Median	-	-0 025	-0 030	-0 020	-0 040	-0 050	-0 060	-0 030
			Q3	-	0 030	0 040	0 040	0 020	0 040	0 010	0 020
			Max	-	0 36	0 42	0 36	0 42	0 32	0 17	0 29
		Placebo	n	-	78	79	74	70	67	73	75
			Mean	-	-0 020	-0 034	-0 045	-0 057	-0 058	-0 083	-0 054
			SD	-	0 0961	0 1042	0 1147	0 1232	0 1083	0 1466	0 1195
			Min	-	-0 27	-0 32	-0 28	-0 34	-0 30	-0 40	-0 33
			Q1	-	-0 070	-0 080	-0 140	-0 140	-0 130	-0 180	-0 140
			Median	-	-0 020	-0 030	-0 020	-0 070	-0 070	-0 110	-0 040
			Q3	-	0 040	0 040	0 040	0 020	0 020	0 030	0 030
			Max	-	0 19	0 18	0 18	0 25	0 19	0 31	0 22
	Percent Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	-2 24	-2 69	-2 94	-4 15	-4 97	-6 45	-3 71
			SD	-	10 681	13 751	12 877	12 231	13 722	12 185	10 943
			Min	-	-25 0	-29 6	-31 3	-28 1	-28 0	-31 5	-34 2
			Q1	-	-10 83	-12 16	-11 11	-13 76	-16 95	-14 12	-11 83
			Median	-	-2 40	-3 19	-2 63	-4 00	-5 15	-7 29	-3 80
			Q3	-	3 97	3 53	5 00	2 50	4 26	1 25	2 04
			Max	-	45 0	52 5	36 0	48 8	30 8	21 3	38 7
		Placebo	n	-	78	79	74	70	67	73	75
			Mean	-	-1 65	-2 88	-4 16	-5 50	-5 73	-8 02	-5 00
			SD	-	9 484	9 934	11 343	11 630	10 898	14 536	11 713
			Min	-	-24 5	-29 1	-26 8	-28 1	-30 9	-33 1	-27 3
			Q1	-	-7 95	-7 87	-13 79	-12 50	-13 64	-17 46	-14 71
			Median	-	-2 04	-2 68	-1 84	-8 09	-7 41	-10 53	-4 65
			Q3	-	3 53	3 70	5 26	2 13	1 56	3 06	3 41
			Max	-	22 6	19 4	19 1	21 0	20 0	36 9	25 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys02）表 14-17 を引用

表 2.7.4-152 血液凝固系検査（SHBG）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period	Extension Period
				Visit 3	Visit 8 / Discontinuation	Visit 17 / Discontinuation
Sex Hormone Binding Globulin (nmol/L)	Value	FSN-013	n	81	81	77
			Mean	156.32	235.02	176.24
			SD	62.179	93.772	92.484
			Min	31.0	34.6	23.6
			Q1	111.30	168.50	107.60
			Median	159.30	226.00	155.00
			Q3	191.90	323.80	245.50
			Max	298.4	393.2	392.3
		Placebo	n	79	79	74
			Mean	150.61	148.40	173.08
			SD	59.465	63.416	80.625
			Min	37.4	34.5	38.1
			Q1	110.50	102.50	115.10
			Median	143.40	139.40	172.25
			Q3	190.50	179.70	217.90
			Max	292.9	363.9	492.4
	Change from Baseline	FSN-013	n	-	81	77
			Mean	-	78.70	18.22
			SD	-	76.035	77.034
			Min	-	-161.6	-238.6
			Q1	-	29.50	-36.40
			Median	-	83.60	14.60
			Q3	-	134.50	72.20
			Max	-	210.2	231.5
		Placebo	n	-	79	74
			Mean	-	-2.20	23.81
			SD	-	46.598	71.858
			Min	-	-127.3	-158.4
			Q1	-	-31.50	-27.20
			Median	-	-7.90	7.15
			Q3	-	25.30	76.60
			Max	-	151.3	209.6

表 2.7.4-152 血液凝固系検査（SHBG）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period	Extension Period
				Visit 3	Visit 8 / Discontinuation	Visit 17 / Discontinuation
Sex Hormone Binding Globulin (nmol/L)	Percent Change from Baseline	FSN-013	n	-	81	77
			Mean	-	59.82	19.67
			SD	-	56.129	75.453
			Min	-	-59.2	-87.4
			Q1	-	16.84	-25.72
			Median	-	63.03	8.36
			Q3	-	94.58	37.95
			Max	-	210.1	481.3
		Placebo	n	-	79	74
			Mean	-	2.60	25.34
			SD	-	31.856	59.261
			Min	-	-45.8	-76.0
			Q1	-	-21.02	-17.04
			Median	-	-7.80	6.07
			Q3	-	22.54	54.48
			Max	-	122.0	226.1

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 9 to Visit 17.

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys02）表 14-18 を引用

表 2.7.4-153 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period					Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Thrombin Antithrombin Complex (ng/mL)	Value	FSN-013	n	81	80	79	81	77	77	75	75	77	79
			Mean	1 30	1 24	1 84	2 56	1 05	1 53	1 27	1 14	1 22	1 30
			SD	0 868	0 644	6 929	12 179	0 177	2 174	0 972	0 307	0 823	1 095
			Min	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Q3	1 20	1 10	1 00	1 00	1 00	1 00	1 00	1 10	1 10	1 20
			Max	7 1	4 8	62 6	110 3	2 2	18 0	7 3	2 8	7 3	8 6
		Placebo	n	79	78	76	79	74	74	71	67	73	75
			Mean	1 17	1 57	1 15	1 60	1 08	3 06	1 49	1 14	1 97	1 14
			SD	0 403	3 077	0 418	3 852	0 277	11 324	2 659	0 728	6 817	0 339
			Min	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Q3	1 20	1 10	1 00	1 20	1 00	1 20	1 20	1 00	1 20	1 10
			Max	3 5	24 8	3 0	35 2	2 7	92 3	23 2	6 9	59 3	3 2
	Change from Baseline	FSN-013	n	-	80	79	81	77	77	75	75	77	79
			Mean	-	-0 07	0 53	1 25	-0 26	0 22	-0 04	-0 17	-0 09	-0 01
			SD	-	0 952	7 009	12 246	0 916	2 360	1 359	0 971	1 050	1 390
			Min	-	-6 1	-5 2	-6 1	-6 1	-6 1	-6 1	-6 1	-6 1	-5 6
			Q1	-	-0 10	-0 20	-0 20	-0 20	-0 20	-0 10	-0 20	-0 20	-0 20
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 10	0 00	0 00
			Max	-	2 0	61 6	109 3	1 2	17 0	6 1	1 8	3 5	7 6
		Placebo	n	-	78	76	79	74	74	71	67	73	75
			Mean	-	0 40	-0 03	0 43	-0 09	1 89	0 31	-0 05	0 79	-0 04
			SD	-	3 069	0 468	3 875	0 470	11 361	2 405	0 858	6 849	0 562
			Min	-	-2 5	-1 7	-1 7	-2 5	-2 5	-1 3	-2 5	-2 0	-2 5
			Q1	-	0 00	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 10	0 00	0 10	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	23 4	1 7	34 1	1 7	91 3	19 7	5 9	58 3	2 2

表 2.7.4-153 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period					Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Thrombin Antithrombin Complex (ng/mL)	Percent Change from Baseline	FSN-013	n	-	80	79	81	77	77	75	75	77	79
			Mean	-	4 75	70 66	142 16	-7 52	36 22	12 94	1 40	2 46	14 99
			SD	-	41 034	694 612	1219 660	27 104	216 298	91 500	38 731	43 576	112 436
			Min	-	-85 9	-75 6	-85 9	-85 9	-85 9	-85 9	-85 9	-85 9	-78 9
			Q1	-	-9 09	-16 67	-13 04	-16 67	-16 67	-9 09	-16 67	-16 67	-16 67
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	10 00	0 00	0 00
			Max	-	200 0	6160 0	10930 0	120 0	1700 0	530 0	180 0	258 3	760 0
		Placebo	n	-	78	76	79	74	74	71	67	73	75
			Mean	-	33 04	1 73	44 90	-2 71	194 84	15 58	3 03	85 32	3 79
			SD	-	217 534	33 235	350 801	29 316	1134 151	84 100	75 754	683 220	39 833
			Min	-	-71 4	-63 0	-63 0	-71 4	-71 4	-56 5	-71 4	-57 1	-71 4
			Q1	-	0 00	-9 09	-9 09	-9 09	-9 09	-9 09	-9 09	-9 09	-9 09
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	7 69	0 00	10 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	1671 4	170 0	3100 0	170 0	9130 0	562 9	590 0	5830 0	220 0
D-Dimer (ug/mL)	Value	FSN-013	n	81	80	79	81	77	77	75	75	77	79
			Mean	0 352	0 359	0 344	0 364	0 363	0 353	0 351	0 367	0 365	0 391
			SD	0 1189	0 1461	0 0951	0 1328	0 1446	0 1334	0 1041	0 1428	0 1179	0 1421
			Min	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Q3	0 350	0 325	0 320	0 360	0 350	0 320	0 350	0 400	0 400	0 440
			Max	1 11	1 17	0 74	0 89	1 04	1 14	0 73	1 19	0 93	0 90
		Placebo	n	79	78	76	79	74	74	71	67	73	75
			Mean	0 347	0 375	0 390	0 372	0 368	0 414	0 399	0 370	0 388	0 383
			SD	0 1241	0 1168	0 1607	0 1166	0 1430	0 2562	0 3377	0 1617	0 2233	0 1803
			Min	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Q3	0 340	0 440	0 405	0 450	0 360	0 390	0 380	0 340	0 370	0 400
			Max	1 07	0 73	1 03	0 80	1 01	1 77	3 02	1 19	1 70	1 59

表 2.7.4-153 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period					Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
D-Dimer (ug/mL)	Change from Baseline	FSN-013	n	-	80	79	81	77	77	75	75	77	79
			Mean	-	0 006	-0 006	0 012	0 012	0 002	-0 002	0 015	0 014	0 038
			SD	-	0 1436	0 1200	0 1525	0 1639	0 1649	0 1450	0 1650	0 1600	0 1468
			Min	-	-0 81	-0 81	-0 81	-0 81	-0 81	-0 71	-0 81	-0 81	-0 57
			Q1	-	0 000	-0 010	0 000	0 000	0 000	-0 020	0 000	0 000	0 000
			Median	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Q3	-	0 000	0 000	0 020	0 000	0 000	0 000	0 040	0 010	0 070
			Max	-	0 49	0 25	0 59	0 51	0 84	0 43	0 75	0 52	0 60
		Placebo	n	-	78	76	79	74	74	71	67	73	75
			Mean	-	0 027	0 043	0 025	0 019	0 065	0 049	0 017	0 038	0 035
			SD	-	0 1379	0 1431	0 1337	0 1472	0 2070	0 3466	0 1669	0 2171	0 1540
			Min	-	-0 55	-0 24	-0 63	-0 63	-0 23	-0 63	-0 63	-0 45	-0 50
			Q1	-	0 000	0 000	0 000	0 000	0 000	0 000	-0 020	0 000	0 000
			Median	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Q3	-	0 030	0 050	0 080	0 020	0 020	0 010	0 000	0 000	0 050
			Max	-	0 40	0 57	0 40	0 71	0 84	2 72	0 87	1 40	0 97
	Percent Change from Baseline	FSN-013	n	-	80	79	81	77	77	75	75	77	79
			Mean	-	3 81	1 53	7 29	7 24	5 19	4 48	7 95	9 07	14 13
			SD	-	27 925	22 359	37 165	40 671	43 801	35 366	36 256	36 342	39 159
			Min	-	-73 0	-73 0	-73 0	-73 0	-73 0	-64 0	-73 0	-73 0	-51 4
			Q1	-	0 00	-2 56	0 00	0 00	0 00	-5 88	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	6 25	0 00	0 00	0 00	10 00	3 33	17 95
			Max	-	146 7	76 7	196 7	170 0	280 0	143 3	170 5	136 7	200 0
		Placebo	n	-	78	76	79	74	74	71	67	73	75
			Mean	-	12 43	15 50	11 46	8 92	18 81	19 62	8 46	14 03	11 27
			SD	-	36 826	42 544	33 407	39 304	55 203	111 478	44 468	66 510	31 847
			Min	-	-59 1	-38 7	-67 7	-67 7	-37 1	-67 7	-67 7	-48 4	-53 8
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	-6 25	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	10 00	16 67	25 00	5 26	5 88	2 70	0 00	0 00	16 67
			Max	-	133 3	190 0	133 3	236 7	260 0	906 7	271 9	466 7	156 5

表 2.7.4-153 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period					Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Soluble Fibrin Monomer Complex (ug/mL)	Value	FSN-013	n	81	80	79	81	77	77	75	75	77	79
			Mean	5 32	5 69	6 85	6 03	5 05	6 49	5 41	5 04	5 00	6 00
			SD	1 895	5 033	16 426	7 307	0 255	7 413	2 429	0 312	0 034	5 439
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Max	18 7	48 7	151 0	68 8	7 0	48 6	21 8	7 7	5 3	40 4
		Placebo	n	79	78	76	79	74	74	71	67	73	75
			Mean	5 07	6 13	5 07	6 45	5 02	6 73	6 75	5 37	5 83	5 00
			SD	0 420	7 338	0 406	12 211	0 127	11 626	12 430	3 066	7 093	0 000
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Max	7 8	62 1	8 1	113 5	5 9	103 7	108 9	30 1	65 6	5 0
	Change from Baseline	FSN-013	n	-	80	79	81	77	77	75	75	77	79
			Mean	-	0 37	1 53	0 71	-0 28	1 15	0 06	-0 30	-0 33	0 68
			SD	-	4 245	16 574	7 592	1 967	7 071	3 171	1 999	1 944	4 957
			Min	-	-13 7	-13 7	-13 7	-13 7	-13 7	-13 7	-13 7	-13 7	-13 7
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	33 4	146 0	63 8	2 0	43 6	16 8	2 7	0 3	31 3
		Placebo	n	-	78	76	79	74	74	71	67	73	75
			Mean	-	1 06	0 00	1 38	-0 05	1 66	1 67	0 29	0 75	-0 07
			SD	-	7 361	0 495	12 223	0 372	11 645	12 147	3 110	7 115	0 431
			Min	-	-2 8	-2 8	-2 8	-2 5	-2 8	-2 8	-2 8	-2 8	-2 8
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	57 1	3 1	108 5	0 5	98 7	101 4	25 1	60 6	0 0

表 2.7.4-153 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period					Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Soluble Fibrin Monomer Complex (ug/mL)	Percent Change from Baseline	FSN-013	n	-	80	79	81	77	77	75	75	77	79
			Mean	-	4 42	34 96	18 53	-1 17	21 26	5 88	-1 48	-2 10	11 87
			SD	-	36 251	328 948	146 850	12 668	126 799	50 310	13 297	11 486	78 033
			Min	-	-73 3	-73 3	-73 3	-73 3	-73 3	-73 3	-73 3	-73 3	-73 3
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	228 0	2920 0	1276 0	40 0	872 0	336 0	54 0	6 0	626 0
		Placebo	n	-	78	76	79	74	74	71	67	73	75
			Mean	-	21 73	0 34	27 95	-0 61	33 61	24 20	6 37	15 57	-1 00
			SD	-	147 011	8 454	244 371	5 047	232 733	163 992	61 755	142 090	5 627
			Min	-	-35 9	-35 9	-35 9	-33 3	-35 9	-35 9	-35 9	-35 9	-35 9
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	1142 0	62 0	2170 0	10 0	1974 0	1352 0	502 0	1212 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-19 を引用

表 2.7.4-154 血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	FSN-013		Placebo	
	N = 81		N = 74	
	Above Upper Limit n (%)	Below Lower Limit n (%)	Above Upper Limit n (%)	Below Lower Limit n (%)
Prothrombin Time (sec)	13 (16.0)	0 (0.0)	9 (12.2)	0 (0.0)
Prothrombin Control (sec)	-	-	-	-
Prothrombin Activity (%)	65 (80.2)	0 (0.0)	58 (78.4)	0 (0.0)
Prothrombin Intl. Normalized Ratio	2 (2.5)	1 (1.2)	2 (2.7)	1 (1.4)
Activated Partial Thromboplastin Time (sec)	10 (12.3)	2 (2.5)	3 (4.1)	5 (6.8)
Activated Partial Thromboplastin Control (sec)	-	-	-	-
Fibrinogen (mg/dL)	5 (6.2)	1 (1.2)	1 (1.4)	0 (0.0)
Antithrombin Activity (%)	20 (24.7)	0 (0.0)	18 (24.3)	0 (0.0)
Plasminogen (%)	11 (13.6)	4 (4.9)	10 (13.5)	4 (5.4)
Thrombin Antithrombin Complex (ng/mL)	16 (19.8)	-	12 (16.2)	-
Factor XIV Activity (%)	13 (16.0)	0 (0.0)	16 (21.6)	1 (1.4)
D-Dimer (ug/mL)	4 (4.9)	-	8 (10.8)	-
Soluble Fibrin Monomer Complex (ug/mL)	14 (17.3)	-	10 (13.5)	-
Protein S Activity Actual/Control	24 (29.6)	5 (6.2)	12 (16.2)	2 (2.7)
Protein S Total Activity (IU/mL)	10 (12.3)	21 (25.9)	6 (8.1)	9 (12.2)
Protein S, Free (%)	5 (6.2)	3 (3.7)	7 (9.5)	1 (1.4)
Protein S (IU/mL)	8 (9.9)	21 (25.9)	5 (6.8)	19 (25.7)
Sex Hormone Binding Globulin (nmol/L)	-	-	-	-

FSN-013 group is counted from the comparative period onward, and placebo group is counted from extension period onward.

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-33 を引用

2.7.4.3.1.3.2 FSN-013P-04 試験

2.7.4.3.1.3.2.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、血液凝固系検査の測定値、ベースラインからの変化量及び変化率を表 2.7.4-155～表 2.7.4-157 に、血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度を表 2.7.4-158 に示す。

トロンビン・アンチトロンビン III 複合体、可溶性フィブリンモノマー複合体、プロテイン C、プロテイン S 及び D-ダイマーに関する投与前後の平均変化量に特記すべき異常変動はみられなかった。また、D-ダイマーの基準値上限を逸脱した被験者割合は、FSN-013 群では 6.3%（5/79 例）、プラセボ群では 8.4%（7/83 例）であり、両群間で同様であった。その他のいずれの項目も経時的推移は FSN-013 群、プラセボ群で同様であり、FSN-013 群及びプラセボ群の基準値上限超、基準値下限未満の頻度に大差は認められなかった。

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Prothrombin Time (sec)	Value	FSN-013	n	79	78	78	78
			Mean	11 38	11 28	11 45	11 38
			SD	0 710	0 697	0 700	0 717
			Min	9 7	9 7	9 7	9 5
			Q1	10 80	10 80	10 90	10 90
			Median	11 40	11 30	11 40	11 40
			Q3	11 90	11 70	11 90	11 90
			Max	13 3	12 9	13 9	13 3
		Placebo	n	83	82	80	83
			Mean	11 33	11 53	11 66	11 67
			SD	0 732	0 764	0 717	0 760
			Min	10 0	9 6	9 8	10 1
			Q1	10 80	11 00	11 20	11 20
			Median	11 30	11 50	11 60	11 60
			Q3	11 80	12 00	12 10	12 10
			Max	13 5	13 5	14 3	14 2
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 10	0 08	0 01
			SD	-	0 732	0 720	0 833
			Min	-	-2 1	-1 6	-2 8
			Q1	-	-0 50	-0 40	-0 50
			Median	-	-0 05	0 00	0 00
			Q3	-	0 50	0 60	0 60
			Max	-	1 3	2 1	1 6
		Placebo	n	-	82	80	83
			Mean	-	0 20	0 33	0 34
			SD	-	0 632	0 682	0 668
			Min	-	-2 3	-2 1	-1 6
			Q1	-	-0 20	-0 05	0 00
			Median	-	0 20	0 40	0 30
			Q3	-	0 70	0 80	0 70
			Max	-	1 9	2 0	2 5
Prothrombin Time (sec)	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 64	0 87	0 38
			SD	-	6 302	6 326	7 178
			Min	-	-16 3	-12 5	-21 9
			Q1	-	-4 10	-3 25	-4 72
			Median	-	-0 42	0 00	0 00
			Q3	-	4 42	5 36	5 61
			Max	-	11 7	19 6	14 0
		Placebo	n	-	82	80	83
			Mean	-	1 93	3 12	3 18
			SD	-	5 511	5 984	5 917
			Min	-	-17 0	-15 6	-11 9
			Q1	-	-1 71	-0 42	0 00
			Median	-	1 70	3 52	2 54
			Q3	-	6 14	6 64	6 42
			Max	-	18 8	19 4	23 8

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Prothrombin Control (sec)	Value	FSN-013	n	79	78	78	78
			Mean	11 50	11 50	11 50	11 50
			SD	0 000	0 000	0 000	0 000
			Min	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	11 50	11 50
			Median	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	11 50	11 50
			Max	11 5	11 5	11 5	11 5
		Placebo	n	83	82	80	83
			Mean	11 50	11 50	11 50	11 50
			SD	0 000	0 000	0 000	0 000
			Min	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	11 50	11 50
			Median	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	11 50	11 50
			Max	11 5	11 5	11 5	11 5
Prothrombin Control (sec)	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0
		Placebo	n	-	82	80	83
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0
		Placebo	n	-	82	80	83
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Prothrombin Activity (%)	Value	FSN-013	n	79	78	78	78
			Mean	96 0	97 2	95 9	96 7
			SD	6 12	4 90	6 36	5 84
			Min	76	80	71	76
			Q1	92 0	95 0	92 0	92 0
			Median	98 0	99 5	99 0	100 0
			Q3	101 0	101 0	101 0	101 0
			Max	101	101	101	101
		Placebo	n	83	82	80	83
			Mean	96 4	95 6	94 5	94 8
			SD	5 91	6 49	6 92	7 20
			Min	78	77	71	72
			Q1	93 0	92 0	90 5	90 0
			Median	99 0	98 0	96 0	97 0
			Q3	101 0	101 0	101 0	101 0
			Max	101	101	101	101
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	1 1	-0 2	0 6
			SD	-	6 04	7 09	7 48
			Min	-	-15	-18	-18
			Q1	-	-1 0	-2 0	-3 0
			Median	-	0 0	0 0	0 0
			Q3	-	4 0	3 0	4 0
			Max	-	19	19	24
		Placebo	n	-	82	80	83
			Mean	-	-0 7	-1 9	-1 6
			SD	-	5 81	6 20	6 14
			Min	-	-18	-15	-22
			Q1	-	-4 0	-5 5	-4 0
			Median	-	0 0	-0 5	0 0
			Q3	-	2 0	0 0	0 0
			Max	-	22	23	17
Prothrombin Activity (%)	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	1 42	0 09	0 93
			SD	-	6 832	7 808	8 399
			Min	-	-14 9	-17 8	-19 1
			Q1	-	-1 04	-2 13	-2 97
			Median	-	0 00	0 00	0 00
			Q3	-	4 12	3 09	4 12
			Max	-	23 7	25 0	31 6
		Placebo	n	-	82	80	83
			Mean	-	-0 60	-1 82	-1 52
			SD	-	6 486	6 903	6 608
			Min	-	-18 8	-15 6	-21 8
			Q1	-	-3 96	-6 10	-4 76
			Median	-	0 00	-0 50	0 00
			Q3	-	2 02	0 00	0 00
			Max	-	28 2	29 5	21 8

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Prothrombin Intl Normalized Ratio	Value	FSN-013	n	79	78	78	78
			Mean	0 990	0 981	0 995	0 990
			SD	0 0601	0 0594	0 0609	0 0611
			Min	0 85	0 85	0 84	0 83
			Q1	0 940	0 940	0 950	0 950
			Median	0 990	0 980	0 990	0 990
			Q3	1 030	1 020	1 030	1 030
			Max	1 15	1 12	1 21	1 15
		Placebo	n	83	82	80	83
			Mean	0 985	1 003	1 013	1 015
			SD	0 0620	0 0647	0 0616	0 0652
			Min	0 87	0 84	0 85	0 88
			Q1	0 940	0 960	0 970	0 970
			Median	0 980	1 000	1 010	1 010
			Q3	1 030	1 040	1 050	1 050
			Max	1 17	1 17	1 24	1 23
Prothrombin Intl Normalized Ratio	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 008	0 006	0 001
			SD	-	0 0625	0 0616	0 0704
			Min	-	-0 18	-0 14	-0 24
			Q1	-	-0 040	-0 030	-0 040
			Median	-	0 000	0 000	0 000
			Q3	-	0 040	0 050	0 050
			Max	-	0 11	0 18	0 13
		Placebo	n	-	82	80	83
			Mean	-	0 017	0 028	0 029
			SD	-	0 0534	0 0582	0 0566
			Min	-	-0 20	-0 18	-0 14
			Q1	-	-0 010	-0 005	0 000
			Median	-	0 015	0 035	0 030
			Q3	-	0 060	0 070	0 060
			Max	-	0 16	0 17	0 21
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 62	0 78	0 35
			SD	-	6 190	6 215	6 971
			Min	-	-16 1	-12 6	-21 6
			Q1	-	-3 92	-3 06	-4 35
			Median	-	0 00	0 00	0 00
			Q3	-	4 30	5 43	5 38
			Max	-	11 3	19 4	14 0
		Placebo	n	-	82	80	83
			Mean	-	1 89	3 00	3 13
			SD	-	5 339	5 864	5 755
			Min	-	-17 1	-15 4	-12 0
			Q1	-	-1 03	-0 45	0 00
			Median	-	1 50	3 41	2 73
			Q3	-	6 06	6 70	6 32
			Max	-	18 2	18 9	22 8

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Activated Partial Thromboplastin Time (sec)	Value	FSN-013	n	79	78	78	78
			Mean	33 58	30 96	31 13	30 86
			SD	10 307	2 758	2 618	2 860
			Min	25 3	21 8	24 6	24 6
			Q1	30 70	29 30	29 50	29 30
			Median	32 70	31 20	31 20	30 65
			Q3	34 00	32 90	33 00	32 20
			Max	120 1	37 3	37 5	40 2
		Placebo	n	83	82	80	83
			Mean	31 82	31 90	31 22	31 36
			SD	3 244	2 507	2 810	2 416
			Min	24 6	25 6	23 3	23 0
			Q1	29 60	30 60	29 85	30 10
			Median	31 50	31 45	31 25	31 30
			Q3	33 20	33 40	32 95	32 70
			Max	48 5	39 1	39 4	37 9
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-2 62	-2 44	-2 73
			SD	-	10 042	10 399	10 418
			Min	-	-88 3	-90 9	-91 5
			Q1	-	-2 80	-2 50	-2 90
			Median	-	-1 30	-1 20	-1 50
			Q3	-	-0 30	0 10	-0 20
			Max	-	3 7	3 6	5 9
		Placebo	n	-	82	80	83
			Mean	-	0 09	-0 58	-0 46
			SD	-	2 884	3 247	3 028
			Min	-	-18 9	-19 8	-18 4
			Q1	-	-0 60	-1 15	-1 30
			Median	-	0 35	-0 10	-0 20
			Q3	-	1 40	1 20	1 20
			Max	-	6 8	6 0	6 9
Activated Partial Thromboplastin Time (sec)	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-5 32	-4 61	-5 56
			SD	-	9 930	10 523	10 296
			Min	-	-73 5	-75 7	-76 2
			Q1	-	-8 43	-7 62	-9 09
			Median	-	-3 98	-3 62	-4 67
			Q3	-	-0 95	0 30	-0 62
			Max	-	12 5	12 6	17 2
		Placebo	n	-	82	80	83
			Mean	-	0 77	-1 33	-0 90
			SD	-	7 542	8 615	8 180
			Min	-	-39 0	-40 8	-37 9
			Q1	-	-2 07	-3 67	-3 97
			Median	-	1 11	-0 33	-0 65
			Q3	-	4 81	3 61	3 79
			Max	-	27 6	24 4	28 0

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Activated Partial Thromboplastin Control (sec)	Value	FSN-013	n	79	78	78	78
			Mean	28 70	28 70	28 70	28 70
			SD	0 000	0 000	0 000	0 000
			Min	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	28 70	28 70
			Median	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	28 70	28 70
			Max	28 7	28 7	28 7	28 7
		Placebo	n	83	82	80	83
			Mean	28 70	28 70	28 70	28 70
			SD	0 000	0 000	0 000	0 000
			Min	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	28 70	28 70
			Median	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	28 70	28 70
			Max	28 7	28 7	28 7	28 7
Activated Partial Thromboplastin Control (sec)	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0
		Placebo	n	-	82	80	83
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0
		Placebo	n	-	82	80	83
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Fibrinogen (mg/dL)	Value	FSN-013	n	79	78	78	78
			Mean	268 9	284 6	276 9	285 8
			SD	49 53	49 17	45 36	44 98
			Min	170	185	150	172
			Q1	237 0	251 0	247 0	254 0
			Median	259 0	278 0	275 5	284 5
			Q3	299 0	313 0	307 0	314 0
			Max	438	444	390	410
		Placebo	n	83	82	80	83
			Mean	253 2	270 9	263 8	273 5
			SD	40 58	47 30	45 27	45 89
			Min	134	168	169	146
			Q1	225 0	232 0	231 0	243 0
			Median	253 0	269 0	257 0	271 0
			Q3	278 0	304 0	296 0	305 0
			Max	378	388	370	400
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	16 1	8 5	17 8
			SD	-	40 99	43 42	41 97
			Min	-	-116	-122	-96
			Q1	-	-5 0	-15 0	-15 0
			Median	-	15 0	7 5	20 0
			Q3	-	39 0	42 0	50 0
			Max	-	166	90	109
		Placebo	n	-	82	80	83
			Mean	-	18 4	11 1	20 3
			SD	-	37 95	41 64	44 45
			Min	-	-68	-99	-104
			Q1	-	-4 0	-19 5	-6 0
			Median	-	16 5	11 0	22 0
			Q3	-	43 0	33 5	47 0
			Max	-	127	118	152
Fibrinogen (mg/dL)	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	7 25	4 70	8 19
			SD	-	15 182	16 157	16 107
			Min	-	-37 9	-39 8	-25 7
			Q1	-	-1 27	-6 30	-3 96
			Median	-	6 15	2 87	7 71
			Q3	-	17 47	16 05	19 90
			Max	-	59 7	40 3	45 8
		Placebo	n	-	82	80	83
			Mean	-	8 08	5 55	9 56
			SD	-	15 087	17 146	19 937
			Min	-	-21 0	-30 6	-35 7
			Q1	-	-1 94	-7 01	-2 51
			Median	-	5 82	4 50	8 81
			Q3	-	17 37	13 87	18 58
			Max	-	48 7	57 3	91 6

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Antithrombin Activity (%)	Value	FSN-013	n	79	78	78	78
			Mean	113 4	109 6	108 5	110 0
			SD	10 98	11 06	11 45	10 49
			Min	88	87	71	88
			Q1	106 0	102 0	101 0	103 0
			Median	113 0	109 0	108 5	110 0
			Q3	119 0	116 0	116 0	117 0
			Max	141	142	140	136
		Placebo	n	83	82	80	83
			Mean	109 6	108 5	107 4	109 2
			SD	9 75	9 21	10 69	11 46
			Min	82	88	80	83
			Q1	104 0	103 0	100 5	102 0
			Median	109 0	109 0	107 0	108 0
			Q3	115 0	115 0	114 5	117 0
			Max	135	138	131	139
Antithrombin Activity (%)	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-3 8	-5 0	-3 2
			SD	-	9 34	8 39	8 70
			Min	-	-23	-33	-28
			Q1	-	-10 0	-11 0	-9 0
			Median	-	-4 0	-4 0	-3 0
			Q3	-	1 0	0 0	2 0
			Max	-	27	15	17
		Placebo	n	-	82	80	83
			Mean	-	-0 9	-2 2	-0 4
			SD	-	6 65	9 20	8 77
			Min	-	-21	-25	-24
			Q1	-	-5 0	-8 0	-6 0
			Median	-	-2 0	-2 0	0 0
			Q3	-	3 0	3 0	4 0
			Max	-	14	23	21
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-3 04	-4 18	-2 52
			SD	-	8 380	7 446	7 669
			Min	-	-20 0	-31 7	-21 1
			Q1	-	-8 57	-9 48	-8 26
			Median	-	-3 56	-3 43	-2 99
			Q3	-	0 80	0 00	1 57
			Max	-	23 9	17 0	19 3
		Placebo	n	-	82	80	83
			Mean	-	-0 56	-1 78	-0 19
			SD	-	6 218	8 552	8 079
			Min	-	-16 4	-23 4	-22 4
			Q1	-	-4 39	-6 73	-5 74
			Median	-	-1 75	-1 79	0 00
			Q3	-	2 94	2 97	3 96
			Max	-	17 1	28 0	19 6

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Plasminogen (%)	Value	FSN-013	n	79	78	78	78
			Mean	98 1	106 1	107 6	107 3
			SD	15 79	16 32	17 53	16 63
			Min	48	55	52	52
			Q1	92 0	97 0	99 0	100 0
			Median	98 0	106 0	107 5	108 0
			Q3	109 0	115 0	119 0	120 0
			Max	134	148	145	143
		Placebo	n	83	82	80	83
			Mean	94 2	95 0	94 3	94 0
			SD	14 30	15 11	15 49	15 27
			Min	50	48	47	47
			Q1	89 0	88 0	88 5	88 0
			Median	95 0	96 0	95 0	96 0
			Q3	102 0	103 0	102 0	103 0
			Max	121	134	129	127
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	8 0	9 5	9 7
			SD	-	7 79	8 78	9 22
			Min	-	-10	-15	-12
			Q1	-	2 0	3 0	5 0
			Median	-	7 5	10 0	9 0
			Q3	-	14 0	15 0	13 0
			Max	-	25	37	33
		Placebo	n	-	82	80	83
			Mean	-	0 9	0 1	-0 2
			SD	-	6 73	7 88	7 25
			Min	-	-19	-18	-22
			Q1	-	-4 0	-4 5	-4 0
			Median	-	1 0	0 5	-1 0
			Q3	-	6 0	6 0	5 0
			Max	-	24	19	17
Plasminogen (%)	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	8 73	10 00	10 32
			SD	-	8 786	9 067	9 740
			Min	-	-7 5	-11 2	-12 6
			Q1	-	1 98	3 03	4 95
			Median	-	8 07	9 72	9 45
			Q3	-	13 86	16 09	16 09
			Max	-	40 0	40 2	35 9
		Placebo	n	-	82	80	83
			Mean	-	1 10	0 27	-0 11
			SD	-	7 069	8 400	7 583
			Min	-	-15 7	-20 2	-18 8
			Q1	-	-4 00	-4 70	-5 15
			Median	-	1 02	0 44	-0 98
			Q3	-	5 43	5 83	5 10
			Max	-	21 8	18 8	19 8

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Factor XIV Activity (%)	Value	FSN-013	n	79	78	78	78
			Mean	113 7	108 9	108 6	108 3
			SD	16 84	16 68	16 48	16 60
			Min	81	83	78	81
			Q1	101 0	98 0	100 0	96 0
			Median	112 0	106 0	106 5	105 0
			Q3	123 0	117 0	119 0	117 0
			Max	149	151	151	150
		Placebo	n	83	82	80	83
			Mean	108 0	101 5	102 1	102 8
			SD	14 17	14 15	15 13	15 09
			Min	57	55	62	58
			Q1	98 0	93 0	92 5	92 0
			Median	109 0	100 5	101 0	101 0
			Q3	118 0	109 0	110 5	111 0
			Max	140	137	145	150
Factor XIV Activity (%)	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-4 9	-5 2	-5 1
			SD	-	10 43	11 29	11 12
			Min	-	-25	-39	-31
			Q1	-	-12 0	-13 0	-12 0
			Median	-	-6 0	-5 5	-5 0
			Q3	-	3 0	5 0	2 0
			Max	-	32	13	30
		Placebo	n	-	82	80	83
			Mean	-	-6 7	-6 2	-5 3
			SD	-	10 08	10 87	10 36
			Min	-	-32	-42	-29
			Q1	-	-13 0	-12 5	-11 0
			Median	-	-6 0	-6 5	-5 0
			Q3	-	0 0	1 0	0 0
			Max	-	21	13	24
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-3 90	-4 16	-4 03
			SD	-	8 945	9 387	9 670
			Min	-	-20 7	-26 5	-21 1
			Q1	-	-9 40	-11 94	-11 22
			Median	-	-5 32	-4 82	-4 94
			Q3	-	2 83	3 42	2 47
			Max	-	26 9	14 1	28 6
		Placebo	n	-	82	80	83
			Mean	-	-5 85	-5 39	-4 58
			SD	-	8 798	9 428	9 333
			Min	-	-27 1	-35 6	-24 6
			Q1	-	-11 86	-10 50	-10 34
			Median	-	-5 94	-5 53	-4 76
			Q3	-	0 00	1 06	0 00
			Max	-	18 6	12 4	23 1

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Protein S Activity Actual/Control	Value	FSN-013	n	79	78	78	78
			Mean	1 073	1 068	1 064	1 061
			SD	0 1095	0 0832	0 1152	0 1015
			Min	0 74	0 74	0 68	0 70
			Q1	1 000	1 010	1 000	0 990
			Median	1 070	1 080	1 060	1 060
			Q3	1 140	1 120	1 120	1 120
			Max	1 37	1 24	1 49	1 35
		Placebo	n	83	82	80	83
			Mean	1 065	1 083	1 081	1 072
			SD	0 1037	0 1065	0 1191	0 1071
			Min	0 65	0 66	0 67	0 62
			Q1	0 990	1 000	1 010	1 010
			Median	1 060	1 080	1 065	1 060
			Q3	1 140	1 160	1 130	1 140
			Max	1 33	1 36	1 46	1 32
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 005	-0 009	-0 012
			SD	-	0 0942	0 1146	0 0987
			Min	-	-0 25	-0 21	-0 25
			Q1	-	-0 040	-0 090	-0 070
			Median	-	0 015	-0 020	0 000
			Q3	-	0 040	0 060	0 060
			Max	-	0 25	0 43	0 23
		Placebo	n	-	82	80	83
			Mean	-	0 018	0 017	0 007
			SD	-	0 0866	0 0938	0 0857
			Min	-	-0 19	-0 23	-0 21
			Q1	-	-0 020	-0 045	-0 060
			Median	-	0 020	0 005	0 010
			Q3	-	0 070	0 070	0 060
			Max	-	0 20	0 27	0 21
Protein S Activity Actual/Control	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	0 10	-0 31	-0 65
			SD	-	8 423	11 045	9 029
			Min	-	-20 0	-16 7	-20 2
			Q1	-	-3 45	-8 11	-6 25
			Median	-	1 48	-1 90	0 00
			Q3	-	4 17	5 66	5 21
			Max	-	28 7	49 4	24 5
		Placebo	n	-	82	80	83
			Mean	-	1 97	1 84	0 93
			SD	-	8 084	8 777	7 992
			Min	-	-15 4	-17 3	-15 8
			Q1	-	-2 06	-4 21	-4 84
			Median	-	2 08	0 40	1 02
			Q3	-	7 37	6 90	5 83
			Max	-	20 6	26 2	21 2

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Protein S Total Activity (IU/mL)	Value	FSN-013	n	79	78	78	78
			Mean	1 102	1 052	1 033	1 003
			SD	0 2235	0 1780	0 1772	0 1841
			Min	0 73	0 72	0 63	0 56
			Q1	0 930	0 910	0 910	0 850
			Median	1 070	1 050	1 045	1 025
			Q3	1 220	1 170	1 140	1 120
			Max	1 92	1 54	1 54	1 56
		Placebo	n	83	82	80	83
			Mean	1 012	1 030	1 012	0 986
			SD	0 1650	0 1558	0 1593	0 1504
			Min	0 57	0 63	0 60	0 63
			Q1	0 890	0 910	0 915	0 870
			Median	1 010	1 040	1 030	0 990
			Q3	1 120	1 140	1 130	1 110
			Max	1 45	1 33	1 35	1 32
Protein S Total Activity (IU/mL)	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 048	-0 068	-0 094
			SD	-	0 1456	0 1749	0 1844
			Min	-	-0 56	-0 60	-0 74
			Q1	-	-0 130	-0 160	-0 170
			Median	-	-0 030	-0 065	-0 070
			Q3	-	0 050	0 050	0 030
			Max	-	0 25	0 28	0 27
		Placebo	n	-	82	80	83
			Mean	-	0 018	0 000	-0 026
			SD	-	0 1017	0 1178	0 1136
			Min	-	-0 24	-0 31	-0 30
			Q1	-	-0 050	-0 080	-0 110
			Median	-	0 030	0 000	-0 020
			Q3	-	0 090	0 075	0 070
			Max	-	0 25	0 32	0 19
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-3 26	-4 77	-7 30
			SD	-	11 213	13 850	13 889
			Min	-	-32 4	-33 5	-43 3
			Q1	-	-10 48	-14 29	-15 73
			Median	-	-2 95	-6 49	-7 45
			Q3	-	3 49	4 82	3 09
			Max	-	21 2	23 0	22 1
		Placebo	n	-	82	80	83
			Mean	-	2 45	0 75	-1 73
			SD	-	10 168	11 283	10 957
			Min	-	-20 5	-21 4	-23 8
			Q1	-	-4 24	-7 31	-10 00
			Median	-	3 27	0 00	-1 74
			Q3	-	9 80	8 42	7 37
			Max	-	29 8	31 1	28 1

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Protein S, Free (%)	Value	FSN-013	n	79	78	78	78
			Mean	91 6	92 4	92 5	92 2
			SD	13 48	14 38	15 32	14 95
			Min	62	59	60	62
			Q1	82 0	82 0	80 0	80 0
			Median	92 0	91 0	92 0	92 5
			Q3	98 0	104 0	103 0	101 0
			Max	120	127	128	124
		Placebo	n	83	82	80	83
			Mean	92 0	91 0	89 6	91 4
			SD	13 78	12 59	13 59	12 74
			Min	47	56	52	53
			Q1	83 0	83 0	82 0	83 0
			Median	92 0	92 5	91 0	92 0
			Q3	102 0	99 0	99 0	100 0
			Max	131	126	115	126
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	1 0	1 2	0 9
			SD	-	9 52	10 34	9 71
			Min	-	-20	-22	-22
			Q1	-	-6 0	-5 0	-6 0
			Median	-	1 0	0 5	1 0
			Q3	-	7 0	7 0	8 0
			Max	-	28	29	26
		Placebo	n	-	82	80	83
			Mean	-	-1 1	-2 8	-0 7
			SD	-	7 87	9 96	9 32
			Min	-	-20	-28	-24
			Q1	-	-5 0	-7 5	-6 0
			Median	-	-2 0	-3 0	0 0
			Q3	-	4 0	2 5	5 0
			Max	-	21	24	22
Protein S, Free (%)	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	1 61	1 64	1 37
			SD	-	11 252	11 570	10 903
			Min	-	-25 0	-25 0	-23 4
			Q1	-	-5 94	-6 10	-6 03
			Median	-	1 00	0 53	1 03
			Q3	-	7 78	9 21	8 89
			Max	-	35 5	29 3	26 5
		Placebo	n	-	82	80	83
			Mean	-	-0 65	-2 50	-0 02
			SD	-	8 812	10 839	10 288
			Min	-	-16 7	-29 1	-24 5
			Q1	-	-6 25	-8 85	-6 36
			Median	-	-1 83	-2 93	0 00
			Q3	-	4 00	2 54	6 41
			Max	-	23 6	32 0	29 3

表 2.7.4-155 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Protein S (IU/mL)	Value	FSN-013	n	79	78	78	78
			Mean	1 028	0 988	0 975	0 951
			SD	0 1802	0 1631	0 1663	0 1773
			Min	0 70	0 64	0 63	0 59
			Q1	0 890	0 860	0 850	0 820
			Median	1 040	0 975	0 975	0 940
			Q3	1 140	1 130	1 080	1 090
			Max	1 69	1 36	1 48	1 44
		Placebo	n	83	82	80	83
			Mean	0 952	0 955	0 942	0 924
			SD	0 1371	0 1414	0 1494	0 1446
			Min	0 60	0 62	0 58	0 65
			Q1	0 850	0 840	0 825	0 810
			Median	0 960	0 945	0 920	0 890
			Q3	1 050	1 060	1 080	1 020
			Max	1 30	1 24	1 24	1 26
Protein S (IU/mL)	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 039	-0 051	-0 073
			SD	-	0 1030	0 1289	0 1423
			Min	-	-0 45	-0 47	-0 56
			Q1	-	-0 110	-0 120	-0 150
			Median	-	-0 040	-0 060	-0 065
			Q3	-	0 020	0 020	0 020
			Max	-	0 17	0 32	0 23
		Placebo	n	-	82	80	83
			Mean	-	0 003	-0 011	-0 027
			SD	-	0 0795	0 1164	0 1005
			Min	-	-0 21	-0 34	-0 30
			Q1	-	-0 050	-0 085	-0 090
			Median	-	0 020	-0 005	-0 030
			Q3	-	0 060	0 070	0 050
			Max	-	0 20	0 22	0 24
	Percent Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-3 23	-4 27	-6 56
			SD	-	9 206	11 734	12 529
			Min	-	-26 6	-27 8	-33 3
			Q1	-	-10 00	-11 90	-14 42
			Median	-	-3 71	-5 84	-7 20
			Q3	-	2 13	2 22	2 15
			Max	-	17 2	36 0	19 1
		Placebo	n	-	82	80	83
			Mean	-	0 62	-0 65	-2 45
			SD	-	8 375	11 812	10 239
			Min	-	-20 8	-30 6	-27 0
			Q1	-	-4 92	-9 12	-9 38
			Median	-	2 08	-0 63	-3 41
			Q3	-	6 06	7 37	5 21
			Max	-	24 1	25 0	25 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-26 を引用

表 2.7.4-156 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period
				Visit 3	Visit 10 / Discontinuation
Sex Hormone Binding Globulin (nmol/L)	Value	FSN-013	n	79	78
			Mean	154.29	219.12
			SD	67.258	85.541
			Min	23.5	40.2
			Q1	107.10	165.90
			Median	147.90	214.30
			Q3	205.80	271.50
			Max	338.3	379.2
		Placebo	n	83	83
			Mean	147.84	128.44
			SD	61.716	55.868
			Min	57.1	22.5
			Q1	101.60	81.50
			Median	132.60	127.20
			Q3	190.10	152.50
			Max	382.3	327.5
	Change from Baseline	FSN-013	n	-	78
			Mean	-	64.87
			SD	-	71.321
			Min	-	-126.4
			Q1	-	10.60
			Median	-	65.80
			Q3	-	110.20
			Max	-	218.8
		Placebo	n	-	83
			Mean	-	-19.40
			SD	-	40.577
			Min	-	-122.6
			Q1	-	-45.40
			Median	-	-14.70
			Q3	-	3.80
			Max	-	90.3
Sex Hormone Binding Globulin (nmol/L)	Percent Change from Baseline	FSN-013	n	-	78
			Mean	-	53.98
			SD	-	55.479
			Min	-	-48.5
			Q1	-	10.36
			Median	-	50.49
			Q3	-	89.03
			Max	-	176.6
		Placebo	n	-	83
			Mean	-	-10.03
			SD	-	27.375
			Min	-	-66.9
			Q1	-	-28.63
			Median	-	-13.23
			Q3	-	2.66
			Max	-	96.4

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-27 を引用

表 2.7.4-157 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体、）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			
				Visit 3	Visit 5	Visit 6	Visit 8	Visit 10 / Discontinuation
Thrombin Antithrombin Complex (ng/mL)	Value	FSN-013	n	79	78	78	78	78
			Mean	1 54	2 19	1 37	1 58	1 39
			SD	1 495	6 475	1 867	2 428	1 312
			Min	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00
			Q3	1 30	1 30	1 00	1 20	1 10
			Max	9 2	57 7	16 7	18 1	9 6
		Placebo	n	83	82	81	80	83
			Mean	2 37	1 37	1 14	1 66	1 88
			SD	9 457	0 744	0 484	2 621	3 930
			Min	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00
			Q3	1 20	1 50	1 00	1 40	1 20
			Max	87 2	5 5	4 0	22 8	34 7
	Change from Baseline	FSN-013	n	-	78	78	78	78
			Mean	-	0 65	-0 17	0 04	-0 15
			SD	-	6 588	2 440	2 915	1 448
			Min	-	-6 2	-7 8	-8 2	-6 2
			Q1	-	-0 20	-0 20	-0 20	-0 20
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 10	0 00	0 00	0 00
			Max	-	56 7	15 7	17 1	5 1
		Placebo	n	-	82	81	80	83
			Mean	-	-1 00	-1 20	-0 70	-0 49
			SD	-	9 536	9 583	10 020	10 330
			Min	-	-85 7	-86 1	-85 8	-86 2
			Q1	-	-0 10	-0 10	-0 05	-0 10
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 30	0 00	0 15	0 00
			Max	-	4 5	2 6	21 8	33 7
Thrombin Antithrombin Complex (ng/mL)	Percent Change from Baseline	FSN-013	n	-	78	78	78	78
			Mean	-	89 58	20 14	39 39	5 09
			SD	-	645 582	190 103	245 959	53 865
			Min	-	-86 1	-86 1	-89 1	-86 1
			Q1	-	-15 38	-16 67	-15 38	-16 67
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	7 69	0 00	0 00	0 00
			Max	-	5670 0	1570 0	1710 0	290 0
		Placebo	n	-	82	81	80	83
			Mean	-	20 90	-2 62	49 71	62 69
			SD	-	82 294	40 319	265 617	386 991
			Min	-	-98 3	-98 7	-98 4	-98 9
			Q1	-	-9 09	-6 25	-4 17	-8 33
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	28 57	0 00	15 00	0 00
			Max	-	450 0	236 4	2180 0	3370 0

表 2.7.4-157 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体、）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			
				Visit 3	Visit 5	Visit 6	Visit 8	Visit 10 / Discontinuation
D-Dimer (ug/mL)	Value	FSN-013	n	79	78	78	78	78
			Mean	0 410	0 410	0 401	0 389	0 368
			SD	0 1800	0 2390	0 2338	0 1833	0 1116
			Min	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300
			Median	0 330	0 310	0 300	0 300	0 300
			Q3	0 440	0 400	0 420	0 400	0 400
			Max	1 47	1 60	1 91	1 15	0 77
		Placebo	n	83	82	81	80	83
			Mean	0 362	0 378	0 407	0 380	0 425
			SD	0 1348	0 1468	0 2003	0 1519	0 3408
			Min	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300
			Q3	0 320	0 390	0 420	0 385	0 460
			Max	0 85	1 03	1 17	0 92	3 20
D-Dimer (ug/mL)	Change from Baseline	FSN-013	n	-	78	78	78	78
			Mean	-	-0 001	-0 010	-0 022	-0 043
			SD	-	0 2448	0 1884	0 1842	0 1405
			Min	-	-0 43	-0 45	-0 45	-0 70
			Q1	-	-0 090	-0 090	-0 090	-0 080
			Median	-	0 000	0 000	0 000	0 000
			Q3	-	0 030	0 020	0 000	0 000
			Max	-	1 24	0 59	0 78	0 24
		Placebo	n	-	82	81	80	83
			Mean	-	0 015	0 043	0 015	0 063
			SD	-	0 1442	0 2012	0 1499	0 3597
			Min	-	-0 45	-0 54	-0 51	-0 54
			Q1	-	0 000	0 000	0 000	0 000
			Median	-	0 000	0 000	0 000	0 000
			Q3	-	0 060	0 070	0 055	0 070
			Max	-	0 46	0 87	0 58	2 90
	Percent Change from Baseline	FSN-013	n	-	78	78	78	78
			Mean	-	6 68	2 42	1 46	-4 85
			SD	-	59 174	43 261	49 302	24 220
			Min	-	-57 1	-60 0	-60 0	-60 0
			Q1	-	-21 05	-21 05	-21 05	-18 60
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	10 00	2 33	0 00	0 00
			Max	-	344 4	193 3	260 0	80 0
		Placebo	n	-	82	81	80	83
			Mean	-	8 45	17 53	8 69	25 99
			SD	-	32 678	56 773	37 755	114 445
			Min	-	-60 0	-64 3	-60 7	-64 3
			Q1	-	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	16 67	22 35	14 48	17 95
			Max	-	136 7	290 0	193 3	966 7

表 2.7.4-157 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体、）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			
				Visit 3	Visit 5	Visit 6	Visit 8	Visit 10 / Discontinuation
Soluble Fibrin Monomer Complex (ug/mL)	Value	FSN-013	n	79	78	78	78	78
			Mean	5 64	6 90	5 80	6 46	5 90
			SD	3 228	9 909	5 030	9 346	4 461
			Min	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00
			Max	30 7	81 3	41 5	82 5	33 9
		Placebo	n	83	82	81	80	83
			Mean	5 68	5 01	5 10	6 10	7 58
			SD	5 597	0 133	0 736	8 238	16 616
			Min	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00
			Max	56 0	6 2	11 4	77 4	151 0
	Change from Baseline	FSN-013	n	-	78	78	78	78
			Mean	-	1 25	0 15	0 81	0 24
			SD	-	9 255	4 436	8 952	2 753
			Min	-	-8 7	-9 6	-9 6	-8 7
			Q1	-	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00
			Max	-	76 3	36 5	77 5	19 8
		Placebo	n	-	82	81	80	83
			Mean	-	-0 66	-0 59	0 40	1 90
			SD	-	5 635	5 726	10 096	17 634
			Min	-	-51 0	-51 0	-51 0	-51 0
			Q1	-	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00
			Max	-	1 2	6 4	72 4	146 0
Soluble Fibrin Monomer Complex (ug/mL)	Percent Change from Baseline	FSN-013	n	-	78	78	78	78
			Mean	-	22 59	6 52	18 93	4 58
			SD	-	174 895	83 817	176 261	46 678
			Min	-	-63 5	-65 8	-65 8	-63 5
			Q1	-	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00
			Max	-	1526 0	730 0	1550 0	396 0
		Placebo	n	-	82	81	80	83
			Mean	-	-1 74	-0 03	19 89	49 46
			SD	-	11 132	18 503	165 403	332 835
			Min	-	-91 1	-91 1	-91 1	-91 1
			Q1	-	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00
			Max	-	24 0	128 0	1448 0	2920 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-28 を引用

表 2.7.4-158 血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	FSN-013 N = 79		Placebo N = 83	
	Above Upper Limit n (%)	Below Lower Limit n (%)	Above Upper Limit n (%)	Below Lower Limit n (%)
Prothrombin Time (sec)	8 (10.1)	0 (0.0)	17 (20.5)	0 (0.0)
Prothrombin Control (sec)	-	-	-	-
Prothrombin Activity (%)	52 (65.8)	0 (0.0)	45 (54.2)	0 (0.0)
Prothrombin Intl. Normalized Ratio	1 (1.3)	1 (1.3)	4 (4.8)	1 (1.2)
Activated Partial Thromboplastin Time (sec)	6 (7.6)	2 (2.5)	5 (6.0)	2 (2.4)
Activated Partial Thromboplastin Control (sec)	-	-	-	-
Fibrinogen (mg/dL)	1 (1.3)	1 (1.3)	0 (0.0)	1 (1.2)
Antithrombin Activity (%)	13 (16.5)	1 (1.3)	13 (15.7)	1 (1.2)
Plasminogen (%)	9 (11.4)	4 (5.1)	2 (2.4)	7 (8.4)
Thrombin Antithrombin Complex (ng/mL)	14 (17.7)	-	13 (15.7)	-
Factor XIV Activity (%)	10 (12.7)	0 (0.0)	4 (4.8)	1 (1.2)
D-Dimer (ug/mL)	5 (6.3)	-	7 (8.4)	-
Soluble Fibrin Monomer Complex (ug/mL)	9 (11.4)	-	10 (12.0)	-
Protein S Activity Actual/Control	15 (19.0)	2 (2.5)	25 (30.1)	1 (1.2)
Protein S Total Activity (IU/mL)	7 (8.9)	4 (5.1)	1 (1.2)	5 (6.0)
Protein S, Free (%)	1 (1.3)	1 (1.3)	0 (0.0)	1 (1.2)
Protein S (IU/mL)	5 (6.3)	10 (12.7)	0 (0.0)	6 (7.2)
Sex Hormone Binding Globulin (nmol/L)	-	-	-	-

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-35 を引用

2.7.4.3.1.3.2.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、血液凝固系検査の測定値、ベースラインからの変化量及び変化率を表 2.7.4-159～表 2.7.4-161 に、血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度を表 2.7.4-162 に示す。

トロンビン・アンチトロンビン III 複合体、可溶性フィブリンモノマー複合体、プロテイン C、プロテイン S 及び D-ダイマーに関する投与前後の平均変化量に特記すべき異常変動はみられなかった。また、D-ダイマーの基準値上限を逸脱した被験者の割合は、FSN-013 群では 13.9%（11/79 例）、プラセボ群では 7.8%（6/77 例）であった。その他のいずれの項目も経時的推移は FSN-013 群及びプラセボ群で特記すべき異常変動はなく、FSN-013 群（52 週投与）の基準値上限超、基準値下限未満の頻度は、FSN-013 群（24 週投与、表 2.7.4-158）と比べて大差は認められなかった。

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Time (sec)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	11 38	11 28	11 45	11 38	11 41	11 32	10 99	11 02
			SD	0 710	0 697	0 700	0 717	0 642	0 639	0 686	0 734
			Min	9 7	9 7	9 7	9 5	9 6	9 1	9 7	9 6
			Q1	10 80	10 80	10 90	10 90	11 00	11 00	10 50	10 50
			Median	11 40	11 30	11 40	11 40	11 40	11 30	11 00	10 90
			Q3	11 90	11 70	11 90	11 90	11 90	11 80	11 25	11 40
			Max	13 3	12 9	13 9	13 3	13 2	12 6	12 8	13 8
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	11 33	11 53	11 66	11 67	11 40	11 36	11 12	11 00
			SD	0 732	0 764	0 717	0 760	0 625	0 735	0 748	0 641
			Min	10 0	9 6	9 8	10 1	10 0	9 6	9 4	9 6
			Q1	10 80	11 00	11 20	11 20	10 90	11 00	10 60	10 60
			Median	11 30	11 50	11 60	11 60	11 40	11 30	11 20	11 00
			Q3	11 80	12 00	12 10	12 10	11 70	11 80	11 55	11 30
			Max	13 5	13 5	14 3	14 2	13 0	13 3	13 2	13 4
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 10	0 08	0 01	0 04	-0 05	-0 37	-0 35
			SD	-	0 732	0 720	0 833	0 774	0 850	0 690	0 798
			Min	-	-2 1	-1 6	-2 8	-2 5	-2 9	-2 5	-2 5
			Q1	-	-0 50	-0 40	-0 50	-0 50	-0 50	-0 70	-0 90
			Median	-	-0 05	0 00	0 00	0 10	0 00	-0 40	-0 30
			Q3	-	0 50	0 60	0 60	0 60	0 50	0 10	0 10
			Max	-	1 3	2 1	1 6	1 8	1 5	0 9	1 9
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 20	0 33	0 34	0 07	0 03	-0 21	-0 33
			SD	-	0 632	0 682	0 668	0 663	0 781	0 733	0 612
			Min	-	-2 3	-2 1	-1 6	-2 4	-3 5	-3 1	-2 1
			Q1	-	-0 20	-0 05	0 00	-0 40	-0 40	-0 60	-0 70
			Median	-	0 20	0 40	0 30	0 10	0 10	-0 10	-0 25
			Q3	-	0 70	0 80	0 70	0 50	0 50	0 30	0 10
			Max	-	1 9	2 0	2 5	1 3	1 9	1 4	1 2
Prothrombin Time (sec)	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 64	0 87	0 38	0 57	-0 11	-3 10	-2 84
			SD	-	6 302	6 326	7 178	6 685	7 291	5 813	6 744
			Min	-	-16 3	-12 5	-21 9	-18 8	-21 8	-19 5	-19 5
			Q1	-	-4 10	-3 25	-4 72	-4 13	-4 13	-6 51	-7 50
			Median	-	-0 42	0 00	0 00	0 92	0 00	-3 45	-2 61
			Q3	-	4 42	5 36	5 61	5 13	4 13	0 92	0 93
			Max	-	11 7	19 6	14 0	16 7	13 5	8 1	16 0
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	1 93	3 12	3 18	0 89	0 52	-1 63	-2 72
			SD	-	5 511	5 984	5 917	5 792	6 660	6 185	5 271
			Min	-	-17 0	-15 6	-11 9	-17 8	-25 9	-23 0	-15 6
			Q1	-	-1 71	-0 42	0 00	-3 33	-4 00	-5 64	-6 61
			Median	-	1 70	3 52	2 54	0 94	0 90	-0 88	-2 18
			Q3	-	6 14	6 64	6 42	4 59	4 72	2 84	0 89
			Max	-	18 8	19 4	23 8	12 6	17 9	12 5	11 9

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Control (sec)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			SD	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Median	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Max	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			SD	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Median	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Max	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5
Prothrombin Control (sec)	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Activity (%)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	96 0	97 2	95 9	96 7	96 8	96 9	98 1	97 1
			SD	6 12	4 90	6 36	5 84	5 59	4 67	4 78	5 86
			Min	76	80	71	76	80	83	79	73
			Q1	92 0	95 0	92 0	92 0	94 0	94 0	97 0	95 0
			Median	98 0	99 5	99 0	100 0	100 0	98 0	101 0	100 0
			Q3	101 0	101 0	101 0	101 0	101 0	101 0	101 0	101 0
			Max	101	101	101	101	101	101	101	101
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	96 4	95 6	94 5	94 8	97 3	96 7	96 8	97 4
			SD	5 91	6 49	6 92	7 20	5 62	5 97	5 96	5 12
			Min	78	77	71	72	80	76	77	76
			Q1	93 0	92 0	90 5	90 0	94 0	94 0	94 0	95 5
			Median	99 0	98 0	96 0	97 0	101 0	100 0	100 5	99 0
			Q3	101 0	101 0	101 0	101 0	101 0	101 0	101 0	101 0
			Max	101	101	101	101	101	101	101	101
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	1 1	-0 2	0 6	0 8	0 9	1 9	0 9
			SD	-	6 04	7 09	7 48	6 78	7 04	5 74	6 52
			Min	-	-15	-18	-18	-16	-18	-8	-19
			Q1	-	-1 0	-2 0	-3 0	-3 0	-3 0	0 0	-2 0
			Median	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q3	-	4 0	3 0	4 0	4 0	3 0	4 0	3 0
			Max	-	19	19	24	25	25	24	25
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-0 7	-1 9	-1 6	1 0	0 4	0 6	1 0
			SD	-	5 81	6 20	6 14	5 28	5 99	5 95	4 69
			Min	-	-18	-15	-22	-13	-17	-18	-10
			Q1	-	-4 0	-5 5	-4 0	-1 0	-1 0	-0 5	-2 0
			Median	-	0 0	-0 5	0 0	0 0	0 0	0 0	0 0
			Q3	-	2 0	0 0	0 0	4 0	3 0	2 0	4 0
			Max	-	22	23	17	23	23	23	17
Prothrombin Activity (%)	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	1 42	0 09	0 93	1 10	1 32	2 25	1 24
			SD	-	6 832	7 808	8 399	7 703	8 007	6 710	7 583
			Min	-	-14 9	-17 8	-19 1	-15 8	-17 8	-8 3	-20 7
			Q1	-	-1 04	-2 13	-2 97	-3 09	-2 97	0 00	-1 98
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	4 12	3 09	4 12	4 12	3 41	4 12	3 16
			Max	-	23 7	25 0	31 6	32 9	32 9	31 6	32 9
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-0 60	-1 82	-1 52	1 24	0 65	0 85	1 19
			SD	-	6 486	6 903	6 608	5 940	6 692	6 684	5 227
			Min	-	-18 8	-15 6	-21 8	-13 5	-16 8	-17 8	-9 9
			Q1	-	-3 96	-6 10	-4 76	-0 99	-1 14	-0 52	-1 98
			Median	-	0 00	-0 50	0 00	0 00	0 00	0 00	0 00
			Q3	-	2 02	0 00	0 00	4 12	3 09	2 02	4 12
			Max	-	28 2	29 5	21 8	29 5	29 5	29 5	21 8

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Prothrombin Intl Normalized Ratio	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	0 990	0 981	0 995	0 990	0 991	0 990	0 974	0 988
			SD	0 0601	0 0594	0 0609	0 0611	0 0550	0 0518	0 0563	0 0627
			Min	0 85	0 85	0 84	0 83	0 84	0 80	0 88	0 87
			Q1	0 940	0 940	0 950	0 950	0 960	0 970	0 935	0 940
			Median	0 990	0 980	0 990	0 990	0 990	0 990	0 970	0 980
			Q3	1 030	1 020	1 030	1 030	1 030	1 030	1 005	1 020
			Max	1 15	1 12	1 21	1 15	1 15	1 09	1 11	1 23
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	0 985	1 003	1 013	1 015	0 992	0 994	0 985	0 987
			SD	0 0620	0 0647	0 0616	0 0652	0 0541	0 0618	0 0673	0 0559
			Min	0 87	0 84	0 85	0 88	0 87	0 84	0 82	0 87
			Q1	0 940	0 960	0 970	0 970	0 950	0 960	0 940	0 950
			Median	0 980	1 000	1 010	1 010	0 990	0 990	0 980	0 980
			Q3	1 030	1 040	1 050	1 050	1 020	1 030	1 025	1 020
			Max	1 17	1 17	1 24	1 23	1 13	1 15	1 18	1 20
Prothrombin Intl Normalized Ratio	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 008	0 006	0 001	0 002	0 001	-0 014	0 000
			SD	-	0 0625	0 0616	0 0704	0 0647	0 0665	0 0536	0 0664
			Min	-	-0 18	-0 14	-0 24	-0 21	-0 21	-0 18	-0 18
			Q1	-	-0 040	-0 030	-0 040	-0 040	-0 040	-0 050	-0 040
			Median	-	0 000	0 000	0 000	0 010	0 010	-0 015	0 000
			Q3	-	0 040	0 050	0 050	0 050	0 040	0 030	0 040
			Max	-	0 11	0 18	0 13	0 15	0 12	0 08	0 20
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 017	0 028	0 029	0 006	0 008	-0 001	0 002
			SD	-	0 0534	0 0582	0 0566	0 0567	0 0618	0 0597	0 0520
			Min	-	-0 20	-0 18	-0 14	-0 20	-0 27	-0 23	-0 14
			Q1	-	-0 010	-0 005	0 000	-0 030	-0 020	-0 045	-0 040
			Median	-	0 015	0 035	0 030	0 010	0 010	0 000	0 010
			Q3	-	0 060	0 070	0 060	0 050	0 050	0 035	0 035
			Max	-	0 16	0 17	0 21	0 11	0 17	0 16	0 14
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 62	0 78	0 35	0 46	0 39	-1 27	0 16
			SD	-	6 190	6 215	6 971	6 421	6 592	5 241	6 547
			Min	-	-16 1	-12 6	-21 6	-18 3	-18 3	-16 2	-16 2
			Q1	-	-3 92	-3 06	-4 35	-3 81	-3 81	-4 98	-4 00
			Median	-	0 00	0 00	0 00	1 01	0 98	-1 51	0 00
			Q3	-	4 30	5 43	5 38	4 90	4 04	3 16	4 21
			Max	-	11 3	19 4	14 0	15 8	13 2	8 8	19 4
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	1 89	3 00	3 13	0 83	1 05	0 10	0 34
			SD	-	5 339	5 864	5 755	5 690	6 102	5 881	5 277
			Min	-	-17 1	-15 4	-12 0	-17 1	-23 1	-19 7	-12 0
			Q1	-	-1 03	-0 45	0 00	-3 00	-2 02	-4 19	-3 79
			Median	-	1 50	3 41	2 73	1 03	1 05	0 00	0 97
			Q3	-	6 06	6 70	6 32	4 81	4 90	3 65	3 57
			Max	-	18 2	18 9	22 8	12 2	18 5	16 5	15 9

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Activated Partial Thromboplastin Time (sec)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	33 58	30 96	31 13	30 86	30 80	30 15	29 63	30 53
			SD	10 307	2 758	2 618	2 860	2 861	2 458	2 367	2 828
			Min	25 3	21 8	24 6	24 6	24 2	24 5	23 1	22 1
			Q1	30 70	29 30	29 50	29 30	29 20	28 50	28 10	29 00
			Median	32 70	31 20	31 20	30 65	30 80	30 40	29 55	30 00
			Q3	34 00	32 90	33 00	32 20	32 70	32 00	31 25	32 70
			Max	120 1	37 3	37 5	40 2	38 1	34 7	35 9	37 5
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	31 82	31 90	31 22	31 36	30 27	30 78	29 13	29 67
			SD	3 244	2 507	2 810	2 416	2 782	7 773	2 445	2 658
			Min	24 6	25 6	23 3	23 0	23 2	23 8	23 3	21 6
			Q1	29 60	30 60	29 85	30 10	28 20	28 10	27 45	28 20
			Median	31 50	31 45	31 25	31 30	30 20	29 50	29 15	29 50
			Q3	33 20	33 40	32 95	32 70	31 90	31 50	30 70	31 55
			Max	48 5	39 1	39 4	37 9	40 1	92 9	35 9	38 6
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-2 62	-2 44	-2 73	-2 81	-3 54	-3 99	-3 09
			SD	-	10 042	10 399	10 418	10 342	10 960	10 543	10 445
			Min	-	-88 3	-90 9	-91 5	-88 5	-92 1	-92 7	-90 5
			Q1	-	-2 80	-2 50	-2 90	-2 80	-2 90	-3 90	-2 90
			Median	-	-1 30	-1 20	-1 50	-1 90	-1 90	-2 50	-1 80
			Q3	-	-0 30	0 10	-0 20	0 00	-0 70	-1 45	-0 90
			Max	-	3 7	3 6	5 9	2 3	1 6	1 9	5 4
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 09	-0 58	-0 46	-1 48	-0 98	-2 63	-2 05
			SD	-	2 884	3 247	3 028	3 372	5 792	3 201	3 152
			Min	-	-18 9	-19 8	-18 4	-21 8	-10 6	-25 0	-24 9
			Q1	-	-0 60	-1 15	-1 30	-2 80	-2 70	-3 50	-2 70
			Median	-	0 35	-0 10	-0 20	-1 40	-1 40	-2 25	-1 65
			Q3	-	1 40	1 20	1 20	0 30	-0 40	-1 20	-0 60
			Max	-	6 8	6 0	6 9	4 9	44 4	1 5	3 5
Activated Partial Thromboplastin Time (sec)	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-5 32	-4 61	-5 56	-5 73	-7 62	-9 25	-6 61
			SD	-	9 930	10 523	10 296	10 299	10 699	9 866	10 145
			Min	-	-73 5	-75 7	-76 2	-73 7	-76 7	-77 2	-75 4
			Q1	-	-8 43	-7 62	-9 09	-9 00	-9 15	-11 79	-8 95
			Median	-	-3 98	-3 62	-4 67	-5 62	-6 01	-7 76	-5 81
			Q3	-	-0 95	0 30	-0 62	0 00	-2 18	-4 34	-2 75
			Max	-	12 5	12 6	17 2	7 9	5 0	5 9	18 9
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 77	-1 33	-0 90	-4 15	-3 56	-7 79	-6 04
			SD	-	7 542	8 615	8 180	8 674	13 026	7 383	7 602
			Min	-	-39 0	-40 8	-37 9	-44 9	-27 0	-51 5	-51 3
			Q1	-	-2 07	-3 67	-3 97	-8 88	-8 47	-11 34	-8 69
			Median	-	1 11	-0 33	-0 65	-4 68	-4 45	-7 38	-5 47
			Q3	-	4 81	3 61	3 79	0 96	-1 38	-3 56	-1 90
			Max	-	27 6	24 4	28 0	19 9	91 5	4 8	14 2

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Activated Partial Thromboplastin Control (sec)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			SD	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Median	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Max	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			SD	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Median	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Max	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7
Activated Partial Thromboplastin Control (sec)	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Fibrinogen (mg/dL)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	268 9	284 6	276 9	285 8	284 4	284 3	286 5	262 3
			SD	49 53	49 17	45 36	44 98	52 10	38 61	38 03	39 51
			Min	170	185	150	172	153	219	218	195
			Q1	237 0	251 0	247 0	254 0	247 0	252 0	259 0	231 0
			Median	259 0	278 0	275 5	284 5	281 5	281 0	280 5	261 0
			Q3	299 0	313 0	307 0	314 0	313 0	306 0	313 5	294 0
			Max	438	444	390	410	426	385	405	358
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	253 2	270 9	263 8	273 5	282 7	280 5	289 3	263 9
			SD	40 58	47 30	45 27	45 89	44 31	46 74	68 14	41 80
			Min	134	168	169	146	194	192	157	188
			Q1	225 0	232 0	231 0	243 0	249 0	247 0	256 0	232 0
			Median	253 0	269 0	257 0	271 0	277 0	279 0	280 5	261 0
			Q3	278 0	304 0	296 0	305 0	318 0	300 0	309 0	285 0
			Max	378	388	370	400	395	416	698	392
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	16 1	8 5	17 8	16 9	17 2	19 0	-5 7
			SD	-	40 99	43 42	41 97	45 84	46 37	40 74	40 62
			Min	-	-116	-122	-96	-106	-139	-104	-122
			Q1	-	-5 0	-15 0	-15 0	-10 0	-15 0	-5 0	-28 0
			Median	-	15 0	7 5	20 0	21 5	26 0	18 0	0 0
			Q3	-	39 0	42 0	50 0	46 0	45 0	47 0	25 0
			Max	-	166	90	109	117	121	104	74
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	18 4	11 1	20 3	29 3	27 0	36 3	10 4
			SD	-	37 95	41 64	44 45	41 68	41 00	60 01	40 46
			Min	-	-68	-99	-104	-123	-101	-77	-121
			Q1	-	-4 0	-19 5	-6 0	9 0	4 0	11 5	-10 5
			Median	-	16 5	11 0	22 0	34 0	27 0	28 0	4 0
			Q3	-	43 0	33 5	47 0	56 0	52 0	49 5	29 0
			Max	-	127	118	152	113	138	420	139
Fibrinogen (mg/dL)	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	7 25	4 70	8 19	7 72	8 64	9 05	-0 62
			SD	-	15 182	16 157	16 107	17 155	17 188	15 794	14 330
			Min	-	-37 9	-39 8	-25 7	-40 9	-34 9	-23 7	-27 9
			Q1	-	-1 27	-6 30	-3 96	-3 19	-5 21	-1 97	-12 12
			Median	-	6 15	2 87	7 71	8 02	10 18	7 30	0 00
			Q3	-	17 47	16 05	19 90	19 78	19 42	21 45	10 44
			Max	-	59 7	40 3	45 8	41 5	66 5	55 3	35 1
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	8 08	5 55	9 56	13 15	12 06	15 26	5 46
			SD	-	15 087	17 146	19 937	18 227	18 226	23 344	16 490
			Min	-	-21 0	-30 6	-35 7	-38 0	-26 7	-23 8	-38 8
			Q1	-	-1 94	-7 01	-2 51	3 46	1 41	3 92	-4 12
			Median	-	5 82	4 50	8 81	12 37	11 30	11 72	1 57
			Q3	-	17 37	13 87	18 58	23 39	18 14	21 31	13 54
			Max	-	48 7	57 3	91 6	84 3	100 7	151 1	65 9

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Antithrombin Activity (%)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	113 4	109 6	108 5	110 0	110 2	110 9	111 2	108 1
			SD	10 98	11 06	11 45	10 49	10 91	10 65	10 90	9 54
			Min	88	87	71	88	83	93	89	90
			Q1	106 0	102 0	101 0	103 0	104 0	104 0	104 0	101 0
			Median	113 0	109 0	108 5	110 0	109 0	111 0	111 0	107 0
			Q3	119 0	116 0	116 0	117 0	115 0	117 0	119 0	114 0
			Max	141	142	140	136	147	143	134	131
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	109 6	108 5	107 4	109 2	109 4	109 4	109 1	106 7
			SD	9 75	9 21	10 69	11 46	9 19	10 80	10 91	9 84
			Min	82	88	80	83	88	85	91	82
			Q1	104 0	103 0	100 5	102 0	103 0	101 0	100 5	101 0
			Median	109 0	109 0	107 0	108 0	110 0	108 0	108 5	106 5
			Q3	115 0	115 0	114 5	117 0	116 0	118 0	117 5	113 5
			Max	135	138	131	139	131	142	134	130
Antithrombin Activity (%)	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-3 8	-5 0	-3 2	-3 0	-2 1	-2 1	-5 1
			SD	-	9 34	8 39	8 70	9 19	9 54	9 78	9 21
			Min	-	-23	-33	-28	-30	-27	-21	-31
			Q1	-	-10 0	-11 0	-9 0	-8 0	-8 0	-8 5	-10 0
			Median	-	-4 0	-4 0	-3 0	-2 0	-3 0	-3 5	-6 0
			Q3	-	1 0	0 0	2 0	3 0	3 0	4 0	1 0
			Max	-	27	15	17	17	19	27	20
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-0 9	-2 2	-0 4	-0 4	-0 4	-0 5	-2 8
			SD	-	6 65	9 20	8 77	7 48	8 78	9 47	8 98
			Min	-	-21	-25	-24	-15	-20	-25	-23
			Q1	-	-5 0	-8 0	-6 0	-6 0	-5 0	-7 0	-7 5
			Median	-	-2 0	-2 0	0 0	-2 0	0 0	-1 0	-3 0
			Q3	-	3 0	3 0	4 0	4 0	5 0	8 0	3 0
			Max	-	14	23	21	18	20	20	21
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-3 04	-4 18	-2 52	-2 28	-1 43	-1 47	-4 06
			SD	-	8 380	7 446	7 669	8 072	8 457	9 096	7 945
			Min	-	-20 0	-31 7	-21 1	-26 5	-20 3	-18 9	-22 5
			Q1	-	-8 57	-9 48	-8 26	-6 90	-7 55	-7 24	-9 22
			Median	-	-3 56	-3 43	-2 99	-1 98	-2 83	-2 90	-5 17
			Q3	-	0 80	0 00	1 57	3 33	3 19	3 62	0 88
			Max	-	23 9	17 0	19 3	19 3	21 6	30 7	20 8
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-0 56	-1 78	-0 19	-0 07	-0 11	-0 16	-2 23
			SD	-	6 218	8 552	8 079	7 190	7 975	8 703	8 064
			Min	-	-16 4	-23 4	-22 4	-11 7	-17 3	-19 5	-19 6
			Q1	-	-4 39	-6 73	-5 74	-4 72	-4 72	-6 12	-6 75
			Median	-	-1 75	-1 79	0 00	-1 74	0 00	-0 86	-3 05
			Q3	-	2 94	2 97	3 96	3 77	4 76	6 91	2 67
			Max	-	17 1	28 0	19 6	19 5	19 8	18 7	19 3

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Plasminogen (%)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	98 1	106 1	107 6	107 3	105 1	106 2	105 5	94 8
			SD	15 79	16 32	17 53	16 63	16 36	15 11	15 65	13 20
			Min	48	55	52	52	51	53	54	46
			Q1	92 0	97 0	99 0	100 0	100 0	100 0	99 0	89 0
			Median	98 0	106 0	107 5	108 0	107 0	107 0	106 5	95 0
			Q3	109 0	115 0	119 0	120 0	116 0	113 0	116 0	102 0
			Max	134	148	145	143	132	130	137	124
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	94 2	95 0	94 3	94 0	104 5	104 2	104 3	94 1
			SD	14 30	15 11	15 49	15 27	16 47	17 51	17 35	13 45
			Min	50	48	47	47	52	51	48	50
			Q1	89 0	88 0	88 5	88 0	97 0	97 0	96 0	88 0
			Median	95 0	96 0	95 0	96 0	106 0	104 5	104 5	95 5
			Q3	102 0	103 0	102 0	103 0	114 0	112 0	115 0	102 0
			Max	121	134	129	127	140	145	137	119
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	8 0	9 5	9 7	7 8	8 3	8 1	-3 4
			SD	-	7 79	8 78	9 22	9 35	9 19	9 64	7 46
			Min	-	-10	-15	-12	-14	-24	-12	-22
			Q1	-	2 0	3 0	5 0	2 0	1 0	2 0	-9 0
			Median	-	7 5	10 0	9 0	9 5	9 0	8 0	-2 0
			Q3	-	14 0	15 0	13 0	14 0	15 0	14 0	2 0
			Max	-	25	37	33	30	32	32	12
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 9	0 1	-0 2	9 6	9 5	9 8	-0 5
			SD	-	6 73	7 88	7 25	8 25	9 54	9 59	7 23
			Min	-	-19	-18	-22	-11	-6	-13	-19
			Q1	-	-4 0	-4 5	-4 0	4 0	3 0	2 0	-5 0
			Median	-	1 0	0 5	-1 0	10 0	9 0	9 5	-1 0
			Q3	-	6 0	6 0	5 0	16 0	16 0	16 0	4 0
			Max	-	24	19	17	36	41	36	19
Plasminogen (%)	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	8 73	10 00	10 32	8 52	9 04	9 06	-3 00
			SD	-	8 786	9 067	9 740	9 961	9 422	10 461	7 381
			Min	-	-7 5	-11 2	-12 6	-13 2	-17 9	-11 6	-19 8
			Q1	-	1 98	3 03	4 95	2 00	1 67	2 01	-9 09
			Median	-	8 07	9 72	9 45	9 61	9 47	8 18	-1 96
			Q3	-	13 86	16 09	16 09	16 09	16 36	16 79	1 82
			Max	-	40 0	40 2	35 9	34 5	33 0	36 4	15 6
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	1 10	0 27	-0 11	10 39	10 17	10 56	-0 06
			SD	-	7 069	8 400	7 583	8 648	10 027	10 336	7 675
			Min	-	-15 7	-20 2	-18 8	-11 7	-5 9	-12 7	-17 0
			Q1	-	-4 00	-4 70	-5 15	4 85	2 94	2 14	-5 69
			Median	-	1 02	0 44	-0 98	10 00	9 16	9 47	-0 96
			Q3	-	5 43	5 83	5 10	17 53	17 82	17 30	4 47
			Max	-	21 8	18 8	19 8	34 6	39 4	41 9	20 2

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Factor XIV Activity (%)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	113 7	108 9	108 6	108 3	107 6	108 3	112 8	111 7
			SD	16 84	16 68	16 48	16 60	15 20	13 79	17 58	15 03
			Min	81	83	78	81	80	72	80	81
			Q1	101 0	98 0	100 0	96 0	96 0	98 0	101 5	100 0
			Median	112 0	106 0	106 5	105 0	107 0	108 0	110 0	110 0
			Q3	123 0	117 0	119 0	117 0	117 0	116 0	123 0	122 0
			Max	149	151	151	150	151	144	151	148
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	108 0	101 5	102 1	102 8	105 6	106 8	109 1	110 5
			SD	14 17	14 15	15 13	15 09	15 51	15 73	13 82	15 99
			Min	57	55	62	58	61	55	58	59
			Q1	98 0	93 0	92 5	92 0	95 0	97 0	99 5	101 0
			Median	109 0	100 5	101 0	101 0	105 0	106 0	107 5	110 0
			Q3	118 0	109 0	110 5	111 0	115 0	113 0	118 0	121 0
			Max	140	137	145	150	147	151	151	151
Factor XIV Activity (%)	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-4 9	-5 2	-5 1	-5 6	-4 5	-0 6	-1 8
			SD	-	10 43	11 29	11 12	11 41	11 14	13 27	10 85
			Min	-	-25	-39	-31	-41	-53	-31	-29
			Q1	-	-12 0	-13 0	-12 0	-14 0	-9 0	-9 5	-8 0
			Median	-	-6 0	-5 5	-5 0	-4 0	-4 0	-0 5	0 0
			Q3	-	3 0	5 0	2 0	2 0	1 0	7 5	5 0
			Max	-	32	13	30	25	16	30	26
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-6 7	-6 2	-5 3	-2 6	-1 4	1 1	2 4
			SD	-	10 08	10 87	10 36	10 05	11 55	10 77	9 64
			Min	-	-32	-42	-29	-28	-30	-25	-19
			Q1	-	-13 0	-12 5	-11 0	-9 0	-8 0	-6 5	-5 0
			Median	-	-6 0	-6 5	-5 0	-3 0	-2 0	2 0	2 5
			Q3	-	0 0	1 0	0 0	4 0	5 0	8 0	8 0
			Max	-	21	13	24	23	31	26	32
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-3 90	-4 16	-4 03	-4 35	-3 25	0 01	-0 92
			SD	-	8 945	9 387	9 670	9 869	9 250	11 710	9 181
			Min	-	-20 7	-26 5	-21 1	-27 9	-36 1	-23 7	-19 5
			Q1	-	-9 40	-11 94	-11 22	-11 97	-7 69	-8 02	-8 04
			Median	-	-5 32	-4 82	-4 94	-3 48	-2 94	-0 38	0 00
			Q3	-	2 83	3 42	2 47	1 80	1 04	6 17	4 27
			Max	-	26 9	14 1	28 6	24 8	17 4	34 1	24 5
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-5 85	-5 39	-4 58	-2 13	-0 91	1 70	2 45
			SD	-	8 798	9 428	9 333	9 344	10 334	10 263	8 966
			Min	-	-27 1	-35 6	-24 6	-27 7	-23 9	-21 4	-15 6
			Q1	-	-11 86	-10 50	-10 34	-8 57	-7 69	-5 56	-3 80
			Median	-	-5 94	-5 53	-4 76	-2 88	-2 25	1 74	2 76
			Q3	-	0 00	1 06	0 00	3 33	5 26	7 22	7 09
			Max	-	18 6	12 4	23 1	20 4	25 8	28 8	30 5

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S Activity Actual/Control	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	1 073	1 068	1 064	1 061	1 046	1 062	1 055	1 070
			SD	0 1095	0 0832	0 1152	0 1015	0 0908	0 0900	0 0900	0 1004
			Min	0 74	0 74	0 68	0 70	0 75	0 76	0 76	0 72
			Q1	1 000	1 010	1 000	0 990	1 000	1 000	1 005	1 010
			Median	1 070	1 080	1 060	1 060	1 040	1 060	1 050	1 060
			Q3	1 140	1 120	1 120	1 120	1 110	1 130	1 100	1 140
			Max	1 37	1 24	1 49	1 35	1 24	1 26	1 25	1 26
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	1 065	1 083	1 081	1 072	1 049	1 097	1 061	1 076
			SD	0 1037	0 1065	0 1191	0 1071	0 1078	0 2711	0 1009	0 1078
			Min	0 65	0 66	0 67	0 62	0 62	0 67	0 60	0 64
			Q1	0 990	1 000	1 010	1 010	0 990	1 010	1 010	1 020
			Median	1 060	1 080	1 065	1 060	1 050	1 070	1 050	1 080
			Q3	1 140	1 160	1 130	1 140	1 130	1 150	1 120	1 160
			Max	1 33	1 36	1 46	1 32	1 36	3 22	1 32	1 33
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 005	-0 009	-0 012	-0 022	-0 004	-0 016	-0 001
			SD	-	0 0942	0 1146	0 0987	0 1073	0 0900	0 0918	0 1168
			Min	-	-0 25	-0 21	-0 25	-0 27	-0 25	-0 22	-0 28
			Q1	-	-0 040	-0 090	-0 070	-0 090	-0 050	-0 070	-0 070
			Median	-	0 015	-0 020	0 000	-0 020	0 000	0 010	0 020
			Q3	-	0 040	0 060	0 060	0 050	0 060	0 045	0 080
			Max	-	0 25	0 43	0 23	0 24	0 17	0 15	0 25
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 018	0 017	0 007	-0 013	0 034	0 001	0 015
			SD	-	0 0866	0 0938	0 0857	0 0858	0 2598	0 0761	0 1008
			Min	-	-0 19	-0 23	-0 21	-0 22	-0 23	-0 16	-0 28
			Q1	-	-0 020	-0 045	-0 060	-0 070	-0 030	-0 050	-0 055
			Median	-	0 020	0 005	0 010	-0 020	0 015	0 000	0 015
			Q3	-	0 070	0 070	0 060	0 050	0 060	0 050	0 090
			Max	-	0 20	0 27	0 21	0 16	2 13	0 28	0 23
Protein S Activity Actual/Control	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	0 10	-0 31	-0 65	-1 43	0 12	-1 02	0 60
			SD	-	8 423	11 045	9 029	9 788	8 235	8 349	10 723
			Min	-	-20 0	-16 7	-20 2	-21 0	-20 3	-19 3	-22 8
			Q1	-	-3 45	-8 11	-6 25	-8 33	-4 39	-6 70	-6 25
			Median	-	1 48	-1 90	0 00	-1 92	0 00	0 91	1 75
			Q3	-	4 17	5 66	5 21	5 10	6 19	4 46	7 84
			Max	-	28 7	49 4	24 5	27 6	17 3	16 1	28 7
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	1 97	1 84	0 93	-0 95	3 34	0 31	1 75
			SD	-	8 084	8 777	7 992	7 924	23 811	7 299	9 499
			Min	-	-15 4	-17 3	-15 8	-18 8	-21 1	-13 9	-23 7
			Q1	-	-2 06	-4 21	-4 84	-6 14	-2 97	-4 70	-4 98
			Median	-	2 08	0 40	1 02	-2 02	1 33	0 00	1 42
			Q3	-	7 37	6 90	5 83	4 76	5 88	5 08	9 09
			Max	-	20 6	26 2	21 2	15 2	195 4	28 3	23 7

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S Total Activity (IU/mL)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	1 102	1 052	1 033	1 003	0 992	1 007	1 041	1 037
			SD	0 2235	0 1780	0 1772	0 1841	0 1844	0 1792	0 1919	0 1669
			Min	0 73	0 72	0 63	0 56	0 62	0 64	0 62	0 63
			Q1	0 930	0 910	0 910	0 850	0 870	0 880	0 875	0 910
			Median	1 070	1 050	1 045	1 025	1 015	1 010	1 060	1 000
			Q3	1 220	1 170	1 140	1 120	1 110	1 170	1 190	1 190
			Max	1 92	1 54	1 54	1 56	1 50	1 43	1 65	1 33
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	1 012	1 030	1 012	0 986	0 967	0 991	1 013	1 013
			SD	0 1650	0 1558	0 1593	0 1504	0 1819	0 2310	0 2106	0 1807
			Min	0 57	0 63	0 60	0 63	0 55	0 57	0 53	0 56
			Q1	0 890	0 910	0 915	0 870	0 860	0 860	0 865	0 875
			Median	1 010	1 040	1 030	0 990	0 960	0 970	1 005	1 005
			Q3	1 120	1 140	1 130	1 110	1 110	1 100	1 150	1 165
			Max	1 45	1 33	1 35	1 32	1 37	2 16	1 82	1 45
Protein S Total Activity (IU/mL)	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 048	-0 068	-0 094	-0 095	-0 073	-0 052	-0 056
			SD	-	0 1456	0 1749	0 1844	0 1740	0 1721	0 1723	0 1846
			Min	-	-0 56	-0 60	-0 74	-0 72	-0 74	-0 68	-0 74
			Q1	-	-0 130	-0 160	-0 170	-0 190	-0 140	-0 150	-0 150
			Median	-	-0 030	-0 065	-0 070	-0 065	-0 040	-0 025	-0 020
			Q3	-	0 050	0 050	0 030	0 030	0 040	0 055	0 050
			Max	-	0 25	0 28	0 27	0 20	0 31	0 27	0 28
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 018	0 000	-0 026	-0 043	-0 019	0 007	0 006
			SD	-	0 1017	0 1178	0 1136	0 1308	0 1827	0 1500	0 1261
			Min	-	-0 24	-0 31	-0 30	-0 40	-0 30	-0 30	-0 34
			Q1	-	-0 050	-0 080	-0 110	-0 130	-0 110	-0 090	-0 060
			Median	-	0 030	0 000	-0 020	-0 050	-0 030	0 005	0 000
			Q3	-	0 090	0 075	0 070	0 060	0 040	0 090	0 100
			Max	-	0 25	0 32	0 19	0 24	1 23	0 69	0 38
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-3 26	-4 77	-7 30	-7 60	-5 49	-3 55	-3 44
			SD	-	11 213	13 850	13 889	13 859	13 525	14 133	14 345
			Min	-	-32 4	-33 5	-43 3	-37 5	-38 5	-35 4	-38 7
			Q1	-	-10 48	-14 29	-15 73	-17 24	-14 61	-12 88	-14 02
			Median	-	-2 95	-6 49	-7 45	-5 95	-3 77	-2 26	-2 27
			Q3	-	3 49	4 82	3 09	2 78	4 17	5 88	5 75
			Max	-	21 2	23 0	22 1	17 4	34 8	27 4	29 2
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	2 45	0 75	-1 73	-3 77	-1 52	1 01	1 07
			SD	-	10 168	11 283	10 957	12 812	19 052	14 883	12 292
			Min	-	-20 5	-21 4	-23 8	-35 7	-27 7	-25 9	-29 1
			Q1	-	-4 24	-7 31	-10 00	-12 35	-9 23	-8 75	-6 87
			Median	-	3 27	0 00	-1 74	-5 26	-3 35	0 39	0 00
			Q3	-	9 80	8 42	7 37	5 83	3 57	8 60	9 88
			Max	-	29 8	31 1	28 1	30 8	132 3	61 1	42 2

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S, Free (%)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	91 6	92 4	92 5	92 2	93 1	93 4	93 8	90 3
			SD	13 48	14 38	15 32	14 95	17 16	15 89	17 08	14 71
			Min	62	59	60	62	61	65	58	51
			Q1	82 0	82 0	80 0	80 0	81 0	82 0	83 0	80 0
			Median	92 0	91 0	92 0	92 5	91 5	91 0	91 0	89 0
			Q3	98 0	104 0	103 0	101 0	105 0	105 0	102 5	100 0
			Max	120	127	128	124	132	133	151	128
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	92 0	91 0	89 6	91 4	93 7	93 9	93 1	90 5
			SD	13 78	12 59	13 59	12 74	14 10	14 79	16 27	16 04
			Min	47	56	52	53	58	55	46	56
			Q1	83 0	83 0	82 0	83 0	82 0	86 0	82 0	78 0
			Median	92 0	92 5	91 0	92 0	93 0	93 0	93 5	91 0
			Q3	102 0	99 0	99 0	100 0	104 0	103 0	104 0	101 5
			Max	131	126	115	126	137	128	142	128
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	1 0	1 2	0 9	2 1	2 6	3 0	-0 5
			SD	-	9 52	10 34	9 71	11 35	11 18	12 35	9 57
			Min	-	-20	-22	-22	-34	-29	-30	-23
			Q1	-	-6 0	-5 0	-6 0	-5 0	-4 0	-6 5	-8 0
			Median	-	1 0	0 5	1 0	3 0	2 0	4 0	-1 0
			Q3	-	7 0	7 0	8 0	10 0	11 0	10 0	6 0
			Max	-	28	29	26	26	29	31	19
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-1 1	-2 8	-0 7	1 6	2 0	0 9	-1 3
			SD	-	7 87	9 96	9 32	9 70	10 75	11 86	10 62
			Min	-	-20	-28	-24	-19	-20	-31	-30
			Q1	-	-5 0	-7 5	-6 0	-6 0	-5 0	-5 5	-8 5
			Median	-	-2 0	-3 0	0 0	2 0	2 0	1 5	-1 0
			Q3	-	4 0	2 5	5 0	8 0	8 0	7 5	7 0
			Max	-	21	24	22	31	29	36	19
Protein S, Free (%)	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	1 61	1 64	1 37	2 51	3 29	3 68	-0 25
			SD	-	11 252	11 570	10 903	12 760	12 921	13 777	10 989
			Min	-	-25 0	-25 0	-23 4	-35 4	-29 6	-28 8	-25 0
			Q1	-	-5 94	-6 10	-6 03	-5 95	-4 30	-6 87	-8 25
			Median	-	1 00	0 53	1 03	3 72	2 22	4 31	-1 04
			Q3	-	7 78	9 21	8 89	10 31	11 11	12 32	6 94
			Max	-	35 5	29 3	26 5	38 7	38 7	34 3	27 3
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	-0 65	-2 50	-0 02	2 38	2 82	1 44	-1 12
			SD	-	8 812	10 839	10 288	11 324	12 060	13 058	11 615
			Min	-	-16 7	-29 1	-24 5	-18 6	-18 9	-27 7	-29 4
			Q1	-	-6 25	-8 85	-6 36	-5 51	-6 25	-6 32	-9 18
			Median	-	-1 83	-2 93	0 00	2 50	2 11	1 55	-1 30
			Q3	-	4 00	2 54	6 41	8 70	10 17	8 27	7 89
			Max	-	23 6	32 0	29 3	41 3	35 8	48 0	21 3

表 2.7.4-159 血液凝固系検査の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Protein S (IU/mL)	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	1 028	0 988	0 975	0 951	0 952	0 952	0 990	0 974
			SD	0 1802	0 1631	0 1663	0 1773	0 1849	0 1704	0 1810	0 1562
			Min	0 70	0 64	0 63	0 59	0 57	0 61	0 62	0 71
			Q1	0 890	0 860	0 850	0 820	0 820	0 840	0 840	0 840
			Median	1 040	0 975	0 975	0 940	0 955	0 950	0 985	0 970
			Q3	1 140	1 130	1 080	1 090	1 080	1 060	1 110	1 080
			Max	1 69	1 36	1 48	1 44	1 40	1 46	1 55	1 33
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	0 952	0 955	0 942	0 924	0 922	0 909	0 957	0 944
			SD	0 1371	0 1414	0 1494	0 1446	0 1520	0 1589	0 1856	0 1540
			Min	0 60	0 62	0 58	0 65	0 63	0 59	0 54	0 64
			Q1	0 850	0 840	0 825	0 810	0 820	0 800	0 830	0 835
			Median	0 960	0 945	0 920	0 890	0 930	0 910	0 940	0 945
			Q3	1 050	1 060	1 080	1 020	1 000	1 010	1 060	1 035
			Max	1 30	1 24	1 24	1 26	1 31	1 40	1 63	1 48
Protein S (IU/mL)	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 039	-0 051	-0 073	-0 066	-0 063	-0 031	-0 049
			SD	-	0 1030	0 1289	0 1423	0 1277	0 1399	0 1310	0 1154
			Min	-	-0 45	-0 47	-0 56	-0 46	-0 61	-0 34	-0 40
			Q1	-	-0 110	-0 120	-0 150	-0 160	-0 120	-0 110	-0 120
			Median	-	-0 040	-0 060	-0 065	-0 070	-0 060	-0 045	-0 050
			Q3	-	0 020	0 020	0 020	0 020	0 010	0 040	0 020
			Max	-	0 17	0 32	0 23	0 19	0 25	0 35	0 23
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 003	-0 011	-0 027	-0 031	-0 041	0 006	-0 007
			SD	-	0 0795	0 1164	0 1005	0 0979	0 0949	0 1233	0 1029
			Min	-	-0 21	-0 34	-0 30	-0 21	-0 25	-0 22	-0 27
			Q1	-	-0 050	-0 085	-0 090	-0 100	-0 100	-0 070	-0 080
			Median	-	0 020	-0 005	-0 030	-0 030	-0 040	0 010	0 010
			Q3	-	0 060	0 070	0 050	0 040	0 030	0 075	0 055
			Max	-	0 20	0 22	0 24	0 21	0 23	0 49	0 27
	Percent Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-3 23	-4 27	-6 56	-6 18	-5 39	-2 45	-3 96
			SD	-	9 206	11 734	12 529	11 948	12 574	13 075	10 854
			Min	-	-26 6	-27 8	-33 3	-29 6	-36 1	-27 2	-26 8
			Q1	-	-10 00	-11 90	-14 42	-15 60	-13 10	-10 71	-12 00
			Median	-	-3 71	-5 84	-7 20	-7 82	-6 19	-5 00	-4 94
			Q3	-	2 13	2 22	2 15	2 22	0 93	4 14	1 87
			Max	-	17 2	36 0	19 1	19 1	27 7	50 0	32 9
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 62	-0 65	-2 45	-2 92	-4 17	0 76	-0 36
			SD	-	8 375	11 812	10 239	10 139	9 917	13 019	10 770
			Min	-	-20 8	-30 6	-27 0	-23 8	-29 8	-28 9	-28 1
			Q1	-	-4 92	-9 12	-9 38	-11 11	-10 23	-7 70	-7 33
			Median	-	2 08	-0 63	-3 41	-3 33	-4 49	1 09	0 92
			Q3	-	6 06	7 37	5 21	4 26	3 57	7 57	5 46
			Max	-	24 1	25 0	25 5	25 0	19 7	43 0	27 8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-17 を引用

表 2.7.4-160 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period	Extension Period
				Visit 3	Visit 10 / Discontinuation	Visit 17 / Discontinuation
Sex Hormone Binding Globulin (nmol/L)	Value	FSN-013	n	79	78	76
			Mean	154 29	219 12	164 69
			SD	67 258	85 541	76 870
			Min	23 5	40 2	21 1
			Q1	107 10	165 90	107 65
			Median	147 90	214 30	158 95
			Q3	205 80	271 50	200 20
			Max	338 3	379 2	367 8
		Placebo	n	83	83	76
			Mean	147 84	128 44	160 69
			SD	61 716	55 868	80 210
			Min	57 1	22 5	31 3
			Q1	101 60	81 50	95 70
			Median	132 60	127 20	146 85
			Q3	190 10	152 50	219 30
			Max	382 3	327 5	397 7
	Change from Baseline	FSN-013	n	-	78	76
			Mean	-	64 87	11 03
			SD	-	71 321	68 941
			Min	-	-126 4	-162 9
			Q1	-	10 60	-27 20
			Median	-	65 80	3 75
			Q3	-	110 20	55 90
			Max	-	218 8	212 1
		Placebo	n	-	83	76
			Mean	-	-19 40	13 83
			SD	-	40 577	63 915
			Min	-	-122 6	-133 8
			Q1	-	-45 40	-27 10
			Median	-	-14 70	13 85
			Q3	-	3 80	51 90
			Max	-	90 3	185 2
Sex Hormone Binding Globulin (nmol/L)	Percent Change from Baseline	FSN-013	n	-	78	76
			Mean	-	53 98	14 78
			SD	-	55 479	46 404
			Min	-	-48 5	-57 2
			Q1	-	10 36	-13 45
			Median	-	50 49	3 70
			Q3	-	89 03	40 06
			Max	-	176 6	142 0
		Placebo	n	-	83	76
			Mean	-	-10 03	12 60
			SD	-	27 375	44 867
			Min	-	-66 9	-68 9
			Q1	-	-28 63	-23 84
			Median	-	-13 23	6 38
			Q3	-	2 66	39 58
			Max	-	96 4	134 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-18 を引用

表 2.7.4-161 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体定量、）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period				Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Thrombin Antithrombin Complex (ng/mL)	Value	FSN-013	n	79	78	78	78	78	75	74	71	76	75
			Mean	1 54	2 19	1 37	1 58	1 39	1 10	1 26	2 18	1 29	1 72
			SD	1 495	6 475	1 867	2 428	1 312	0 360	0 738	7 036	0 573	3 008
			Min	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Q3	1 30	1 30	1 00	1 20	1 10	1 00	1 30	1 20	1 30	1 30
			Max	9 2	57 7	16 7	18 1	9 6	3 0	6 6	59 6	3 9	25 1
		Placebo	n	83	82	81	80	83	76	75	74	76	80
			Mean	2 37	1 37	1 14	1 66	1 88	1 19	1 61	1 24	2 96	1 74
			SD	9 457	0 744	0 484	2 621	3 930	1 052	1 667	0 476	13 747	3 143
			Min	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Q3	1 20	1 50	1 00	1 40	1 20	1 00	1 20	1 20	1 30	1 25
			Max	87 2	5 5	4 0	22 8	34 7	9 2	9 1	3 6	120 1	23 7
	Change from Baseline	FSN-013	n	-	78	78	78	78	75	74	71	76	75
			Mean	-	0 65	-0 17	0 04	-0 15	-0 46	-0 31	0 60	-0 27	0 16
			SD	-	6 588	2 440	2 915	1 448	1 554	1 506	7 266	1 641	2 586
			Min	-	-6 2	-7 8	-8 2	-6 2	-8 2	-7 6	-7 1	-8 2	-6 2
			Q1	-	-0 20	-0 20	-0 20	-0 20	-0 30	-0 20	-0 20	-0 15	-0 10
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 10	0 00	0 00	0 00	0 00	0 10	0 10	0 10	0 20
			Max	-	56 7	15 7	17 1	5 1	2 0	3 0	58 5	2 9	15 9
		Placebo	n	-	82	81	80	83	76	75	74	76	80
			Mean	-	-1 00	-1 20	-0 70	-0 49	-1 23	-0 84	-1 23	0 54	-0 68
			SD	-	9 536	9 583	10 020	10 330	8 968	9 489	9 938	4 292	9 771
			Min	-	-85 7	-86 1	-85 8	-86 2	-78 0	-80 6	-85 3	-3 9	-82 2
			Q1	-	-0 10	-0 10	-0 05	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 30	0 00	0 15	0 00	0 00	0 00	0 00	0 20	0 00
			Max	-	4 5	2 6	21 8	33 7	4 2	8 0	2 5	32 9	22 7
Thrombin Antithrombin Complex (ng/mL)	Percent Change from Baseline	FSN-013	n	-	78	78	78	78	75	74	71	76	75
			Mean	-	89 58	20 14	39 39	5 09	-7 34	-0 39	90 72	9 37	23 85
			SD	-	645 582	190 103	245 959	53 865	38 790	36 728	643 755	63 463	123 049
			Min	-	-86 1	-86 1	-89 1	-86 1	-89 1	-85 9	-86 1	-89 1	-86 1
			Q1	-	-15 38	-16 67	-15 38	-16 67	-23 08	-16 67	-16 67	-10 80	-9 09
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	7 69	0 00	0 00	0 00	0 00	6 67	10 00	9 55	20 00
			Max	-	5670 0	1570 0	1710 0	290 0	200 0	154 5	5318 2	290 0	760 0
		Placebo	n	-	82	81	80	83	76	75	74	76	80
			Mean	-	20 90	-2 62	49 71	62 69	-4 31	32 39	4 88	26 95	42 08
			SD	-	82 294	40 319	265 617	386 991	56 359	146 282	49 418	192 583	279 170
			Min	-	-98 3	-98 7	-98 4	-98 9	-89 4	-92 4	-97 8	-79 6	-94 3
			Q1	-	-9 09	-6 25	-4 17	-8 33	-9 09	-9 09	-9 09	-9 09	-9 09
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	28 57	0 00	15 00	0 00	0 00	0 00	0 00	16 78	0 00
			Max	-	450 0	236 4	2180 0	3370 0	420 0	800 0	227 3	1640 0	2270 0

表 2.7.4-161 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体定量、）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period				Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
D-Dimer (ug/mL)	Value	FSN-013	n	79	78	78	78	78	75	74	71	76	75
			Mean	0 410	0 410	0 401	0 389	0 368	0 442	0 371	0 380	0 388	0 461
			SD	0 1800	0 2390	0 2338	0 1833	0 1116	0 5399	0 1358	0 1333	0 1776	0 2600
			Min	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 330	0 310	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 330
			Q3	0 440	0 400	0 420	0 400	0 400	0 400	0 390	0 450	0 405	0 530
			Max	1 47	1 60	1 91	1 15	0 77	4 88	0 91	0 86	1 36	1 67
		Placebo	n	83	82	81	80	83	76	75	74	76	80
			Mean	0 362	0 378	0 407	0 380	0 425	0 352	0 361	0 379	0 409	0 453
			SD	0 1348	0 1468	0 2003	0 1519	0 3408	0 0957	0 1401	0 3182	0 2473	0 3232
			Min	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Q3	0 320	0 390	0 420	0 385	0 460	0 370	0 340	0 350	0 390	0 460
			Max	0 85	1 03	1 17	0 92	3 20	0 75	1 18	2 90	1 58	2 54
D-Dimer (ug/mL)	Change from Baseline	FSN-013	n	-	78	78	78	78	75	74	71	76	75
			Mean	-	-0 001	-0 010	-0 022	-0 043	0 032	-0 035	-0 026	-0 025	0 051
			SD	-	0 2448	0 1884	0 1842	0 1405	0 5213	0 1440	0 1788	0 2135	0 2950
			Min	-	-0 43	-0 45	-0 45	-0 70	-0 75	-0 56	-0 73	-0 98	-1 11
			Q1	-	-0 090	-0 090	-0 090	-0 080	-0 060	-0 080	-0 060	-0 080	-0 060
			Median	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Q3	-	0 030	0 020	0 000	0 000	0 000	0 000	0 010	0 020	0 130
			Max	-	1 24	0 59	0 78	0 24	4 28	0 58	0 50	0 75	1 37
		Placebo	n	-	82	81	80	83	76	75	74	76	80
			Mean	-	0 015	0 043	0 015	0 063	-0 016	-0 008	0 010	0 047	0 088
			SD	-	0 1442	0 2012	0 1499	0 3597	0 1163	0 1420	0 2951	0 2755	0 2888
			Min	-	-0 45	-0 54	-0 51	-0 54	-0 54	-0 54	-0 50	-0 54	-0 54
			Q1	-	0 000	0 000	0 000	0 000	-0 005	0 000	-0 010	-0 005	0 000
			Median	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Q3	-	0 060	0 070	0 055	0 070	0 000	0 000	0 000	0 040	0 150
			Max	-	0 46	0 87	0 58	2 90	0 24	0 42	2 14	1 19	1 78
	Percent Change from Baseline	FSN-013	n	-	78	78	78	78	75	74	71	76	75
			Mean	-	6 68	2 42	1 46	-4 85	8 43	-3 25	0 92	0 26	21 71
			SD	-	59 174	43 261	49 302	24 220	89 238	32 385	38 804	37 957	78 259
			Min	-	-57 1	-60 0	-60 0	-60 0	-60 0	-60 0	-65 1	-66 7	-75 5
			Q1	-	-21 05	-21 05	-21 05	-18 60	-16 28	-20 29	-14 29	-20 53	-14 63
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	10 00	2 33	0 00	0 00	0 00	0 00	3 33	6 67	33 33
			Max	-	344 4	193 3	260 0	80 0	713 3	193 3	166 7	177 1	456 7
		Placebo	n	-	82	81	80	83	76	75	74	76	80
			Mean	-	8 45	17 53	8 69	25 99	0 70	2 18	4 66	21 29	25 72
			SD	-	32 678	56 773	37 755	114 445	23 146	29 187	47 301	78 800	59 916
			Min	-	-60 0	-64 3	-60 7	-64 3	-64 3	-64 3	-59 5	-64 3	-64 3
			Q1	-	0 00	0 00	0 00	0 00	-0 66	0 00	-3 23	-0 79	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	16 67	22 35	14 48	17 95	0 00	0 00	0 00	13 33	45 20
			Max	-	136 7	290 0	193 3	966 7	80 0	130 0	281 6	370 0	256 7

表 2.7.4-161 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体定量、）の測定値、ベースラインからの変化量及び変化率［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period				Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 6	Visit 8	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Soluble Fibrin Monomer Complex (ug/mL)	Value	FSN-013	n	79	78	78	78	78	75	74	71	76	75
			Mean	5 64	6 90	5 80	6 46	5 90	5 41	5 49	7 36	5 37	5 92
			SD	3 228	9 909	5 030	9 346	4 461	2 961	3 536	13 085	3 223	4 867
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Max	30 7	81 3	41 5	82 5	33 9	30 1	34 9	105 1	33 1	37 5
		Placebo	n	83	82	81	80	83	76	75	74	76	80
			Mean	5 68	5 01	5 10	6 10	7 58	5 31	6 21	5 06	8 20	7 50
			SD	5 597	0 133	0 736	8 238	16 616	2 174	4 457	0 477	19 989	14 453
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Max	56 0	6 2	11 4	77 4	151 0	23 6	30 9	9 1	151 0	105 3
	Change from Baseline	FSN-013	n	-	78	78	78	78	75	74	71	76	75
			Mean	-	1 25	0 15	0 81	0 24	-0 27	-0 20	1 65	-0 30	0 24
			SD	-	9 255	4 436	8 952	2 753	1 689	1 796	12 874	1 566	3 169
			Min	-	-8 7	-9 6	-9 6	-8 7	-9 6	-9 6	-9 6	-9 6	-8 7
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	76 3	36 5	77 5	19 8	5 6	6 0	100 1	2 4	22 9
		Placebo	n	-	82	81	80	83	76	75	74	76	80
			Mean	-	-0 66	-0 59	0 40	1 90	-0 43	0 47	-0 70	2 47	1 80
			SD	-	5 635	5 726	10 096	17 634	3 755	5 823	5 954	15 491	15 652
			Min	-	-51 0	-51 0	-51 0	-51 0	-32 4	-34 9	-51 0	-1 7	-51 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	1 2	6 4	72 4	146 0	3 9	25 9	4 1	97 1	100 3
Soluble Fibrin Monomer Complex (ug/mL)	Percent Change from Baseline	FSN-013	n	-	78	78	78	78	75	74	71	76	75
			Mean	-	22 59	6 52	18 93	4 58	-1 49	-1 19	36 38	-2 82	3 02
			SD	-	174 895	83 817	176 261	46 678	17 909	18 812	255 204	12 005	33 477
			Min	-	-63 5	-65 8	-65 8	-63 5	-65 8	-65 8	-65 8	-65 8	-63 5
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	1526 0	730 0	1550 0	396 0	112 0	120 0	2002 0	7 8	228 0
		Placebo	n	-	82	81	80	83	76	75	74	76	80
			Mean	-	-1 74	-0 03	19 89	49 46	-0 55	17 72	-1 14	26 79	47 82
			SD	-	11 132	18 503	165 403	332 835	12 122	82 212	14 960	223 518	289 667
			Min	-	-91 1	-91 1	-91 1	-91 1	-57 9	-62 3	-91 1	-25 4	-91 1
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	24 0	128 0	1448 0	2920 0	78 0	518 0	82 0	1942 0	2006 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-19 を引用

表 2.7.4-162 血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	FSN-013		Placebo	
	N = 79		N = 77	
	Above Upper Limit n (%)	Below Lower Limit n (%)	Above Upper Limit n (%)	Below Lower Limit n (%)
Prothrombin Time (sec)	14 (17.7)	2 (2.5)	8 (10.4)	0 (0.0)
Prothrombin Control (sec)	-	-	-	-
Prothrombin Activity (%)	63 (79.7)	0 (0.0)	56 (72.7)	0 (0.0)
Prothrombin Intl. Normalized Ratio	2 (2.5)	3 (3.8)	2 (2.6)	2 (2.6)
Activated Partial Thromboplastin Time (sec)	7 (8.9)	4 (5.1)	4 (5.2)	6 (7.8)
Activated Partial Thromboplastin Control (sec)	-	-	-	-
Fibrinogen (mg/dL)	3 (3.8)	2 (2.5)	3 (3.9)	0 (0.0)
Antithrombin Activity (%)	20 (25.3)	1 (1.3)	18 (23.4)	0 (0.0)
Plasminogen (%)	12 (15.2)	5 (6.3)	9 (11.7)	5 (6.5)
Thrombin Antithrombin Complex (ng/mL)	22 (27.8)	-	11 (14.3)	-
Factor XIV Activity (%)	14 (17.7)	0 (0.0)	10 (13.0)	1 (1.3)
D-Dimer (ug/mL)	11 (13.9)	-	6 (7.8)	-
Soluble Fibrin Monomer Complex (ug/mL)	12 (15.2)	-	11 (14.3)	-
Protein S Activity Actual/Control	20 (25.3)	3 (3.8)	20 (26.0)	4 (5.2)
Protein S Total Activity (IU/mL)	8 (10.1)	10 (12.7)	5 (6.5)	14 (18.2)
Protein S, Free (%)	5 (6.3)	2 (2.5)	2 (2.6)	2 (2.6)
Protein S (IU/mL)	8 (10.1)	13 (16.5)	6 (7.8)	16 (20.8)
Sex Hormone Binding Globulin (nmol/L)	-	-	-	-

FSN-013 group is counted from the comparative period onward, and placebo group is counted from extension period onward.

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-26 を引用

2.7.4.3.1.3.3 FSN-013P-03 試験及び FSN-013P-04 試験の併合

2.7.4.3.1.3.3.1 24 週投与

投与 6 周期終了時点までの Primary Safety Population を対象とした、血液凝固系検査の測定値、ベースラインからの変化量及び変化率を表 2.7.4-163～表 2.7.4-165 に、血液凝固線溶系検査について血液凝固系検査値の基準値上限超、基準値下限未満の頻度集計を表 2.7.4-166 に示す。

トロンビン・アンチトロンビン III 複合体、可溶性フィブリンモノマー複合体、プロテイン C、プロテイン S 及び D-ダイマーに関する投与前後の平均変化量に特記すべき異常変動はみられなかった。また、D-ダイマーの基準値上限を逸脱した被験者割合は、FSN-013 群では 5.0%（8/160 例）であり、同じ投与期間である FSN-013P-04 試験のプラセボ群（表 2.7.4-158）と比較して同様であった。

その他のいずれの項目も経時的推移は FSN-013 群、プラセボ群で同様であり、FSN-013 群の基準値上限超、基準値下限未満の頻度は、同じ投与期間である FSN-013P-04 試験のプラセボ群（表 2.7.4-158）と比較して、大差は認められなかった。

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Time (sec)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	11 33	11 29	11 39	11 38
			SD	0 757	0 679	0 690	0 715
			Min	9 7	9 7	9 6	9 5
			Q1	10 75	10 80	10 90	10 90
			Median	11 30	11 30	11 40	11 30
			Q3	11 80	11 70	11 80	11 90
			Max	13 6	12 9	13 9	13 3
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0 04	0 07	0 04
			SD	-	0 687	0 675	0 754
			Min	-	-2 1	-1 6	-2 8
			Q1	-	-0 40	-0 40	-0 50
			Median	-	0 00	0 00	0 10
			Q3	-	0 50	0 50	0 60
			Max	-	1 7	2 1	1 6

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

				Baseline Observation Period	Post-Baseline Period		
Parameter	Value	Treatment	Statistic	Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Time (sec)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0.16	0.79	0.62
			SD	-	5.988	5.972	6.546
			Min	-	-16.3	-12.5	-21.9
			Q1	-	-3.70	-3.25	-4.39
			Median	-	0.00	0.00	0.88
			Q3	-	4.27	4.59	5.17
			Max	-	16.8	19.6	14.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

				Baseline Observation Period	Post-Baseline Period		
Parameter	Value	Treatment	Statistic	Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Control (sec)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	11 50	11 50	11 50	11 50
			SD	0 000	0 000	0 000	0 000
			Min	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	11 50	11 50
			Median	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	11 50	11 50
			Max	11 5	11 5	11 5	11 5
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Control (sec)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Activity (%)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	96 3	97 1	96 5	96 7
			SD	6 17	5 09	5 93	5 79
			Min	75	80	71	76
			Q1	93 0	95 0	93 0	92 0
			Median	100 0	99 5	100 0	100 0
			Q3	101 0	101 0	101 0	101 0
			Max	101	101	101	101
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0 8	0 2	0 5
			SD	-	5 50	6 19	6 65
			Min	-	-15	-18	-18
			Q1	-	-2 0	-2 0	-3 0
			Median	-	0 0	0 0	0 0
			Q3	-	3 0	3 0	4 0
			Max	-	19	19	24

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Activity (%)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	1.10	0.49	0.80
			SD	-	6.170	6.811	7.447
			Min	-	-14.9	-17.8	-19.1
			Q1	-	-1.98	-1.98	-2.97
			Median	-	0.00	0.00	0.00
			Q3	-	3.66	3.09	4.12
			Max	-	23.7	25.0	31.6

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
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Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Intl Normalized Ratio	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	0 985	0 982	0 990	0 990
			SD	0 0642	0 0579	0 0592	0 0613
			Min	0 85	0 85	0 84	0 83
			Q1	0 935	0 940	0 950	0 950
			Median	0 980	0 980	0 990	0 980
			Q3	1 030	1 020	1 030	1 030
			Max	1 17	1 12	1 21	1 15
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0 004	0 005	0 004
			SD	-	0 0585	0 0572	0 0636
			Min	-	-0 18	-0 14	-0 24
			Q1	-	-0 040	-0 030	-0 040
			Median	-	0 000	0 000	0 000
			Q3	-	0 040	0 040	0 050
			Max	-	0 15	0 18	0 13

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Prothrombin Intl. Normalized Ratio	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0.16	0.72	0.58
			SD	-	5.875	5.813	6.350
			Min	-	-16.1	-12.6	-21.6
			Q1	-	-3.92	-3.06	-4.08
			Median	-	0.00	0.00	0.00
			Q3	-	4.12	4.44	5.00
			Max	-	17.0	19.4	14.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Time (sec)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	33 22	31 13	31 16	31 08
			SD	8 202	2 752	2 645	2 847
			Min	25 3	21 8	24 6	24 6
			Q1	30 70	29 40	29 50	29 30
			Median	32 45	31 00	31 00	30 80
			Q3	34 10	32 90	32 90	32 30
			Max	120 1	39 8	38 8	41 7
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-2 10	-2 05	-2 19
			SD	-	7 935	8 184	8 319
			Min	-	-88 3	-90 9	-91 5
			Q1	-	-2 50	-2 50	-2 70
			Median	-	-1 10	-1 30	-1 40
			Q3	-	-0 20	0 00	0 00
			Max	-	3 7	3 6	5 9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Time (sec)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-4.58	-4.30	-4.73
			SD	-	8.877	9.366	9.620
			Min	-	-73.5	-75.7	-76.2
			Q1	-	-7.40	-7.40	-8.13
			Median	-	-3.32	-3.87	-4.40
			Q3	-	-0.58	0.00	0.00
			Max	-	12.5	12.6	17.2

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Control (sec)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	28 70	28 70	28 70	28 70
			SD	0 000	0 000	0 000	0 000
			Min	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	28 70	28 70
			Median	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	28 70	28 70
			Max	28 7	28 7	28 7	28 7
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Activated Partial Thromboplastin Control (sec)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0.00	0.00	0.00
			SD	-	0.000	0.000	0.000
			Min	-	0.0	0.0	0.0
			Q1	-	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00
			Max	-	0.0	0.0	0.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Fibrinogen (mg/dL)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	260 1	273 4	276 1	279 5
			SD	48 58	45 81	47 00	49 93
			Min	170	185	150	126
			Q1	229 0	245 0	240 0	243 0
			Median	252 0	268 5	274 0	279 0
			Q3	284 5	299 0	307 0	313 0
			Max	438	444	432	421
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	13 1	16 3	19 7
			SD	-	39 88	45 77	47 42
			Min	-	-124	-122	-106
			Q1	-	-7 0	-8 0	-15 0
			Median	-	12 5	14 0	20 0
			Q3	-	38 0	44 0	50 0
			Max	-	166	189	206

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Fibrinogen (mg/dL)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	6.37	7.94	9.17
			SD	-	14.947	18.468	18.923
			Min	-	-37.9	-39.8	-32.3
			Q1	-	-2.93	-2.88	-3.96
			Median	-	5.22	4.53	7.89
			Q3	-	17.03	17.25	20.08
			Max	-	59.7	86.0	95.8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
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Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Antithrombin Activity (%)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	112 9	108 7	108 0	108 9
			SD	11 06	10 87	11 35	10 71
			Min	87	84	71	82
			Q1	105 0	102 0	100 0	102 0
			Median	112 0	108 0	108 0	108 0
			Q3	119 0	115 0	116 0	116 0
			Max	141	142	140	136
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-4 2	-4 9	-3 8
			SD	-	9 08	9 05	9 01
			Min	-	-31	-33	-28
			Q1	-	-11 0	-11 0	-10 0
			Median	-	-5 0	-5 0	-3 0
			Q3	-	1 0	0 0	3 0
			Max	-	27	22	18

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Antithrombin Activity (%)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-3.39	-4.08	-3.04
			SD	-	8.127	8.008	7.938
			Min	-	-26.3	-31.7	-21.1
			Q1	-	-9.16	-9.49	-8.57
			Median	-	-4.02	-4.00	-2.88
			Q3	-	0.90	0.00	2.40
			Max	-	23.9	21.1	19.3

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Plasminogen (%)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	97 7	106 2	108 6	107 9
			SD	14 87	15 60	16 49	16 48
			Min	48	55	51	52
			Q1	91 5	98 0	100 0	100 0
			Median	98 0	106 0	109 0	108 0
			Q3	106 0	115 0	120 0	120 0
			Max	134	148	145	143
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	8 5	10 9	10 5
			SD	-	9 15	9 55	9 73
			Min	-	-12	-18	-16
			Q1	-	3 0	5 0	5 0
			Median	-	7 5	10 0	11 0
			Q3	-	14 0	17 0	16 0
			Max	-	39	37	39

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
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Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Plasminogen (%)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	9.33	11.65	11.19
			SD	-	10.068	10.157	10.280
			Min	-	-10.6	-15.9	-13.3
			Q1	-	2.73	4.21	4.95
			Median	-	7.91	10.57	11.00
			Q3	-	14.58	17.89	17.02
			Max	-	43.7	42.0	40.7

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Factor XIV Activity (%)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	111 9	108 3	108 6	108 1
			SD	15 79	15 54	15 75	16 33
			Min	72	81	78	79
			Q1	101 0	97 0	100 0	96 0
			Median	111 0	106 0	107 0	105 0
			Q3	123 0	117 0	119 0	117 0
			Max	151	151	151	151
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-3 7	-3 4	-3 6
			SD	-	9 80	11 00	10 97
			Min	-	-25	-39	-31
			Q1	-	-10 0	-12 0	-10 0
			Median	-	-5 0	-2 0	-5 0
			Q3	-	3 0	5 0	4 0
			Max	-	32	21	30

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Factor XIV Activity (%)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-2.91	-2.61	-2.85
			SD	-	8.626	9.577	9.845
			Min	-	-20.7	-26.5	-22.0
			Q1	-	-9.38	-10.17	-9.90
			Median	-	-4.50	-2.38	-4.39
			Q3	-	2.91	4.55	3.08
			Max	-	26.9	19.4	28.6

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Activity Actual/Control	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	1 082	1 085	1 043	1 051
			SD	0 1193	0 1136	0 1214	0 1015
			Min	0 59	0 51	0 60	0 61
			Q1	1 010	1 030	0 960	0 990
			Median	1 075	1 090	1 050	1 040
			Q3	1 155	1 140	1 120	1 110
			Max	1 41	1 43	1 49	1 35
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0 003	-0 039	-0 031
			SD	-	0 0959	0 1238	0 0989
			Min	-	-0 25	-0 44	-0 25
			Q1	-	-0 050	-0 100	-0 100
			Median	-	0 010	-0 040	-0 030
			Q3	-	0 060	0 030	0 050
			Max	-	0 25	0 43	0 23

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Activity Actual/Control	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0.73	-3.03	-2.37
			SD	-	8.814	11.401	8.895
			Min	-	-27.1	-36.1	-20.2
			Q1	-	-4.24	-9.24	-9.16
			Median	-	1.05	-4.03	-2.34
			Q3	-	6.19	3.00	4.46
			Max	-	28.7	49.4	24.5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Total Activity (IU/mL)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	1 067	1 037	0 985	0 982
			SD	0 1978	0 1846	0 1879	0 1985
			Min	0 64	0 45	0 53	0 54
			Q1	0 930	0 910	0 830	0 810
			Median	1 065	1 050	1 000	0 980
			Q3	1 170	1 150	1 110	1 110
			Max	1 92	1 56	1 54	1 62
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0 031	-0 081	-0 083
			SD	-	0 1319	0 1654	0 1749
			Min	-	-0 56	-0 64	-0 74
			Q1	-	-0 100	-0 170	-0 180
			Median	-	-0 020	-0 090	-0 080
			Q3	-	0 050	0 030	0 030
			Max	-	0 25	0 35	0 39

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S Total Activity (IU/mL)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-2.21	-6.72	-7.09
			SD	-	11.416	14.106	14.604
			Min	-	-35.7	-41.6	-43.3
			Q1	-	-9.68	-14.62	-18.26
			Median	-	-1.79	-8.67	-7.84
			Q3	-	4.90	2.73	3.23
			Max	-	27.8	33.7	36.9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S, Free (%)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	91 6	93 0	92 6	91 8
			SD	15 39	15 51	15 90	15 92
			Min	38	55	53	52
			Q1	81 0	82 0	81 0	79 0
			Median	92 5	91 5	92 0	94 0
			Q3	100 0	104 0	103 0	102 0
			Max	134	134	134	141
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	1 4	1 1	0 6
			SD	-	8 82	9 46	9 89
			Min	-	-20	-22	-26
			Q1	-	-4 0	-5 0	-6 0
			Median	-	2 0	1 0	1 0
			Q3	-	7 0	7 0	7 0
			Max	-	28	29	40

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S, Free (%)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	2.14	1.72	1.25
			SD	-	11.193	10.850	12.082
			Min	-	-25.0	-25.0	-25.7
			Q1	-	-4.12	-5.36	-6.48
			Median	-	1.68	1.45	0.82
			Q3	-	7.50	8.24	7.94
			Max	-	68.4	47.4	65.8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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Data Source: adlb

表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S (IU/mL)	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	0 989	0 959	0 948	0 937
			SD	0 1659	0 1601	0 1679	0 1775
			Min	0 67	0 64	0 60	0 55
			Q1	0 870	0 820	0 820	0 800
			Median	0 965	0 960	0 930	0 920
			Q3	1 090	1 050	1 070	1 060
			Max	1 69	1 36	1 48	1 46
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0 031	-0 040	-0 051
			SD	-	0 1015	0 1282	0 1374
			Min	-	-0 45	-0 47	-0 56
			Q1	-	-0 110	-0 120	-0 130
			Median	-	-0 030	-0 050	-0 050
			Q3	-	0 030	0 030	0 030
			Max	-	0 36	0 42	0 36

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
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表 2.7.4-163 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Protein S (IU/mL)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-2.73	-3.46	-4.76
			SD	-	9.961	12.786	12.791
			Min	-	-26.6	-29.6	-33.3
			Q1	-	-10.32	-12.16	-13.16
			Median	-	-3.30	-5.22	-4.65
			Q3	-	2.68	3.28	3.88
			Max	-	45.0	52.5	36.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01） 表 6-64 引用

表 2.7.4-164 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.2.1.4 Summary of Coagulation Factors (2) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period
				Visit 3	End of week 24
Sex Hormone Binding Globulin (nmol/L)	Value	FSN-013 Pooled	n	160	159
			Mean	155 32	227 17
			SD	64 540	89 820
			Min	23 5	34 6
			Q1	110 50	166 50
			Median	150 35	219 80
			Q3	198 20	306 10
			Max	338 3	393 2
	Change from Baseline	FSN-013 Pooled	n	-	159
			Mean	-	71 86
			SD	-	73 773
			Min	-	-161 6
			Q1	-	16 70
			Median	-	75 20
			Q3	-	126 30
			Max	-	218 8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

End of Week 24 includes Visit 8/discontinuation or Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_2_1_4.sas / Output: t_4_4_2_1_4.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-164 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.4 Summary of Coagulation Factors (2) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period
				Visit 3	End of week 24
Sex Hormone Binding Globulin (nmol/L)	Percent Change from Baseline	FSN-013 Pooled	n	-	159
			Mean	-	56.93
			SD	-	55.687
			Min	-	-59.2
			Q1	-	13.72
			Median	-	58.28
			Q3	-	90.73
			Max	-	210.1

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
End of Week 24 includes Visit 8/discontinuation or Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04.

Program Name: t_4_4_2_1_4.sas / Output: t_4_4_2_1_4.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01） 表 6-65 を引用

表 2.7.4-165 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period			
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Thrombin Antithrombin Complex (ng/mL)	Value	FSN-013 Pooled	n	160	158	157	159	155
			Mean	1 42	1 71	1 61	2 08	1 46
			SD	1 220	4 582	5 077	8 844	1 788
			Min	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00
			Q3	1 30	1 20	1 00	1 10	1 00
			Max	9 2	57 7	62 6	110 3	18 0
	Change from Baseline	FSN-013 Pooled	n	-	158	157	159	155
			Mean	-	0 29	0 18	0 66	0 03
			SD	-	4 677	5 256	8 969	1 958
			Min	-	-6 2	-7 8	-8 2	-6 2
			Q1	-	-0 10	-0 20	-0 20	-0 20
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00
			Max	-	56 7	61 6	109 3	17 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_5.sas / Output: t_4_4_2_1_5.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-165 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period			
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Thrombin Antithrombin Complex (ng/mL)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	157	159	155
			Mean	-	46.63	45.56	91.75	20.56
			SD	-	455.043	509.630	886.193	157.427
			Min	-	-86.1	-86.1	-89.1	-86.1
			Q1	-	-9.09	-16.67	-15.38	-16.67
			Median	-	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00
			Max	-	5670.0	6160.0	10930.0	1700.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_5.sas / Output: t_4_4_2_1_5.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-165 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period			
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 10 / Discontinuation
D-Dimer (ug/mL)	Value	FSN-013 Pooled	n	160	158	157	159	155
			Mean	0 381	0 384	0 372	0 377	0 360
			SD	0 1544	0 1986	0 1797	0 1595	0 1227
			Min	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300
			Q3	0 405	0 380	0 370	0 390	0 370
			Max	1 47	1 60	1 91	1 15	1 14
	Change from Baseline	FSN-013 Pooled	n	-	158	157	159	155
			Mean	-	0 003	-0 008	-0 005	-0 021
			SD	-	0 1994	0 1573	0 1691	0 1543
			Min	-	-0 81	-0 81	-0 81	-0 81
			Q1	-	-0 060	-0 050	-0 060	-0 050
			Median	-	0 000	0 000	0 000	0 000
			Q3	-	0 020	0 000	0 000	0 000
			Max	-	1 24	0 59	0 78	0 84

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

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表 2.7.4-165 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

				Baseline Observation Period	Post-Baseline Period			
Parameter	Value	Treatment	Statistic	Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 10 / Discontinuation
D-Dimer (ug/mL)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	157	159	155
			Mean	-	5.23	1.98	4.43	0.14
			SD	-	45.954	34.263	43.503	35.574
			Min	-	-73.0	-73.0	-73.0	-73.0
			Q1	-	-14.06	-11.11	-14.29	-12.82
			Median	-	0.00	0.00	0.00	0.00
			Q3	-	6.67	0.00	0.00	0.00
			Max	-	344.4	193.3	260.0	280.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_5.sas / Output: t_4_4_2_1_5.rtf
Date of Table Generation: 2023-02-20 8:49
Data Source: adlb

表 2.7.4-165 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period			
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Soluble Fibrin Monomer Complex (ug/mL)	Value	FSN-013 Pooled	n	160	158	157	159	155
			Mean	5 48	6 29	6 33	6 24	6 19
			SD	2 635	7 828	12 152	8 345	6 096
			Min	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00
			Max	30 7	81 3	151 0	82 5	48 6
	Change from Baseline	FSN-013 Pooled	n	-	158	157	159	155
			Mean	-	0 81	0 84	0 76	0 70
			SD	-	7 160	12 147	8 261	5 355
			Min	-	-13 7	-13 7	-13 7	-13 7
			Q1	-	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00
			Max	-	76 3	146 0	77 5	43 6

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_5.sas / Output: t_4_4_2_1_5.rtf
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表 2.7.4-165 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period			
				Visit 3	Visit 5	Visit 6	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Soluble Fibrin Monomer Complex (ug/mL)	Percent Change from Baseline	FSN-013 Pooled	n	-	158	157	159	155
			Mean	-	13.39	20.83	18.72	12.87
			SD	-	125.484	240.363	161.430	95.363
			Min	-	-73.3	-73.3	-73.3	-73.3
			Q1	-	0.00	0.00	0.00	0.00
			Median	-	0.00	0.00	0.00	0.00
			Q3	-	0.00	0.00	0.00	0.00
			Max	-	1526.0	2920.0	1550.0	872.0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_5.sas / Output: t_4_4_2_1_5.rtf
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引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01） 表 6-66 を引用

表 2.7.4-166 血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.2.2.3 Frequency of Coagulation Factors Above or Below the Reference Limits (SAS)

Parameter	FSN-013 Pooled N = 160	
	Above Upper Limit n(%)	Below Lower Limit n(%)
Prothrombin Time (sec)	16 (10.0)	0 (0.0)
Prothrombin Control (sec)	-	-
Prothrombin Activity (%)	109 (68.1)	0 (0.0)
Prothrombin Intl. Normalized Ratio	1 (0.6)	2 (1.3)
Activated Partial Thromboplastin Time (sec)	14 (8.8)	2 (1.3)
Activated Partial Thromboplastin Control (sec)	-	-
Fibrinogen (mg/dL)	3 (1.9)	2 (1.3)
Antithrombin Activity (%)	25 (15.6)	1 (0.6)
Plasminogen (%)	18 (11.3)	7 (4.4)
Thrombin Antithrombin Complex (ng/mL)	24 (15.0)	-
Factor XIV Activity (%)	19 (11.9)	0 (0.0)
D-Dimer (ug/mL)	8 (5.0)	-
Soluble Fibrin Monomer Complex (ug/mL)	19 (11.9)	-
Protein S Activity Actual/Control	34 (21.3)	7 (4.4)
Protein S Total Activity (IU/mL)	15 (9.4)	21 (13.1)
Protein S, Free (%)	3 (1.9)	3 (1.9)
Protein S (IU/mL)	11 (6.9)	23 (14.4)
Sex Hormone Binding Globulin (nmol/L)	-	-

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引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01） 表 6-71 を引用

2.7.4.3.1.3.3.2 52 週投与

投与 13 周期終了時点までの Primary Safety Population 及び Secondary Safety Population を対象とした、血液凝固系検査の測定値、ベースラインからの変化量及び変化率を表 2.7.4-167～表 2.7.4-169 に、血液凝固線溶系検査について血液凝固系検査値の基準値上限超、基準値下限未満の頻度集計を表 2.7.4-170 に示す。

トロンビン・アンチトロンビン III 複合体、可溶性フィブリンモノマー複合体、プロテイン C、プロテイン S 及び D-ダイマーに関する投与前後の平均変化量に特記すべき異常変動は認められなかった。その他のいずれの項目も試験期間を通じて特記すべき変動は認められなかった。また、Primary Safety Population（52 週投与）の基準値上限超、基準値下限未満の頻度は、Primary Safety Population（24 週投与、表 2.7.4-166）と比べて大差は認められなかった。

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Time (sec)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	11 33	11 29	-	11 39	11 38	11 31	11 33	11 10	11 07
			SD	0 757	0 679	-	0 690	0 715	0 633	0 674	0 730	0 670
			Min	9 7	9 7	-	9 6	9 5	9 6	9 1	9 7	9 6
			Q1	10 75	10 80	-	10 90	10 90	10 90	10 90	10 60	10 60
			Median	11 30	11 30	-	11 40	11 30	11 30	11 30	11 00	11 00
			Q3	11 80	11 70	-	11 80	11 90	11 70	11 80	11 60	11 40
			Max	13 6	12 9	-	13 9	13 3	13 2	14 2	13 4	13 8
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	11 30	11 29	11 38	11 37	11 38	11 31	11 33	11 11	11 04
			SD	0 763	0 679	0 683	0 702	0 691	0 633	0 674	0 747	0 676
			Min	9 3	9 7	9 4	9 4	9 5	9 6	9 1	9 4	9 6
			Q1	10 70	10 80	11 00	10 90	10 90	10 90	10 90	10 60	10 60
			Median	11 20	11 30	11 30	11 30	11 30	11 30	11 30	11 00	11 00
			Q3	11 80	11 70	11 70	11 80	11 80	11 70	11 80	11 60	11 40
			Max	13 6	12 9	13 7	13 9	13 3	13 2	14 2	14 2	13 8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Time (sec)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 04	-	0 07	0 04	-0 02	0 01	-0 23	-0 24
			SD	-	0 687	-	0 675	0 754	0 754	0 767	0 740	0 742
			Min	-	-2 1	-	-1 6	-2 8	-2 5	-2 9	-2 5	-2 5
			Q1	-	-0 40	-	-0 40	-0 50	-0 50	-0 40	-0 70	-0 60
			Median	-	0 00	-	0 00	0 10	0 00	0 05	-0 30	-0 20
			Q3	-	0 50	-	0 50	0 60	0 50	0 50	0 20	0 20
			Max	-	1 7	-	2 1	1 6	1 8	2 6	2 4	1 9
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-0 04	0 11	0 08	0 09	-0 02	0 01	-0 20	-0 26
			SD	-	0 687	0 686	0 722	0 731	0 754	0 767	0 728	0 689
			Min	-	-2 1	-2 4	-3 5	-2 8	-2 5	-2 9	-3 1	-2 5
			Q1	-	-0 40	-0 30	-0 35	-0 40	-0 50	-0 40	-0 60	-0 70
			Median	-	0 00	0 10	0 10	0 10	0 00	0 05	-0 20	-0 20
			Q3	-	0 50	0 60	0 50	0 60	0 50	0 50	0 20	0 20
			Max	-	1 7	1 5	2 1	2 5	1 8	2 6	2 4	1 9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Data Source: adlb

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Time (sec)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 16	-	0 79	0 62	0 12	0 33	-1 84	-1 91
			SD	-	5 988	-	5 972	6 546	6 498	6 629	6 427	6 379
			Min	-	-16 3	-	-12 5	-21 9	-18 8	-21 8	-19 5	-19 5
			Q1	-	-3 70	-	-3 25	-4 39	-4 27	-3 42	-5 83	-5 66
			Median	-	0 00	-	0 00	0 88	0 00	0 41	-2 42	-1 78
			Q3	-	4 27	-	4 59	5 17	4 67	4 27	1 89	1 71
			Max	-	16 8	-	19 6	14 0	16 7	22 4	22 2	16 0
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-0 16	1 21	0 92	1 04	0 12	0 33	-1 52	-2 06
			SD	-	5 988	6 138	6 362	6 452	6 498	6 629	6 314	5 937
			Min	-	-16 3	-17 8	-25 9	-21 9	-18 8	-21 8	-23 0	-19 5
			Q1	-	-3 70	-2 78	-3 02	-3 42	-4 27	-3 42	-5 56	-5 88
			Median	-	0 00	0 93	0 85	0 92	0 00	0 41	-1 60	-1 80
			Q3	-	4 27	5 77	4 81	5 22	4 67	4 27	2 00	1 71
			Max	-	16 8	16 1	19 6	26 9	16 7	22 4	22 2	16 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Control (sec)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	11 50	11 50	-	11 50	11 50	11 50	11 50	11 50	11 50
			SD	0 000	0 000	-	0 000	0 000	0 000	0 000	0 000	0 000
			Min	11 5	11 5	-	11 5	11 5	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	-	11 50	11 50	11 50	11 50	11 50	11 50
			Median	11 50	11 50	-	11 50	11 50	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	-	11 50	11 50	11 50	11 50	11 50	11 50
			Max	11 5	11 5	-	11 5	11 5	11 5	11 5	11 5	11 5
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			SD	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5
			Q1	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Median	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Q3	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50	11 50
			Max	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5	11 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Control (sec)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	-	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Control (sec)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	-	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Activity (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	96 3	97 1	-	96 5	96 7	97 4	96 9	97 2	96 8
			SD	6 17	5 09	-	5 93	5 79	5 13	5 45	5 50	5 38
			Min	75	80	-	71	76	80	72	75	73
			Q1	93 0	95 0	-	93 0	92 0	95 0	94 0	95 0	94 0
			Median	100 0	99 5	-	100 0	100 0	101 0	100 0	101 0	99 0
			Q3	101 0	101 0	-	101 0	101 0	101 0	101 0	101 0	101 0
			Max	101	101	-	101	101	101	101	101	101
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	96 4	97 1	97 2	96 6	96 9	97 4	96 9	97 0	96 9
			SD	6 03	5 09	5 69	5 85	5 84	5 13	5 45	5 81	5 41
			Min	75	80	76	71	76	80	72	70	73
			Q1	93 0	95 0	94 0	93 0	94 0	95 0	94 0	95 0	94 0
			Median	100 0	99 5	101 0	100 0	101 0	101 0	100 0	101 0	99 0
			Q3	101 0	101 0	101 0	101 0	101 0	101 0	101 0	101 0	101 0
			Max	101	101	101	101	101	101	101	101	101

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Activity (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 8	-	0 2	0 5	1 2	0 7	0 9	0 5
			SD	-	5 50	-	6 19	6 65	6 36	6 52	5 95	5 77
			Min	-	-15	-	-18	-18	-16	-23	-21	-19
			Q1	-	-2 0	-	-2 0	-3 0	-1 0	-2 0	-1 0	-2 0
			Median	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
			Q3	-	3 0	-	3 0	4 0	4 0	3 0	3 0	3 0
			Max	-	19	-	19	24	25	25	24	25
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 8	0 5	0 1	0 4	1 2	0 7	0 6	0 5
			SD	-	5 50	5 55	6 13	6 26	6 36	6 52	5 84	5 44
			Min	-	-15	-14	-18	-18	-16	-23	-21	-19
			Q1	-	-2 0	-1 0	-2 0	-3 0	-1 0	-2 0	-1 0	-2 0
			Median	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q3	-	3 0	4 0	2 0	3 0	4 0	3 0	2 0	3 0
			Max	-	19	23	23	24	25	25	24	25

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Activity (%)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	1 10	-	0 49	0 80	1 55	1 04	1 24	0 81
			SD	-	6 170	-	6 811	7 447	7 261	7 303	6 734	6 606
			Min	-	-14 9	-	-17 8	-19 1	-15 8	-24 2	-20 8	-20 7
			Q1	-	-1 98	-	-1 98	-2 97	-1 10	-2 06	-0 99	-2 08
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	3 66	-	3 09	4 12	4 12	3 41	3 13	3 13
			Max	-	23 7	-	25 0	31 6	32 9	32 9	31 6	32 9
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	1 10	0 75	0 37	0 62	1 55	1 04	0 88	0 73
			SD	-	6 170	6 089	6 736	6 976	7 261	7 303	6 590	6 144
			Min	-	-14 9	-13 9	-17 8	-19 1	-15 8	-24 2	-20 8	-20 7
			Q1	-	-1 98	-1 14	-1 98	-2 97	-1 10	-2 06	-0 99	-2 06
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	3 66	4 12	2 34	3 85	4 12	3 41	2 06	3 06
			Max	-	23 7	29 5	29 5	31 6	32 9	32 9	31 6	32 9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.

a) Includes data for only FSN-013 groups of both studies.
b) Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Intl Normalized Ratio	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	0 985	0 982	-	0 990	0 990	0 983	0 988	0 985	0 992
			SD	0 0642	0 0579	-	0 0592	0 0613	0 0541	0 0560	0 0601	0 0570
			Min	0 85	0 85	-	0 84	0 83	0 84	0 80	0 88	0 87
			Q1	0 935	0 940	-	0 950	0 950	0 950	0 950	0 940	0 960
			Median	0 980	0 980	-	0 990	0 980	0 980	0 980	0 980	0 990
			Q3	1 030	1 020	-	1 030	1 030	1 020	1 030	1 030	1 030
			Max	1 17	1 12	-	1 21	1 15	1 15	1 23	1 16	1 23
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	0 983	0 982	0 990	0 990	0 990	0 983	0 988	0 986	0 990
			SD	0 0645	0 0579	0 0587	0 0600	0 0591	0 0541	0 0560	0 0639	0 0586
			Min	0 82	0 85	0 82	0 82	0 83	0 84	0 80	0 82	0 87
			Q1	0 930	0 940	0 960	0 950	0 950	0 950	0 950	0 940	0 950
			Median	0 970	0 980	0 980	0 985	0 980	0 980	0 980	0 980	0 990
			Q3	1 030	1 020	1 020	1 030	1 030	1 020	1 030	1 030	1 030
			Max	1 17	1 12	1 19	1 21	1 15	1 15	1 23	1 27	1 23

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Intl Normalized Ratio	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 004	-	0 005	0 004	-0 002	0 003	-0 001	0 008
			SD	-	0 0585	-	0 0572	0 0636	0 0633	0 0617	0 0603	0 0615
			Min	-	-0 18	-	-0 14	-0 24	-0 21	-0 21	-0 18	-0 18
			Q1	-	-0 040	-	-0 030	-0 040	-0 040	-0 030	-0 040	-0 030
			Median	-	0 000	-	0 000	0 000	0 000	0 010	0 000	0 010
			Q3	-	0 040	-	0 040	0 050	0 040	0 040	0 040	0 040
			Max	-	0 15	-	0 18	0 13	0 15	0 22	0 21	0 20
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-0 004	0 009	0 008	0 007	-0 002	0 003	0 002	0 007
			SD	-	0 0585	0 0586	0 0601	0 0617	0 0633	0 0617	0 0606	0 0584
			Min	-	-0 18	-0 20	-0 27	-0 24	-0 21	-0 21	-0 23	-0 18
			Q1	-	-0 040	-0 030	-0 030	-0 030	-0 040	-0 030	-0 030	-0 030
			Median	-	0 000	0 010	0 010	0 010	0 000	0 010	0 000	0 010
			Q3	-	0 040	0 050	0 050	0 050	0 040	0 040	0 040	0 040
			Max	-	0 15	0 13	0 18	0 21	0 15	0 22	0 21	0 20

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Prothrombin Intl Normalized Ratio	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 16	-	0 72	0 58	0 01	0 54	0 10	1 06
			SD	-	5 875	-	5 813	6 350	6 265	6 157	6 110	6 193
			Min	-	-16 1	-	-12 6	-21 6	-18 3	-18 3	-16 2	-16 2
			Q1	-	-3 92	-	-3 06	-4 08	-4 12	-3 09	-3 92	-2 83
			Median	-	0 00	-	0 00	0 00	0 00	0 96	0 00	1 06
			Q3	-	4 12	-	4 44	5 00	4 60	4 35	4 00	4 30
			Max	-	17 0	-	19 4	14 0	15 8	21 8	22 3	19 4
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-0 16	1 15	0 98	0 98	0 01	0 54	0 40	0 98
			SD	-	5 875	6 013	6 095	6 249	6 265	6 157	6 114	5 910
			Min	-	-16 1	-17 1	-23 1	-21 6	-18 3	-18 3	-19 7	-16 2
			Q1	-	-3 92	-2 88	-2 84	-3 09	-4 12	-3 09	-3 26	-3 00
			Median	-	0 00	1 03	0 94	1 02	0 00	0 96	0 00	1 04
			Q3	-	4 12	5 49	4 88	5 15	4 60	4 35	4 04	4 59
			Max	-	17 0	14 6	19 4	25 6	15 8	21 8	23 2	19 4

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Activated Partial Thromboplastin Time (sec)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	33 22	31 13	-	31 16	31 08	30 92	30 60	29 84	30 66
			SD	8 202	2 752	-	2 645	2 847	2 864	2 641	2 500	2 725
			Min	25 3	21 8	-	24 6	24 6	23 6	24 5	23 1	22 1
			Q1	30 70	29 40	-	29 50	29 30	29 20	28 80	28 40	29 20
			Median	32 45	31 00	-	31 00	30 80	30 80	30 45	29 60	30 25
			Q3	34 10	32 90	-	32 90	32 30	32 70	32 30	31 30	32 30
			Max	120 1	39 8	-	38 8	41 7	38 9	38 5	37 0	37 5
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	32 73	31 13	30 50	30 94	30 97	30 92	30 60	29 60	30 31
			SD	6 402	2 752	2 840	4 488	2 804	2 864	2 641	2 488	2 713
			Min	24 6	21 8	23 2	23 8	24 6	23 6	24 5	23 1	21 6
			Q1	30 30	29 40	28 60	29 05	29 20	29 20	28 80	28 00	28 60
			Median	32 10	31 00	30 40	30 70	30 70	30 80	30 45	29 40	30 10
			Q3	34 00	32 90	32 00	32 50	32 20	32 70	32 30	31 20	32 00
			Max	120 1	39 8	40 1	92 9	41 8	38 9	38 5	37 2	38 6

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Activated Partial Thromboplastin Time (sec)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-2 10	-	-2 05	-2 19	-2 34	-2 68	-3 45	-2 61
			SD	-	7 935	-	8 184	8 319	8 193	8 550	8 258	8 153
			Min	-	-88 3	-	-90 9	-91 5	-88 5	-92 1	-92 7	-90 5
			Q1	-	-2 50	-	-2 50	-2 70	-2 60	-2 80	-3 80	-2 90
			Median	-	-1 10	-	-1 30	-1 40	-1 40	-1 85	-2 40	-1 70
			Q3	-	-0 20	-	0 00	0 00	-0 10	-0 40	-1 50	-0 70
			Max	-	3 7	-	3 6	5 9	2 3	3 2	1 9	5 4
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-2 10	-1 72	-1 79	-2 15	-2 34	-2 68	-3 16	-2 43
			SD	-	7 935	3 381	6 756	7 218	8 193	8 550	6 300	6 213
			Min	-	-88 3	-23 7	-90 9	-91 5	-88 5	-92 1	-92 7	-90 5
			Q1	-	-2 50	-2 80	-2 70	-2 90	-2 60	-2 80	-3 70	-2 80
			Median	-	-1 10	-1 40	-1 40	-1 50	-1 40	-1 85	-2 50	-1 80
			Q3	-	-0 20	-0 10	-0 15	-0 10	-0 10	-0 40	-1 50	-0 90
			Max	-	3 7	4 9	44 4	5 9	2 3	3 2	1 9	5 4

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Activated Partial Thromboplastin Time (sec)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-4 58	-	-4 30	-4 73	-5 20	-6 07	-8 54	-6 06
			SD	-	8 877	-	9 366	9 620	9 327	9 744	8 907	9 036
			Min	-	-73 5	-	-75 7	-76 2	-73 7	-76 7	-77 2	-75 4
			Q1	-	-7 40	-	-7 40	-8 13	-8 14	-7 94	-11 27	-8 95
			Median	-	-3 32	-	-3 87	-4 40	-4 52	-5 39	-7 65	-5 05
			Q3	-	-0 58	-	0 00	0 00	-0 31	-1 29	-4 56	-1 95
			Max	-	12 5	-	12 6	17 2	7 9	9 1	5 9	18 9
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-4 58	-4 79	-4 47	-5 01	-5 20	-6 07	-8 44	-6 25
			SD	-	8 877	8 321	9 973	9 179	9 327	9 744	8 059	8 223
			Min	-	-73 5	-44 9	-75 7	-76 2	-73 7	-76 7	-77 2	-75 4
			Q1	-	-7 40	-8 54	-8 02	-8 45	-8 14	-7 94	-11 36	-8 79
			Median	-	-3 32	-4 40	-4 36	-4 53	-4 52	-5 39	-7 86	-5 52
			Q3	-	-0 58	-0 36	-0 47	-0 34	-0 31	-1 29	-4 57	-2 86
			Max	-	12 5	19 9	91 5	17 2	7 9	9 1	6 6	18 9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Activated Partial Thromboplastin Control (sec)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	28 70	28 70	-	28 70	28 70	28 70	28 70	28 70	28 70
			SD	0 000	0 000	-	0 000	0 000	0 000	0 000	0 000	0 000
			Min	28 7	28 7	-	28 7	28 7	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	-	28 70	28 70	28 70	28 70	28 70	28 70
			Median	28 70	28 70	-	28 70	28 70	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	-	28 70	28 70	28 70	28 70	28 70	28 70
			Max	28 7	28 7	-	28 7	28 7	28 7	28 7	28 7	28 7
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			SD	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7
			Q1	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Median	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Q3	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70	28 70
			Max	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7	28 7

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Activated Partial Thromboplastin Control (sec)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	-	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Activated Partial Thromboplastin Control (sec)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	-	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	-	0 0	0 0	0 0	0 0	0 0	0 0
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			SD	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Min	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Fibrinogen (mg/dL)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	260 1	273 4	-	276 1	279 5	279 2	285 6	282 8	257 6
			SD	48 58	45 81	-	47 00	49 93	49 43	46 64	42 69	39 28
			Min	170	185	-	150	126	153	195	203	180
			Q1	229 0	245 0	-	240 0	243 0	243 0	252 0	254 0	231 0
			Median	252 0	268 5	-	274 0	279 0	279 0	281 5	277 0	254 0
			Q3	284 5	299 0	-	307 0	313 0	306 0	308 0	310 0	285 0
			Max	438	444	-	432	421	451	519	489	358
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	259 6	273 4	285 5	279 5	283 6	279 2	285 6	286 3	261 7
			SD	44 31	45 81	42 71	45 40	47 04	49 43	46 64	50 61	41 20
			Min	134	185	194	150	126	153	195	157	180
			Q1	231 0	245 0	256 0	247 0	249 0	243 0	252 0	257 0	233 0
			Median	256 0	268 5	279 0	279 0	285 0	279 0	281 5	281 0	256 0
			Q3	283 0	299 0	318 0	305 0	314 0	306 0	308 0	313 0	285 0
			Max	438	444	405	432	421	451	519	698	421

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Fibrinogen (mg/dL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	13 1	-	16 3	19 7	19 7	26 4	23 3	-2 2
			SD	-	39 88	-	45 77	47 42	45 94	46 98	39 93	40 44
			Min	-	-124	-	-122	-106	-106	-139	-104	-122
			Q1	-	-7 0	-	-8 0	-15 0	-5 0	4 0	-1 0	-22 0
			Median	-	12 5	-	14 0	20 0	23 0	28 5	25 0	-0 5
			Q3	-	38 0	-	44 0	50 0	45 0	50 0	47 0	24 0
			Max	-	166	-	189	206	236	268	147	93
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	13 1	26 0	20 2	22 2	19 7	26 4	27 0	2 4
			SD	-	39 88	39 67	42 75	44 60	45 94	46 98	46 69	41 10
			Min	-	-124	-123	-122	-106	-106	-139	-104	-122
			Q1	-	-7 0	0 0	-3 0	-4 0	-5 0	4 0	0 0	-21 0
			Median	-	12 5	29 0	19 0	24 5	23 0	28 5	25 0	2 0
			Q3	-	38 0	53 0	44 5	50 0	45 0	50 0	50 0	27 0
			Max	-	166	113	189	206	236	268	420	180

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Fibrinogen (mg/dL)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	6 37	-	7 94	9 17	9 18	12 06	10 78	0 78
			SD	-	14 947	-	18 468	18 923	18 151	18 187	16 459	15 098
			Min	-	-37 9	-	-39 8	-32 3	-40 9	-34 9	-23 7	-30 6
			Q1	-	-2 93	-	-2 88	-3 96	-1 67	1 48	-0 35	-10 05
			Median	-	5 22	-	4 53	7 89	8 71	11 26	8 99	-0 21
			Q3	-	17 03	-	17 25	20 08	18 78	20 08	21 15	10 23
			Max	-	59 7	-	86 0	95 8	109 8	106 8	69 7	49 2
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	6 37	11 32	9 27	9 94	9 18	12 06	11 85	2 34
			SD	-	14 947	16 532	17 635	17 661	18 151	18 187	18 619	15 972
			Min	-	-37 9	-38 0	-39 8	-32 3	-40 9	-34 9	-27 2	-30 6
			Q1	-	-2 93	0 00	-0 99	-1 37	-1 67	1 48	0 00	-8 19
			Median	-	5 22	11 01	7 63	9 67	8 71	11 26	9 15	0 66
			Q3	-	17 03	19 80	17 04	20 24	18 78	20 08	21 15	11 30
			Max	-	59 7	84 3	100 7	95 8	109 8	106 8	151 1	74 7

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Antithrombin Activity (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	112 9	108 7	-	108 0	108 9	109 9	111 1	110 5	107 7
			SD	11 06	10 87	-	11 35	10 71	10 18	10 57	10 76	9 85
			Min	87	84	-	71	82	83	88	85	82
			Q1	105 0	102 0	-	100 0	102 0	103 0	104 0	103 0	100 0
			Median	112 0	108 0	-	108 0	108 0	110 0	111 0	111 0	107 0
			Q3	119 0	115 0	-	116 0	116 0	116 0	117 0	117 0	114 0
			Max	141	142	-	140	136	147	143	138	133
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	112 4	108 7	109 8	108 5	109 8	109 9	111 1	109 9	107 7
			SD	10 91	10 87	9 75	11 01	10 41	10 18	10 57	10 90	9 98
			Min	82	84	86	71	82	83	88	83	82
			Q1	105 0	102 0	103 0	101 0	103 0	103 0	104 0	102 0	101 0
			Median	112 0	108 0	110 0	108 0	109 5	110 0	111 0	110 0	107 0
			Q3	119 0	115 0	116 0	116 0	116 0	116 0	117 0	117 0	114 0
			Max	141	142	143	142	138	147	143	138	137

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Antithrombin Activity (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-4 2	-	-4 9	-3 8	-2 9	-1 7	-2 3	-5 0
			SD	-	9 08	-	9 05	9 01	8 95	8 82	10 07	9 29
			Min	-	-31	-	-33	-28	-30	-27	-31	-31
			Q1	-	-11 0	-	-11 0	-10 0	-9 0	-6 0	-9 0	-10 0
			Median	-	-5 0	-	-5 0	-3 0	-3 0	-2 0	-3 0	-5 0
			Q3	-	1 0	-	0 0	3 0	3 0	3 0	4 0	1 0
			Max	-	27	-	22	18	19	24	27	20
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-4 2	-2 0	-3 7	-3 2	-2 9	-1 7	-2 3	-4 4
			SD	-	9 08	8 23	9 36	8 94	8 95	8 82	9 84	9 03
			Min	-	-31	-22	-33	-28	-30	-27	-31	-31
			Q1	-	-11 0	-7 0	-10 0	-9 0	-9 0	-6 0	-9 0	-10 0
			Median	-	-5 0	-2 0	-4 0	-3 0	-3 0	-2 0	-3 0	-4 0
			Q3	-	1 0	4 0	2 0	3 0	3 0	3 0	4 0	1 0
			Max	-	27	20	30	21	19	24	27	21

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Antithrombin Activity (%)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-3 39	-	-4 08	-3 04	-2 22	-1 14	-1 62	-4 03
			SD	-	8 127	-	8 008	7 938	7 934	7 917	9 175	8 080
			Min	-	-26 3	-	-31 7	-21 1	-26 5	-20 3	-23 7	-22 6
			Q1	-	-9 16	-	-9 49	-8 57	-7 44	-5 31	-7 96	-9 26
			Median	-	-4 02	-	-4 00	-2 88	-2 52	-1 78	-2 42	-4 27
			Q3	-	0 90	-	0 00	2 40	2 97	2 80	3 92	0 89
			Max	-	23 9	-	21 1	19 3	19 3	25 3	30 7	20 8
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-3 39	-1 47	-3 00	-2 45	-2 22	-1 14	-1 67	-3 60
			SD	-	8 127	7 493	8 406	7 950	7 934	7 917	8 938	7 916
			Min	-	-26 3	-16 7	-31 7	-21 1	-26 5	-20 3	-23 7	-22 6
			Q1	-	-9 16	-6 54	-9 05	-7 96	-7 44	-5 31	-7 76	-8 80
			Median	-	-4 02	-1 85	-3 34	-2 68	-2 52	-1 78	-2 52	-3 88
			Q3	-	0 90	3 28	1 92	3 06	2 97	2 80	4 08	1 06
			Max	-	23 9	21 5	32 3	22 6	19 3	25 3	30 7	20 8

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Plasminogen (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	97 7	106 2	-	108 6	107 9	106 9	107 2	106 4	95 2
			SD	14 87	15 60	-	16 49	16 48	16 30	15 72	15 76	12 86
			Min	48	55	-	51	52	51	48	54	45
			Q1	91 5	98 0	-	100 0	100 0	100 0	100 0	99 0	89 0
			Median	98 0	106 0	-	109 0	108 0	109 0	108 5	107 0	96 0
			Q3	106 0	115 0	-	120 0	120 0	116 0	117 0	116 0	102 0
			Max	134	148	-	145	143	141	148	141	126
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	96 9	106 2	105 7	107 2	107 7	106 9	107 2	106 0	95 1
			SD	14 99	15 60	15 94	16 85	16 10	16 30	15 72	16 35	13 33
			Min	48	55	52	51	52	51	48	48	45
			Q1	91 0	98 0	98 0	99 0	101 0	100 0	100 0	98 0	88 0
			Median	97 0	106 0	107 0	107 5	107 0	109 0	108 5	107 0	96 0
			Q3	106 0	115 0	116 0	117 0	119 0	116 0	117 0	116 0	103 0
			Max	135	148	140	145	143	141	148	141	126

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

				Baseline Observation Period	Post-Administration Period							Follow-up Period
Parameter	Value	Treatment	Statistic	Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Plasminogen (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	8 5	-	10 9	10 5	9 5	9 5	9 1	-2 8
			SD	-	9 15	-	9 55	9 73	10 04	10 04	10 93	7 84
			Min	-	-12	-	-18	-16	-14	-24	-27	-25
			Q1	-	3 0	-	5 0	5 0	3 0	3 0	2 0	-8 0
			Median	-	7 5	-	10 0	11 0	10 0	8 5	10 0	-2 0
			Q3	-	14 0	-	17 0	16 0	15 0	16 0	16 0	2 0
			Max	-	39	-	37	39	42	39	42	24
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	8 5	9 3	10 3	10 2	9 5	9 5	9 2	-2 1
			SD	-	9 15	8 24	9 52	9 50	10 04	10 04	10 26	7 72
			Min	-	-12	-11	-18	-16	-14	-24	-27	-25
			Q1	-	3 0	3 0	3 0	4 0	3 0	3 0	2 0	-7 0
			Median	-	7 5	10 0	10 0	10 0	10 0	8 5	9 0	-1 0
			Q3	-	14 0	15 0	16 0	15 0	15 0	16 0	16 0	2 0
			Max	-	39	36	41	46	42	39	42	24

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Data Source: adlb

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Plasminogen (%)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	9 33	-	11 65	11 19	10 22	10 29	10 10	-2 47
			SD	-	10 068	-	10 157	10 280	10 789	10 600	11 545	7 843
			Min	-	-10 6	-	-15 9	-13 3	-13 2	-17 9	-22 5	-21 1
			Q1	-	2 73	-	4 21	4 95	3 23	2 68	2 30	-8 26
			Median	-	7 91	-	10 57	11 00	10 23	9 50	9 90	-1 92
			Q3	-	14 58	-	17 89	17 02	16 16	16 50	17 35	2 13
			Max	-	43 7	-	42 0	40 7	48 1	43 2	42 4	29 6
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	9 33	10 01	10 93	10 90	10 22	10 29	10 08	-1 68
			SD	-	10 068	8 744	10 120	10 211	10 789	10 600	10 900	7 820
			Min	-	-10 6	-11 7	-15 9	-13 3	-13 2	-17 9	-22 5	-21 1
			Q1	-	2 73	4 17	3 54	4 00	3 23	2 68	2 30	-6 45
			Median	-	7 91	9 88	9 87	10 56	10 23	9 50	9 52	-1 18
			Q3	-	14 58	16 50	17 14	16 24	16 16	16 50	16 98	2 91
			Max	-	43 7	34 6	42 0	54 1	48 1	43 2	42 4	29 6

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Factor XIV Activity (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	111 9	108 3	-	108 6	108 1	108 6	108 6	112 0	111 7
			SD	15 79	15 54	-	15 75	16 33	15 38	14 68	16 70	15 21
			Min	72	81	-	78	79	80	71	77	80
			Q1	101 0	97 0	-	100 0	96 0	97 0	98 0	100 0	101 0
			Median	111 0	106 0	-	107 0	105 0	107 0	107 5	109 0	111 0
			Q3	123 0	117 0	-	119 0	117 0	118 0	117 0	122 0	122 0
			Max	151	151	-	151	151	151	146	151	151
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	111 4	108 3	107 5	108 1	108 7	108 6	108 6	111 6	111 7
			SD	15 92	15 54	15 48	16 16	16 54	15 38	14 68	16 68	15 89
			Min	57	81	61	55	77	80	71	58	59
			Q1	101 0	97 0	97 0	97 0	96 0	97 0	98 0	100 0	101 0
			Median	111 0	106 0	107 0	107 0	105 5	107 0	107 5	109 0	111 0
			Q3	122 0	117 0	116 0	118 0	118 0	118 0	117 0	121 0	122 0
			Max	151	151	151	151	151	151	146	151	151

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Data Source: adlb

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Factor XIV Activity (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-3 7	-	-3 4	-3 6	-3 1	-2 9	0 2	-0 2
			SD	-	9 80	-	11 00	10 97	11 90	11 05	12 47	11 00
			Min	-	-25	-	-39	-31	-41	-53	-31	-37
			Q1	-	-10 0	-	-12 0	-10 0	-12 0	-9 0	-6 0	-7 0
			Median	-	-5 0	-	-2 0	-5 0	-3 0	-2 0	0 0	0 0
			Q3	-	3 0	-	5 0	4 0	4 0	4 0	7 0	7 0
			Max	-	32	-	21	30	29	22	30	27
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-3 7	-3 5	-3 2	-3 4	-3 1	-2 9	0 3	0 4
			SD	-	9 80	10 41	11 20	11 61	11 90	11 05	12 11	11 33
			Min	-	-25	-32	-39	-36	-41	-53	-31	-62
			Q1	-	-10 0	-10 0	-10 0	-10 0	-12 0	-9 0	-6 0	-6 0
			Median	-	-5 0	-3 0	-3 0	-5 0	-3 0	-2 0	0 0	1 0
			Q3	-	3 0	3 0	5 0	4 0	4 0	4 0	7 0	7 0
			Max	-	32	23	31	50	29	22	36	33

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a]	Cycle 2[b]	Cycle 4[c]	Cycle 6[d]	Cycle 8[a]	Cycle 10[a]	End of Treatment[c] (Visit 17/ Discontinuation)	Follow-up[c] (Visit 19)
Factor XIV Activity (%)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-2 91	-	-2 61	-2 85	-2 20	-1 99	0 72	0 39
			SD	-	8 626	-	9 577	9 845	10 665	9 636	11 114	9 624
			Min	-	-20 7	-	-26 5	-22 0	-27 9	-36 1	-23 7	-27 6
			Q1	-	-9 38	-	-10 17	-9 90	-10 62	-7 55	-5 56	-5 60
			Median	-	-4 50	-	-2 38	-4 39	-2 29	-2 06	0 00	0 00
			Q3	-	2 91	-	4 55	3 08	3 92	3 88	6 56	7 34
			Max	-	26 9	-	19 4	28 6	30 9	22 2	34 1	24 5
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-2 91	-2 70	-2 48	-2 61	-2 20	-1 99	0 80	0 87
			SD	-	8 626	9 212	9 810	10 457	10 665	9 636	10 930	9 921
			Min	-	-20 7	-27 7	-26 8	-24 1	-27 9	-36 1	-23 7	-49 6
			Q1	-	-9 38	-9 30	-9 14	-9 35	-10 62	-7 55	-5 41	-5 00
			Median	-	-4 50	-2 97	-2 68	-4 08	-2 29	-2 06	0 00	0 91
			Q3	-	2 91	3 03	4 39	3 08	3 92	3 88	7 08	7 21
			Max	-	26 9	20 4	25 8	54 3	30 9	22 2	39 1	35 9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S Activity Actual/Control	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	1 082	1 085	-	1 043	1 051	1 046	1 058	1 056	1 063
			SD	0 1193	0 1136	-	0 1214	0 1015	0 0909	0 0897	0 0880	0 1000
			Min	0 59	0 51	-	0 60	0 61	0 61	0 66	0 64	0 63
			Q1	1 010	1 030	-	0 960	0 990	1 000	1 000	1 000	1 010
			Median	1 075	1 090	-	1 050	1 040	1 040	1 060	1 050	1 060
			Q3	1 155	1 140	-	1 120	1 110	1 110	1 110	1 100	1 130
			Max	1 41	1 43	-	1 49	1 35	1 24	1 27	1 25	1 26
		Secondary FSN-013 Pooled	n	311	158	149	303	222	149	146	301	303
			Mean	1 076	1 085	1 047	1 057	1 052	1 046	1 058	1 055	1 064
			SD	0 1090	0 1136	0 1082	0 1664	0 0976	0 0909	0 0897	0 0903	0 1000
			Min	0 59	0 51	0 62	0 60	0 61	0 61	0 66	0 60	0 63
			Q1	1 010	1 030	0 980	0 990	0 990	1 000	1 000	1 010	1 010
			Median	1 070	1 090	1 060	1 050	1 050	1 040	1 060	1 050	1 060
			Q3	1 150	1 140	1 130	1 120	1 110	1 110	1 110	1 110	1 130
			Max	1 41	1 43	1 37	3 22	1 35	1 24	1 27	1 32	1 33

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S Activity Actual/Control	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 003	-	-0 039	-0 031	-0 034	-0 022	-0 025	-0 015
			SD	-	0 0959	-	0 1238	0 0989	0 0956	0 0976	0 0895	0 1050
			Min	-	-0 25	-	-0 44	-0 25	-0 27	-0 33	-0 29	-0 28
			Q1	-	-0 050	-	-0 100	-0 100	-0 100	-0 080	-0 080	-0 090
			Median	-	0 010	-	-0 040	-0 030	-0 030	-0 010	-0 010	-0 010
			Q3	-	0 060	-	0 030	0 050	0 030	0 040	0 040	0 060
			Max	-	0 25	-	0 43	0 23	0 24	0 17	0 17	0 25
		Secondary FSN-013 Pooled	n	-	158	149	303	222	149	146	301	303
			Mean	-	0 003	-0 022	-0 019	-0 029	-0 034	-0 022	-0 021	-0 010
			SD	-	0 0959	0 0940	0 1638	0 0964	0 0956	0 0976	0 0855	0 1023
			Min	-	-0 25	-0 25	-0 44	-0 27	-0 27	-0 33	-0 29	-0 28
			Q1	-	-0 050	-0 080	-0 090	-0 100	-0 100	-0 080	-0 080	-0 080
			Median	-	0 010	-0 030	-0 020	-0 020	-0 030	-0 010	-0 010	-0 010
			Q3	-	0 060	0 040	0 040	0 050	0 030	0 040	0 040	0 060
			Max	-	0 25	0 26	2 13	0 23	0 24	0 17	0 17	0 25

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S Activity Actual/Control	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 73	-	-3 03	-2 37	-2 60	-1 40	-1 81	-0 81
			SD	-	8 814	-	11 401	8 895	8 561	8 706	7 970	9 551
			Min	-	-27 1	-	-36 1	-20 2	-21 0	-23 4	-22 7	-22 8
			Q1	-	-4 24	-	-9 24	-9 16	-8 77	-6 78	-6 78	-7 56
			Median	-	1 05	-	-4 03	-2 34	-2 88	-1 02	-0 96	-0 99
			Q3	-	6 19	-	3 00	4 46	3 09	3 96	3 48	5 49
			Max	-	28 7	-	49 4	24 5	27 6	17 6	17 0	28 7
		Secondary FSN-013 Pooled	n	-	158	149	303	222	149	146	301	303
			Mean	-	0 73	-1 83	-1 34	-2 25	-2 60	-1 40	-1 49	-0 42
			SD	-	8 814	8 614	14 990	8 640	8 561	8 706	7 680	9 385
			Min	-	-27 1	-20 3	-36 1	-21 4	-21 0	-23 4	-23 0	-23 7
			Q1	-	-4 24	-7 77	-8 08	-8 77	-8 77	-6 78	-6 86	-7 34
			Median	-	1 05	-2 52	-2 06	-2 03	-2 88	-1 02	-0 93	-0 92
			Q3	-	6 19	4 04	3 96	4 55	3 09	3 96	3 81	6 14
			Max	-	28 7	23 4	195 4	24 5	27 6	17 6	17 0	28 7

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S Total Activity (IU/mL)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	1 067	1 037	-	0 985	0 982	0 970	0 978	0 986	1 000
			SD	0 1978	0 1846	-	0 1879	0 1985	0 1780	0 1893	0 1792	0 1711
			Min	0 64	0 45	-	0 53	0 54	0 58	0 56	0 61	0 63
			Q1	0 930	0 910	-	0 830	0 810	0 840	0 840	0 850	0 870
			Median	1 065	1 050	-	1 000	0 980	0 980	0 990	0 970	0 980
			Q3	1 170	1 150	-	1 110	1 110	1 090	1 120	1 130	1 140
			Max	1 92	1 56	-	1 54	1 62	1 50	1 47	1 65	1 43
		Secondary FSN-013 Pooled	n	311	158	149	303	222	149	146	301	303
			Mean	1 056	1 037	0 984	0 987	0 984	0 970	0 978	0 987	1 002
			SD	0 1796	0 1846	0 1753	0 1963	0 1894	0 1780	0 1893	0 1879	0 1678
			Min	0 57	0 45	0 55	0 53	0 54	0 58	0 56	0 53	0 56
			Q1	0 930	0 910	0 860	0 860	0 820	0 840	0 840	0 850	0 880
			Median	1 060	1 050	0 980	0 980	0 980	0 980	0 990	0 980	0 990
			Q3	1 160	1 150	1 100	1 100	1 110	1 090	1 120	1 130	1 140
			Max	1 92	1 56	1 37	2 16	1 62	1 50	1 47	1 82	1 45

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S Total Activity (IU/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 031	-	-0 081	-0 083	-0 090	-0 078	-0 076	-0 061
			SD	-	0 1319	-	0 1654	0 1749	0 1501	0 1587	0 1511	0 1462
			Min	-	-0 56	-	-0 64	-0 74	-0 72	-0 74	-0 68	-0 74
			Q1	-	-0 100	-	-0 170	-0 180	-0 180	-0 180	-0 180	-0 140
			Median	-	-0 020	-	-0 090	-0 080	-0 070	-0 060	-0 060	-0 060
			Q3	-	0 050	-	0 030	0 030	0 010	0 020	0 020	0 040
			Max	-	0 25	-	0 35	0 39	0 29	0 31	0 27	0 28
		Secondary FSN-013 Pooled	n	-	158	149	303	222	149	146	301	303
			Mean	-	-0 031	-0 061	-0 067	-0 084	-0 090	-0 078	-0 066	-0 050
			SD	-	0 1319	0 1297	0 1657	0 1626	0 1501	0 1587	0 1550	0 1391
			Min	-	-0 56	-0 40	-0 64	-0 74	-0 72	-0 74	-0 68	-0 74
			Q1	-	-0 100	-0 150	-0 150	-0 190	-0 180	-0 180	-0 180	-0 130
			Median	-	-0 020	-0 060	-0 070	-0 080	-0 070	-0 060	-0 060	-0 050
			Q3	-	0 050	0 030	0 030	0 030	0 010	0 020	0 030	0 040
			Max	-	0 25	0 24	1 23	0 39	0 29	0 31	0 69	0 38

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S Total Activity (IU/mL)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-2 21	-	-6 72	-7 09	-7 75	-6 73	-6 36	-4 85
			SD	-	11 416	-	14 106	14 604	12 873	13 779	13 190	12 012
			Min	-	-35 7	-	-41 6	-43 3	-37 5	-38 5	-35 4	-38 7
			Q1	-	-9 68	-	-14 62	-18 26	-16 87	-16 94	-16 39	-13 08
			Median	-	-1 79	-	-8 67	-7 84	-7 14	-6 11	-6 49	-5 65
			Q3	-	4 90	-	2 73	3 23	1 03	1 64	1 77	3 54
			Max	-	27 8	-	33 7	36 9	34 1	34 8	27 4	29 2
		Secondary FSN-013 Pooled	n	-	158	149	303	222	149	146	301	303
			Mean	-	-2 21	-5 45	-5 74	-7 31	-7 75	-6 73	-5 61	-3 94
			SD	-	11 416	12 450	15 285	13 843	12 873	13 779	14 296	12 215
			Min	-	-35 7	-35 7	-41 6	-43 3	-37 5	-38 5	-35 4	-38 7
			Q1	-	-9 68	-13 68	-14 29	-17 36	-16 87	-16 94	-16 24	-12 17
			Median	-	-1 79	-5 94	-7 27	-8 26	-7 14	-6 11	-6 03	-4 65
			Q3	-	4 90	3 03	2 65	2 63	1 03	1 64	3 15	4 35
			Max	-	27 8	30 8	132 3	36 9	34 1	34 8	61 1	42 2

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S, Free (%)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	91 6	93 0	-	92 6	91 8	93 5	93 1	94 0	91 8
			SD	15 39	15 51	-	15 90	15 92	17 07	16 99	17 96	16 06
			Min	38	55	-	53	52	53	52	54	51
			Q1	81 0	82 0	-	81 0	79 0	82 0	82 0	82 0	81 0
			Median	92 5	91 5	-	92 0	94 0	92 0	91 0	93 0	90 0
			Q3	100 0	104 0	-	103 0	102 0	105 0	105 0	103 0	102 0
			Max	134	134	-	134	141	134	144	151	139
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	92 2	93 0	94 6	93 1	92 5	93 5	93 1	94 0	91 8
			SD	15 18	15 51	15 20	15 70	15 90	17 07	16 99	17 06	16 25
			Min	38	55	45	50	48	53	52	46	36
			Q1	82 0	82 0	86 0	82 5	82 0	82 0	82 0	82 0	80 0
			Median	92 0	91 5	93 0	92 0	93 0	92 0	91 0	93 0	91 0
			Q3	102 0	104 0	104 0	102 5	102 0	105 0	105 0	104 0	102 0
			Max	138	134	144	138	142	134	144	151	139

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S, Free (%)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	1 4	-	1 1	0 6	2 4	2 1	3 1	0 8
			SD	-	8 82	-	9 46	9 89	10 16	10 15	12 09	10 21
			Min	-	-20	-	-22	-26	-34	-33	-30	-31
			Q1	-	-4 0	-	-5 0	-6 0	-4 0	-4 0	-5 0	-6 0
			Median	-	2 0	-	1 0	1 0	3 0	1 0	3 0	1 0
			Q3	-	7 0	-	7 0	7 0	9 0	9 0	11 0	8 0
			Max	-	28	-	29	40	26	29	31	29
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	1 4	1 9	1 3	1 1	2 4	2 1	2 2	0 0
			SD	-	8 82	9 35	9 81	9 51	10 16	10 15	11 38	10 13
			Min	-	-20	-19	-25	-26	-34	-33	-31	-31
			Q1	-	-4 0	-5 0	-5 0	-5 0	-4 0	-4 0	-5 0	-6 0
			Median	-	2 0	2 0	2 0	1 0	3 0	1 0	3 0	0 0
			Q3	-	7 0	9 0	7 0	7 0	9 0	9 0	10 0	7 0
			Max	-	28	31	29	40	26	29	36	29

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S, Free (%)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	2 14	-	1 72	1 25	3 08	2 73	3 88	1 50
			SD	-	11 193	-	10 850	12 082	12 251	12 108	13 530	12 655
			Min	-	-25 0	-	-25 0	-25 7	-35 4	-32 4	-28 8	-30 4
			Q1	-	-4 12	-	-5 36	-6 48	-4 72	-3 64	-5 56	-7 14
			Median	-	1 68	-	1 45	0 82	3 45	1 28	4 17	1 14
			Q3	-	7 50	-	8 24	7 94	9 76	9 30	13 79	8 49
			Max	-	68 4	-	47 4	65 8	63 2	55 3	42 1	76 3
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	2 14	2 64	1 96	1 75	3 08	2 73	2 89	0 46
			SD	-	11 193	10 671	11 076	11 309	12 251	12 108	12 564	11 876
			Min	-	-25 0	-23 5	-25 0	-25 7	-35 4	-32 4	-28 8	-30 4
			Q1	-	-4 12	-5 36	-5 46	-5 62	-4 72	-3 64	-5 68	-7 27
			Median	-	1 68	1 92	1 77	1 27	3 45	1 28	3 30	0 00
			Q3	-	7 50	9 00	8 28	7 77	9 76	9 30	10 58	7 78
			Max	-	68 4	41 3	47 4	65 8	63 2	55 3	48 0	76 3

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 3.sas / Output: t 4 4 2 1 3.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S (IU/mL)	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	0 989	0 959	-	0 948	0 937	0 931	0 927	0 937	0 943
			SD	0 1659	0 1601	-	0 1679	0 1775	0 1725	0 1748	0 1675	0 1523
			Min	0 67	0 64	-	0 60	0 55	0 57	0 57	0 58	0 63
			Q1	0 870	0 820	-	0 820	0 800	0 810	0 820	0 810	0 800
			Median	0 965	0 960	-	0 930	0 920	0 920	0 915	0 920	0 930
			Q3	1 090	1 050	-	1 070	1 060	1 040	1 030	1 030	1 050
			Max	1 69	1 36	-	1 48	1 46	1 40	1 46	1 55	1 33
		Secondary FSN-013 Pooled	n	311	158	149	303	222	149	146	301	303
			Mean	0 985	0 959	0 943	0 938	0 938	0 931	0 927	0 939	0 946
			SD	0 1555	0 1601	0 1553	0 1660	0 1729	0 1725	0 1748	0 1756	0 1536
			Min	0 60	0 64	0 63	0 59	0 55	0 57	0 57	0 54	0 63
			Q1	0 880	0 820	0 830	0 820	0 800	0 810	0 820	0 810	0 820
			Median	0 970	0 960	0 940	0 920	0 920	0 920	0 915	0 930	0 930
			Q3	1 090	1 050	1 040	1 040	1 060	1 040	1 030	1 050	1 050
			Max	1 69	1 36	1 48	1 48	1 46	1 40	1 46	1 63	1 55

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 3.sas / Output: t 4 4 2 1 3.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S (IU/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 031	-	-0 040	-0 051	-0 054	-0 055	-0 050	-0 044
			SD	-	0 1015	-	0 1282	0 1374	0 1217	0 1357	0 1264	0 1098
			Min	-	-0 45	-	-0 47	-0 56	-0 46	-0 61	-0 34	-0 40
			Q1	-	-0 110	-	-0 120	-0 130	-0 140	-0 140	-0 120	-0 110
			Median	-	-0 030	-	-0 050	-0 050	-0 050	-0 060	-0 060	-0 040
			Q3	-	0 030	-	0 030	0 030	0 020	0 020	0 040	0 020
			Max	-	0 36	-	0 42	0 36	0 42	0 32	0 35	0 29
		Secondary FSN-013 Pooled	n	-	158	149	303	222	149	146	301	303
			Mean	-	-0 031	-0 038	-0 044	-0 053	-0 054	-0 055	-0 044	-0 037
			SD	-	0 1015	0 1065	0 1195	0 1291	0 1217	0 1357	0 1345	0 1120
			Min	-	-0 45	-0 28	-0 47	-0 56	-0 46	-0 61	-0 40	-0 40
			Q1	-	-0 110	-0 120	-0 120	-0 130	-0 140	-0 140	-0 120	-0 110
			Median	-	-0 030	-0 030	-0 050	-0 050	-0 050	-0 060	-0 060	-0 030
			Q3	-	0 030	0 040	0 030	0 020	0 020	0 020	0 050	0 030
			Max	-	0 36	0 21	0 42	0 36	0 42	0 32	0 49	0 29

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 3.sas / Output: t 4 4 2 1 3.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

表 2.7.4-167 血液凝固系検査の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.3 Summary of Coagulation Factors (1) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Protein S (IU/mL)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-2 73	-	-3 46	-4 76	-5 16	-5 17	-4 46	-3 83
			SD	-	9 961	-	12 786	12 791	12 093	13 133	12 753	10 865
			Min	-	-26 6	-	-29 6	-33 3	-29 6	-36 1	-31 5	-34 2
			Q1	-	-10 32	-	-12 16	-13 16	-14 29	-15 52	-11 97	-11 93
			Median	-	-3 30	-	-5 22	-4 65	-5 32	-6 15	-6 12	-4 42
			Q3	-	2 68	-	3 28	3 88	2 27	2 13	3 74	1 89
			Max	-	45 0	-	52 5	36 0	48 8	30 8	50 0	38 7
		Secondary FSN-013 Pooled	n	-	158	149	303	222	149	146	301	303
			Mean	-	-2 73	-3 53	-4 11	-5 05	-5 16	-5 17	-4 00	-3 25
			SD	-	9 961	10 735	11 869	12 234	12 093	13 133	13 611	11 162
			Min	-	-26 6	-26 8	-29 8	-33 3	-29 6	-36 1	-33 1	-34 2
			Q1	-	-10 32	-11 36	-11 90	-13 19	-14 29	-15 52	-12 77	-11 24
			Median	-	-3 30	-2 73	-5 05	-5 49	-5 32	-6 15	-5 77	-3 13
			Q3	-	2 68	4 26	3 28	2 67	2 27	2 13	5 32	3 41
			Max	-	45 0	25 0	52 5	36 0	48 8	30 8	50 0	38 7

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

Program Name: t_4_4_2_1_3.sas / Output: t_4_4_2_1_3.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-65 引用

表 2.7.4-168 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.1.4 Summary of Coagulation Factors (2) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period		
				Cycle -1 (Visit 3)	Cycle 4[a)]	Cycle 6[b)]	End of Treatment[c)] (Visit 17/Discontinuation)
Sex Hormone Binding Globulin (nmol/L)	Value	Primary FSN-013 Pooled	n	160	81	78	153
			Mean	155 32	235 02	219 12	170 50
			SD	64 540	93 772	85 541	85 005
			Min	23 5	34 6	40 2	21 1
			Q1	110 50	168 50	165 90	107 60
			Median	150 35	226 00	214 30	156 80
			Q3	198 20	323 80	271 50	227 80
			Max	338 3	393 2	379 2	392 3
		Secondary FSN-013 Pooled	n	311	81	78	302
			Mean	151 86	235 02	219 12	169 01
			SD	62 554	93 772	85 541	82 555
			Min	23 5	34 6	40 2	21 1
			Q1	109 70	168 50	165 90	107 10
			Median	140 70	226 00	214 30	154 60
			Q3	190 50	323 80	271 50	222 00
			Max	382 3	393 2	379 2	492 4

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 group of FSN-013P-03 study.
b) : Includes data for only FSN-013 group of FSN-013P-04 study.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 9 to Visit 17 of FSN-013P-03 and subjects who discontinued from visit 11 to Visit 17 of FSN-013P-04

Program Name: t 4 4 2 1 4.sas / Output: t 4 4 2 1 4.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

表 2.7.4-168 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.4 Summary of Coagulation Factors (2) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period		
				Cycle -1 (Visit 3)	Cycle 4[a)]	Cycle 6[b)]	End of Treatment[c)] (Visit 17/Discontinuation)
Sex Hormone Binding Globulin (nmol/L)	Change from Baseline	Primary FSN-013 Pooled	n	-	81	78	153
			Mean	-	78 70	64 87	14 65
			SD	-	76 035	71 321	72 975
			Min	-	-161 6	-126 4	-238 6
			Q1	-	29 50	10 60	-29 20
			Median	-	83 60	65 80	11 90
			Q3	-	134 50	110 20	58 60
			Max	-	210 2	218 8	231 5
		Secondary FSN-013 Pooled	n	-	81	78	302
			Mean	-	78 70	64 87	16 74
			SD	-	76 035	71 321	70 533
			Min	-	-161 6	-126 4	-238 6
			Q1	-	29 50	10 60	-28 80
			Median	-	83 60	65 80	12 20
			Q3	-	134 50	110 20	63 20
			Max	-	210 2	218 8	231 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 group of FSN-013P-03 study.
b) : Includes data for only FSN-013 group of FSN-013P-04 study.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 9 to Visit 17 of FSN-013P-03 and subjects who discontinued from visit 11 to Visit 17 of FSN-013P-04

Program Name: t 4 4 2 1 4.sas / Output: t 4 4 2 1 4.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

表 2.7.4-168 血液凝固系検査（SHBG）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.4 Summary of Coagulation Factors (2) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period		
				Cycle -1 (Visit 3)	Cycle 4[a)]	Cycle 6[b)]	End of Treatment[c)] (Visit 17/Discontinuation)
Sex Hormone Binding Globulin (nmol/L)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	81	78	153
			Mean	-	59 82	53 98	17 24
			SD	-	56 129	55 479	62 571
			Min	-	-59 2	-48 5	-87 4
			Q1	-	16 84	10 36	-17 66
			Median	-	63 03	50 49	7 77
			Q3	-	94 58	89 03	40 02
			Max	-	210 1	176 6	481 3
		Secondary FSN-013 Pooled	n	-	81	78	302
			Mean	-	59 82	53 98	18 12
			SD	-	56 129	55 479	57 878
			Min	-	-59 2	-48 5	-87 4
			Q1	-	16 84	10 36	-17 89
			Median	-	63 03	50 49	6 39
			Q3	-	94 58	89 03	44 26
			Max	-	210 1	176 6	481 3

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 group of FSN-013P-03 study.
b) : Includes data for only FSN-013 group of FSN-013P-04 study.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 9 to Visit 17 of FSN-013P-03 and subjects who discontinued from visit 11 to Visit 17 of FSN-013P-04

Program Name: t 4 4 2 1 4.sas / Output: t 4 4 2 1 4.rtf
Date of Table Generation: 2023-09-22 20:57
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-66 引用

表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period									Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[b)]	Cycle 2[b)]	Cycle 4[b)]	Cycle 5[d)]	Cycle 6[c)]	Cycle 7[c)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[b)] (Visit 17/Discontinuation)	Follow-up[b)] (Visit 19)
Thrombin Antithrombin Complex (ng/mL)	Value	Primary FSN-013 Pooled	n	160	158	157	159	77	155	75	149	146	153	154
			Mean	1 42	1 71	1 61	2 08	1 05	1 46	1 10	1 27	1 65	1 25	1 50
			SD	1 220	4 582	5 077	8 844	0 177	1 788	0 360	0 861	4 922	0 709	2 243
			Min	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Q3	1 30	1 20	1 00	1 10	1 00	1 00	1 00	1 10	1 10	1 20	1 20
			Max	9 2	57 7	62 6	110 3	2 2	18 0	3 0	7 3	59 6	7 3	25 1
		Secondary FSN-013 Pooled	n	311	308	306	304	77	222	75	149	146	301	303
			Mean	1 61	1 43	1 96	1 74	1 05	1 36	1 10	1 27	1 65	1 86	1 48
			SD	4 964	3 333	6 704	6 528	0 177	1 552	0 360	0 861	4 922	7 691	2 281
			Min	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0	1 0
			Q1	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Median	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00	1 00
			Q3	1 20	1 00	1 00	1 10	1 00	1 00	1 00	1 10	1 10	1 20	1 20
			Max	87 2	57 7	92 3	110 3	2 2	18 0	3 0	7 3	59 6	120 1	25 1

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

Program Name: t_4_4_2_1_5.sas / Output: t_4_4_2_1_5.rtf
Date of Table Generation: 2023-09-22 20:58
Data Source: adlb

表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period									Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[b]	Cycle 2[b]	Cycle 4[b]	Cycle 5[d]	Cycle 6[c]	Cycle 7[e]	Cycle 8[a]	Cycle 10[a]	End of Treatment[b] (Visit 17/Discontinuation)	Follow-up[b] (Visit 19)
Thrombin Antithrombin Complex (ng/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	157	159	77	155	75	149	146	153	154
			Mean	-	0 29	0 18	0 66	-0 26	0 03	-0 46	-0 17	0 20	-0 18	0 07
			SD	-	4 677	5 256	8 969	0 916	1 958	1 554	1 435	5 110	1 374	2 056
			Min	-	-6 2	-7 8	-8 2	-6 1	-6 2	-8 2	-7 6	-7 1	-8 2	-6 2
			Q1	-	-0 10	-0 20	-0 20	-0 20	-0 20	-0 30	-0 20	-0 20	-0 20	-0 10
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 10	0 00	0 00
			Max	-	56 7	61 6	109 3	1 2	17 0	2 0	6 1	58 5	3 5	15 9
		Secondary FSN-013 Pooled	n	-	308	306	304	77	222	75	149	146	301	303
			Mean	-	-0 18	0 35	0 12	-0 26	0 01	-0 46	-0 17	0 20	0 23	-0 14
			SD	-	5 592	8 234	8 227	0 916	1 700	1 554	1 435	5 110	4 124	5 220
			Min	-	-78 0	-80 6	-85 3	-6 1	-6 2	-8 2	-7 6	-7 1	-8 2	-82 2
			Q1	-	-0 10	-0 10	-0 15	-0 20	-0 20	-0 30	-0 20	-0 20	-0 10	-0 10
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 10	0 10	0 00
			Max	-	56 7	91 3	109 3	1 2	17 0	2 0	6 1	58 5	58 3	22 7

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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Data Source: adlb

表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

				Baseline Observation Period	Post-Administration Period									Follow-up Period
Parameter	Value	Treatment	Statistic	Cycle -1 (Visit 3)	Cycle 1[b)]	Cycle 2[b)]	Cycle 4[b)]	Cycle 5[d)]	Cycle 6[c)]	Cycle 7[c)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[b)] (Visit 17/Discontinuation)	Follow-up[b)] (Visit 19)
Thrombin Antithrombin Complex (ng/mL)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	157	159	77	155	75	149	146	153	154
			Mean	-	46 63	45 56	91 75	-7 52	20 56	-7 34	6 32	44 83	5 89	19 30
			SD	-	455 043	509 630	886 193	27 104	157 427	38 790	69 973	450 375	54 302	117 421
			Min	-	-86 1	-86 1	-89 1	-85 9	-86 1	-89 1	-85 9	-86 1	-89 1	-86 1
			Q1	-	-9 09	-16 67	-15 38	-16 67	-16 67	-23 08	-15 38	-16 67	-12 50	-9 09
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	10 00	0 00	0 00
			Max	-	5670 0	6160 0	10930 0	120 0	1700 0	200 0	530 0	5318 2	290 0	760 0
		Secondary FSN-013 Pooled	n	-	308	306	304	77	222	75	149	146	301	303
			Mean	-	22 20	78 43	52 81	-7 52	15 27	-7 34	6 32	44 83	30 23	21 75
			SD	-	327 877	671 020	642 977	27 104	138 017	38 790	69 973	450 375	351 896	166 922
			Min	-	-89 4	-92 4	-97 8	-85 9	-86 1	-89 1	-85 9	-86 1	-89 1	-94 3
			Q1	-	-9 09	-9 09	-10 80	-16 67	-15 38	-23 08	-15 38	-16 67	-9 09	-9 09
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	10 00	9 09	0 00
			Max	-	5670 0	9130 0	10930 0	120 0	1700 0	200 0	530 0	5318 2	5830 0	2270 0

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a) : Includes data for FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

				Baseline Observation Period	Post-Administration Period									Follow-up Period
Parameter	Value	Treatment	Statistic	Cycle -1 (Visit 3)	Cycle 1[b]	Cycle 2[b]	Cycle 4[b]	Cycle 5[d]	Cycle 6[c]	Cycle 7[e]	Cycle 8[a]	Cycle 10[a]	End of Treatment[b] (Visit 17/Discontinuation)	Follow-up[b] (Visit 19)
D-Dimer (ug/mL)	Value	Primary FSN-013 Pooled	n	160	158	157	159	77	155	75	149	146	153	154
			Mean	0 381	0 384	0 372	0 377	0 363	0 360	0 442	0 361	0 374	0 377	0 425
			SD	0 1544	0 1986	0 1797	0 1595	0 1446	0 1227	0 5399	0 1209	0 1379	0 1505	0 2102
			Min	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 310
			Q3	0 405	0 380	0 370	0 390	0 350	0 370	0 400	0 380	0 410	0 400	0 470
			Max	1 47	1 60	1 91	1 15	1 04	1 14	4 88	0 91	1 19	1 36	1 67
		Secondary FSN-013 Pooled	n	311	308	306	304	77	222	75	149	146	301	303
			Mean	0 370	0 372	0 379	0 383	0 363	0 363	0 442	0 361	0 374	0 384	0 423
			SD	0 1447	0 1656	0 1934	0 2532	0 1446	0 1354	0 5399	0 1209	0 1379	0 1882	0 2411
			Min	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30
			Q1	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Median	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300	0 300
			Q3	0 370	0 370	0 370	0 380	0 350	0 370	0 400	0 380	0 410	0 400	0 450
			Max	1 47	1 60	1 91	3 02	1 04	1 19	4 88	0 91	1 19	1 70	2 54

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
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c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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Data Source: adlb

表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

				Baseline Observation Period	Post-Administration Period									Follow-up Period
Parameter	Value	Treatment	Statistic	Cycle -1 (Visit 3)	Cycle 1[b)]	Cycle 2[b)]	Cycle 4[b)]	Cycle 5[d)]	Cycle 6[c)]	Cycle 7[e)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[b)] (Visit 17/Discontinuation)	Follow-up[b)] (Visit 19)
D-Dimer (ug/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	157	159	77	155	75	149	146	153	154
			Mean	-	0 003	-0 008	-0 005	0 012	-0 021	0 032	-0 018	-0 005	-0 005	0 044
			SD	-	0 1994	0 1573	0 1691	0 1639	0 1543	0 5213	0 1450	0 1725	0 1889	0 2305
			Min	-	-0 81	-0 81	-0 81	-0 81	-0 81	-0 75	-0 71	-0 81	-0 98	-1 11
			Q1	-	-0 060	-0 050	-0 060	0 000	-0 050	-0 060	-0 050	-0 040	-0 040	-0 010
			Median	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Q3	-	0 020	0 000	0 000	0 000	0 000	0 000	0 000	0 020	0 020	0 080
			Max	-	1 24	0 59	0 78	0 51	0 84	4 28	0 58	0 75	0 75	1 37
		Secondary FSN-013 Pooled	n	-	308	306	304	77	222	75	149	146	301	303
			Mean	-	0 002	0 010	0 012	0 012	-0 010	0 032	-0 018	-0 005	0 015	0 053
			SD	-	0 1701	0 1696	0 2532	0 1639	0 1587	0 5213	0 1450	0 1725	0 2121	0 2342
			Min	-	-0 81	-0 81	-0 81	-0 81	-0 81	-0 75	-0 71	-0 81	-0 98	-1 11
			Q1	-	-0 010	-0 020	-0 030	0 000	-0 040	-0 060	-0 050	-0 040	-0 010	0 000
			Median	-	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000	0 000
			Q3	-	0 010	0 000	0 000	0 000	0 000	0 000	0 000	0 020	0 020	0 080
			Max	-	1 24	0 84	2 72	0 51	0 87	4 28	0 58	0 75	1 40	1 78

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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Data Source: adlb

表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

				Baseline Observation Period	Post-Administration Period									Follow-up Period
Parameter	Value	Treatment	Statistic	Cycle -1 (Visit 3)	Cycle 1[b)]	Cycle 2[b)]	Cycle 4[b)]	Cycle 5[d)]	Cycle 6[c)]	Cycle 7[e)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[b)] (Visit 17/Discontinuation)	Follow-up[b)] (Visit 19)
D-Dimer (ug/mL)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	157	159	77	155	75	149	146	153	154
			Mean	-	5 23	1 98	4 43	7 24	0 14	8 43	0 64	4 53	4 69	17 82
			SD	-	45 954	34 263	43 503	40 671	35 574	89 238	34 026	37 552	37 293	61 306
			Min	-	-73 0	-73 0	-73 0	-73 0	-73 0	-60 0	-64 0	-73 0	-73 0	-75 5
			Q1	-	-14 06	-11 11	-14 29	0 00	-12 82	-16 28	-14 29	-9 09	-9 30	-3 23
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	6 67	0 00	0 00	0 00	0 00	0 00	0 00	4 55	6 06	22 03
			Max	-	344 4	193 3	260 0	170 0	280 0	713 3	193 3	170 5	177 1	456 7
		Secondary FSN-013 Pooled	n	-	308	306	304	77	222	75	149	146	301	303
			Mean	-	5 00	6 10	8 03	7 24	2 65	8 43	0 64	4 53	9 93	18 24
			SD	-	39 831	39 853	66 618	40 671	38 562	89 238	34 026	37 552	54 197	55 723
			Min	-	-73 0	-73 0	-73 0	-73 0	-73 0	-60 0	-64 0	-73 0	-73 0	-75 5
			Q1	-	-3 23	-5 88	-8 03	0 00	-9 09	-16 28	-14 29	-9 09	-1 59	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	3 23	0 00	0 00	0 00	0 00	0 00	0 00	4 55	6 67	25 00
			Max	-	344 4	260 0	906 7	170 0	280 0	713 3	193 3	170 5	466 7	456 7

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b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period									Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[b)]	Cycle 2[b)]	Cycle 4[b)]	Cycle 5[d)]	Cycle 6[c)]	Cycle 7[e)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[b)] (Visit 17/Discontinuation)	Follow-up[b)] (Visit 19)
Soluble Fibrin Monomer Complex (ug/mL)	Value	Primary FSN-013 Pooled	n	160	158	157	159	77	155	75	149	146	153	154
			Mean	5 48	6 29	6 33	6 24	5 05	6 19	5 41	5 44	6 17	5 19	5 96
			SD	2 635	7 828	12 152	8 345	0 255	6 096	2 961	3 020	9 169	2 272	5 152
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Max	30 7	81 3	151 0	82 5	7 0	48 6	30 1	34 9	105 1	33 1	40 4
		Secondary FSN-013 Pooled	n	311	308	306	304	77	222	75	149	146	301	303
			Mean	5 44	5 74	6 40	6 07	5 05	5 94	5 41	5 44	6 17	6 10	6 15
			SD	3 455	5 729	10 618	8 511	0 255	5 370	2 961	3 020	9 169	10 777	8 300
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Median	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Q3	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00	5 00
			Max	56 0	81 3	151 0	108 9	7 0	48 6	30 1	34 9	105 1	151 0	105 3

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c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
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Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period									Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[b]	Cycle 2[b]	Cycle 4[b]	Cycle 5[d]	Cycle 6[c]	Cycle 7[e]	Cycle 8[a]	Cycle 10[a]	End of Treatment[b] (Visit 17/Discontinuation)	Follow-up[b] (Visit 19)
Soluble Fibrin Monomer Complex (ug/mL)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	157	159	77	155	75	149	146	153	154
			Mean	-	0 81	0 84	0 76	-0 28	0 70	-0 27	-0 07	0 64	-0 31	0 46
			SD	-	7 160	12 147	8 261	1 967	5 355	1 689	2 576	9 111	1 760	4 175
			Min	-	-13 7	-13 7	-13 7	-13 7	-13 7	-9 6	-13 7	-13 7	-13 7	-13 7
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	76 3	146 0	77 5	2 0	43 6	5 6	16 8	100 1	2 4	31 3
		Secondary FSN-013 Pooled	n	-	308	306	304	77	222	75	149	146	301	303
			Mean	-	0 30	0 95	0 62	-0 28	0 57	-0 27	-0 07	0 64	0 65	0 70
			SD	-	5 476	10 786	8 883	1 967	4 786	1 689	2 576	9 111	8 662	8 570
			Min	-	-32 4	-34 9	-51 0	-13 7	-13 7	-9 6	-13 7	-13 7	-13 7	-51 0
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	76 3	146 0	101 4	2 0	43 6	5 6	16 8	100 1	97 1	100 3

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study.
d) : Includes data for FSN-013 group of FSN-013P-03 study only.
e) : Includes data for FSN-013 group of FSN-013P-04 study only.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 5.sas / Output: t 4 4 2 1 5.rtf
Date of Table Generation: 2023-09-22 20:58
Data Source: adlb

表 2.7.4-169 血液凝固系検査（トロンビン・アンチトロンビン III 複合体、D-ダイマー、可溶性フィブリンモノマー複合体）の測定値、ベースラインからの変化量及び変化率（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.5 Summary of Coagulation Factors (3) (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period									Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[b]	Cycle 2[b]	Cycle 4[b]	Cycle 5[d]	Cycle 6[c]	Cycle 7[e]	Cycle 8[a]	Cycle 10[a]	End of Treatment[b] (Visit 17/Discontinuation)	Follow-up[b] (Visit 19)
Soluble Fibrin Monomer Complex (ug/mL)	Percent Change from Baseline	Primary FSN-013 Pooled	n	-	158	157	159	77	155	75	149	146	153	154
			Mean	-	13 39	20 83	18 72	-1 17	12 87	-1 49	2 36	16 93	-2 46	7 56
			SD	-	125 484	240 363	161 430	12 668	95 363	17 909	38 114	178 585	11 714	60 548
			Min	-	-73 3	-73 3	-73 3	-73 3	-73 3	-65 8	-73 3	-73 3	-73 3	-73 3
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	1526 0	2920 0	1550 0	40 0	872 0	112 0	336 0	2002 0	7 8	626 0
		Secondary FSN-013 Pooled	n	-	308	306	304	77	222	75	149	146	301	303
			Mean	-	6 59	23 16	15 17	-1 17	10 91	-1 49	2 36	16 93	9 29	16 27
			SD	-	90 242	210 216	141 232	12 668	86 515	17 909	38 114	178 585	132 523	155 510
			Min	-	-73 3	-73 3	-91 1	-73 3	-73 3	-65 8	-73 3	-73 3	-73 3	-91 1
			Q1	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Max	-	1526 0	2920 0	1550 0	40 0	872 0	112 0	336 0	2002 0	1942 0	2006 0

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 groups of both studies and Placebo group of FSN-013P-03 study
d) : Includes data for FSN-013 group of FSN-013P-03 study only
e) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

Program Name: t 4 4 2 1 5.sas / Output: t 4 4 2 1 5.rtf
Date of Table Generation: 2023-09-22 20:58
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-67 引用

表 2.7.4-170 血液凝固線溶系検査について投与開始後の検査値の基準値上限超、基準値下限未満の頻度（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.2.3 Frequency of Coagulation Factors Above or Below the Reference Limits (SAS)

Parameter	Primary FSN-013 Pooled N=160		Secondary FSN-013 Pooled N=311	
	Above Upper Limit n(%)	Below Lower Limit n(%)	Above Upper Limit n(%)	Below Lower Limit n(%)
Prothrombin Time (sec)	27 (16.9)	2 (1.3)	44 (14.1)	2 (0.6)
Prothrombin Control (sec)	-	-	-	-
Prothrombin Activity (%)	128 (80.0)	0 (0.0)	242 (77.8)	0 (0.0)
Prothrombin Intl. Normalized Ratio	4 (2.5)	4 (2.5)	8 (2.6)	7 (2.3)
Activated Partial Thromboplastin Time (sec)	17 (10.6)	6 (3.8)	24 (7.7)	17 (5.5)
Activated Partial Thromboplastin Control (sec)	-	-	-	-
Fibrinogen (mg/dL)	8 (5.0)	3 (1.9)	12 (3.9)	3 (1.0)
Antithrombin Activity (%)	40 (25.0)	1 (0.6)	76 (24.4)	1 (0.3)
Plasminogen (%)	23 (14.4)	9 (5.6)	42 (13.5)	18 (5.8)
Thrombin Antithrombin Complex (ng/mL)	38 (23.8)	-	61 (19.6)	-
Factor XIV Activity (%)	27 (16.9)	0 (0.0)	53 (17.0)	2 (0.6)
D-Dimer (ug/mL)	15 (9.4)	-	29 (9.3)	-
Soluble Fibrin Monomer Complex (ug/mL)	26 (16.3)	-	47 (15.1)	-
Protein S Activity Actual/Control	44 (27.5)	8 (5.0)	76 (24.4)	14 (4.5)
Protein S Total Activity (IU/mL)	18 (11.3)	31 (19.4)	29 (9.3)	54 (17.4)
Protein S, Free (%)	10 (6.3)	5 (3.1)	19 (6.1)	8 (2.6)
Protein S (IU/mL)	16 (10.0)	34 (21.3)	27 (8.7)	69 (22.2)
Sex Hormone Binding Globulin (nmol/L)	-	-	-	-

Program Name: t_4_4_2_2_3.sas / Output: t_4_4_2_2_3.rtf
Date of Table Generation: 2023-09-22 21:02
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-73 を引用

2.7.4.3.1.3.4 FSN-013P-02 試験

血液凝固系検査値の要約を表 2.7.4-171～表 2.7.4-173 に、血液凝固系検査値の異常変動ありの例数を表 2.7.4-174 に示す。

血液凝固系検査値については周期投与群、連続投与群とも、試験期間を通じて特記すべき変動は認められなかった。

また、SHBG 値の要約を表 2.7.4-175～表 2.7.4-177 に示す。SHBG の平均値は連続投与群で投薬期 2 及び投薬期 3 で増加し、後観察期でも高値のままであった。

表 2.7.4-171 臨床検査値の要約 血液凝固系検査 全体（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
PT (sec)	スクリーニング	42	10.69	0.426	4.0	9.9	10.60	11.5
	投薬期1	42	10.62	0.454	4.3	9.9	10.50	11.6
	投薬期2	42	10.61	0.408	3.8	9.8	10.60	11.5
	投薬期3	40	10.57	0.408	3.9	9.6	10.50	11.8
	後観察期	42	10.60	0.323	3.0	10.0	10.60	11.3
APTT (sec)	スクリーニング	42	29.68	2.494	8.4	25.0	29.75	33.7
	投薬期1	42	29.61	2.229	7.5	25.8	29.30	33.5
	投薬期2	42	28.92	2.269	7.8	24.9	28.90	32.8
	投薬期3	40	28.88	2.466	8.5	24.1	29.15	33.5
	後観察期	42	28.87	2.668	9.2	22.1	29.15	35.6
フィブリノーゲン (mg/dl)	スクリーニング	42	228.1	52.06	22.8	156	212.5	407
	投薬期1	42	248.9	43.86	17.6	175	244.0	381
	投薬期2	42	244.0	37.60	15.4	160	241.5	358
	投薬期3	40	240.0	42.39	17.7	174	230.5	378
	後観察期	42	221.3	40.16	18.1	147	213.0	370
AT-Ⅲ (%)	スクリーニング	42	113.1	10.19	9.0	97	114.0	136
	投薬期1	42	106.7	9.23	8.7	87	106.0	126
	投薬期2	42	105.8	11.16	10.5	77	105.5	136
	投薬期3	40	108.0	10.23	9.5	88	108.5	131
	後観察期	42	107.3	12.37	11.5	84	106.0	137
プラスミノーゲン (%)	スクリーニング	42	100.4	13.97	13.9	71	99.5	152
	投薬期1	42	96.2	11.50	11.9	55	96.0	125
	投薬期2	42	102.4	12.97	12.7	61	101.5	132
	投薬期3	40	103.0	12.60	12.2	62	103.0	132
	後観察期	42	97.7	13.70	14.0	58	96.0	137
トロンビン・アンチトロンビン3複合体 (ng/mL)	スクリーニング	42	1.72	0.928	54.0	0.6	1.50	6.7
	投薬期1	42	1.66	0.944	56.9	0.5	1.40	4.9
	投薬期2	42	1.64	0.934	56.9	0.6	1.30	5.1
	投薬期3	40	1.33	0.484	36.4	0.5	1.20	3.4
	後観察期	42	1.53	1.722	112.6	0.5	1.10	11.9
プロテインC (%)	スクリーニング	42	115.7	16.85	14.6	82	113.0	151
	投薬期1	42	106.8	15.27	14.3	70	107.0	135
	投薬期2	42	110.1	14.34	13.0	74	111.5	137
	投薬期3	40	111.5	16.83	15.1	66	110.0	151
	後観察期	42	113.9	17.99	15.8	78	114.0	150
プロテインS (%)	スクリーニング	42	79.55	13.471	16.9	60.0	80.00	122.0
	投薬期1	42	73.51	12.188	16.6	54.0	74.50	103.0
	投薬期2	42	73.59	11.556	15.7	54.0	71.50	105.0
	投薬期3	40	74.25	13.363	18.0	51.0	74.80	100.0
	後観察期	42	71.23	12.061	16.9	51.0	68.50	97.0
Dダイマー (μg/mL)	スクリーニング	42	0.388	0.1615	41.6	0.30	0.300	0.90
	投薬期1	42	0.506	0.2234	44.2	0.30	0.420	0.93
	投薬期2	42	0.416	0.2227	53.5	0.30	0.300	1.29
	投薬期3	40	0.431	0.2706	62.8	0.30	0.300	1.40
	後観察期	42	0.412	0.2206	53.6	0.30	0.300	1.16

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-32 を引用

表 2.7.4-172 臨床検査値の要約 血液凝固系検査 周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
PT (sec)	スクリーニング	20	10.58	0.394	3.7	10.1	10.45	11.4
	投薬期1	20	10.50	0.387	3.7	9 9	10.50	11.6
	投薬期2	20	10.53	0.371	3.5	9 9	10.60	11.4
	投薬期3	19	10.51	0.440	4.2	9.6	10.40	11.8
	後観察期	20	10.61	0.326	3.1	10.0	10.60	11.3
APTT (sec)	スクリーニング	20	29.63	2.563	8.6	25.0	29.60	33.7
	投薬期1	20	29.18	2.388	8.2	25.8	28.50	33.1
	投薬期2	20	28.78	2.674	9.3	24.9	28.70	32.8
	投薬期3	19	28.52	2.609	9.1	24.1	27.80	33.5
	後観察期	20	29.30	2.276	7.8	25.2	29.10	33.3
フィブリノーゲン (mg/dl)	スクリーニング	20	235.2	54.94	23.4	184	220.5	407
	投薬期1	20	257.4	38.90	15.1	201	252.0	358
	投薬期2	20	247.5	30.29	12.2	199	241.5	319
	投薬期3	19	245.4	39.55	16.1	195	247.0	354
	後観察期	20	228.2	48.19	21.1	159	215.5	370
AT-Ⅲ (%)	スクリーニング	20	115.3	11.37	9.9	97	111.0	136
	投薬期1	20	110.8	9 19	8.3	90	113.5	126
	投薬期2	20	110.1	12.35	11.2	89	108.0	136
	投薬期3	19	111.8	11.44	10.2	88	112.0	131
	後観察期	20	109.3	14.73	13.5	84	106.5	137
プラスミノーゲン (%)	スクリーニング	20	100.3	12.32	12.3	71	102.0	125
	投薬期1	20	96.6	12.80	13.3	55	99.0	116
	投薬期2	20	99.8	13.49	13.5	61	100.0	132
	投薬期3	19	101.7	12.82	12.6	62	103.0	129
	後観察期	20	95.4	14.79	15.5	58	94.0	125
トロンビン・	スクリーニング	20	1.55	0.442	28.5	0 9	1.50	2.7
アンチトロンビン3複合体	投薬期1	20	1.47	0.678	46.3	0 5	1.35	3.8
(ng/mL)	投薬期2	20	1.83	1.076	59.0	0.6	1.45	5 1
	投薬期3	19	1.42	0.638	45.1	0 5	1.20	3.4
	後観察期	20	1.85	2.436	132.0	0 5	1.15	11.9
プロテインC (%)	スクリーニング	20	118.7	13.40	11.3	87	118.5	136
	投薬期1	20	110.0	13.03	11.9	87	110.0	134
	投薬期2	20	112.4	11.84	10.5	91	112.0	131
	投薬期3	19	115.2	15.21	13.2	90	116.0	151
	後観察期	20	114.6	15.85	13.8	89	113.0	150
プロテインS (%)	スクリーニング	20	78.91	12.477	15.8	60.0	77.50	101.0
	投薬期1	20	73.16	11 261	15.4	54.0	75.10	99.0
	投薬期2	20	74.32	10 547	14.2	54.0	73.00	93.3
	投薬期3	19	75.84	13 284	17.5	51.0	77.00	99.0
	後観察期	20	71.08	11.863	16.7	52.0	71.00	90.0
Dダイマー (μg/mL)	スクリーニング	20	0.373	0.1451	39.0	0.30	0.300	0.80
	投薬期1	20	0.493	0.1979	40.2	0.30	0.460	0.93
	投薬期2	20	0.383	0.1483	38.7	0.30	0.300	0.82
	投薬期3	19	0.401	0.2102	52.4	0.30	0.300	0.96
	後観察期	20	0.357	0.1267	35.5	0.30	0.300	0.70

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-33 を引用

表 2.7.4-173 臨床検査値の要約 血液凝固系検査 連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
PT (sec)	スクリーニング	22	10.79	0.437	4.1	9.9	10.75	11.5
	投薬期1	22	10.73	0.490	4.6	10.0	10.60	11.5
	投薬期2	22	10.68	0.434	4.1	9.8	10.65	11.5
	投薬期3	21	10.63	0.376	3.5	9.8	10.60	11.4
	後観察期	22	10.58	0.328	3.1	10.0	10.55	11.2
APTT (sec)	スクリーニング	22	29.73	2.490	8.4	25.0	30.20	33.5
	投薬期1	22	30.00	2.049	6.8	26.1	29.60	33.5
	投薬期2	22	29.04	1.885	6.5	25.4	29.00	32.5
	投薬期3	21	29.20	2.346	8.0	25.1	29.40	33.1
	後観察期	22	28.49	2.981	10.5	22.1	29.20	35.6
フィブリノーゲン (mg/dl)	スクリーニング	22	221.7	49.69	22.4	156	208.0	358
	投薬期1	22	241.3	47.51	19.7	175	239.0	381
	投薬期2	22	240.9	43.69	18.1	160	242.0	358
	投薬期3	21	235.0	45.19	19.2	174	229.0	378
	後観察期	22	215.0	31.01	14.4	147	213.0	266
AT-Ⅲ (%)	スクリーニング	22	111.2	8.80	7.9	97	114.5	123
	投薬期1	22	103.0	7.72	7.5	87	104.0	116
	投薬期2	22	101.9	8.46	8.3	77	102.5	114
	投薬期3	21	104.4	7.68	7.4	88	103.0	116
	後観察期	22	105.5	9.76	9.3	92	104.0	123
プラスミノーゲン (%)	スクリーニング	22	100.5	15.62	15.5	77	98 5	152
	投薬期1	22	95.9	10.46	10.9	77	94 5	125
	投薬期2	22	104.9	12.29	11.7	85	105.0	131
	投薬期3	21	104.1	12.60	12.1	86	103.0	132
	後観察期	22	99.8	12.61	12.6	76	98.0	137
トロンビン・	スクリーニング	22	1.87	1.205	64.3	0.6	1.55	6.7
アンチトロンビン3複合体	投薬期1	22	1.84	1.121	61.0	0.8	1.50	4.9
(ng/mL)	投薬期2	22	1.47	0.770	52.3	0.7	1.15	3.6
	投薬期3	21	1.25	0.277	22.1	1.0	1.10	1.9
	後観察期	22	1.24	0.490	39.5	0.8	1.00	2.8
プロテインC (%)	スクリーニング	22	113.0	19.38	17.1	82	110.0	151
	投薬期1	22	104.0	16.86	16.2	70	99.0	135
	投薬期2	22	108.1	16.29	15.1	74	110.5	137
	投薬期3	21	108.2	17.90	16.5	66	109.0	151
	後観察期	22	113.4	20.09	17.7	78	115.5	150
プロテインS (%)	スクリーニング	22	80.14	14.584	18.2	62.0	80.45	122.0
	投薬期1	22	73.84	13.231	17.9	55.0	73.50	103.0
	投薬期2	22	72.93	12.613	17.3	57.0	70.50	105.0
	投薬期3	21	72.80	13.593	18.7	54.0	71.00	100.0
	後観察期	22	71.37	12.516	17.5	51.0	68.00	97.0
Dダイマー (μg/mL)	スクリーニング	22	0.402	0.1774	44.1	0.30	0.300	0 90
	投薬期1	22	0.518	0.2483	48.0	0.30	0.390	0 91
	投薬期2	22	0.446	0.2737	61.3	0.30	0.300	1 29
	投薬期3	21	0.458	0.3185	69.6	0.30	0.300	1.40
	後観察期	22	0.461	0.2740	59.4	0.30	0.300	1 16

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-34 を引用

表 2.7.4-174 臨床検査値異常変動 血液凝固系検査（FSN-013P-02 試験）（安全性解析対象集団）

		全体			周期投与群			連続投与群		
			異常変動			異常変動			異常変動	
	観察時点	例数	例数	割合 (%)	例数	例数	割合 (%)	例数	例数	割合 (%)
PT (sec)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
APTT (sec)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
フィブリノーゲン (mg/dl)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
AT-Ⅲ (%)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
プラスミノーゲン (%)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
トロンビン・	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
アンチトロンビン3複合体	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
(ng／mL)	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	1	2 4	20	1	5 0	22	0	0 0
プロテインC (%)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
プロテインS (%)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0
Dダイマー (μg/mL)	スクリーニング	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期1	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期2	42	0	0 0	20	0	0 0	22	0	0 0
	投薬期3	40	0	0 0	19	0	0 0	21	0	0 0
	後観察期	42	0	0 0	20	0	0 0	22	0	0 0

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-46 を引用

表 2.7.4-175 臨床検査値の要約 SHBG 全体（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
SHBG (nmol/L)	スクリーニング	42	88.74	30.630	34.5	35.8	81.35	179.8
	投薬期1	42	87.04	30.381	34.9	43.4	82.65	166.3
	投薬期2	42	128.04	58.583	45.8	53.1	106.65	296.0
	投薬期3	40	120.35	56.122	46.6	55.1	107.90	281.0
	後観察期	42	98.73	40.219	40.7	36.7	88.20	203.3

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-35 を引用

表 2.7.4-176 臨床検査値の要約 SHBG 周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
SHBG (nmol/L)	スクリーニング	20	84.07	24.832	29.5	35.8	81.35	136.7
	投薬期1	20	89.15	29.777	33.4	44.7	86.00	135.2
	投薬期2	20	104.49	45.847	43.9	53.1	85.15	247.9
	投薬期3	19	99.86	37.812	37.9	55.1	91.90	224.4
	後観察期	20	84.01	28.368	33.8	49.6	82.15	153.0

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-36 を引用

表 2.7.4-177 臨床検査値の要約 SHBG 連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
SHBG (nmol/L)	スクリーニング	22	92.99	35.131	37.8	48.1	84.50	179.8
	投薬期1	22	85.13	31.492	37.0	43.4	80.45	166.3
	投薬期2	22	149.45	61.567	41.2	60.4	139.40	296.0
	投薬期3	21	138.88	63.998	46.1	60.9	124.50	281.0
	後観察期	22	112.12	45.121	40.2	36.7	105.10	203.3

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-37 を引用

2.7.4.3.1.3.5 FSN-013P-05 試験

FSN-013P-05 試験では薬力学的検査項目の評価が実施された。FSN-013 群では EE/DRSP フレックス投与群と比べ、ほぼ全てのパラメータで変動は小さかった。詳細は 2.7.2.4.3.1 項を参照。

2.7.4.3.1.3.6 海外 ISS

海外 ISS に含めた試験のうち、Es0001-C201 試験のみに血液凝固系検査項目の評価が実施された。FSN-013 投与時、EE/LNG 0.03 mg/0.15 mg 及び EE/DRSP 0.02 mg/3 mg と比較して、それぞれの凝固系パラメータの変化量は小さかった。詳細は 2.7.2.4.3.2.1 項を参照。

2.7.4.3.1.4 尿検査

2.7.4.3.1.4.1 FSN-013P-03 試験

2.7.4.3.1.4.1.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、尿検査の定量値の測定値及びベースラインからの変化量を表 2.7.4-178 に、尿検査値の定性値のシフトテーブルを表 2.7.4-179～表 2.7.4-181 に示す。

尿検査値について、経時的推移はFSN-013群及びプラセボ群で同様であり、試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-178 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
pH	Value	FSN-013	n	81	80	81	77
			Mean	6.38	6.45	6.31	6.42
			SD	0.959	0.870	0.785	0.807
			Min	5.0	5.0	5.0	5.0
			Q1	5.50	5.50	5.50	6.00
			Median	6.00	6.50	6.00	6.50
			Q3	7.00	7.00	7.00	7.00
			Max	8.5	8.5	8.0	8.0
		Placebo	n	79	78	79	74
			Mean	6.37	6.28	6.47	6.46
			SD	0.850	0.878	0.845	0.734
			Min	5.0	5.0	5.0	5.0
			Q1	5.50	5.50	6.00	6.00
			Median	6.50	6.00	6.50	6.50
			Q3	7.00	7.00	7.00	7.00
			Max	8.0	8.5	8.5	8.5
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0.07	-0.07	0.01
			SD	-	1.040	1.202	1.185
			Min	-	-2.5	-2.5	-3.0
			Q1	-	-0.50	-1.00	-1.00
			Median	-	0.00	0.00	0.00
			Q3	-	1.00	0.50	1.00
			Max	-	2.0	2.5	2.5
		Placebo	n	-	78	79	74
			Mean	-	-0.10	0.10	0.07
			SD	-	1.042	1.033	1.028
			Min	-	-2.5	-2.5	-1.5
			Q1	-	-0.50	-0.50	-0.50
			Median	-	0.00	0.00	0.00
			Q3	-	0.50	0.50	0.50
			Max	-	2.5	3.5	3.0

表 2.7.4-178 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Specific Gravity	Value	FSN-013	n	81	80	81	77
			Mean	1 0166	1 0168	1 0163	1 0166
			SD	0 00784	0 00771	0 00811	0 00746
			Min	1 002	1 004	1 003	1 004
			Q1	1 0090	1 0100	1 0090	1 0100
			Median	1 0180	1 0170	1 0160	1 0170
			Q3	1 0230	1 0240	1 0230	1 0210
			Max	1 030	1 030	1 033	1 033
		Placebo	n	79	78	79	74
			Mean	1 0163	1 0172	1 0183	1 0164
			SD	0 00822	0 00821	0 00920	0 00848
			Min	1 002	1 002	1 002	1 002
			Q1	1 0090	1 0100	1 0110	1 0090
			Median	1 0160	1 0165	1 0180	1 0155
			Q3	1 0240	1 0250	1 0250	1 0230
			Max	1 033	1 031	1 041	1 033
	Change from Baseline	FSN-013	n	-	80	81	77
			Mean	-	0 0002	-0 0003	0 0002
			SD	-	0 00898	0 00948	0 00955
			Min	-	-0 018	-0 025	-0 023
			Q1	-	-0 0050	-0 0060	-0 0060
			Median	-	0 0005	0 0000	0 0000
			Q3	-	0 0040	0 0050	0 0050
			Max	-	0 020	0 020	0 026
		Placebo	n	-	78	79	74
			Mean	-	0 0011	0 0019	0 0004
			SD	-	0 00913	0 00945	0 01031
			Min	-	-0 022	-0 027	-0 026
			Q1	-	-0 0040	-0 0040	-0 0070
			Median	-	0 0010	0 0010	0 0000
			Q3	-	0 0060	0 0080	0 0070
			Max	-	0 022	0 028	0 021

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-27 を引用

表 2.7.4-179 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013	Comparative Period	Visit 5	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	81 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 81)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	77 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	78 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-179 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013	Comparative Period	Visit 5	(-)	66 (82.5)	4 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	6 (7.5)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	1 (1.3)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	70 (86.4)	4 (4.9)	0 (0.0)	0 (0.0)	1 (1.2)
			(n = 81)	(+-)	2 (2.5)	1 (1.2)	1 (1.2)	0 (0.0)	0 (0.0)
				(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	62 (80.5)	3 (3.9)	1 (1.3)	0 (0.0)	1 (1.3)
			(n = 77)	(+-)	7 (9.1)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	64 (82.1)	5 (6.4)	5 (6.4)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	64 (81.0)	3 (3.8)	5 (6.3)	0 (0.0)	0 (0.0)
			(n = 79)	(+-)	2 (2.5)	2 (2.5)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	57 (77.0)	3 (4.1)	5 (6.8)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	6 (8.1)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-179 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013	Comparative Period	Visit 5	(-)	46 (57.5)	3 (3.8)	2 (2.5)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	7 (8.8)	2 (2.5)	1 (1.3)	1 (1.3)	0 (0.0)
				(+)	8 (10.0)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	2 (2.5)	1 (1.3)	0 (0.0)
				(3+)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
			Visit 8 / Discontinuation	(-)	58 (71.6)	3 (3.7)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 81)	(+-)	2 (2.5)	2 (2.5)	1 (1.2)	0 (0.0)	0 (0.0)
				(+)	2 (2.5)	0 (0.0)	1 (1.2)	1 (1.2)	0 (0.0)
				(2+)	2 (2.5)	1 (1.2)	2 (2.5)	0 (0.0)	0 (0.0)
				(3+)	2 (2.5)	0 (0.0)	1 (1.2)	1 (1.2)	1 (1.2)
		Extension Period	Visit 10 / Discontinuation	(-)	53 (68.8)	2 (2.6)	3 (3.9)	1 (1.3)	0 (0.0)
			(n = 77)	(+-)	4 (5.2)	2 (2.6)	2 (2.6)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	2 (2.6)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(3+)	2 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
	Placebo	Comparative Period	Visit 5	(-)	62 (79.5)	2 (2.6)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 78)	(+-)	3 (3.8)	2 (2.6)	1 (1.3)	1 (1.3)	1 (1.3)
				(+)	1 (1.3)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
			Visit 8 / Discontinuation	(-)	54 (68.4)	3 (3.8)	0 (0.0)	2 (2.5)	1 (1.3)
			(n = 79)	(+-)	8 (10.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.5)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)
				(2+)	2 (2.5)	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
				(3+)	2 (2.5)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	44 (59.5)	4 (5.4)	0 (0.0)	0 (0.0)	1 (1.4)
			(n = 74)	(+-)	8 (10.8)	1 (1.4)	1 (1.4)	3 (4.1)	0 (0.0)
				(+)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	8 (10.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-28 を引用

表 2.7.4-180 尿検査値の定性値のベースラインからのシフトテーブル（2）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013	Comparative Period	Visit 5	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	81 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 81)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	77 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	79 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-180 尿検査値の定性値のベースラインからのシフトテーブル（2）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Ketones	FSN-013	Comparative Period	Visit 5	(-)	78 (97.5)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 80)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	80 (98.8)	0 (0.0)	1 (1.2)	0 (0.0)
			(n = 81)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	74 (96.1)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 77)	(+)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	73 (93.6)	2 (2.6)	1 (1.3)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	75 (94.9)	2 (2.5)	1 (1.3)	0 (0.0)
			(n = 79)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	71 (95.9)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10.

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-29 を引用

表 2.7.4-181 尿検査値の定性値のベースラインからのシフトテーブル（3）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（24 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013	Comparative Period	Visit 5	(+-)	79 (98.8)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(+-)	80 (98.8)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 81)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(+-)	76 (98.7)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(+-)	77 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(+-)	78 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(+-)	73 (98.6)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10.

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-30 を引用

2.7.4.3.1.4.1.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、尿検査の定量値の測定値及びベースラインからの変化量を表 2.7.4-182 に、尿検査値の定性値のシフトテーブルを表 2.7.4-183～表 2.7.4-185 に示す。

尿検査値について、経時的推移は FSN-013 群及びプラセボ群で試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-182 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
pH	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	6.38	6.45	6.31	6.42	6.34	6.13	6.32	6.41
			SD	0.959	0.870	0.785	0.807	0.741	0.637	0.683	0.703
			Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
			Q1	5.50	5.50	5.50	6.00	6.00	5.50	6.00	6.00
			Median	6.00	6.50	6.00	6.50	6.00	6.00	6.00	6.50
			Q3	7.00	7.00	7.00	7.00	7.00	6.50	7.00	7.00
			Max	8.5	8.5	8.0	8.0	8.0	8.0	8.0	8.0
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	6.37	6.28	6.47	6.46	6.30	6.36	6.44	6.44
			SD	0.850	0.878	0.845	0.734	0.724	0.717	0.612	0.793
			Min	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
			Q1	5.50	5.50	6.00	6.00	5.50	5.50	6.00	5.50
			Median	6.50	6.00	6.50	6.50	6.00	6.50	6.50	6.50
			Q3	7.00	7.00	7.00	7.00	7.00	7.00	7.00	7.00
			Max	8.0	8.5	8.5	8.5	8.0	8.0	7.5	8.5
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0.07	-0.07	0.01	-0.10	-0.31	-0.10	0.00
			SD	-	1.040	1.202	1.185	1.139	1.032	1.085	0.954
			Min	-	-2.5	-2.5	-3.0	-2.5	-3.0	-3.0	-2.0
			Q1	-	-0.50	-1.00	-1.00	-1.00	-1.00	-1.00	-0.50
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	1.00	0.50	1.00	0.50	0.50	0.50	0.50
			Max	-	2.0	2.5	2.5	2.5	2.0	3.0	2.0
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	-0.10	0.10	0.07	-0.08	-0.01	0.03	0.07
			SD	-	1.042	1.033	1.028	0.937	0.927	0.951	0.949
			Min	-	-2.5	-2.5	-1.5	-2.5	-2.0	-2.0	-2.0
			Q1	-	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.50	0.50	0.50	0.50	0.50	0.50	0.50
			Max	-	2.5	3.5	3.0	2.5	2.0	2.0	3.5

表 2.7.4-182 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period				Follow-up Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Specific Gravity	Value	FSN-013	n	81	80	81	77	75	75	77	79
			Mean	1 0166	1 0168	1 0163	1 0166	1 0160	1 0158	1 0151	1 0163
			SD	0 00784	0 00771	0 00811	0 00746	0 00773	0 00771	0 00829	0 00759
			Min	1 002	1 004	1 003	1 004	1 004	1 002	1 002	1 003
			Q1	1 0090	1 0100	1 0090	1 0100	1 0090	1 0090	1 0080	1 0100
			Median	1 0180	1 0170	1 0160	1 0170	1 0160	1 0160	1 0150	1 0170
			Q3	1 0230	1 0240	1 0230	1 0210	1 0210	1 0220	1 0210	1 0230
			Max	1 030	1 030	1 033	1 033	1 034	1 032	1 038	1 030
		Placebo	n	79	78	79	74	71	67	73	75
			Mean	1 0163	1 0172	1 0183	1 0164	1 0160	1 0161	1 0152	1 0177
			SD	0 00822	0 00821	0 00920	0 00848	0 00897	0 00820	0 00818	0 00834
			Min	1 002	1 002	1 002	1 002	1 002	1 002	1 003	1 003
			Q1	1 0090	1 0100	1 0110	1 0090	1 0070	1 0090	1 0080	1 0100
			Median	1 0160	1 0165	1 0180	1 0155	1 0140	1 0160	1 0150	1 0180
			Q3	1 0240	1 0250	1 0250	1 0230	1 0240	1 0220	1 0220	1 0250
			Max	1 033	1 031	1 041	1 033	1 034	1 034	1 033	1 032
	Change from Baseline	FSN-013	n	-	80	81	77	75	75	77	79
			Mean	-	0 0002	-0 0003	0 0002	-0 0002	-0 0004	-0 0013	0 0000
			SD	-	0 00898	0 00948	0 00955	0 00860	0 00928	0 00831	0 00903
			Min	-	-0 018	-0 025	-0 023	-0 024	-0 021	-0 027	-0 021
			Q1	-	-0 0050	-0 0060	-0 0060	-0 0050	-0 0070	-0 0060	-0 0060
			Median	-	0 0005	0 0000	0 0000	0 0000	-0 0010	-0 0010	-0 0010
			Q3	-	0 0040	0 0050	0 0050	0 0040	0 0060	0 0030	0 0080
			Max	-	0 020	0 020	0 026	0 021	0 023	0 026	0 019
		Placebo	n	-	78	79	74	71	67	73	75
			Mean	-	0 0011	0 0019	0 0004	0 0001	0 0001	-0 0007	0 0016
			SD	-	0 00913	0 00945	0 01031	0 00983	0 00889	0 00961	0 00804
			Min	-	-0 022	-0 027	-0 026	-0 020	-0 017	-0 021	-0 019
			Q1	-	-0 0040	-0 0040	-0 0070	-0 0050	-0 0040	-0 0080	-0 0030
			Median	-	0 0010	0 0010	0 0000	0 0000	0 0000	-0 0010	0 0010
			Q3	-	0 0060	0 0080	0 0070	0 0060	0 0060	0 0040	0 0060
			Max	-	0 022	0 028	0 021	0 024	0 026	0 025	0 023

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-20 を引用

表 2.7.4-183 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013	Comparative Period	Visit 5	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	81 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 81)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	77 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	77 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	79 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-183 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Glucose	Placebo	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	78 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	70 (98.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 71)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	67 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 67)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	73 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 73)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	74 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-183 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013	Comparative Period	Visit 5	(-)	66 (82.5)	4 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	6 (7.5)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)	1 (1.3)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	70 (86.4)	4 (4.9)	0 (0.0)	0 (0.0)	1 (1.2)
			(n = 81)	(+-)	2 (2.5)	1 (1.2)	1 (1.2)	0 (0.0)	0 (0.0)
				(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	62 (80.5)	3 (3.9)	1 (1.3)	0 (0.0)	1 (1.3)
			(n = 77)	(+-)	7 (9.1)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	64 (85.3)	2 (2.7)	1 (1.3)	0 (0.0)	1 (1.3)
			(n = 75)	(+-)	4 (5.3)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	65 (86.7)	4 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	3 (4.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
			Visit 17 / Discontinuation	(-)	65 (84.4)	3 (3.9)	1 (1.3)	0 (0.0)	1 (1.3)
			(n = 77)	(+-)	4 (5.2)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	65 (82.3)	4 (5.1)	2 (2.5)	0 (0.0)	1 (1.3)
			(n = 79)	(+-)	6 (7.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-183 尿検査値の定性値のベースラインからのシフトテーブル（1）[FSN-013P-03 試験（継続投与期）]（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Protein	Placebo	Comparative Period	Visit 5	(-)	64 (82.1)	5 (6.4)	5 (6.4)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	64 (81.0)	3 (3.8)	5 (6.3)	0 (0.0)	0 (0.0)
			(n = 79)	(+-)	2 (2.5)	2 (2.5)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	57 (77.0)	3 (4.1)	5 (6.8)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	6 (8.1)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	58 (81.7)	3 (4.2)	3 (4.2)	0 (0.0)	0 (0.0)
			(n = 71)	(+-)	3 (4.2)	1 (1.4)	1 (1.4)	0 (0.0)	0 (0.0)
				(+)	1 (1.4)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	52 (77.6)	4 (6.0)	2 (3.0)	0 (0.0)	0 (0.0)
			(n = 67)	(+-)	4 (6.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)
				(+)	2 (3.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	54 (74.0)	4 (5.5)	5 (6.8)	0 (0.0)	0 (0.0)
			(n = 73)	(+-)	9 (12.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	58 (77.3)	3 (4.0)	3 (4.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	6 (8.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)

表 2.7.4-183 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013	Comparative Period	Visit 5	(-)	46 (57.5)	3 (3.8)	2 (2.5)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	7 (8.8)	2 (2.5)	1 (1.3)	1 (1.3)	0 (0.0)
				(+)	8 (10.0)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	2 (2.5)	1 (1.3)	0 (0.0)
				(3+)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
			Visit 8 / Discontinuation	(-)	58 (71.6)	3 (3.7)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 81)	(+-)	2 (2.5)	2 (2.5)	1 (1.2)	0 (0.0)	0 (0.0)
				(+)	2 (2.5)	0 (0.0)	1 (1.2)	1 (1.2)	0 (0.0)
				(2+)	2 (2.5)	1 (1.2)	2 (2.5)	0 (0.0)	0 (0.0)
				(3+)	2 (2.5)	0 (0.0)	1 (1.2)	1 (1.2)	1 (1.2)
		Extension Period	Visit 10 / Discontinuation	(-)	53 (68.8)	2 (2.6)	3 (3.9)	1 (1.3)	0 (0.0)
			(n = 77)	(+-)	4 (5.2)	2 (2.6)	2 (2.6)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	2 (2.6)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(3+)	2 (2.6)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)
			Visit 12	(-)	49 (65.3)	3 (4.0)	3 (4.0)	0 (0.0)	1 (1.3)
			(n = 75)	(+-)	6 (8.0)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	4 (5.3)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)
			Visit 14	(-)	49 (65.3)	1 (1.3)	2 (2.7)	0 (0.0)	1 (1.3)
			(n = 75)	(+-)	5 (6.7)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.7)	2 (2.7)	3 (4.0)	2 (2.7)	0 (0.0)
				(2+)	2 (2.7)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(3+)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	51 (66.2)	1 (1.3)	3 (3.9)	1 (1.3)	0 (0.0)
			(n = 77)	(+-)	6 (7.8)	4 (5.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	4 (5.2)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
		Follow-up Period	Visit 19	(-)	57 (72.2)	5 (6.3)	3 (3.8)	1 (1.3)	0 (0.0)
			(n = 79)	(+-)	2 (2.5)	1 (1.3)	3 (3.8)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	3 (3.8)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)

表 2.7.4-183 尿検査値の定性値のベースラインからのシフトテーブル（1）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Placebo	Comparative Period	Visit 5	(-)	62 (79 5)	2 (2 6)	0 (0 0)	1 (1 3)	0 (0 0)
			(n = 78)	(+-)	3 (3 8)	2 (2 6)	1 (1 3)	1 (1 3)	1 (1 3)
				(+)	1 (1 3)	1 (1 3)	0 (0 0)	1 (1 3)	0 (0 0)
				(2+)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(3+)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 3)
			Visit 8 / Discontinuation	(-)	54 (68 4)	3 (3 8)	0 (0 0)	2 (2 5)	1 (1 3)
			(n = 79)	(+-)	8 (10 1)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(+)	2 (2 5)	0 (0 0)	1 (1 3)	1 (1 3)	0 (0 0)
				(2+)	2 (2 5)	1 (1 3)	0 (0 0)	0 (0 0)	1 (1 3)
				(3+)	2 (2 5)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
		Extension Period	Visit 10 / Discontinuation	(-)	44 (59 5)	4 (5 4)	0 (0 0)	0 (0 0)	1 (1 4)
			(n = 74)	(+-)	8 (10 8)	1 (1 4)	1 (1 4)	3 (4 1)	0 (0 0)
				(+)	3 (4 1)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 4)
				(2+)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(3+)	8 (10 8)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
			Visit 12	(-)	51 (71 8)	4 (5 6)	0 (0 0)	0 (0 0)	1 (1 4)
			(n = 71)	(+-)	4 (5 6)	0 (0 0)	0 (0 0)	2 (2 8)	0 (0 0)
				(+)	1 (1 4)	1 (1 4)	0 (0 0)	0 (0 0)	1 (1 4)
				(2+)	2 (2 8)	0 (0 0)	1 (1 4)	0 (0 0)	0 (0 0)
				(3+)	3 (4 2)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
			Visit 14	(-)	45 (67 2)	2 (3 0)	1 (1 5)	1 (1 5)	1 (1 5)
			(n = 67)	(+-)	6 (9 0)	0 (0 0)	0 (0 0)	1 (1 5)	0 (0 0)
				(+)	1 (1 5)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 5)
				(2+)	3 (4 5)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(3+)	3 (4 5)	2 (3 0)	0 (0 0)	0 (0 0)	0 (0 0)
			Visit 17 / Discontinuation	(-)	48 (65 8)	3 (4 1)	1 (1 4)	3 (4 1)	1 (1 4)
			(n = 73)	(+-)	5 (6 8)	2 (2 7)	0 (0 0)	0 (0 0)	0 (0 0)
				(+)	5 (6 8)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 4)
				(2+)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(3+)	4 (5 5)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		Follow-up Period	Visit 19	(-)	56 (74 7)	3 (4 0)	1 (1 3)	3 (4 0)	0 (0 0)
			(n = 75)	(+-)	7 (9 3)	1 (1 3)	0 (0 0)	0 (0 0)	1 (1 3)
				(+)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(2+)	0 (0 0)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
				(3+)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 3)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-21 を引用

表 2.7.4-184 尿検査値の定性値のベースラインからのシフトテーブル（2）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013	Comparative Period	Visit 5	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	81 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 81)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	77 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	77 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	79 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-184 尿検査値の定性値のベースラインからのシフトテーブル（2）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Bilirubin	Placebo	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	79 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	71 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 71)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	67 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 67)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	73 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 73)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-184 尿検査値の定性値のベースラインからのシフトテーブル（2）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Ketones	FSN-013	Comparative Period	Visit 5	(-)	78 (97.5)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 80)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	80 (98.8)	0 (0.0)	1 (1.2)	0 (0.0)
			(n = 81)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	74 (96.1)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 77)	(+)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	74 (98.7)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	74 (98.7)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	75 (97.4)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	77 (97.5)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 79)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-184 尿検査値の定性値のベースラインからのシフトテーブル（2）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Ketones	Placebo	Comparative Period	Visit 5	(-)	73 (93.6)	2 (2.6)	1 (1.3)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(-)	75 (94.9)	2 (2.5)	1 (1.3)	0 (0.0)
			(n = 79)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(-)	71 (95.9)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(-)	68 (95.8)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 71)	(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	65 (97.0)	1 (1.5)	0 (0.0)	0 (0.0)
			(n = 67)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	71 (97.3)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 73)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	71 (94.7)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-29 を引用

表 2.7.4-185 尿検査値の定性値のベースラインからのシフトテーブル（3）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013	Comparative Period	Visit 5	(+-)	79 (98.8)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(+-)	80 (98.8)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 81)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(+-)	76 (98.7)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(+-)	73 (97.3)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(+-)	73 (97.3)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(+-)	76 (98.7)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 77)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(+-)	78 (98.7)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 79)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-185 尿検査値の定性値のベースラインからのシフトテーブル（3）［FSN-013P-03 試験（継続投与期）］（（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(+-)	(+)	(2+)	(3+)
Urobilinogen	Placebo	Comparative Period	Visit 5	(+-)	77 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8 / Discontinuation	(+-)	78 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 79)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 10 / Discontinuation	(+-)	73 (98.6)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 12	(+-)	71 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 71)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(+-)	66 (98.5)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 67)	(+)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(+-)	73 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 73)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(+-)	74 (98.7)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-30 を引用

2.7.4.3.1.4.2 FSN-013P-04 試験

2.7.4.3.1.4.2.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、尿検査の定量値の測定値及びベースラインからの変化量を表 2.7.4-186 に、尿検査値の定性値のシフトテーブルを表 2.7.4-187～表 2.7.4-189 に示す。

尿検査値について、経時的推移は FSN-013 群及びプラセボ群で同様であり、試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-186 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
pH	Value	FSN-013	n	79	78	78	78
			Mean	6.24	6.31	6.28	6.35
			SD	0.905	0.770	0.763	0.744
			Min	5.0	5.0	5.0	5.0
			Q1	5.50	5.50	5.50	5.50
			Median	6.00	6.25	6.00	6.00
			Q3	7.00	7.00	6.50	7.00
			Max	8.5	8.0	8.5	8.0
		Placebo	n	83	82	80	83
			Mean	6.23	6.29	6.30	6.27
			SD	0.839	0.868	0.778	0.770
			Min	5.0	5.0	5.0	5.0
			Q1	5.50	5.50	5.50	5.50
			Median	6.00	6.00	6.50	6.00
			Q3	7.00	7.00	7.00	7.00
			Max	8.0	8.5	8.0	8.0
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	0.08	0.06	0.12
			SD	-	0.931	0.879	0.926
			Min	-	-1.5	-2.0	-2.5
			Q1	-	-0.50	-0.50	-0.50
			Median	-	0.00	0.00	0.00
			Q3	-	0.50	0.50	0.50
			Max	-	2.0	2.5	2.5
		Placebo	n	-	82	80	83
			Mean	-	0.04	0.06	0.03
			SD	-	1.081	1.011	1.075
			Min	-	-2.5	-2.5	-3.0
			Q1	-	-0.50	-0.50	-1.00
			Median	-	0.00	0.00	0.00
			Q3	-	1.00	0.75	0.50
			Max	-	2.5	2.0	2.5

表 2.7.4-186 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Specific Gravity	Value	FSN-013	n	79	78	78	78
			Mean	1.0166	1.0159	1.0156	1.0151
			SD	0.00835	0.00792	0.00807	0.00749
			Min	1.002	1.003	1.002	1.002
			Q1	1.0090	1.0090	1.0090	1.0080
			Median	1.0170	1.0150	1.0140	1.0155
			Q3	1.0230	1.0230	1.0220	1.0210
			Max	1.032	1.032	1.033	1.029
		Placebo	n	83	82	80	83
			Mean	1.0181	1.0182	1.0174	1.0184
			SD	0.00846	0.00813	0.00824	0.00772
			Min	1.002	1.003	1.003	1.003
			Q1	1.0110	1.0130	1.0110	1.0130
			Median	1.0200	1.0180	1.0185	1.0190
			Q3	1.0250	1.0250	1.0240	1.0250
			Max	1.034	1.033	1.036	1.036
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0.0008	-0.0011	-0.0013
			SD	-	0.00701	0.00724	0.00877
			Min	-	-0.015	-0.019	-0.022
			Q1	-	-0.0060	-0.0060	-0.0050
			Median	-	-0.0010	-0.0010	-0.0010
			Q3	-	0.0030	0.0040	0.0040
			Max	-	0.019	0.019	0.023
		Placebo	n	-	82	80	83
			Mean	-	0.0001	-0.0005	0.0004
			SD	-	0.00934	0.00955	0.00962
			Min	-	-0.023	-0.023	-0.020
			Q1	-	-0.0060	-0.0070	-0.0060
			Median	-	0.0000	-0.0010	0.0010
			Q3	-	0.0060	0.0060	0.0060
			Max	-	0.024	0.020	0.026

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-29 を引用

表 2.7.4-187 尿検査値の定性値のシフトテーブル（1）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	82 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 82)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	78 (97.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	83 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 83)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-187 尿検査値の定性値のシフトテーブル（1）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013	Comparative Period	Visit 5	(-)	65 (83.3)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	3 (3.8)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	67 (85.9)	5 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	3 (3.8)	2 (2.6)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	68 (87.2)	7 (9.0)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	74 (90.2)	2 (2.4)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 82)	(+-)	2 (2.4)	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	69 (86.3)	4 (5.0)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	5 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	69 (83.1)	4 (4.8)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 83)	(+-)	7 (8.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-187 尿検査値の定性値のシフトテーブル（1）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（24 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013	Comparative Period	Visit 5	(-)	48 (61.5)	4 (5.1)	0 (0.0)	0 (0.0)	1 (1.3)
			(n = 78)	(+-)	4 (5.1)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)
				(+)	4 (5.1)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	3 (3.8)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(3+)	7 (9.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
			Visit 8	(-)	52 (66.7)	3 (3.8)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 78)	(+-)	9 (11.5)	4 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)
				(2+)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	57 (73.1)	3 (3.8)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 78)	(+-)	6 (7.7)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	1 (1.3)
				(3+)	3 (3.8)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	66 (80.5)	3 (3.7)	2 (2.4)	0 (0.0)	0 (0.0)
			(n = 82)	(+-)	5 (6.1)	1 (1.2)	0 (0.0)	1 (1.2)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
				(3+)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	57 (71.3)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	3 (3.8)	0 (0.0)	0 (0.0)	2 (2.5)	0 (0.0)
				(+)	5 (6.3)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)
				(2+)	2 (2.5)	2 (2.5)	0 (0.0)	1 (1.3)	0 (0.0)
				(3+)	2 (2.5)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	55 (66.3)	2 (2.4)	0 (0.0)	1 (1.2)	0 (0.0)
			(n = 83)	(+-)	5 (6.0)	1 (1.2)	1 (1.2)	1 (1.2)	0 (0.0)
				(+)	2 (2.4)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
				(3+)	9 (10.8)	3 (3.6)	1 (1.2)	0 (0.0)	0 (0.0)

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-30 を引用

表 2.7.4-188 尿検査値の定性値のシフトテーブル（2）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（24 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	82 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 82)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	83 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 83)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-188 尿検査値の定性値のシフトテーブル（2）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Ketones	FSN-013	Comparative Period	Visit 5	(-)	75 (96.2)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	75 (96.2)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(-)	79 (96.3)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 82)	(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	77 (96.3)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	78 (94.0)	1 (1.2)	1 (1.2)	0 (0.0)
			(n = 83)	(+)	1 (1.2)	0 (0.0)	1 (1.2)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-31 を引用

表 2.7.4-189 尿検査値の定性値のシフトテーブル（3）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（24 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013	Comparative Period	Visit 5	(+-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(+-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(+-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Placebo	Comparative Period	Visit 5	(+-)	81 (98.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 82)	(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(+-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(+-)	82 (98.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 83)	(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-32 を引用

2.7.4.3.1.4.2.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、尿検査の定量値の測定値及びベースラインからの変化量を表 2.7.4-190 に、尿検査値の定性値のシフトテーブルを表 2.7.4-191～表 2.7.4-193 に示す。

尿検査値について、経時的推移は FSN-013 群及びプラセボ群で試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-190 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
pH	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	6.24	6.31	6.28	6.35	6.28	6.26	6.34	6.33
			SD	0.905	0.770	0.763	0.744	0.799	0.726	0.754	0.773
			Min	5.0	5.0	5.0	5.0	5.0	5.5	5.5	5.0
			Q1	5.50	5.50	5.50	5.50	5.50	5.50	5.50	5.50
			Median	6.00	6.25	6.00	6.00	6.00	6.00	6.25	6.50
			Q3	7.00	7.00	6.50	7.00	7.00	6.50	7.00	7.00
			Max	8.5	8.0	8.5	8.0	8.0	8.0	8.0	8.0
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	6.23	6.29	6.30	6.27	6.44	6.26	6.24	6.43
			SD	0.839	0.868	0.778	0.770	0.726	0.569	0.557	0.680
			Min	5.0	5.0	5.0	5.0	5.5	5.0	5.0	5.0
			Q1	5.50	5.50	5.50	5.50	6.00	6.00	6.00	6.00
			Median	6.00	6.00	6.50	6.00	6.50	6.00	6.50	6.50
			Q3	7.00	7.00	7.00	7.00	7.00	6.50	6.50	7.00
			Max	8.0	8.5	8.0	8.0	8.5	7.5	7.5	7.5
	Change from Baseline	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	0.08	0.06	0.12	0.09	0.05	0.13	0.13
			SD	-	0.931	0.879	0.926	0.973	0.846	0.957	1.024
			Min	-	-1.5	-2.0	-2.5	-2.5	-2.5	-2.0	-2.5
			Q1	-	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Q3	-	0.50	0.50	0.50	0.50	0.50	1.00	1.00
			Max	-	2.0	2.5	2.5	3.0	2.0	2.0	2.0
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0.04	0.06	0.03	0.22	0.05	-0.01	0.18
			SD	-	1.081	1.011	1.075	1.119	0.882	0.896	1.013
			Min	-	-2.5	-2.5	-3.0	-2.5	-2.0	-2.0	-2.5
			Q1	-	-0.50	-0.50	-1.00	-0.50	-0.50	-0.50	-0.50
			Median	-	0.00	0.00	0.00	0.00	0.00	0.00	0.50
			Q3	-	1.00	0.75	0.50	1.00	1.00	0.50	1.00
			Max	-	2.5	2.0	2.5	3.0	1.5	2.0	2.0

表 2.7.4-190 尿検査の定量値の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period			Follow-up Period
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 12	Visit 14	Visit 17 / Discontinuation	Visit 19
Specific Gravity	Value	FSN-013	n	79	78	78	78	74	71	76	75
			Mean	1 0166	1 0159	1 0156	1 0151	1 0176	1 0168	1 0166	1 0166
			SD	0 00835	0 00792	0 00807	0 00749	0 00883	0 00806	0 00806	0 00754
			Min	1 002	1 003	1 002	1 002	1 002	1 003	1 002	1 003
			Q1	1 0090	1 0090	1 0090	1 0080	1 0110	1 0100	1 0100	1 0110
			Median	1 0170	1 0150	1 0140	1 0155	1 0170	1 0180	1 0160	1 0170
			Q3	1 0230	1 0230	1 0220	1 0210	1 0240	1 0240	1 0230	1 0230
			Max	1 032	1 032	1 033	1 029	1 038	1 031	1 035	1 034
		Placebo	n	83	82	80	83	75	74	76	80
			Mean	1 0181	1 0182	1 0174	1 0184	1 0163	1 0176	1 0165	1 0172
			SD	0 00846	0 00813	0 00824	0 00772	0 00812	0 00802	0 00829	0 00769
			Min	1 002	1 003	1 003	1 003	1 003	1 003	1 003	1 003
			Q1	1 0110	1 0130	1 0110	1 0130	1 0100	1 0100	1 0090	1 0120
			Median	1 0200	1 0180	1 0185	1 0190	1 0160	1 0175	1 0160	1 0160
			Q3	1 0250	1 0250	1 0240	1 0250	1 0230	1 0240	1 0235	1 0235
			Max	1 034	1 033	1 036	1 036	1 033	1 032	1 032	1 033
	Change from Baselin	FSN-013	n	-	78	78	78	74	71	76	75
			Mean	-	-0 0008	-0 0011	-0 0013	0 0012	0 0007	0 0001	0 0003
			SD	-	0 00701	0 00724	0 00877	0 00913	0 00809	0 00743	0 00829
			Min	-	-0 015	-0 019	-0 022	-0 018	-0 018	-0 022	-0 020
			Q1	-	-0 0060	-0 0060	-0 0050	-0 0050	-0 0040	-0 0050	-0 0050
			Median	-	-0 0010	-0 0010	-0 0010	0 0015	0 0010	0 0000	0 0000
			Q3	-	0 0030	0 0040	0 0040	0 0080	0 0060	0 0055	0 0040
			Max	-	0 019	0 019	0 023	0 020	0 022	0 016	0 029
		Placebo	n	-	82	80	83	75	74	76	80
			Mean	-	0 0001	-0 0005	0 0004	-0 0020	-0 0007	-0 0016	-0 0007
			SD	-	0 00934	0 00955	0 00962	0 00930	0 00881	0 01015	0 00932
			Min	-	-0 023	-0 023	-0 020	-0 025	-0 019	-0 026	-0 024
			Q1	-	-0 0060	-0 0070	-0 0060	-0 0090	-0 0070	-0 0090	-0 0065
			Median	-	0 0000	-0 0010	0 0010	-0 0010	0 0000	0 0000	0 0000
			Q3	-	0 0060	0 0060	0 0060	0 0050	0 0050	0 0050	0 0065
			Max	-	0 024	0 020	0 026	0 016	0 019	0 025	0 021

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-20 を引用

表 2.7.4-191 尿検査値の定性値のシフトテーブル（1）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（52 週）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	71 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 71)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	76 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 76)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-191 尿検査値の定性値のシフトテーブル（1）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Glucose	Placebo	Comparative Period	Visit 5	(-)	82 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 82)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	78 (97.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	83 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 83)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	76 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 76)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	79 (98.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-191 尿検査値の定性値のシフトテーブル（1）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013	Comparative Period	Visit 5	(-)	65 (83.3)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	3 (3.8)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	67 (85.9)	5 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	3 (3.8)	2 (2.6)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	68 (87.2)	7 (9.0)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 78)	(+-)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	54 (73.0)	4 (5.4)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	9 (12.2)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	60 (84.5)	6 (8.5)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 71)	(+-)	3 (4.2)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	63 (82.9)	4 (5.3)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 76)	(+-)	5 (6.6)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	64 (85.3)	6 (8.0)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-191 尿検査値の定性値のシフトテーブル（1）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Protein	Placebo	Comparative Period	Visit 5	(-)	74 (90.2)	2 (2.4)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 82)	(+-)	2 (2.4)	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	69 (86.3)	4 (5.0)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	5 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	69 (83.1)	4 (4.8)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 83)	(+-)	7 (8.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	63 (84.0)	4 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+-)	3 (4.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	4 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	57 (77.0)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+-)	9 (12.2)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	4 (5.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	62 (81.6)	2 (2.6)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 76)	(+-)	6 (7.9)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	3 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	67 (83.8)	3 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+-)	8 (10.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-191 尿検査値の定性値のシフトテーブル（1）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013	Comparative Period	Visit 5	(-)	48 (61.5)	4 (5.1)	0 (0.0)	0 (0.0)	1 (1.3)
			(n = 78)	(+-)	4 (5.1)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)
				(+)	4 (5.1)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	3 (3.8)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
				(3+)	7 (9.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
			Visit 8	(-)	52 (66.7)	3 (3.8)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 78)	(+-)	9 (11.5)	4 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	2 (2.6)	1 (1.3)	1 (1.3)	1 (1.3)	1 (1.3)
				(2+)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	57 (73.1)	3 (3.8)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 78)	(+-)	6 (7.7)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	1 (1.3)
				(3+)	3 (3.8)	1 (1.3)	1 (1.3)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	50 (67.6)	1 (1.4)	0 (0.0)	1 (1.4)	1 (1.4)
			(n = 74)	(+-)	3 (4.1)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	4 (5.4)	2 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)
				(2+)	2 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)
				(3+)	3 (4.1)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	43 (60.6)	1 (1.4)	0 (0.0)	1 (1.4)	1 (1.4)
			(n = 71)	(+-)	7 (9.9)	4 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	5 (7.0)	2 (2.8)	1 (1.4)	1 (1.4)	0 (0.0)
				(2+)	4 (5.6)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	53 (69.7)	4 (5.3)	0 (0.0)	1 (1.3)	1 (1.3)
			(n = 76)	(+-)	7 (9.2)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(+)	3 (3.9)	2 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	1 (1.3)	0 (0.0)	1 (1.3)	1 (1.3)	0 (0.0)
				(3+)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	54 (72.0)	4 (5.3)	0 (0.0)	1 (1.3)	0 (0.0)
			(n = 75)	(+-)	7 (9.3)	2 (2.7)	0 (0.0)	1 (1.3)	1 (1.3)
				(+)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-191 尿検査値の定性値のシフトテーブル（1）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline				
					(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Placebo	Comparative Period	Visit 5 (n = 82)	(-)	66 (80 5)	3 (3 7)	2 (2 4)	0 (0 0)	0 (0 0)
				(+-)	5 (6 1)	1 (1 2)	0 (0 0)	1 (1 2)	0 (0 0)
				(+)	0 (0 0)	0 (0 0)	0 (0 0)	2 (2 4)	0 (0 0)
				(2+)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 2)	0 (0 0)
				(3+)	0 (0 0)	1 (1 2)	0 (0 0)	0 (0 0)	0 (0 0)
			Visit 8 (n = 80)	(-)	57 (71 3)	3 (3 8)	0 (0 0)	0 (0 0)	0 (0 0)
				(+-)	3 (3 8)	0 (0 0)	0 (0 0)	2 (2 5)	0 (0 0)
				(+)	5 (6 3)	0 (0 0)	1 (1 3)	1 (1 3)	0 (0 0)
				(2+)	2 (2 5)	2 (2 5)	0 (0 0)	1 (1 3)	0 (0 0)
				(3+)	2 (2 5)	0 (0 0)	1 (1 3)	0 (0 0)	0 (0 0)
			Visit 10 / Discontinuation (n = 83)	(-)	55 (66 3)	2 (2 4)	0 (0 0)	1 (1 2)	0 (0 0)
				(+-)	5 (6 0)	1 (1 2)	1 (1 2)	1 (1 2)	0 (0 0)
				(+)	2 (2 4)	0 (0 0)	0 (0 0)	1 (1 2)	0 (0 0)
				(2+)	0 (0 0)	0 (0 0)	0 (0 0)	1 (1 2)	0 (0 0)
				(3+)	9 (10 8)	3 (3 6)	1 (1 2)	0 (0 0)	0 (0 0)
		Extension Period	Visit 12 (n = 75)	(-)	45 (60 0)	2 (2 7)	0 (0 0)	1 (1 3)	0 (0 0)
				(+-)	7 (9 3)	2 (2 7)	0 (0 0)	2 (2 7)	0 (0 0)
				(+)	3 (4 0)	0 (0 0)	1 (1 3)	1 (1 3)	0 (0 0)
				(2+)	4 (5 3)	0 (0 0)	1 (1 3)	0 (0 0)	0 (0 0)
				(3+)	5 (6 7)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
			Visit 14 (n = 74)	(-)	54 (73 0)	2 (2 7)	0 (0 0)	1 (1 4)	0 (0 0)
				(+-)	7 (9 5)	1 (1 4)	2 (2 7)	1 (1 4)	0 (0 0)
				(+)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
				(2+)	0 (0 0)	1 (1 4)	0 (0 0)	2 (2 7)	0 (0 0)
				(3+)	2 (2 7)	1 (1 4)	0 (0 0)	0 (0 0)	0 (0 0)
			Visit 17 / Discontinuation (n = 76)	(-)	58 (76 3)	2 (2 6)	0 (0 0)	1 (1 3)	0 (0 0)
				(+-)	3 (3 9)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
				(+)	1 (1 3)	0 (0 0)	2 (2 6)	1 (1 3)	0 (0 0)
				(2+)	1 (1 3)	1 (1 3)	0 (0 0)	1 (1 3)	0 (0 0)
				(3+)	3 (3 9)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
		Follow-up Period	Visit 19 (n = 80)	(-)	60 (75 0)	4 (5 0)	0 (0 0)	1 (1 3)	0 (0 0)
				(+-)	5 (6 3)	1 (1 3)	0 (0 0)	2 (2 5)	0 (0 0)
				(+)	1 (1 3)	1 (1 3)	1 (1 3)	0 (0 0)	0 (0 0)
				(2+)	1 (1 3)	0 (0 0)	1 (1 3)	1 (1 3)	0 (0 0)
				(3+)	1 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-21 を引用

表 2.7.4-192 尿検査値の定性値のシフトテーブル（2）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（52 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013	Comparative Period	Visit 5	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	78 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	71 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 71)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	76 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 76)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-192 尿検査値の定性値のシフトテーブル（2）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Bilirubin	Placebo	Comparative Period	Visit 5	(-)	82 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 82)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	83 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 83)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	74 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	76 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 76)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-192 尿検査値の定性値のシフトテーブル（2）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Ketones	FSN-013	Comparative Period	Visit 5	(-)	75 (96.2)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	75 (96.2)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	73 (98.6)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	70 (98.6)	1 (1.4)	0 (0.0)	0 (0.0)
			(n = 71)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	73 (96.1)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 76)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	73 (97.3)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-192 尿検査値の定性値のシフトテーブル（2）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(-)	(+)	(2+)	(3+)
Ketones	Placebo	Comparative Period	Visit 5	(-)	79 (96.3)	1 (1.2)	0 (0.0)	0 (0.0)
			(n = 82)	(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(-)	77 (96.3)	1 (1.3)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(-)	78 (94.0)	1 (1.2)	1 (1.2)	0 (0.0)
			(n = 83)	(+)	1 (1.2)	0 (0.0)	1 (1.2)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(-)	71 (94.7)	1 (1.3)	1 (1.3)	0 (0.0)
			(n = 75)	(+)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(-)	70 (94.6)	1 (1.4)	1 (1.4)	0 (0.0)
			(n = 74)	(+)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(-)	74 (97.4)	1 (1.3)	1 (1.3)	0 (0.0)
			(n = 76)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(-)	77 (96.3)	1 (1.3)	2 (2.5)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-22 を引用

表 2.7.4-193 尿検査値の定性値のシフトテーブル（3）[FSN-013P-04 試験（継続投与期）]（安全性解析対象集団）（52 週）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013	Comparative Period	Visit 5	(+-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(+-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(+-)	76 (97.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 78)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(+-)	72 (97.3)	2 (2.7)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(+-)	68 (95.8)	2 (2.8)	0 (0.0)	0 (0.0)
			(n = 71)	(+)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(+-)	71 (93.4)	2 (2.6)	0 (0.0)	0 (0.0)
			(n = 76)	(+)	3 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(+-)	72 (96.0)	2 (2.7)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4-193 尿検査値の定性値のシフトテーブル（3）［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Treatment	Period	Analysis Visit		Baseline			
					(+-)	(+)	(2+)	(3+)
Urobilinogen	Placebo	Comparative Period	Visit 5	(+-)	81 (98.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 82)	(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 8	(+-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 10 / Discontinuation	(+-)	82 (98.8)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 83)	(+)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Extension Period	Visit 12	(+-)	75 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 75)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 14	(+-)	72 (97.3)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 74)	(+)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
			Visit 17 / Discontinuation	(+-)	76 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 76)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Follow-up Period	Visit 19	(+-)	80 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
			(n = 80)	(+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(2+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
				(3+)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-23 を引用

2.7.4.3.1.4.3 FSN-013P-03 試験及び FSN-013P-04 試験の併合

2.7.4.3.1.4.3.1 24 週投与

投与 6 周期終了時点までの Primary Safety Population を対象とした、尿検査の測定値及びベースラインからの変化量を表 2.7.4-194 に、尿検査値の定性値のシフトテーブルを表 2.7.4-195 に示す。

尿検査値については試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-194 尿検査値の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.2.1.6 Summary of Urinalysis Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
pH	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	6 31	6 38	6 30	6 38
			SD	0 933	0 823	0 772	0 775
			Min	5 0	5 0	5 0	5 0
			Q1	5 50	5 50	5 50	5 50
			Median	6 00	6 50	6 00	6 50
			Q3	7 00	7 00	7 00	7 00
			Max	8 5	8 5	8 5	8 0
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	0 08	-0 01	0 06
			SD	-	0 984	1 055	1 060
			Min	-	-2 5	-2 5	-3 0
			Q1	-	-0 50	-0 50	-1 00
			Median	-	0 00	0 00	0 00
			Q3	-	0 50	0 50	1 00
			Max	-	2 0	2 5	2 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_6.sas / Output: t_4_4_2_1_6.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-194 尿検査値の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.6 Summary of Urinalysis Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 10 / Discontinuation
Specific Gravity	Value	FSN-013 Pooled	n	160	158	159	155
			Mean	1 0166	1 0163	1 0159	1 0159
			SD	0 00807	0 00780	0 00807	0 00749
			Min	1 002	1 003	1 002	1 002
			Q1	1 0090	1 0090	1 0090	1 0100
			Median	1 0170	1 0160	1 0150	1 0160
			Q3	1 0230	1 0230	1 0230	1 0210
			Max	1 032	1 032	1 033	1 033
	Change from Baseline	FSN-013 Pooled	n	-	158	159	155
			Mean	-	-0 0003	-0 0007	-0 0006
			SD	-	0 00806	0 00844	0 00917
			Min	-	-0 018	-0 025	-0 023
			Q1	-	-0 0060	-0 0060	-0 0050
			Median	-	0 0000	-0 0010	0 0000
			Q3	-	0 0040	0 0050	0 0040
			Max	-	0 020	0 020	0 026

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_2_1_6.sas / Output: t_4_4_2_1_6.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-67 を引用

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period					
				Visit 5				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013 Pooled	(-)	158	158 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+-)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 8 / Discontinuation n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013 Pooled	(-)	159	159 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+-)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 10 / Discontinuation n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	FSN-013 Pooled	(-)	155	155 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+-)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period					
				Visit 5				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013 Pooled	(-)	158	131 (82.9)	7 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)
		(+-)		9 (5.7)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		2 (1.3)	1 (0.6)	3 (1.9)	0 (0.0)	1 (0.6)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 8 / Discontinuation n	(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013 Pooled	(-)	159	137 (86.2)	9 (5.7)	0 (0.0)	0 (0.0)	1 (0.6)
		(+-)		5 (3.1)	3 (1.9)	2 (1.3)	0 (0.0)	0 (0.0)
		(+)		1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period					
			Visit 10 / Discontinuation					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	FSN-013 Pooled	(-)	155	130 (83.9)	10 (6.5)	2 (1.3)	0 (0.0)	1 (0.6)
		(+-)		9 (5.8)	1 (0.6)	1 (0.6)	0 (0.0)	0 (0.0)
		(+)		1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 5 n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013 Pooled	(-)	158	94 (59.5)	7 (4.4)	2 (1.3)	0 (0.0)	1 (0.6)
		(+-)		11 (7.0)	3 (1.9)	1 (0.6)	2 (1.3)	0 (0.0)
		(+)		12 (7.6)	3 (1.9)	1 (0.6)	0 (0.0)	0 (0.0)
		(2+)		4 (2.5)	1 (0.6)	3 (1.9)	1 (0.6)	0 (0.0)
		(3+)		10 (6.3)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.6)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 8 / Discontinuation n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013 Pooled	(-)	159	110 (69.2)	6 (3.8)	1 (0.6)	1 (0.6)	0 (0.0)
		(+-)		11 (6.9)	6 (3.8)	1 (0.6)	0 (0.0)	0 (0.0)
		(+)		4 (2.5)	1 (0.6)	2 (1.3)	2 (1.3)	1 (0.6)
		(2+)		4 (2.5)	1 (0.6)	2 (1.3)	0 (0.0)	0 (0.0)
		(3+)		3 (1.9)	0 (0.0)	1 (0.6)	1 (0.6)	1 (0.6)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 10 / Discontinuation n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	FSN-013 Pooled	(-)	155	110 (71.0)	5 (3.2)	3 (1.9)	2 (1.3)	0 (0.0)
		(+-)		10 (6.5)	4 (2.6)	2 (1.3)	0 (0.0)	0 (0.0)
		(+)		2 (1.3)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		2 (1.3)	2 (1.3)	1 (0.6)	1 (0.6)	1 (0.6)
		(3+)		5 (3.2)	1 (0.6)	1 (0.6)	1 (0.6)	1 (0.6)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period				
				Visit 5			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013 Pooled	(-)	158	158 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 8 / Discontinuation n	(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013 Pooled	(-)	159	159 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 10 / Discontinuation n	(-)	(+)	(2+)	(3+)
Bilirubin	FSN-013 Pooled	(-)	155	155 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 5 n	(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013 Pooled	(+-)	158	155 (98.1)	3 (1.9)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 8 / Discontinuation n	(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013 Pooled	(+-)	159	156 (98.1)	3 (1.9)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period				
			Visit 10 / Discontinuation				
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	FSN-013 Pooled	(+-)	155	152 (98.1)	3 (1.9)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period				
				Visit 5			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	FSN-013 Pooled	(-)	158	153 (96.8)	2 (1.3)	1 (0.6)	0 (0.0)
		(+)		2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Baseline Period: Visit 8 / Discontinuation n	(-)	(+)	(2+)	(3+)
Ketones	FSN-013 Pooled	(-)	159	156 (98.1)	2 (1.3)	1 (0.6)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

表 2.7.4-195 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Baseline Period				
			Visit 10 / Discontinuation				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	FSN-013 Pooled	(-)	155	149 (96.1)	2 (1.3)	1 (0.6)	0 (0.0)
		(+)		3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-02-20 8:50
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-68 を引用

2.7.4.3.1.4.3.2 52 週投与

投与 13 周期終了時点までの Primary Safety Population 及び Secondary Safety Population を対象とした、尿検査の測定値及びベースラインからの変化量を表 2.7.4-196 に、尿検査値の定性値のシフトテーブルを表 2.7.4-197 に示す。

Primary Safety Population 及び Secondary Safety Population において、いずれも尿検査値については試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-196 尿検査値の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.1.6 Summary of Urinalysis Tests (SAS)

				Baseline Observation Period	Post-Administration Period							Follow-up Period
Parameter	Value	Treatment	Statistic	Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
pH	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	6 31	6 38	-	6 30	6 38	6 31	6 19	6 33	6 37
			SD	0 933	0 823	-	0 772	0 775	0 768	0 683	0 717	0 736
			Min	5 0	5 0	-	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 50	5 50	-	5 50	5 50	5 50	5 50	5 50	6 00
			Median	6 00	6 50	-	6 00	6 50	6 00	6 00	6 00	6 50
			Q3	7 00	7 00	-	7 00	7 00	7 00	6 50	7 00	7 00
			Max	8 5	8 5	-	8 5	8 0	8 0	8 0	8 0	8 0
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	6 31	6 38	6 45	6 29	6 38	6 31	6 19	6 34	6 40
			SD	0 891	0 823	0 728	0 714	0 756	0 768	0 683	0 656	0 735
			Min	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0	5 0
			Q1	5 50	5 50	6 00	5 50	5 50	5 50	5 50	6 00	6 00
			Median	6 00	6 50	6 50	6 00	6 50	6 00	6 00	6 50	6 50
			Q3	7 00	7 00	7 00	7 00	7 00	7 00	6 50	6 50	7 00
			Max	8 5	8 5	8 5	8 5	8 0	8 0	8 0	8 0	8 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 6.sas / Output: t 4 4 2 1 6.rtf
Date of Table Generation: 2023-09-22 20:59
Data Source: adlb

表 2.7.4-196 尿検査値の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.6 Summary of Urinalysis Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
pH	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	0 08	-	-0 01	0 06	-0 01	-0 14	0 02	0 06
			SD	-	0 984	-	1 055	1 060	1 061	0 960	1 027	0 988
			Min	-	-2 5	-	-2 5	-3 0	-2 5	-3 0	-3 0	-2 5
			Q1	-	-0 50	-	-0 50	-1 00	-0 50	-0 50	-0 50	-0 50
			Median	-	0 00	-	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 50	-	0 50	1 00	0 50	0 50	0 50	0 50
			Max	-	2 0	-	2 5	2 5	3 0	2 0	3 0	2 0
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	0 08	0 14	-0 01	0 04	-0 01	-0 14	0 02	0 10
			SD	-	0 984	1 074	0 986	1 020	1 061	0 960	0 974	0 983
			Min	-	-2 5	-2 5	-2 5	-3 0	-2 5	-3 0	-3 0	-2 5
			Q1	-	-0 50	-0 50	-0 50	-0 50	-0 50	-0 50	-0 50	-0 50
			Median	-	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00
			Q3	-	0 50	1 00	0 50	0 50	0 50	0 50	0 50	0 50
			Max	-	2 0	3 0	2 5	2 5	3 0	2 0	3 0	3 5

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

Program Name: t 4 4 2 1 6.sas / Output: t 4 4 2 1 6.rtf
Date of Table Generation: 2023-09-22 20:59
Data Source: adlb

表 2.7.4-196 尿検査値の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.6 Summary of Urinalysis Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Specific Gravity	Value	Primary FSN-013 Pooled	n	160	158	-	159	155	149	146	153	154
			Mean	1 0166	1 0163	-	1 0159	1 0159	1 0168	1 0163	1 0159	1 0164
			SD	0 00807	0 00780	-	0 00807	0 00749	0 00831	0 00787	0 00819	0 00754
			Min	1 002	1 003	-	1 002	1 002	1 002	1 002	1 002	1 003
			Q1	1 0090	1 0090	-	1 0090	1 0100	1 0100	1 0100	1 0090	1 0110
			Median	1 0170	1 0160	-	1 0150	1 0160	1 0170	1 0160	1 0160	1 0170
			Q3	1 0230	1 0230	-	1 0230	1 0210	1 0230	1 0230	1 0220	1 0230
			Max	1 032	1 032	-	1 033	1 033	1 038	1 032	1 038	1 034
		Secondary FSN-013 Pooled	n	311	158	149	304	222	149	146	301	303
			Mean	1 0169	1 0163	1 0164	1 0164	1 0159	1 0168	1 0163	1 0159	1 0170
			SD	0 00818	0 00780	0 00827	0 00828	0 00769	0 00831	0 00787	0 00821	0 00773
			Min	1 002	1 003	1 002	1 002	1 002	1 002	1 002	1 002	1 003
			Q1	1 0090	1 0090	1 0100	1 0090	1 0090	1 0100	1 0100	1 0090	1 0110
			Median	1 0180	1 0160	1 0160	1 0160	1 0160	1 0170	1 0160	1 0160	1 0170
			Q3	1 0240	1 0230	1 0230	1 0230	1 0210	1 0230	1 0230	1 0230	1 0230
			Max	1 034	1 032	1 033	1 034	1 034	1 038	1 032	1 038	1 034

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 6.sas / Output: t 4 4 2 1 6.rtf
Date of Table Generation: 2023-09-22 20:59
Data Source: adlb

表 2.7.4-196 尿検査値の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.6 Summary of Urinalysis Tests (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period							Follow-up Period
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 2[b)]	Cycle 4[c)]	Cycle 6[d)]	Cycle 8[a)]	Cycle 10[a)]	End of Treatment[c)] (Visit 17/ Discontinuation)	Follow-up[c)] (Visit 19)
Specific Gravity	Change from Baseline	Primary FSN-013 Pooled	n	-	158	-	159	155	149	146	153	154
			Mean	-	-0 0003	-	-0 0007	-0 0006	0 0005	0 0002	-0 0006	0 0002
			SD	-	0 00806	-	0 00844	0 00917	0 00887	0 00871	0 00789	0 00865
			Min	-	-0 018	-	-0 025	-0 023	-0 024	-0 021	-0 027	-0 021
			Q1	-	-0 0060	-	-0 0060	-0 0050	-0 0050	-0 0060	-0 0050	-0 0050
			Median	-	0 0000	-	-0 0010	0 0000	0 0010	0 0000	-0 0010	-0 0005
			Q3	-	0 0040	-	0 0050	0 0040	0 0060	0 0060	0 0040	0 0060
			Max	-	0 020	-	0 020	0 026	0 021	0 023	0 026	0 029
		Secondary FSN-013 Pooled	n	-	158	149	304	222	149	146	301	303
			Mean	-	-0 0003	-0 0008	-0 0005	-0 0004	0 0005	0 0002	-0 0009	0 0003
			SD	-	0 00806	0 00986	0 00884	0 00907	0 00887	0 00871	0 00892	0 00866
			Min	-	-0 018	-0 026	-0 025	-0 023	-0 024	-0 021	-0 027	-0 024
			Q1	-	-0 0060	-0 0070	-0 0060	-0 0050	-0 0050	-0 0060	-0 0070	-0 0050
			Median	-	0 0000	-0 0010	0 0000	0 0000	0 0010	0 0000	-0 0010	0 0000
			Q3	-	0 0040	0 0060	0 0050	0 0040	0 0060	0 0060	0 0040	0 0060
			Max	-	0 020	0 021	0 024	0 026	0 021	0 023	0 026	0 029

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 6.sas / Output: t 4 4 2 1 6.rtf
Date of Table Generation: 2023-09-22 20:59
Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07）表 6-68 を引用

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 1[a)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	158	158 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	158	158 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 2[b)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)		-	-	-	-	-
		(+-)		-	-	-	-	-
		(+)		-	-	-	-	-
		(2+)		-	-	-	-	-
		(3+)		-	-	-	-	-
	Secondary FSN-013 Pooled	(-)	149	149 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 4[c)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	159	159 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	304	303 (99 7)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 6[d)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	155	155 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	222	222 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 8[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	149	149 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	149	149 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 10[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	146	146 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	146	146 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			End of Treatment[c)] (Visit 17/Discontinuation)					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	153	153 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	301	301 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Follow-up Period					
			Follow-up[c] (Visit 19)					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Glucose	Primary FSN-013 Pooled	(-)	154	154 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	303	301 (99 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 1[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	158	131 (82 9)	7 (4 4)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		9 (5 7)	4 (2 5)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		2 (1 3)	1 (0 6)	3 (1 9)	0 (0 0)	1 (0 6)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	158	131 (82 9)	7 (4 4)	0 (0 0)	0 (0 0)	0 (0 0)
		(+-)		9 (5 7)	4 (2 5)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		2 (1 3)	1 (0 6)	3 (1 9)	0 (0 0)	1 (0 6)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 2[b)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)		-	-	-	-	-
		(+-)		-	-	-	-	-
		(+)		-	-	-	-	-
		(2+)		-	-	-	-	-
		(3+)		-	-	-	-	-
	Secondary FSN-013 Pooled	(-)	149	120 (80 5)	7 (4 7)	5 (3 4)	0 (0 0)	0 (0 0)
		(+-)		9 (6 0)	1 (0 7)	1 (0 7)	0 (0 0)	0 (0 0)
		(+)		6 (4 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 4[c)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	159	137 (86 2)	9 (5 7)	0 (0 0)	0 (0 0)	1 (0 6)
		(+-)		5 (3 1)	3 (1 9)	2 (1 3)	0 (0 0)	0 (0 0)
		(+)		1 (0 6)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	1 (0 6)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	304	252 (82 9)	15 (4 9)	3 (1 0)	0 (0 0)	1 (0 3)
		(+-)		17 (5 6)	5 (1 6)	3 (1 0)	0 (0 0)	0 (0 0)
		(+)		6 (2 0)	0 (0 0)	1 (0 3)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	1 (0 3)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 6[d)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	155	130 (83 9)	10 (6 5)	2 (1 3)	0 (0 0)	1 (0 6)
		(+-)		9 (5 8)	1 (0 6)	1 (0 6)	0 (0 0)	0 (0 0)
		(+)		1 (0 6)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	222	182 (82 0)	14 (6 3)	4 (1 8)	0 (0 0)	1 (0 5)
		(+-)		13 (5 9)	1 (0 5)	2 (0 9)	0 (0 0)	0 (0 0)
		(+)		3 (1 4)	0 (0 0)	2 (0 9)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
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Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 8[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	149	118 (79 2)	6 (4 0)	2 (1 3)	0 (0 0)	1 (0 7)
		(+-)		13 (8 7)	4 (2 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		4 (2 7)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	149	118 (79 2)	6 (4 0)	2 (1 3)	0 (0 0)	1 (0 7)
		(+-)		13 (8 7)	4 (2 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		4 (2 7)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 10[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	146	125 (85 6)	10 (6 8)	1 (0 7)	0 (0 0)	0 (0 0)
		(+-)		6 (4 1)	1 (0 7)	1 (0 7)	0 (0 0)	0 (0 0)
		(+)		1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	1 (0 7)
	Secondary FSN-013 Pooled	(-)	146	125 (85 6)	10 (6 8)	1 (0 7)	0 (0 0)	0 (0 0)
		(+-)		6 (4 1)	1 (0 7)	1 (0 7)	0 (0 0)	0 (0 0)
		(+)		1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	1 (0 7)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
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Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			End of Treatment[c)] (Visit 17/Discontinuation)					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	153	128 (83 7)	7 (4 6)	2 (1 3)	0 (0 0)	1 (0 7)
		(+-)		9 (5 9)	3 (2 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	301	243 (80 7)	13 (4 3)	8 (2 7)	0 (0 0)	1 (0 3)
		(+-)		24 (8 0)	5 (1 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		4 (1 3)	1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	1 (0 3)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Follow-up Period					
				Follow-up[c)] (Visit 19)				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Protein	Primary FSN-013 Pooled	(-)	154	129 (83 8)	10 (6 5)	3 (1 9)	0 (0 0)	1 (0 6)
		(+-)		9 (5 8)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		1 (0 6)	1 (0 6)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	303	249 (82 2)	16 (5 3)	6 (2 0)	0 (0 0)	1 (0 3)
		(+-)		23 (7 6)	1 (0 3)	1 (0 3)	0 (0 0)	0 (0 0)
		(+)		2 (0 7)	2 (0 7)	1 (0 3)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	1 (0 3)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
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Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 1[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	158	94 (59 5)	7 (4 4)	2 (1 3)	0 (0 0)	1 (0 6)
		(+-)		11 (7 0)	3 (1 9)	1 (0 6)	2 (1 3)	0 (0 0)
		(+)		12 (7 6)	3 (1 9)	1 (0 6)	0 (0 0)	0 (0 0)
		(2+)		4 (2 5)	1 (0 6)	3 (1 9)	1 (0 6)	0 (0 0)
		(3+)		10 (6 3)	0 (0 0)	0 (0 0)	1 (0 6)	1 (0 6)
	Secondary FSN-013 Pooled	(-)	158	94 (59 5)	7 (4 4)	2 (1 3)	0 (0 0)	1 (0 6)
		(+-)		11 (7 0)	3 (1 9)	1 (0 6)	2 (1 3)	0 (0 0)
		(+)		12 (7 6)	3 (1 9)	1 (0 6)	0 (0 0)	0 (0 0)
		(2+)		4 (2 5)	1 (0 6)	3 (1 9)	1 (0 6)	0 (0 0)
		(3+)		10 (6 3)	0 (0 0)	0 (0 0)	1 (0 6)	1 (0 6)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
				Cycle 2[b)]				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)		-	-	-	-	-
		(+-)		-	-	-	-	-
		(+)		-	-	-	-	-
		(2+)		-	-	-	-	-
		(3+)		-	-	-	-	-
	Secondary FSN-013 Pooled	(-)	149	89 (59 7)	6 (4 0)	0 (0 0)	1 (0 7)	1 (0 7)
		(+-)		15 (10 1)	3 (2 0)	1 (0 7)	5 (3 4)	0 (0 0)
		(+)		6 (4 0)	0 (0 0)	1 (0 7)	1 (0 7)	1 (0 7)
		(2+)		4 (2 7)	0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)
		(3+)		13 (8 7)	1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 4[c)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	159	110 (69 2)	6 (3 8)	1 (0 6)	1 (0 6)	0 (0 0)
		(+-)		11 (6 9)	6 (3 8)	1 (0 6)	0 (0 0)	0 (0 0)
		(+)		4 (2 5)	1 (0 6)	2 (1 3)	2 (1 3)	1 (0 6)
		(2+)		4 (2 5)	1 (0 6)	2 (1 3)	0 (0 0)	0 (0 0)
		(3+)		3 (1 9)	0 (0 0)	1 (0 6)	1 (0 6)	1 (0 6)
	Secondary FSN-013 Pooled	(-)	304	215 (70 7)	12 (3 9)	1 (0 3)	2 (0 7)	1 (0 3)
		(+-)		22 (7 2)	7 (2 3)	3 (1 0)	3 (1 0)	0 (0 0)
		(+)		5 (1 6)	2 (0 7)	2 (0 7)	2 (0 7)	2 (0 7)
		(2+)		6 (2 0)	2 (0 7)	3 (1 0)	2 (0 7)	0 (0 0)
		(3+)		8 (2 6)	1 (0 3)	1 (0 3)	1 (0 3)	1 (0 3)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 6[d)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	155	110 (71 0)	5 (3 2)	3 (1 9)	2 (1 3)	0 (0 0)
		(+-)		10 (6 5)	4 (2 6)	2 (1 3)	0 (0 0)	0 (0 0)
		(+)		2 (1 3)	1 (0 6)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		2 (1 3)	2 (1 3)	1 (0 6)	1 (0 6)	1 (0 6)
		(3+)		5 (3 2)	1 (0 6)	1 (0 6)	1 (0 6)	1 (0 6)
	Secondary FSN-013 Pooled	(-)	222	155 (69 8)	7 (3 2)	4 (1 8)	3 (1 4)	1 (0 5)
		(+-)		16 (7 2)	4 (1 8)	2 (0 9)	1 (0 5)	0 (0 0)
		(+)		3 (1 4)	1 (0 5)	0 (0 0)	0 (0 0)	1 (0 5)
		(2+)		5 (2 3)	2 (0 9)	1 (0 5)	1 (0 5)	1 (0 5)
		(3+)		8 (3 6)	3 (1 4)	1 (0 5)	1 (0 5)	1 (0 5)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 8[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	149	99 (66 4)	4 (2 7)	3 (2 0)	1 (0 7)	2 (1 3)
		(+-)		9 (6 0)	4 (2 7)	1 (0 7)	0 (0 0)	0 (0 0)
		(+)		5 (3 4)	3 (2 0)	1 (0 7)	2 (1 3)	0 (0 0)
		(2+)		3 (2 0)	0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)
		(3+)		7 (4 7)	2 (1 3)	1 (0 7)	1 (0 7)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	149	99 (66 4)	4 (2 7)	3 (2 0)	1 (0 7)	2 (1 3)
		(+-)		9 (6 0)	4 (2 7)	1 (0 7)	0 (0 0)	0 (0 0)
		(+)		5 (3 4)	3 (2 0)	1 (0 7)	2 (1 3)	0 (0 0)
		(2+)		3 (2 0)	0 (0 0)	1 (0 7)	0 (0 0)	0 (0 0)
		(3+)		7 (4 7)	2 (1 3)	1 (0 7)	1 (0 7)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			Cycle 10[a)]					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	146	92 (63 0)	2 (1 4)	2 (1 4)	1 (0 7)	2 (1 4)
		(+-)		12 (8 2)	5 (3 4)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		7 (4 8)	4 (2 7)	4 (2 7)	3 (2 1)	0 (0 0)
		(2+)		6 (4 1)	2 (1 4)	1 (0 7)	0 (0 0)	0 (0 0)
		(3+)		3 (2 1)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	146	92 (63 0)	2 (1 4)	2 (1 4)	1 (0 7)	2 (1 4)
		(+-)		12 (8 2)	5 (3 4)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		7 (4 8)	4 (2 7)	4 (2 7)	3 (2 1)	0 (0 0)
		(2+)		6 (4 1)	2 (1 4)	1 (0 7)	0 (0 0)	0 (0 0)
		(3+)		3 (2 1)	0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period					
			End of Treatment[c)] (Visit 17/Discontinuation)					
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	153	104 (68 0)	5 (3 3)	3 (2 0)	2 (1 3)	1 (0 7)
		(+-)		13 (8 5)	5 (3 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		7 (4 6)	2 (1 3)	1 (0 7)	0 (0 0)	0 (0 0)
		(2+)		2 (1 3)	0 (0 0)	2 (1 3)	2 (1 3)	0 (0 0)
		(3+)		1 (0 7)	1 (0 7)	1 (0 7)	0 (0 0)	1 (0 7)
	Secondary FSN-013 Pooled	(-)	301	209 (69 4)	10 (3 3)	4 (1 3)	6 (2 0)	2 (0 7)
		(+-)		21 (7 0)	8 (2 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		13 (4 3)	2 (0 7)	3 (1 0)	1 (0 3)	1 (0 3)
		(2+)		3 (1 0)	1 (0 3)	2 (0 7)	3 (1 0)	0 (0 0)
		(3+)		8 (2 7)	2 (0 7)	1 (0 3)	0 (0 0)	1 (0 3)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Follow-up Period					
				Follow-up[e)] (Visit 19)				
Parameter	Treatment	Baseline Values	n	(-)	(+-)	(+)	(2+)	(3+)
Occult Blood	Primary FSN-013 Pooled	(-)	154	111 (72 1)	9 (5 8)	3 (1 9)	2 (1 3)	0 (0 0)
		(+-)		9 (5 8)	3 (1 9)	3 (1 9)	1 (0 6)	1 (0 6)
		(+)		2 (1 3)	0 (0 0)	1 (0 6)	0 (0 0)	0 (0 0)
		(2+)		1 (0 6)	2 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		4 (2 6)	0 (0 0)	0 (0 0)	1 (0 6)	1 (0 6)
	Secondary FSN-013 Pooled	(-)	303	223 (73 6)	15 (5 0)	4 (1 3)	6 (2 0)	0 (0 0)
		(+-)		21 (6 9)	5 (1 7)	3 (1 0)	3 (1 0)	2 (0 7)
		(+)		3 (1 0)	1 (0 3)	2 (0 7)	0 (0 0)	0 (0 0)
		(2+)		2 (0 7)	3 (1 0)	1 (0 3)	1 (0 3)	0 (0 0)
		(3+)		5 (1 7)	0 (0 0)	0 (0 0)	1 (0 3)	2 (0 7)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 1[a)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	158	158 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	158	158 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 2[b)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	.	-	-	-	-
		(+)		-	-	-	-
		(2+)		-	-	-	-
		(3+)		-	-	-	-
	Secondary FSN-013 Pooled	(-)	149	149 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 4[c)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	159	159 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	304	304 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 6[d)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	155	155 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	222	222 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 8[a)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	149	149 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	149	149 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			Cycle 10[a)]				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	146	146 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	146	146 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			End of Treatment[c)] (Visit 17/Discontinuation)				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	153	153 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	301	301 (100 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Follow-up Period				
			Follow-up[c)] (Visit 19)				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Bilirubin	Primary FSN-013 Pooled	(-)	154	154 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	303	303 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			Cycle 1[a)]				
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	158	155 (98 1)	3 (1 9)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(+-)	158	155 (98 1)	3 (1 9)	0 (0 0)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 2[b)]			
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)		-	-	-	-
		(+)		-	-	-	-
		(2+)		-	-	-	-
		(3+)		-	-	-	-
	Secondary FSN-013 Pooled	(+-)	149	148 (99 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(+)		1 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 4[c)]			
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	159	156 (98.1)	3 (1.9)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(+-)	304	299 (98.4)	3 (1.0)	0 (0.0)	0 (0.0)
		(+)		2 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 6[d)]			
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	155	152 (98.1)	3 (1 9)	0 (0.0)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(+-)	222	218 (98.2)	3 (1.4)	0 (0.0)	0 (0.0)
		(+)		1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			Cycle 8[a)]				
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	149	145 (97.3)	3 (2.0)	0 (0.0)	0 (0.0)
		(+)		1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(+-)	149	145 (97.3)	3 (2.0)	0 (0.0)	0 (0.0)
		(+)		1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			Cycle 10[a)]				
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	146	141 (96.6)	3 (2.1)	0 (0.0)	0 (0.0)
		(+)		2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(+-)	146	141 (96.6)	3 (2.1)	0 (0.0)	0 (0.0)
		(+)		2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			End of Treatment[c)] (Visit 17/Discontinuation)				
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	153	147 (96 1)	3 (2 0)	0 (0 0)	0 (0 0)
		(+)		3 (2 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(+-)	301	295 (98 0)	3 (1 0)	0 (0 0)	0 (0 0)
		(+)		3 (1 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Follow-up Period				
				Follow-up[c] (Visit 19)			
Parameter	Treatment	Baseline Values	n	(+-)	(+)	(2+)	(3+)
Urobilinogen	Primary FSN-013 Pooled	(+-)	154	150 (97 4)	3 (1 9)	0 (0 0)	0 (0 0)
		(+)		1 (0 6)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(+-)	303	298 (98 3)	3 (1 0)	0 (0 0)	0 (0 0)
		(+)		2 (0 7)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			Cycle 1[a)]				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	158	153 (96.8)	2 (1.3)	1 (0.6)	0 (0.0)
		(+)		2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	158	153 (96.8)	2 (1.3)	1 (0.6)	0 (0.0)
		(+)		2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name t 4 4 2 1 7.sas / Output t 4 4 2 1 7.rtf
Date of Table Generation 2023-09-22 21 00
Data Source adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 2[b)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	.	-	-	-	-
		(+)		-	-	-	-
		(2+)		-	-	-	-
		(3+)		-	-	-	-
	Secondary FSN-013 Pooled	(-)	149	142 (95.3)	2 (1.3)	1 (0.7)	0 (0.0)
		(+)		3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name t 4 4 2 1 7.sas / Output t 4 4 2 1 7.rtf
Date of Table Generation 2023-09-22 21 00
Data Source adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 4[c)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	159	156 (98 1)	2 (1 3)	1 (0 6)	0 (0 0)
		(+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	304	294 (96 7)	4 (1 3)	2 (0 7)	0 (0 0)
		(+)		3 (1 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t_4_4_2_1_7.sas / Output: t_4_4_2_1_7.rtf
Date of Table Generation: 2023-09-22 21:00
Data Source: adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
				Cycle 6[d)]			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	155	149 (96.1)	2 (1.3)	1 (0.6)	0 (0.0)
		(+)		3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	222	214 (96.4)	3 (1.4)	1 (0.5)	0 (0.0)
		(+)		3 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name t 4 4 2 1 7.sas / Output t 4 4 2 1 7.rtf
Date of Table Generation 2023-09-22 21 00
Data Source adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			Cycle 8[a)]				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	149	147 (98.7)	1 (0.7)	1 (0.7)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	149	147 (98.7)	1 (0.7)	1 (0.7)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name t 4 4 2 1 7.sas / Output t 4 4 2 1 7.rtf
Date of Table Generation 2023-09-22 21 00
Data Source adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

Parameter	Treatment	Baseline Values	Post-Administration Period: Cycle 10[a)] n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	146	144 (98.6)	1 (0.7)	1 (0.7)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	146	144 (98.6)	1 (0.7)	1 (0.7)	0 (0.0)
		(+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name t 4 4 2 1 7.sas / Output t 4 4 2 1 7.rtf
Date of Table Generation 2023-09-22 21 00
Data Source adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Post-Administration Period				
			End of Treatment[c)] (Visit 17/Discontinuation)				
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	153	148 (96.7)	2 (1 3)	0 (0.0)	0 (0.0)
		(+)		2 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Secondary FSN-013 Pooled	(-)	301	292 (97.0)	4 (1 3)	1 (0.3)	0 (0.0)
		(+)		2 (0.7)	0 (0.0)	1 (0.3)	0 (0.0)
		(2+)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		(3+)		1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name t 4 4 2 1 7.sas / Output t 4 4 2 1 7.rtf
Date of Table Generation 2023-09-22 21 00
Data Source adlb

表 2.7.4-197 尿検査値の定性値のシフトテーブル（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.2.1.7 Shift Table from Baseline of Qualitative Urine (SAS)

			Follow-up Period				
				Follow-up[c)] (Visit 19)			
Parameter	Treatment	Baseline Values	n	(-)	(+)	(2+)	(3+)
Ketones	Primary FSN-013 Pooled	(-)	154	150 (97 4)	1 (0 6)	1 (0 6)	0 (0 0)
		(+)		2 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
	Secondary FSN-013 Pooled	(-)	303	293 (96 7)	3 (1 0)	2 (0 7)	0 (0 0)
		(+)		4 (1 3)	0 (0 0)	0 (0 0)	0 (0 0)
		(2+)		0 (0 0)	0 (0 0)	0 (0 0)	0 (0 0)
		(3+)		1 (0 3)	0 (0 0)	0 (0 0)	0 (0 0)

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for only subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
d) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 2 1 7.sas / Output: t 4 4 2 1 7.rtf
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Data Source: adlb

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07） 表 6-69 を引用

2.7.4.3.1.4.4 FSN-013P-02 試験

尿検査値の要約を表 2.7.4-198～表 2.7.4-200 に、尿検査値のシフトテーブルを表 2.7.4-201～表 2.7.4-203 に示す。

尿検査値については周期投与群、連続投与群とも、試験期間を通じて特記すべき変動は認められなかった。

表 2.7.4-198 臨床検査値の要約 尿検査定量 全体（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
尿pH	スクリーニング	42	6.12	0.561	9.2	5.5	6.00	8.0
	投薬期1	42	6.15	0.620	10.1	5.0	6.00	8.5
	投薬期2	42	6.23	0.627	10.1	5.5	6.00	8.0
	投薬期3	40	6.30	0.552	8.8	5.5	6.00	7.5
	後観察期	42	6.17	0.641	10.4	5.0	6.00	7.5
尿比重	スクリーニング	42	1.0088	0.00796	0.8	1.001	1.0070	1.031
	投薬期1	42	1.0111	0.00751	0.7	1.001	1.0115	1.031
	投薬期2	42	1.0124	0.00925	0.9	1.001	1.0095	1.033
	投薬期3	40	1.0129	0.00998	1.0	1.001	1.0095	1.032
	後観察期	42	1.0110	0.00874	0.9	1.001	1.0070	1.028

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-29 を引用

表 2.7.4-199 臨床検査値の要約 尿検査定量 周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
尿pH	スクリーニング	20	6.25	0.618	9.9	5.5	6.00	8.0
	投薬期1	20	6.10	0.447	7.3	5.5	6.00	7.0
	投薬期2	20	6.18	0.674	10.9	5.5	6.00	8.0
	投薬期3	19	6.32	0.506	8.0	5.5	6.00	7.0
	後観察期	20	6.33	0.591	9.3	5.5	6.50	7.5
尿比重	スクリーニング	20	1.0099	0.00962	1.0	1.001	1.0060	1.031
	投薬期1	20	1.0101	0.00719	0.7	1.001	1.0090	1.027
	投薬期2	20	1.0130	0.00952	0.9	1.001	1.0105	1.028
	投薬期3	19	1.0135	0.01047	1.0	1.001	1.0140	1.032
	後観察期	20	1.0112	0.00895	0.9	1.001	1.0120	1.028

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-30 を引用

表 2.7.4-200 臨床検査値の要約 尿検査定量 連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

	観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
尿pH	スクリーニング	22	6.00	0.488	8.1	5.5	6.00	7.0
	投薬期1	22	6.20	0.751	12.1	5.0	6.00	8.5
	投薬期2	22	6.27	0.592	9.4	5.5	6.00	7.5
	投薬期3	21	6.29	0.604	9.6	5.5	6.00	7.5
	後観察期	22	6.02	0.663	11.0	5.0	6.00	7.0
尿比重	スクリーニング	22	1.0079	0.00617	0.6	1.001	1.0070	1.023
	投薬期1	22	1.0120	0.00783	0.8	1.002	1.0120	1.031
	投薬期2	22	1.0119	0.00918	0.9	1.002	1.0070	1.033
	投薬期3	21	1.0124	0.00975	1.0	1.001	1.0090	1.032
	後観察期	22	1.0109	0.00876	0.9	1.001	1.0065	1.027

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-31 を引用

表 2.7.4-201 臨床検査値のシフトテーブル（尿検査）全体（FSN-013P-02 試験）（安全性解析対象集団）

		投薬期1						投薬期2						投薬期3						後観察期					
		-	+-	+	2+	3+	計	-	+-	+	2+	3+	計	-	+-	+	2+	3+	計	-	+-	+	2+	3+	計
尿糖	-	42	0	0	0	0	42	42	0	0	0	0	42	40	0	0	0	0	40	42	0	0	0	0	42
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	42	0	0	0	0	42	42	0	0	0	0	42	40	0	0	0	0	40	42	0	0	0	0	42
尿蛋白	-	42	0	0	0	0	42	41	1	0	0	0	42	40	0	0	0	0	40	42	0	0	0	0	42
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	42	0	0	0	0	42	41	1	0	0	0	42	40	0	0	0	0	40	42	0	0	0	0	42
尿潜血	-	13	2	2	10	14	41	26	3	3	6	3	41	26	3	2	3	5	39	33	0	3	1	4	41
スクリーニング	+-	0	0	0	1	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	1	0	1
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	13	2	2	11	14	42	26	3	4	6	3	42	26	3	3	3	5	40	33	0	3	2	4	42
尿ビリルビン	-	42	0	0	0	0	42	42	0	0	0	0	42	40	0	0	0	0	40	42	0	0	0	0	42
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	42	0	0	0	0	42	42	0	0	0	0	42	40	0	0	0	0	40	42	0	0	0	0	42
尿ウロビリノーゲン	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
スクリーニング	+-	0	42	0	0	0	42	0	42	0	0	0	42	0	40	0	0	0	40	0	42	0	0	0	42
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	0	42	0	0	0	42	0	42	0	0	0	42	0	40	0	0	0	40	0	42	0	0	0	42
尿ケトン体	-	39	1	1	0	0	41	41	0	0	0	0	41	37	1	0	0	1	39	41	0	0	0	0	41
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	1	0	0	1	0	0	1	0	0	1	1	0	0	0	0	1	1	0	0	0	0	1
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	39	1	2	0	0	42	41	0	1	0	0	42	38	1	0	0	1	40	42	0	0	0	0	42

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-38 を引用

表 2.7.4-202 臨床検査値のシフトテーブル（尿検査）周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

		投薬期1						投薬期2						投薬期3						後観察期					
		-	+-	+	2+	3+	計	-	+-	+	2+	3+	計	-	+-	+	2+	3+	計	-	+-	+	2+	3+	計
尿糖	-	20	0	0	0	0	20	20	0	0	0	0	20	19	0	0	0	0	19	20	0	0	0	0	20
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	20	0	0	0	0	20	20	0	0	0	0	20	19	0	0	0	0	19	20	0	0	0	0	20
尿蛋白	-	20	0	0	0	0	20	20	0	0	0	0	20	19	0	0	0	0	19	20	0	0	0	0	20
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	20	0	0	0	0	20	20	0	0	0	0	20	19	0	0	0	0	19	20	0	0	0	0	20
尿潜血	-	6	0	1	6	7	20	13	2	2	3	0	20	13	2	1	1	2	19	20	0	0	0	0	20
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	6	0	1	6	7	20	13	2	2	3	0	20	13	2	1	1	2	19	20	0	0	0	0	20
尿ビリルビン	-	20	0	0	0	0	20	20	0	0	0	0	20	19	0	0	0	0	19	20	0	0	0	0	20
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	20	0	0	0	0	20	20	0	0	0	0	20	19	0	0	0	0	19	20	0	0	0	0	20
尿ウロビリノーゲン	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
スクリーニング	+-	0	20	0	0	0	20	0	20	0	0	0	20	0	19	0	0	0	19	0	20	0	0	0	20
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	0	20	0	0	0	20	0	20	0	0	0	20	0	19	0	0	0	19	0	20	0	0	0	20
尿ケトン体	-	20	0	0	0	0	20	20	0	0	0	0	20	18	0	0	0	1	19	20	0	0	0	0	20
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	20	0	0	0	0	20	20	0	0	0	0	20	18	0	0	0	1	19	20	0	0	0	0	20

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-39 を引用

表 2.7.4-203 臨床検査値のシフトテーブル（尿検査）連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

		投薬期1						投薬期2						投薬期3						後観察期					
		-	+-	+	2+	3+	計	-	+-	+	2+	3+	計	-	+-	+	2+	3+	計	-	+-	+	2+	3+	計
尿糖	-	22	0	0	0	0	22	22	0	0	0	0	22	21	0	0	0	0	21	22	0	0	0	0	22
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	22	0	0	0	0	22	22	0	0	0	0	22	21	0	0	0	0	21	22	0	0	0	0	22
尿蛋白	-	22	0	0	0	0	22	21	1	0	0	0	22	21	0	0	0	0	21	22	0	0	0	0	22
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	22	0	0	0	0	22	21	1	0	0	0	22	21	0	0	0	0	21	22	0	0	0	0	22
尿潜血	-	7	2	1	4	7	21	13	1	1	3	3	21	13	1	1	2	3	20	13	0	3	1	4	21
スクリーニング	+-	0	0	0	1	0	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	0	1	0	1
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	7	2	1	5	7	22	13	1	2	3	3	22	13	1	2	2	3	21	13	0	3	2	4	22
尿ビリルビン	-	22	0	0	0	0	22	22	0	0	0	0	22	21	0	0	0	0	21	22	0	0	0	0	22
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	22	0	0	0	0	22	22	0	0	0	0	22	21	0	0	0	0	21	22	0	0	0	0	22
尿ウロビリノーゲン	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
スクリーニング	+-	0	22	0	0	0	22	0	22	0	0	0	22	0	21	0	0	0	21	0	22	0	0	0	22
	+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	0	22	0	0	0	22	0	22	0	0	0	22	0	21	0	0	0	21	0	22	0	0	0	22
尿ケトン体	-	19	1	1	0	0	21	21	0	0	0	0	21	19	1	0	0	0	20	21	0	0	0	0	21
スクリーニング	+-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	+	0	0	1	0	0	1	0	0	1	0	0	1	1	0	0	0	0	1	1	0	0	0	0	1
	2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	計	19	1	2	0	0	22	21	0	1	0	0	22	20	1	0	0	0	21	22	0	0	0	0	22

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-40 を引用

2.7.4.3.1.4.5 FSN-013P-05 試験

尿検査値（定性値）の測定値及びベースラインからの変化量の要約統計量を表 2.7.4-204 に、尿検査値（定性値）の測定値及びベースラインからの変化量の要約統計量を表 2.7.4-205 に示す。

尿検査値については、FSN-013 群、EE/DRSP フレックス投与群とも、治験期間を通じて特記すべき変動は認められなかった。

表 2.7.4-204 臨床検査値 定性値（尿検査）（FSN-013P-05 試験）（安全性解析対象集団）

			FSN-013群 N=45						ヤーズフレックス配合錠群 N=41					
			Visit2 (ベースライン)						Visit2 (ベースライン)					
検査項目	評価期間		-	±	+	2+	3+	Total	-	±	+	2+	3+	Total
尿糖	Visit 4	-	44 (97.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	44 (97.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 6/中止時	-	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 7	-	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)
尿蛋白	Visit 4	-	40 (88.9)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	41 (91.1)	36 (87.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	36 (87.8)
		±	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
		+	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	2 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.9)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	43 (95.6)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 6/中止時	-	43 (95.6)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	32 (78.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	32 (78.0)
		±	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	5 (12.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (12.2)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.3)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	44 (97.8)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 7	-	42 (93.3)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	43 (95.6)	35 (85.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	35 (85.4)
		±	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	5 (12.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (12.2)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	44 (97.8)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)

表 2.7.4-204 臨床検査値 定性値（尿検査）（FSN-013P-05 試験）（安全性解析対象集団）（続き）

			FSN-013群 N=45						ヤーズフレックス配合錠群 N=41					
			Visit2 (ベースライン)						Visit2 (ベースライン)					
検査項目	評価期間		-	±	+	2+	3+	Total	-	±	+	2+	3+	Total
尿潜血	Visit 4	-	36 (80.0)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	38 (84.4)	24 (58.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	24 (58.5)
		±	3 (6.7)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.9)	3 (7.3)	2 (4.9)	0 (0.0)	1 (2.4)	0 (0.0)	6 (14.6)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
		2+	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	4 (9.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	5 (12.2)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	4 (9.8)
		Total	41 (91.1)	1 (2.2)	2 (4.4)	0 (0.0)	0 (0.0)	44 (97.8)	35 (85.4)	2 (4.9)	0 (0.0)	1 (2.4)	2 (4.9)	40 (97.6)
	Visit 6/中止時	-	38 (84.4)	1 (2.2)	2 (4.4)	0 (0.0)	0 (0.0)	41 (91.1)	27 (65.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	28 (68.3)
		±	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	3 (7.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.3)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.9)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	2 (4.9)
		3+	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	4 (9.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	5 (12.2)
		Total	42 (93.3)	1 (2.2)	2 (4.4)	0 (0.0)	0 (0.0)	45 (100.0)	35 (85.4)	2 (4.9)	0 (0.0)	1 (2.4)	2 (4.9)	40 (97.6)
	Visit 7	-	39 (86.7)	1 (2.2)	2 (4.4)	0 (0.0)	0 (0.0)	42 (93.3)	32 (78.0)	2 (4.9)	0 (0.0)	0 (0.0)	1 (2.4)	35 (85.4)
		±	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	2 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.9)
		+	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	1 (2.4)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.9)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	1 (2.4)
		Total	42 (93.3)	1 (2.2)	2 (4.4)	0 (0.0)	0 (0.0)	45 (100.0)	36 (87.8)	2 (4.9)	0 (0.0)	1 (2.4)	2 (4.9)	41 (100.0)
尿ビリルビン	Visit 4	-	44 (97.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	44 (97.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 6/中止時	-	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 7	-	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)

表 2.7.4-204 臨床検査値 定性値（尿検査）（FSN-013P-05 試験）（安全性解析対象集団）（続き）

			FSN-013群 N=45						ヤーズフレックス配合錠群 N=41					
			Visit2 (ベースライン)						Visit2 (ベースライン)					
検査項目	評価期間		-	±	+	2+	3+	Total	-	±	+	2+	3+	Total
尿ウロビリノーゲン	Visit 4	-	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		±	0 (0.0)	43 (95.6)	0 (0.0)	0 (0.0)	0 (0.0)	43 (95.6)	0 (0.0)	39 (95.1)	0 (0.0)	0 (0.0)	0 (0.0)	39 (95.1)
		+	0 (0.0)	1 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	0 (0.0)	44 (97.8)	0 (0.0)	0 (0.0)	0 (0.0)	44 (97.8)	0 (0.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 6/中止時	-	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		±	0 (0.0)	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	0 (0.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	0 (0.0)	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	0 (0.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 7	-	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		±	0 (0.0)	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	0 (0.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	0 (0.0)	45 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	45 (100.0)	0 (0.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)
尿ケトン体	Visit 4	-	40 (88.9)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	42 (93.3)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	42 (93.3)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	44 (97.8)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 6/中止時	-	43 (95.6)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	45 (100.0)	39 (95.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	39 (95.1)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	43 (95.6)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	45 (100.0)	40 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	40 (97.6)
	Visit 7	-	43 (95.6)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)
		±	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		2+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		3+	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		Total	43 (95.6)	0 (0.0)	2 (4.4)	0 (0.0)	0 (0.0)	45 (100.0)	41 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	41 (100.0)

引用元：FSN-013P-05（資料番号 5.3.4.2-01）表 15.4-8 を引用

表 2.7.4-205 臨床検査値 定量値（尿検査）（FSN-013P-05 試験）（安全性解析対象集団）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
尿pH	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	6.41 (0.955)	6.05 (0.879)		
		CV	14.9	14.5		
		中央値	6.00	6.00		
		Q1 - Q3	5.50 - 7.00	5.50 - 6.50		
		最小値 - 最大値	5.0 - 8.5	5.0 - 8.5		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	6.27 (0.788)	6.16 (0.858)	-0.17 (0.982)	0.10 (0.969)
		CV	12.6	13.9	-576.1	968.7
		中央値	6.00	6.00	0.00	0.00
		Q1 - Q3	5.50 - 7.00	5.50 - 6.50	-0.50 - 0.50	-0.50 - 0.50
		最小値 - 最大値	5.0 - 8.5	5.0 - 8.5	-2.5 - 2.0	-2.0 - 2.5
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	6.23 (0.896)	6.10 (0.761)	-0.18 (1.114)	0.04 (0.827)
		CV	14.4	12.5	-626.5	2206.2
		中央値	6.00	6.00	0.00	0.00
		Q1 - Q3	5.50 - 7.00	5.50 - 6.50	-1.00 - 0.50	-0.50 - 0.50
		最小値 - 最大値	5.0 - 8.0	5.0 - 8.0	-2.5 - 2.0	-2.0 - 2.5
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	6.32 (0.834)	6.29 (0.821)	-0.09 (1.062)	0.24 (1.044)
		CV	13.2	13.1	-1195.0	427.9
		中央値	6.50	6.00	0.00	0.00
		Q1 - Q3	5.50 - 7.00	5.50 - 6.50	-0.50 - 0.50	-0.50 - 1.00
		最小値 - 最大値	5.0 - 8.0	5.0 - 8.5	-3.0 - 2.0	-2.5 - 3.0
尿比重	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	1.0156 (0.00884)	1.0178 (0.00747)		
		CV	0.9	0.7		
		中央値	1.0150	1.0190		
		Q1 - Q3	1.0080 - 1.0230	1.0120 - 1.0230		
		最小値 - 最大値	1.002 - 1.032	1.004 - 1.030		
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	1.0163 (0.00857)	1.0206 (0.00818)	0.0008 (0.00920)	0.0030 (0.00996)
		CV	0.8	0.8	1190.9	337.7
		中央値	1.0160	1.0220	0.0015	0.0030
		Q1 - Q3	1.0090 - 1.0230	1.0140 - 1.0265	-0.0045 - 0.0065	-0.0030 - 0.0080
		最小値 - 最大値	1.002 - 1.033	1.004 - 1.034	-0.023 - 0.017	-0.019 - 0.028
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	1.0174 (0.00953)	1.0205 (0.00775)	0.0017 (0.00981)	0.0029 (0.00842)
		CV	0.9	0.8	566.0	295.3
		中央値	1.0180	1.0225	0.0020	0.0035
		Q1 - Q3	1.0090 - 1.0240	1.0130 - 1.0265	-0.0020 - 0.0070	-0.0030 - 0.0070
		最小値 - 最大値	1.002 - 1.033	1.005 - 1.034	-0.022 - 0.022	-0.018 - 0.027
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	1.0154 (0.00810)	1.0191 (0.00727)	-0.0002 (0.00988)	0.0013 (0.00916)
		CV	0.8	0.7	-5557.2	682.9
		中央値	1.0130	1.0200	0.0000	0.0010
		Q1 - Q3	1.0090 - 1.0230	1.0150 - 1.0240	-0.0060 - 0.0040	-0.0060 - 0.0070
		最小値 - 最大値	1.003 - 1.032	1.002 - 1.036	-0.026 - 0.019	-0.019 - 0.022

引用元：FSN-013P-05（資料番号 5.3.4.2-01）表 15.4-9 を引用

2.7.4.4 バイタルサイン、身体的所見及び安全性に関連する他の観察項目

2.7.4.4.1 バイタルサイン

2.7.4.4.1.1 FSN-013P-03 試験

####### 2.7.4.4.1.1.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量を表 2.7.4-206 に示す。

投与 6 周期終了時点までのバイタルサイン［血圧（収縮期、拡張期）、脈拍数及び体温］に特記すべき異常変動は認められなかった。

表 2.7.4-206 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Systolic Blood Pressure (mmHg)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	107 3	105 9	107 5	107 2	107 7	107 5	106 8	108 4	108 0
			SD	12 87	10 20	11 83	10 90	11 17	10 99	11 33	11 09	11 82
			Min	86	88	85	84	88	87	87	92	87
			Q1	98 0	98 0	98 0	99 0	98 0	100 0	98 0	100 0	100 0
			Median	103 0	104 0	106 0	105 5	106 0	107 0	106 0	105 0	106 0
			Q3	115 0	112 0	116 0	115 0	116 0	115 0	113 0	117 0	116 0
			Max	145	131	134	133	135	138	138	149	142
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	105 8	106 6	107 5	107 5	106 9	107 0	104 8	108 7	106 1
			SD	9 31	9 94	9 18	8 12	9 69	9 93	9 46	9 08	9 37
			Min	92	90	91	93	83	90	80	91	86
			Q1	97 0	98 0	101 0	103 0	100 0	99 0	98 0	102 0	99 0
			Median	105 0	106 0	108 0	106 0	107 0	105 0	105 0	107 0	105 0
			Q3	113 0	112 0	112 0	112 0	114 5	114 0	111 0	114 0	113 0
			Max	133	136	138	134	128	131	130	133	131
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	-0 5	-0 2	-0 2	-0 7	0 5	0 1
			SD	-	-	-	8 75	9 25	8 87	10 65	8 12	10 62
			Min	-	-	-	-29	-25	-24	-25	-21	-26
			Q1	-	-	-	-6 0	-7 0	-5 0	-8 0	-4 0	-6 0
			Median	-	-	-	-1 0	1 0	1 0	1 0	0 0	1 0
			Q3	-	-	-	5 0	6 0	4 0	6 0	7 0	5 0
			Max	-	-	-	26	22	21	31	21	27
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	0 0	-0 3	-0 4	-2 7	1 4	-1 2
			SD	-	-	-	9 35	9 70	10 20	10 65	9 70	10 69
			Min	-	-	-	-24	-25	-25	-25	-24	-30
			Q1	-	-	-	-6 0	-8 0	-8 0	-8 0	-4 0	-9 0
			Median	-	-	-	0 0	1 0	0 5	-3 0	1 0	0 0
			Q3	-	-	-	5 0	6 0	7 0	4 0	7 0	6 0
			Max	-	-	-	26	20	20	22	27	21

表 2.7.4-206 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Diastolic Blood Pressure (mmHg)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	65 5	65 0	65 0	65 8	66 2	66 2	65 5	66 8	66 2
			SD	11 10	9 57	8 96	9 21	9 16	9 20	9 28	9 80	9 98
			Min	50	42	47	46	49	44	50	48	43
			Q1	59 0	59 0	58 0	58 5	60 0	60 0	60 0	61 0	59 0
			Median	62 0	64 0	64 0	66 0	66 0	66 0	63 0	66 0	66 0
			Q3	71 0	72 0	71 0	71 5	71 0	72 0	70 0	73 0	73 0
			Max	101	86	89	88	93	94	94	103	97
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	66 2	66 1	65 8	66 3	65 9	67 1	64 8	66 1	67 6
			SD	9 68	9 45	9 40	8 17	9 15	9 00	9 01	7 83	8 12
			Min	47	45	47	50	45	52	38	54	51
			Q1	59 0	59 0	59 0	60 0	62 0	60 0	59 0	60 0	61 0
			Median	65 0	66 0	65 0	66 0	64 0	67 0	64 0	65 0	68 0
			Q3	74 0	72 0	71 0	72 0	70 0	71 0	71 0	70 0	73 0
			Max	91	98	88	92	98	92	90	88	91
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	0 7	1 2	1 2	0 6	1 8	1 2
			SD	-	-	-	6 12	7 77	7 84	7 91	8 11	8 21
			Min	-	-	-	-19	-21	-16	-20	-23	-18
			Q1	-	-	-	-2 5	-3 0	-3 0	-5 0	-3 0	-4 0
			Median	-	-	-	1 0	2 0	1 0	2 0	3 0	1 0
			Q3	-	-	-	4 0	6 0	6 0	7 0	6 0	7 0
			Max	-	-	-	18	25	18	20	26	19
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	0 4	0 1	1 3	-1 0	0 2	1 8
			SD	-	-	-	8 91	7 67	8 92	9 28	7 72	9 21
			Min	-	-	-	-22	-17	-19	-22	-25	-27
			Q1	-	-	-	-5 0	-5 5	-5 0	-7 0	-4 0	-4 0
			Median	-	-	-	0 0	0 0	0 0	0 0	0 0	2 0
			Q3	-	-	-	5 0	5 0	7 0	4 0	4 0	7 0
			Max	-	-	-	30	25	29	20	20	23

表 2.7.4-206 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Pulse Rate (beats/min)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	70 0	67 6	72 4	68 8	69 1	69 6	67 4	70 1	69 0
			SD	10 52	10 02	11 09	10 23	9 35	10 43	9 90	10 66	9 87
			Min	38	41	45	41	47	45	42	42	40
			Q1	63 0	61 0	64 0	61 5	63 0	63 0	60 0	64 0	62 0
			Median	70 0	68 0	73 0	70 0	69 0	68 5	66 0	68 0	70 0
			Q3	76 0	72 0	80 0	76 0	76 0	75 0	74 0	78 0	75 0
			Max	100	98	100	100	91	98	92	97	94
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	72 3	71 2	73 9	73 2	73 1	73 3	70 8	70 6	71 8
			SD	10 56	9 67	10 35	9 29	10 65	10 50	10 86	9 63	10 24
			Min	51	52	57	57	52	53	40	45	53
			Q1	64 0	65 0	66 0	65 0	65 0	68 0	62 0	65 0	65 0
			Median	72 0	70 0	72 0	73 5	73 5	72 0	70 0	70 0	70 0
			Q3	79 0	77 0	80 0	78 0	82 5	79 0	77 0	76 0	78 0
			Max	101	98	99	102	99	100	96	98	103
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	-3 6	-3 3	-2 6	-5 0	-2 2	-3 2
			SD	-	-	-	9 12	9 80	9 97	9 12	8 71	8 92
			Min	-	-	-	-32	-28	-24	-34	-23	-32
			Q1	-	-	-	-8 0	-10 0	-9 0	-11 0	-7 0	-8 0
			Median	-	-	-	-4 0	-3 0	-2 0	-4 0	-2 0	-3 0
			Q3	-	-	-	2 5	2 0	4 0	1 0	4 0	2 0
			Max	-	-	-	18	19	27	18	18	16
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	-0 8	-1 0	-0 8	-3 1	-3 4	-2 2
			SD	-	-	-	7 68	7 06	8 92	9 52	9 01	8 83
			Min	-	-	-	-24	-19	-19	-23	-28	-27
			Q1	-	-	-	-5 0	-6 0	-7 0	-10 0	-8 0	-8 0
			Median	-	-	-	0 0	-0 5	-0 5	-4 0	-3 0	-2 0
			Q3	-	-	-	4 0	3 0	5 0	2 0	3 0	4 0
			Max	-	-	-	22	16	23	16	15	18

表 2.7.4-206 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Temperature (C)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	36.38	36.43	36.58	36.51	36.50	36.48	36.47	36.53	36.48
			SD	0.454	0.404	0.362	0.414	0.446	0.426	0.427	0.400	0.434
			Min	35.0	35.1	35.4	35.2	35.1	35.6	35.0	35.2	35.1
			Q1	36.20	36.20	36.40	36.30	36.30	36.10	36.20	36.30	36.20
			Median	36.50	36.50	36.60	36.60	36.60	36.50	36.50	36.50	36.60
			Q3	36.70	36.70	36.90	36.80	36.80	36.80	36.70	36.80	36.80
			Max	37.0	37.2	37.2	37.3	37.4	37.3	37.4	37.3	37.3
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	36.49	36.45	36.60	36.50	36.49	36.49	36.44	36.58	36.52
			SD	0.336	0.400	0.365	0.417	0.459	0.385	0.404	0.341	0.406
			Min	35.7	35.0	35.6	35.1	35.0	35.1	35.1	35.4	35.3
			Q1	36.30	36.30	36.40	36.30	36.25	36.40	36.20	36.40	36.30
			Median	36.50	36.50	36.70	36.60	36.60	36.60	36.50	36.60	36.60
			Q3	36.80	36.80	36.90	36.80	36.80	36.70	36.70	36.80	36.80
			Max	37.1	37.0	37.3	37.1	37.3	37.3	37.1	37.4	37.3
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	-0.06	-0.08	-0.10	-0.10	-0.05	-0.10
			SD	-	-	-	0.420	0.456	0.399	0.459	0.415	0.403
			Min	-	-	-	-1.1	-1.5	-1.0	-1.6	-1.5	-1.1
			Q1	-	-	-	-0.40	-0.30	-0.40	-0.30	-0.30	-0.30
			Median	-	-	-	0.00	-0.10	-0.10	-0.10	0.00	-0.10
			Q3	-	-	-	0.20	0.20	0.10	0.10	0.20	0.20
			Max	-	-	-	0.9	1.3	1.3	1.1	1.0	0.9
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	-0.09	-0.11	-0.12	-0.16	-0.04	-0.09
			SD	-	-	-	0.382	0.382	0.367	0.394	0.319	0.361
			Min	-	-	-	-1.0	-1.1	-0.9	-1.1	-0.9	-1.5
			Q1	-	-	-	-0.30	-0.30	-0.30	-0.40	-0.20	-0.30
			Median	-	-	-	-0.10	-0.10	-0.15	-0.20	0.00	-0.10
			Q3	-	-	-	0.10	0.10	0.10	0.10	0.20	0.20
			Max	-	-	-	0.7	0.8	0.8	1.0	0.9	0.6

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10.

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-38 を引用

2.7.4.4.1.1.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量を表 2.7.4-207 に示す。

投与 13 周期終了時点までのバイタルサイン［血圧（収縮期、拡張期）、脈拍数及び体温］に特記すべき異常変動は認められなかった。

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Systolic Blood Pressure (mmHg)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	107.3	105.9	107.5	107.2	107.7	107.5	106.8	108.4	108.0
			SD	12.87	10.20	11.83	10.90	11.17	10.99	11.33	11.09	11.82
			Min	86	88	85	84	88	87	87	92	87
			Q1	98.0	98.0	98.0	99.0	98.0	100.0	98.0	100.0	100.0
			Median	103.0	104.0	106.0	105.5	106.0	107.0	106.0	105.0	106.0
			Q3	115.0	112.0	116.0	115.0	116.0	115.0	113.0	117.0	116.0
			Max	145	131	134	133	135	138	138	149	142
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	105.8	106.6	107.5	107.5	106.9	107.0	104.8	108.7	106.1
			SD	9.31	9.94	9.18	8.12	9.69	9.93	9.46	9.08	9.37
			Min	92	90	91	93	83	90	80	91	86
			Q1	97.0	98.0	101.0	103.0	100.0	99.0	98.0	102.0	99.0
			Median	105.0	106.0	108.0	106.0	107.0	105.0	105.0	107.0	105.0
			Q3	113.0	112.0	112.0	112.0	114.5	114.0	111.0	114.0	113.0
			Max	133	136	138	134	128	131	130	133	131
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	-0.5	-0.2	-0.2	-0.7	0.5	0.1
			SD	-	-	-	8.75	9.25	8.87	10.65	8.12	10.62
			Min	-	-	-	-29	-25	-24	-25	-21	-26
			Q1	-	-	-	-6.0	-7.0	-5.0	-8.0	-4.0	-6.0
			Median	-	-	-	-1.0	1.0	1.0	1.0	0.0	1.0
			Q3	-	-	-	5.0	6.0	4.0	6.0	7.0	5.0
			Max	-	-	-	26	22	21	31	21	27
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	0.0	-0.3	-0.4	-2.7	1.4	-1.2
			SD	-	-	-	9.35	9.70	10.20	10.65	9.70	10.69
			Min	-	-	-	-24	-25	-25	-25	-24	-30
			Q1	-	-	-	-6.0	-8.0	-8.0	-8.0	-4.0	-9.0
			Median	-	-	-	0.0	1.0	0.5	-3.0	1.0	0.0
			Q3	-	-	-	5.0	6.0	7.0	4.0	7.0	6.0
			Max	-	-	-	26	20	20	22	27	21

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Diastolic Blood Pressure (mmHg)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	65.5	65.0	65.0	65.8	66.2	66.2	65.5	66.8	66.2
			SD	11.10	9.57	8.96	9.21	9.16	9.20	9.28	9.80	9.98
			Min	50	42	47	46	49	44	50	48	43
			Q1	59.0	59.0	58.0	58.5	60.0	60.0	60.0	61.0	59.0
			Median	62.0	64.0	64.0	66.0	66.0	66.0	63.0	66.0	66.0
			Q3	71.0	72.0	71.0	71.5	71.0	72.0	70.0	73.0	73.0
			Max	101	86	89	88	93	94	94	103	97
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	66.2	66.1	65.8	66.3	65.9	67.1	64.8	66.1	67.6
			SD	9.68	9.45	9.40	8.17	9.15	9.00	9.01	7.83	8.12
			Min	47	45	47	50	45	52	38	54	51
			Q1	59.0	59.0	59.0	60.0	62.0	60.0	59.0	60.0	61.0
			Median	65.0	66.0	65.0	66.0	64.0	67.0	64.0	65.0	68.0
			Q3	74.0	72.0	71.0	72.0	70.0	71.0	71.0	70.0	73.0
			Max	91	98	88	92	98	92	90	88	91
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	0.7	1.2	1.2	0.6	1.8	1.2
			SD	-	-	-	6.12	7.77	7.84	7.91	8.11	8.21
			Min	-	-	-	-19	-21	-16	-20	-23	-18
			Q1	-	-	-	-2.5	-3.0	-3.0	-5.0	-3.0	-4.0
			Median	-	-	-	1.0	2.0	1.0	2.0	3.0	1.0
			Q3	-	-	-	4.0	6.0	6.0	7.0	6.0	7.0
			Max	-	-	-	18	25	18	20	26	19
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	0.4	0.1	1.3	-1.0	0.2	1.8
			SD	-	-	-	8.91	7.67	8.92	9.28	7.72	9.21
			Min	-	-	-	-22	-17	-19	-22	-25	-27
			Q1	-	-	-	-5.0	-5.5	-5.0	-7.0	-4.0	-4.0
			Median	-	-	-	0.0	0.0	0.0	0.0	0.0	2.0
			Q3	-	-	-	5.0	5.0	7.0	4.0	4.0	7.0
			Max	-	-	-	30	25	29	20	20	23

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Pulse Rate (beats/min)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	70.0	67.6	72.4	68.8	69.1	69.6	67.4	70.1	69.0
			SD	10.52	10.02	11.09	10.23	9.35	10.43	9.90	10.66	9.87
			Min	38	41	45	41	47	45	42	42	40
			Q1	63.0	61.0	64.0	61.5	63.0	63.0	60.0	64.0	62.0
			Median	70.0	68.0	73.0	70.0	69.0	68.5	66.0	68.0	70.0
			Q3	76.0	72.0	80.0	76.0	76.0	75.0	74.0	78.0	75.0
			Max	100	98	100	100	91	98	92	97	94
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	72.3	71.2	73.9	73.2	73.1	73.3	70.8	70.6	71.8
			SD	10.56	9.67	10.35	9.29	10.65	10.50	10.86	9.63	10.24
			Min	51	52	57	57	52	53	40	45	53
			Q1	64.0	65.0	66.0	65.0	65.0	68.0	62.0	65.0	65.0
			Median	72.0	70.0	72.0	73.5	73.5	72.0	70.0	70.0	70.0
			Q3	79.0	77.0	80.0	78.0	82.5	79.0	77.0	76.0	78.0
			Max	101	98	99	102	99	100	96	98	103
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	-3.6	-3.3	-2.6	-5.0	-2.2	-3.2
			SD	-	-	-	9.12	9.80	9.97	9.12	8.71	8.92
			Min	-	-	-	-32	-28	-24	-34	-23	-32
			Q1	-	-	-	-8.0	-10.0	-9.0	-11.0	-7.0	-8.0
			Median	-	-	-	-4.0	-3.0	-2.0	-4.0	-2.0	-3.0
			Q3	-	-	-	2.5	2.0	4.0	1.0	4.0	2.0
			Max	-	-	-	18	19	27	18	18	16
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	-0.8	-1.0	-0.8	-3.1	-3.4	-2.2
			SD	-	-	-	7.68	7.06	8.92	9.52	9.01	8.83
			Min	-	-	-	-24	-19	-19	-23	-28	-27
			Q1	-	-	-	-5.0	-6.0	-7.0	-10.0	-8.0	-8.0
			Median	-	-	-	0.0	-0.5	-0.5	-4.0	-3.0	-2.0
			Q3	-	-	-	4.0	3.0	5.0	2.0	3.0	4.0
			Max	-	-	-	22	16	23	16	15	18

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period				Extension Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Temperature (C)	Value	FSN-013	n	81	81	81	80	79	78	81	77	77
			Mean	36.38	36.43	36.58	36.51	36.50	36.48	36.47	36.53	36.48
			SD	0.454	0.404	0.362	0.414	0.446	0.426	0.427	0.400	0.434
			Min	35.0	35.1	35.4	35.2	35.1	35.6	35.0	35.2	35.1
			Q1	36.20	36.20	36.40	36.30	36.30	36.10	36.20	36.30	36.20
			Median	36.50	36.50	36.60	36.60	36.60	36.50	36.50	36.50	36.60
			Q3	36.70	36.70	36.90	36.80	36.80	36.80	36.70	36.80	36.80
			Max	37.0	37.2	37.2	37.3	37.4	37.3	37.4	37.3	37.3
		Placebo	n	79	79	79	78	76	74	79	74	74
			Mean	36.49	36.45	36.60	36.50	36.49	36.49	36.44	36.58	36.52
			SD	0.336	0.400	0.365	0.417	0.459	0.385	0.404	0.341	0.406
			Min	35.7	35.0	35.6	35.1	35.0	35.1	35.1	35.4	35.3
			Q1	36.30	36.30	36.40	36.30	36.25	36.40	36.20	36.40	36.30
			Median	36.50	36.50	36.70	36.60	36.60	36.60	36.50	36.60	36.60
			Q3	36.80	36.80	36.90	36.80	36.80	36.70	36.70	36.80	36.80
			Max	37.1	37.0	37.3	37.1	37.3	37.3	37.1	37.4	37.3
	Change from Baseline	FSN-013	n	-	-	-	80	79	78	81	77	77
			Mean	-	-	-	-0.06	-0.08	-0.10	-0.10	-0.05	-0.10
			SD	-	-	-	0.420	0.456	0.399	0.459	0.415	0.403
			Min	-	-	-	-1.1	-1.5	-1.0	-1.6	-1.5	-1.1
			Q1	-	-	-	-0.40	-0.30	-0.40	-0.30	-0.30	-0.30
			Median	-	-	-	0.00	-0.10	-0.10	-0.10	0.00	-0.10
			Q3	-	-	-	0.20	0.20	0.10	0.10	0.20	0.20
			Max	-	-	-	0.9	1.3	1.3	1.1	1.0	0.9
		Placebo	n	-	-	-	78	76	74	79	74	74
			Mean	-	-	-	-0.09	-0.11	-0.12	-0.16	-0.04	-0.09
			SD	-	-	-	0.382	0.382	0.367	0.394	0.319	0.361
			Min	-	-	-	-1.0	-1.1	-0.9	-1.1	-0.9	-1.5
			Q1	-	-	-	-0.30	-0.30	-0.30	-0.40	-0.20	-0.30
			Median	-	-	-	-0.10	-0.10	-0.15	-0.20	0.00	-0.10
			Q3	-	-	-	0.10	0.10	0.10	0.10	0.20	0.20
			Max	-	-	-	0.7	0.8	0.8	1.0	0.9	0.6

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Extension Period							Follow-up Period	
				Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Systolic Blood Pressure (mmHg)	Value	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	107.4	106.8	106.3	105.7	107.8	106.8	108.3	108.9	109.4
			SD	10.74	11.04	11.01	10.45	10.79	10.65	11.90	11.76	10.84
			Min	86	86	86	88	84	85	88	87	88
			Q1	99.0	99.0	98.0	98.0	100.0	98.0	100.0	100.5	103.0
			Median	106.0	105.0	105.0	104.0	106.0	106.0	106.0	107.0	108.0
			Q3	116.0	113.0	113.0	111.0	116.0	111.0	116.0	115.5	118.0
			Max	132	136	133	130	139	146	140	154	133
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	107.3	107.6	106.6	104.6	107.4	107.4	108.4	107.1	109.3
			SD	9.17	9.60	9.35	10.49	9.62	9.70	9.42	9.45	11.02
			Min	88	92	87	88	88	92	89	89	89
			Q1	101.0	100.0	100.5	98.0	102.0	99.0	102.0	100.0	101.0
			Median	106.0	106.0	105.5	103.0	106.0	107.0	107.0	107.0	108.0
			Q3	112.5	117.0	112.0	110.0	113.0	113.0	115.0	113.0	115.0
			Max	136	131	132	135	138	130	131	129	148
	Change from Baseline	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	-0.6	-1.2	-1.7	-2.3	-0.2	-1.1	0.4	1.3	1.8
			SD	9.83	9.67	10.35	10.28	9.19	9.21	9.17	9.85	9.57
			Min	-28	-22	-31	-31	-25	-22	-21	-19	-17
			Q1	-6.0	-7.0	-9.0	-9.0	-6.0	-7.0	-5.0	-5.0	-4.0
			Median	-2.0	-1.0	-2.0	-2.0	0.0	0.0	1.0	2.0	1.0
			Q3	5.0	4.0	5.0	4.0	5.0	4.0	7.0	8.0	7.0
			Max	33	32	28	30	20	20	26	23	30
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	0.0	0.4	-0.4	-2.3	0.5	0.4	1.2	-0.3	2.1
			SD	8.40	9.01	9.62	10.98	8.42	11.38	10.13	9.32	10.33
			Min	-25	-21	-25	-35	-22	-31	-27	-21	-18
			Q1	-4.5	-5.0	-6.0	-7.0	-5.0	-4.0	-5.0	-6.0	-6.0
			Median	-1.0	0.0	-1.0	-2.0	1.0	1.0	2.0	0.0	2.0
			Q3	6.0	7.0	7.0	6.0	5.0	6.0	8.0	6.0	9.0
			Max	20	20	23	17	21	29	27	24	30

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Extension Period							Follow-up Period	
				Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Diastolic Blood Pressure (mmHg)	Value	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	66.4	65.5	65.8	66.4	67.4	65.8	68.0	67.7	68.2
			SD	10.12	8.65	9.40	9.24	8.98	8.81	9.45	8.25	8.81
			Min	43	49	45	50	49	50	52	51	48
			Q1	59.0	59.0	59.0	61.0	62.0	59.0	61.0	62.0	62.0
			Median	65.0	65.0	64.0	65.0	66.0	65.0	66.0	67.0	67.0
			Q3	74.0	71.0	71.0	73.0	73.0	71.0	75.0	71.5	73.0
			Max	88	86	97	94	92	87	87	95	94
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	66.8	66.5	66.0	65.0	67.5	67.0	67.9	67.9	68.1
			SD	9.03	8.61	8.28	9.02	9.03	9.23	7.87	8.41	9.54
			Min	48	49	49	51	47	49	48	51	45
			Q1	60.5	61.0	59.0	58.0	60.0	60.0	63.0	62.0	62.0
			Median	66.0	66.0	65.5	63.0	67.0	66.0	68.0	68.0	67.0
			Q3	73.0	71.0	70.5	69.0	72.0	73.0	72.0	74.0	74.0
			Max	90	90	84	92	93	88	87	86	90
	Change from Baseline	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	1.4	0.4	0.7	1.3	2.4	0.5	3.1	2.8	3.2
			SD	8.98	6.82	9.31	10.09	7.14	8.46	7.21	9.01	7.24
			Min	-32	-15	-17	-22	-24	-22	-17	-22	-15
			Q1	-3.0	-3.0	-6.0	-6.0	-1.0	-4.0	-2.0	-3.0	-1.0
			Median	2.0	1.0	0.0	1.0	3.0	2.0	3.0	3.0	4.0
			Q3	8.0	5.0	6.0	8.0	7.0	6.0	8.0	8.5	8.0
			Max	19	17	26	31	17	19	20	28	18
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	1.2	1.1	0.5	-0.3	2.1	1.7	2.2	2.2	2.5
			SD	7.53	8.73	8.39	9.53	8.39	9.12	8.88	9.14	9.91
			Min	-17	-25	-22	-29	-21	-28	-19	-22	-25
			Q1	-4.5	-5.0	-5.0	-7.0	-3.0	-3.0	-2.0	-4.0	-3.0
			Median	1.0	2.0	-0.5	0.0	3.0	1.0	1.0	2.0	2.0
			Q3	6.0	6.0	6.0	6.0	6.0	8.0	9.0	8.0	9.0
			Max	18	26	22	21	29	26	31	22	26

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Extension Period							Follow-up Period	
				Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Pulse Rate (beats/min)	Value	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	70.4	67.2	70.6	69.8	70.4	69.9	69.5	71.4	71.9
			SD	10.62	9.76	10.45	10.85	10.73	10.70	10.02	10.75	11.95
			Min	40	43	42	38	41	39	40	45	41
			Q1	64.0	60.0	64.0	62.0	62.0	64.0	63.0	64.0	65.0
			Median	70.0	67.0	69.0	69.0	70.0	72.0	69.0	71.0	72.0
			Q3	78.0	73.0	78.0	78.0	77.0	75.0	74.0	79.0	78.0
			Max	107	94	107	90	96	94	95	100	108
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	71.9	70.8	71.2	72.0	73.3	71.6	71.7	74.3	73.2
			SD	10.02	9.73	11.73	12.60	10.41	9.75	11.74	11.73	9.85
			Min	54	49	51	54	54	53	52	51	50
			Q1	64.0	63.0	63.0	63.0	66.0	65.0	64.0	66.0	65.0
			Median	72.0	71.0	68.5	71.0	72.0	71.0	68.0	72.0	72.0
			Q3	79.5	78.0	78.5	80.0	78.0	76.0	76.0	83.0	81.0
			Max	96	95	105	113	101	105	113	108	97
	Change from Baseline	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	-1.6	-4.9	-1.5	-2.3	-1.7	-2.4	-2.8	-1.1	-0.6
			SD	8.35	8.33	8.68	9.78	8.26	9.56	8.80	9.20	9.93
			Min	-20	-32	-25	-31	-23	-28	-29	-26	-30
			Q1	-7.0	-11.0	-7.0	-8.0	-7.0	-9.0	-9.0	-7.0	-8.0
			Median	-1.0	-4.0	-2.0	-2.0	-1.0	-3.0	-2.0	-1.0	0.0
			Q3	5.0	0.0	4.0	5.0	4.0	4.0	4.0	6.0	4.0
			Max	13	11	23	18	23	19	14	18	26
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	-2.2	-3.0	-2.7	-1.7	-0.4	-2.1	-2.3	0.3	-0.4
			SD	8.19	8.13	9.41	9.70	8.64	7.79	8.07	9.97	8.81
			Min	-24	-26	-26	-23	-21	-23	-24	-29	-29
			Q1	-7.0	-8.0	-10.0	-9.0	-6.0	-7.0	-8.0	-7.0	-5.0
			Median	-2.5	-3.0	-2.0	-3.0	0.0	-2.0	-2.0	2.0	2.0
			Q3	3.0	2.0	3.0	4.0	6.0	3.0	3.0	7.0	5.0
			Max	17	17	24	23	19	18	14	24	16

表 2.7.4-207 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Extension Period							Follow-up Period	
				Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Temperature (C)	Value	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	36 51	36 38	36 44	36 45	36 46	36 50	36 39	36 42	36 39
			SD	0 441	0 445	0 423	0 404	0 354	0 444	0 409	0 394	0 422
			Min	35 3	35 0	35 3	35 5	35 2	35 2	35 1	35 2	35 1
			Q1	36 20	36 10	36 20	36 20	36 30	36 20	36 20	36 20	36 10
			Median	36 50	36 50	36 40	36 50	36 50	36 50	36 50	36 50	36 40
			Q3	36 80	36 70	36 70	36 70	36 70	36 80	36 60	36 70	36 70
			Max	37 3	37 2	37 3	37 4	37 1	37 4	37 0	37 2	37 2
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	36 54	36 51	36 57	36 51	36 55	36 54	36 47	36 49	36 44
			SD	0 340	0 342	0 357	0 325	0 328	0 347	0 387	0 393	0 416
			Min	35 7	35 6	35 7	35 6	35 8	35 4	35 2	35 2	35 0
			Q1	36 30	36 30	36 30	36 30	36 30	36 30	36 20	36 40	36 30
			Median	36 60	36 60	36 65	36 60	36 60	36 60	36 50	36 60	36 50
			Q3	36 70	36 70	36 85	36 80	36 80	36 80	36 70	36 80	36 70
			Max	37 2	37 4	37 3	37 0	37 1	37 2	37 4	37 0	37 1
	Change from Baseline	FSN-013	n	75	75	75	75	75	71	77	80	79
			Mean	-0 07	-0 20	-0 13	-0 12	-0 12	-0 09	-0 19	-0 16	-0 20
			SD	0 437	0 463	0 458	0 427	0 399	0 472	0 460	0 406	0 400
			Min	-1 3	-1 5	-1 4	-0 9	-1 1	-1 2	-1 5	-1 4	-1 2
			Q1	-0 30	-0 50	-0 40	-0 40	-0 40	-0 30	-0 50	-0 40	-0 50
			Median	-0 10	-0 20	-0 10	-0 10	-0 10	-0 10	-0 20	-0 10	-0 20
			Q3	0 20	0 10	0 10	0 10	0 10	0 20	0 10	0 10	0 10
			Max	1 7	1 2	1 2	1 0	0 9	1 1	1 2	1 1	0 8
		Placebo	n	72	71	68	67	67	67	73	77	75
			Mean	-0 09	-0 12	-0 05	-0 11	-0 08	-0 09	-0 15	-0 11	-0 17
			SD	0 344	0 353	0 335	0 392	0 416	0 336	0 334	0 381	0 396
			Min	-0 8	-0 7	-1 1	-1 3	-0 9	-1 1	-1 2	-1 2	-1 1
			Q1	-0 30	-0 40	-0 20	-0 30	-0 30	-0 30	-0 30	-0 30	-0 40
			Median	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10	-0 10	-0 20
			Q3	0 10	0 10	0 10	0 20	0 20	0 10	0 10	0 20	0 10
			Max	0 7	0 9	0 9	0 7	0 8	0 7	0 5	0 7	0 8

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects from Visit 9 to Visit 10

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-28 を引用

2.7.4.4.1.2 FSN-013P-04 試験

2.7.4.4.1.2.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量を表 2.7.4-208 に示す。

投与 6 周期終了時点までのバイタルサイン［血圧（収縮期、拡張期）、脈拍数及び体温］に特記すべき異常変動は認められなかった。

表 2.7.4-208 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation
Systolic Blood Pressure (mmHg)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78
			Mean	108.2	108.2	107.9	109.0	109.0	110.6	109.2	108.8	108.1
			SD	11.26	10.95	10.71	10.29	10.35	11.25	10.94	10.40	10.69
			Min	86	86	90	89	88	82	86	84	83
			Q1	100.0	102.0	99.0	102.0	102.0	102.0	102.0	102.0	99.0
			Median	106.0	108.0	107.0	107.5	107.0	110.0	108.5	108.0	108.0
			Q3	116.0	117.0	116.0	113.0	115.0	118.0	118.0	116.5	116.0
			Max	136	143	131	138	141	134	140	139	135
		Placebo	n	83	83	83	82	81	81	80	78	83
			Mean	108.1	108.0	107.6	107.9	109.0	108.3	107.7	107.6	108.4
			SD	10.31	11.15	10.13	10.08	11.89	11.70	11.98	10.72	11.04
			Min	88	84	87	89	86	82	88	86	85
			Q1	100.0	100.0	100.0	101.0	102.0	100.0	98.0	100.0	100.0
			Median	107.0	107.0	107.0	108.0	107.0	106.0	107.5	107.0	107.0
			Q3	115.0	116.0	115.0	115.0	116.0	116.0	116.0	114.0	115.0
			Max	147	144	140	133	147	152	140	139	138
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78
			Mean	-	-	-	1.0	1.0	2.5	1.1	0.7	0.0
			SD	-	-	-	8.97	10.35	10.07	11.03	9.27	9.38
			Min	-	-	-	-21	-22	-18	-33	-30	-31
			Q1	-	-	-	-6.0	-5.0	-4.0	-5.0	-5.5	-5.0
			Median	-	-	-	3.0	1.0	1.5	2.0	1.0	1.0
			Q3	-	-	-	8.0	8.0	9.0	8.0	8.0	6.0
			Max	-	-	-	20	38	30	24	18	22
		Placebo	n	-	-	-	82	81	81	80	78	83
			Mean	-	-	-	0.3	1.5	0.8	-0.1	-0.2	0.8
			SD	-	-	-	8.93	8.99	9.93	8.95	9.45	9.95
			Min	-	-	-	-34	-16	-24	-22	-20	-23
			Q1	-	-	-	-5.0	-5.0	-6.0	-6.0	-7.0	-6.0
			Median	-	-	-	-1.0	1.0	1.0	-1.0	-0.5	0.0
			Q3	-	-	-	6.0	8.0	8.0	7.5	6.0	8.0
			Max	-	-	-	24	27	22	19	25	26

表 2.7.4-208 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation
Diastolic Blood Pressure (mmHg)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78
			Mean	66.8	67.8	67.1	68.4	67.7	69.8	68.4	68.5	67.9
			SD	8.41	8.90	8.45	7.98	9.01	8.25	8.34	8.88	8.42
			Min	50	42	46	47	50	55	50	45	49
			Q1	60.0	63.0	60.0	63.0	61.0	64.0	63.0	64.5	62.0
			Median	67.0	67.0	67.0	69.0	66.5	68.0	68.0	69.0	68.0
			Q3	72.0	74.0	72.0	73.0	74.0	75.0	73.0	75.0	74.0
			Max	87	88	85	94	90	99	92	91	90
		Placebo	n	83	83	83	82	81	81	80	78	83
			Mean	67.1	68.2	66.5	67.8	68.4	67.8	67.2	67.5	66.7
			SD	9.92	9.36	9.31	9.71	10.04	9.75	9.50	9.79	10.37
			Min	48	49	44	49	42	49	43	49	45
			Q1	59.0	61.0	60.0	62.0	62.0	61.0	61.0	59.0	58.0
			Median	68.0	68.0	66.0	66.5	68.0	66.0	66.0	68.0	66.0
			Q3	74.0	74.0	72.0	72.0	74.0	73.0	74.0	73.0	73.0
			Max	94	91	90	95	95	93	88	93	96
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78
			Mean	-	-	-	1.3	0.6	2.7	1.3	1.3	0.7
			SD	-	-	-	6.63	8.18	6.70	9.02	8.25	8.55
			Min	-	-	-	-16	-24	-9	-20	-20	-24
			Q1	-	-	-	-3.0	-5.0	-2.0	-6.0	-4.5	-5.0
			Median	-	-	-	1.5	0.0	2.0	1.0	2.0	0.0
			Q3	-	-	-	6.0	5.0	6.0	8.0	7.0	6.0
			Max	-	-	-	18	20	29	19	17	21
		Placebo	n	-	-	-	82	81	81	80	78	83
			Mean	-	-	-	1.2	1.7	1.1	0.4	0.9	0.2
			SD	-	-	-	6.97	7.18	7.05	6.68	7.59	7.72
			Min	-	-	-	-18	-17	-13	-21	-17	-19
			Q1	-	-	-	-3.0	-3.0	-3.0	-3.0	-4.0	-6.0
			Median	-	-	-	0.5	2.0	0.0	0.0	0.0	-1.0
			Q3	-	-	-	5.0	6.0	4.0	3.5	6.0	6.0
			Max	-	-	-	18	18	19	21	22	17

表 2.7.4-208 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation
Pulse Rate (beats/min)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78
			Mean	71.7	71.7	74.6	71.5	73.0	73.4	72.4	73.9	72.5
			SD	10.90	10.37	10.87	10.93	10.73	10.30	9.78	9.77	11.18
			Min	52	51	53	52	53	55	51	52	52
			Q1	64.0	65.0	66.0	64.0	63.0	66.0	65.0	67.0	65.0
			Median	73.0	71.0	73.0	71.0	74.0	72.0	72.0	75.0	72.0
			Q3	79.0	77.0	83.0	77.0	79.0	79.0	79.0	80.0	79.0
			Max	104	104	99	100	104	102	98	98	110
		Placebo	n	83	83	83	82	81	81	80	78	83
			Mean	72.0	70.8	71.4	71.2	73.6	72.6	70.2	71.4	70.8
			SD	11.08	11.04	10.43	9.84	10.65	10.37	10.80	11.00	11.44
			Min	42	48	40	52	48	49	46	47	46
			Q1	64.0	64.0	65.0	65.0	67.0	65.0	63.0	65.0	62.0
			Median	72.0	69.0	70.0	71.0	72.0	72.0	69.5	70.0	70.0
			Q3	78.0	75.0	76.0	76.0	78.0	78.0	75.5	78.0	77.0
			Max	96	107	102	114	109	108	111	106	111
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78
			Mean	-	-	-	-3.0	-1.6	-1.2	-2.2	-1.0	-2.4
			SD	-	-	-	7.25	8.54	9.46	8.46	9.45	9.58
			Min	-	-	-	-21	-27	-24	-25	-25	-26
			Q1	-	-	-	-8.0	-6.0	-6.0	-7.0	-7.0	-7.0
			Median	-	-	-	-4.0	-1.0	-1.5	-1.0	-1.0	-2.0
			Q3	-	-	-	2.0	5.0	5.0	3.0	6.0	3.0
			Max	-	-	-	23	18	17	13	19	29
		Placebo	n	-	-	-	82	81	81	80	78	83
			Mean	-	-	-	-0.3	2.1	1.1	-1.3	0.0	-0.5
			SD	-	-	-	7.82	7.78	9.02	8.23	7.71	9.57
			Min	-	-	-	-18	-18	-24	-26	-15	-28
			Q1	-	-	-	-7.0	-2.0	-3.0	-5.0	-6.0	-7.0
			Median	-	-	-	-1.0	2.0	1.0	-0.5	0.0	-1.0
			Q3	-	-	-	5.0	7.0	7.0	4.0	5.0	6.0
			Max	-	-	-	21	22	24	16	18	25

表 2.7.4-208 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation
Temperature (C)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78
			Mean	36.44	36.38	36.49	36.58	36.57	36.56	36.54	36.57	36.58
			SD	0.393	0.331	0.380	0.324	0.347	0.367	0.378	0.373	0.382
			Min	35.1	35.2	35.6	35.8	35.7	35.4	35.3	35.4	35.0
			Q1	36.20	36.20	36.20	36.40	36.30	36.30	36.40	36.40	36.40
			Median	36.50	36.50	36.60	36.60	36.60	36.60	36.60	36.60	36.60
			Q3	36.70	36.60	36.80	36.80	36.80	36.80	36.80	36.90	36.80
			Max	37.1	36.9	37.3	37.4	37.2	37.2	37.2	37.3	37.5
		Placebo	n	83	83	83	82	81	81	80	78	83
			Mean	36.54	36.49	36.58	36.58	36.62	36.62	36.54	36.50	36.54
			SD	0.315	0.350	0.357	0.340	0.356	0.323	0.371	0.396	0.382
			Min	35.5	35.0	35.6	35.7	35.1	35.7	35.3	35.0	35.4
			Q1	36.30	36.30	36.40	36.40	36.50	36.40	36.20	36.30	36.30
			Median	36.60	36.60	36.70	36.55	36.70	36.70	36.60	36.55	36.60
			Q3	36.80	36.70	36.80	36.80	36.80	36.80	36.80	36.70	36.80
			Max	37.1	37.2	37.3	37.4	37.5	37.3	37.2	37.3	37.1
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78
			Mean	-	-	-	0.09	0.08	0.07	0.04	0.07	0.09
			SD	-	-	-	0.367	0.460	0.444	0.447	0.398	0.458
			Min	-	-	-	-1.0	-1.4	-1.1	-1.1	-1.1	-1.3
			Q1	-	-	-	-0.10	-0.20	-0.10	-0.20	-0.10	-0.10
			Median	-	-	-	0.10	0.10	0.00	0.00	0.10	0.10
			Q3	-	-	-	0.30	0.30	0.30	0.30	0.30	0.40
			Max	-	-	-	1.1	1.2	1.4	1.3	1.2	1.1
		Placebo	n	-	-	-	82	81	81	80	78	83
			Mean	-	-	-	0.00	0.04	0.04	-0.03	-0.07	-0.04
			SD	-	-	-	0.340	0.372	0.380	0.412	0.422	0.360
			Min	-	-	-	-0.8	-1.2	-0.9	-1.3	-1.2	-1.0
			Q1	-	-	-	-0.20	-0.10	-0.20	-0.30	-0.30	-0.30
			Median	-	-	-	0.00	0.00	0.00	-0.10	0.00	0.00
			Q3	-	-	-	0.20	0.20	0.30	0.30	0.20	0.20
			Max	-	-	-	0.9	1.4	0.9	0.8	0.9	0.8

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-37 を引用

2.7.4.4.1.2.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量を表 2.7.4-209 に示す。

投与 13 周期終了時点までのバイタルサイン［血圧（収縮期、拡張期）、脈拍数及び体温］に特記すべき異常変動は認められなかった。

表 2.7.4-209 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period						Extension Period							Follow-up Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Systolic Blood Pressure (mmHg)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	108 2	108 2	107 9	109 0	109 0	110 6	109 2	108 8	108 1	108 9	109 6	108 9	107 4	106 6	108 0	109 8	108 8	110 7
			SD	11 26	10 95	10 71	10 29	10 35	11 25	10 94	10 40	10 69	11 51	10 30	11 06	10 28	9 48	10 93	10 87	10 06	11 59
			Min	86	86	90	89	88	82	86	84	83	86	90	85	85	85	86	88	83	73
			Q1	100 0	102 0	99 0	102 0	102 0	102 0	102 0	102 0	99 0	101 0	103 0	100 5	101 0	100 0	101 0	102 0	100 0	103 0
			Median	106 0	108 0	107 0	107 5	107 0	110 0	108 5	108 0	108 0	108 0	108 0	109 0	108 0	106 0	106 0	109 0	109 0	110 0
			Q3	116 0	117 0	116 0	113 0	115 0	118 0	118 0	116 5	116 0	117 0	116 0	117 5	115 0	113 0	115 0	118 5	117 0	119 0
			Max	136	143	131	138	141	134	140	139	135	138	139	132	130	134	139	131	131	138
		Placebo	n	83	83	83	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	108 1	108 0	107 6	107 9	109 0	108 3	107 7	107 6	108 4	108 0	107 6	108 4	106 3	107 9	107 3	108 9	109 4	108 6
			SD	10 31	11 15	10 13	10 08	11 89	11 70	11 98	10 72	11 04	10 60	10 65	11 37	10 94	11 21	11 05	12 36	10 78	12 02
			Min	88	84	87	89	86	82	88	86	85	84	84	86	86	90	87	77	78	85
			Q1	100 0	100 0	100 0	101 0	102 0	100 0	98 0	100 0	100 0	102 0	100 0	100 0	99 0	100 5	99 0	102 0	101 5	100 0
			Median	107 0	107 0	107 0	108 0	107 0	106 0	107 5	107 0	107 0	107 0	107 0	107 0	103 0	106 0	105 0	107 5	109 0	108 0
			Q3	115 0	116 0	115 0	115 0	116 0	116 0	116 0	114 0	115 0	113 0	113 0	115 0	111 0	115 0	114 0	113 0	115 5	116 5
			Max	147	144	140	133	147	152	140	139	138	146	144	152	146	142	147	158	144	149
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	-	-	-	1 0	1 0	2 5	1 1	0 7	0 0	0 9	1 6	0 7	-0 8	-1 8	-0 4	1 6	0 4	2 4
			SD	-	-	-	8 97	10 35	10 07	11 03	9 27	9 38	9 02	9 46	10 20	11 24	10 13	11 97	10 79	10 37	10 62
			Min	-	-	-	-21	-22	-18	-33	-30	-31	-19	-20	-25	-38	-27	-32	-28	-21	-19
			Q1	-	-	-	-6 0	-5 0	-4 0	-5 0	-5 5	-5 0	-4 0	-5 0	-5 5	-7 0	-9 0	-9 0	-5 0	-6 0	-4 0
			Median	-	-	-	3 0	1 0	1 5	2 0	1 0	1 0	1 0	3 0	1 0	-1 0	-0 5	-1 0	-1 0	0 0	1 0
			Q3	-	-	-	8 0	8 0	9 0	8 0	8 0	6 0	6 0	8 0	7 0	7 0	4 0	9 0	8 5	7 0	8 0
			Max	-	-	-	20	38	30	24	18	22	22	20	23	23	27	25	30	23	38
		Placebo	n	-	-	-	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	-	-	-	0 3	1 5	0 8	-0 1	-0 2	0 8	0 1	-0 2	0 6	-1 5	0 0	-0 4	1 0	1 6	0 9
			SD	-	-	-	8 93	8 99	9 93	8 95	9 45	9 95	8 84	8 73	8 54	10 11	9 59	9 23	10 49	9 43	9 76
			Min	-	-	-	-34	-16	-24	-22	-20	-23	-25	-24	-25	-24	-25	-27	-26	-22	-30
			Q1	-	-	-	-5 0	-5 0	-6 0	-6 0	-7 0	-6 0	-5 0	-7 0	-4 0	-8 0	-6 0	-6 0	-7 5	-4 5	-5 5
			Median	-	-	-	-1 0	1 0	1 0	-1 0	-0 5	0 0	0 0	0 0	1 0	-2 0	0 5	-1 0	4 0	2 0	1 0
			Q3	-	-	-	6 0	8 0	8 0	7 5	6 0	8 0	5 0	5 0	5 0	5 0	6 5	6 0	9 0	8 0	7 5
			Max	-	-	-	24	27	22	19	25	26	22	25	29	23	25	18	35	30	26

表 2.7.4-209 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period						Extension Period							Follow-up Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Diastolic Blood Pressure (mmHg)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	66 8	67 8	67 1	68 4	67 7	69 8	68 4	68 5	67 9	67 5	67 7	68 5	67 5	66 8	68 3	68 7	68 8	69 5
			SD	8 41	8 90	8 45	7 98	9 01	8 25	8 34	8 88	8 42	9 19	8 73	7 82	7 38	8 22	9 43	7 82	8 08	7 96
			Min	50	42	46	47	50	55	50	45	49	44	51	54	52	42	46	53	52	53
			Q1	60 0	63 0	60 0	63 0	61 0	64 0	63 0	64 5	62 0	62 0	63 0	63 0	62 0	62 0	63 0	62 0	63 0	64 0
			Median	67 0	67 0	67 0	69 0	66 5	68 0	68 0	69 0	68 0	68 0	66 5	68 0	68 0	66 0	68 0	67 5	69 0	70 0
			Q3	72 0	74 0	72 0	73 0	74 0	75 0	73 0	75 0	74 0	73 0	72 0	72 5	72 0	71 0	72 0	75 0	75 0	76 0
			Max	87	88	85	94	90	99	92	91	90	94	93	88	86	88	103	88	88	88
		Placebo	n	83	83	83	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	67 1	68 2	66 5	67 8	68 4	67 8	67 2	67 5	66 7	67 3	68 0	68 1	66 7	68 0	67 9	68 9	68 1	68 4
			SD	9 92	9 36	9 31	9 71	10 04	9 75	9 50	9 79	10 37	9 31	9 25	9 35	9 23	9 89	9 87	10 85	9 12	10 20
			Min	48	49	44	49	42	49	43	49	45	52	49	50	50	52	45	46	48	43
			Q1	59 0	61 0	60 0	62 0	62 0	61 0	61 0	59 0	58 0	59 0	63 0	61 0	60 0	60 5	62 0	60 0	63 0	61 0
			Median	68 0	68 0	66 0	66 5	68 0	66 0	66 0	68 0	66 0	67 0	67 0	67 0	66 5	67 0	67 0	66 5	68 0	68 5
			Q3	74 0	74 0	72 0	72 0	74 0	73 0	74 0	73 0	73 0	73 0	73 0	75 0	72 0	73 5	74 0	77 0	73 0	74 5
			Max	94	91	90	95	95	93	88	93	96	92	98	97	95	93	102	94	103	96
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	-	-	-	1 3	0 6	2 7	1 3	1 3	0 7	0 4	0 5	1 1	-0 1	-0 8	0 7	1 5	1 4	2 1
			SD	-	-	-	6 63	8 18	6 70	9 02	8 25	8 55	8 60	7 97	7 81	8 00	8 57	9 31	8 16	8 12	8 02
			Min	-	-	-	-16	-24	-9	-20	-20	-24	-25	-32	-20	-20	-20	-33	-25	-24	-21
			Q1	-	-	-	-3 0	-5 0	-2 0	-6 0	-4 5	-5 0	-4 0	-4 0	-4 0	-5 0	-8 0	-6 0	-4 5	-5 0	-3 0
			Median	-	-	-	1 5	0 0	2 0	1 0	2 0	0 0	1 0	0 0	1 0	0 0	0 0	0 5	1 0	0 0	1 0
			Q3	-	-	-	6 0	5 0	6 0	8 0	7 0	6 0	6 0	6 0	6 5	5 0	6 0	7 0	6 0	7 0	8 0
			Max	-	-	-	18	20	29	19	17	21	24	16	21	18	19	21	23	17	20
		Placebo	n	-	-	-	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	-	-	-	1 2	1 7	1 1	0 4	0 9	0 2	0 7	1 2	1 4	0 0	1 5	1 6	2 3	1 4	1 7
			SD	-	-	-	6 97	7 18	7 05	6 68	7 59	7 72	7 29	6 96	7 44	8 40	8 13	6 93	8 69	8 30	7 10
			Min	-	-	-	-18	-17	-13	-21	-17	-19	-26	-14	-18	-32	-18	-15	-27	-18	-14
			Q1	-	-	-	-3 0	-3 0	-3 0	-3 0	-4 0	-6 0	-4 0	-4 0	-4 0	-5 0	-4 0	-3 0	-1 5	-3 0	-3 5
			Median	-	-	-	0 5	2 0	0 0	0 0	0 0	-1 0	1 0	0 0	2 0	0 5	1 0	2 0	3 0	2 0	1 0
			Q3	-	-	-	5 0	6 0	4 0	3 5	6 0	6 0	6 0	6 0	6 0	6 0	6 5	6 0	7 5	7 5	7 0
			Max	-	-	-	18	18	19	21	22	17	13	22	19	23	23	17	24	23	18

表 2.7.4-209 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period						Extension Period							Follow-up Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Pulse Rate (beats/min)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	71 7	71 7	74 6	71 5	73 0	73 4	72 4	73 9	72 5	74 0	73 1	73 0	72 8	74 3	74 6	74 3	74 0	75 1
			SD	10 90	10 37	10 87	10 93	10 73	10 30	9 78	9 77	11 18	10 79	11 00	11 06	11 24	10 49	11 67	11 73	11 46	10 73
			Min	52	51	53	52	53	55	51	52	52	53	56	54	46	55	50	49	54	49
			Q1	64 0	65 0	66 0	64 0	63 0	66 0	65 0	67 0	65 0	66 0	64 0	65 5	66 0	66 0	68 0	65 0	66 0	68 0
			Median	73 0	71 0	73 0	71 0	74 0	72 0	72 0	75 0	72 0	72 0	72 0	72 0	73 0	73 0	75 5	73 0	74 0	75 0
			Q3	79 0	77 0	83 0	77 0	79 0	79 0	79 0	80 0	79 0	82 0	80 0	78 5	80 0	82 0	81 0	82 5	82 0	83 0
			Max	104	104	99	100	104	102	98	98	110	102	114	113	109	102	103	106	105	96
		Placebo	n	83	83	83	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	72 0	70 8	71 4	71 2	73 6	72 6	70 2	71 4	70 8	71 7	71 2	72 9	72 1	74 9	73 4	72 7	73 3	72 5
			SD	11 08	11 04	10 43	9 84	10 65	10 37	10 80	11 00	11 44	12 87	10 87	11 29	10 76	10 96	11 54	12 82	11 45	10 66
			Min	42	48	40	52	48	49	46	47	46	45	52	55	51	47	48	49	54	48
			Q1	64 0	64 0	65 0	65 0	67 0	65 0	63 0	65 0	62 0	64 0	63 0	64 0	66 0	67 0	66 0	65 0	64 0	66 0
			Median	72 0	69 0	70 0	71 0	72 0	72 0	69 5	70 0	70 0	70 0	69 0	70 0	71 0	74 0	73 0	70 5	72 0	72 0
			Q3	78 0	75 0	76 0	76 0	78 0	78 0	75 5	78 0	77 0	78 0	75 0	81 0	78 0	80 0	79 0	77 0	80 0	77 5
			Max	96	107	102	114	109	108	111	106	111	116	102	102	104	112	105	117	108	104
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	-	-	-	-3 0	-1 6	-1 2	-2 2	-1 0	-2 4	-0 8	-1 7	-2 0	-2 2	-0 6	-0 3	-0 6	-0 9	0 1
			SD	-	-	-	7 25	8 54	9 46	8 46	9 45	9 58	9 17	8 43	8 57	8 54	8 96	8 24	8 78	8 03	9 18
			Min	-	-	-	-21	-27	-24	-25	-25	-26	-23	-26	-20	-22	-25	-24	-25	-25	-30
			Q1	-	-	-	-8 0	-6 0	-6 0	-7 0	-7 0	-7 0	-6 0	-7 0	-7 5	-7 0	-4 0	-6 0	-6 0	-6 0	-5 0
			Median	-	-	-	-4 0	-1 0	-1 5	-1 0	-1 0	-2 0	0 0	-2 5	-2 0	-2 0	-1 0	0 0	-1 5	-2 0	0 0
			Q3	-	-	-	2 0	5 0	5 0	3 0	6 0	3 0	5 0	4 0	3 5	4 0	5 0	5 0	3 0	5 0	7 0
			Max	-	-	-	23	18	17	13	19	29	25	22	27	20	19	19	22	16	20
		Placebo	n	-	-	-	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	-	-	-	-0 3	2 1	1 1	-1 3	0 0	-0 5	0 2	-0 5	1 2	0 5	3 3	2 0	1 1	2 0	1 2
			SD	-	-	-	7 82	7 78	9 02	8 23	7 71	9 57	8 69	7 69	8 48	9 14	8 07	7 01	8 99	8 68	7 49
			Min	-	-	-	-18	-18	-24	-26	-15	-28	-22	-18	-18	-23	-14	-14	-22	-20	-16
			Q1	-	-	-	-7 0	-2 0	-3 0	-5 0	-6 0	-7 0	-5 0	-6 0	-5 0	-5 0	-1 0	-2 0	-3 0	-3 0	-3 0
			Median	-	-	-	-1 0	2 0	1 0	-0 5	0 0	-1 0	0 0	-2 0	0 0	-1 0	2 5	2 0	0 0	1 5	2 0
			Q3	-	-	-	5 0	7 0	7 0	4 0	5 0	6 0	5 0	4 0	6 0	5 0	8 5	6 0	5 0	6 0	5 0
			Max	-	-	-	21	22	24	16	18	25	27	18	24	25	25	18	30	29	24

表 2.7.4-209 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Comparative Period						Extension Period							Follow-up Period	
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10 / Discontinuation	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17 / Discontinuation	Visit 18	Visit 19
Temperature (C)	Value	FSN-013	n	79	79	79	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	36 44	36 38	36 49	36 58	36 57	36 56	36 54	36 57	36 58	36 55	36 54	36 54	36 49	36 54	36 50	36 51	36 50	36 45
			SD	0 393	0 331	0 380	0 324	0 347	0 367	0 378	0 373	0 382	0 378	0 352	0 445	0 432	0 416	0 462	0 429	0 369	0 438
			Min	35 1	35 2	35 6	35 8	35 7	35 4	35 3	35 4	35 0	35 1	35 4	35 4	35 2	35 2	35 1	35 1	35 6	35 1
			Q1	36 20	36 20	36 20	36 40	36 30	36 30	36 40	36 40	36 40	36 30	36 30	36 30	36 30	36 30	36 10	36 30	36 30	36 20
			Median	36 50	36 50	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 70	36 60	36 60	36 60	36 60	36 60	36 60	36 50	36 50
			Q3	36 70	36 60	36 80	36 80	36 80	36 80	36 80	36 90	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 70
			Max	37 1	36 9	37 3	37 4	37 2	37 2	37 2	37 3	37 5	37 3	37 1	37 3	37 0	37 2	37 3	37 2	37 3	37 3
		Placebo	n	83	83	83	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	36 54	36 49	36 58	36 58	36 62	36 62	36 54	36 50	36 54	36 58	36 58	36 57	36 58	36 58	36 56	36 57	36 61	36 53
			SD	0 315	0 350	0 357	0 340	0 356	0 323	0 371	0 396	0 382	0 347	0 342	0 382	0 301	0 376	0 362	0 360	0 348	0 354
			Min	35 5	35 0	35 6	35 7	35 1	35 7	35 3	35 0	35 4	35 6	35 7	35 5	35 9	35 6	35 6	35 4	35 6	35 4
			Q1	36 30	36 30	36 40	36 40	36 50	36 40	36 20	36 30	36 30	36 40	36 40	36 40	36 40	36 40	36 40	36 40	36 30	36 40
			Median	36 60	36 60	36 70	36 55	36 70	36 70	36 60	36 55	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 65	36 60
			Q3	36 80	36 70	36 80	36 80	36 80	36 80	36 80	36 70	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 90	36 85	36 80
			Max	37 1	37 2	37 3	37 4	37 5	37 3	37 2	37 3	37 1	37 4	37 3	37 3	37 1	37 3	37 4	37 4	37 3	37 3
	Change from Baseline	FSN-013	n	-	-	-	78	78	78	78	76	78	75	74	72	71	70	70	76	75	75
			Mean	-	-	-	0 09	0 08	0 07	0 04	0 07	0 09	0 07	0 05	0 06	0 03	0 08	0 03	0 02	0 01	-0 03
			SD	-	-	-	0 367	0 460	0 444	0 447	0 398	0 458	0 430	0 400	0 473	0 475	0 421	0 515	0 485	0 413	0 482
			Min	-	-	-	-1 0	-1 4	-1 1	-1 1	-1 1	-1 3	-1 6	-1 1	-1 2	-1 3	-1 1	-1 3	-1 7	-1 0	-1 1
			Q1	-	-	-	-0 10	-0 20	-0 10	-0 20	-0 10	-0 10	-0 10	-0 20	-0 20	-0 30	-0 10	-0 20	-0 30	-0 30	-0 40
			Median	-	-	-	0 10	0 10	0 00	0 00	0 10	0 10	0 10	0 10	0 00	0 00	0 10	0 00	0 10	-0 10	0 00
			Q3	-	-	-	0 30	0 30	0 30	0 30	0 30	0 40	0 20	0 30	0 40	0 30	0 30	0 40	0 30	0 40	0 30
			Max	-	-	-	1 1	1 2	1 4	1 3	1 2	1 1	1 4	1 2	1 3	1 0	1 1	1 3	0 9	1 1	1 2
		Placebo	n	-	-	-	82	81	81	80	78	83	77	75	75	74	72	71	76	80	80
			Mean	-	-	-	0 00	0 04	0 04	-0 03	-0 07	-0 04	0 00	0 02	0 00	0 01	0 01	-0 01	0 01	0 04	-0 03
			SD	-	-	-	0 340	0 372	0 380	0 412	0 422	0 360	0 366	0 363	0 392	0 345	0 398	0 409	0 418	0 410	0 371
			Min	-	-	-	-0 8	-1 2	-0 9	-1 3	-1 2	-1 0	-1 0	-0 7	-1 0	-0 8	-0 9	-0 7	-1 1	-1 1	-0 9
			Q1	-	-	-	-0 20	-0 10	-0 20	-0 30	-0 30	-0 30	-0 20	-0 20	-0 20	-0 20	-0 30	-0 30	-0 20	-0 30	-0 30
			Median	-	-	-	0 00	0 00	0 00	-0 10	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 00	0 05	0 00	0 00
			Q3	-	-	-	0 20	0 20	0 30	0 30	0 20	0 20	0 20	0 20	0 30	0 30	0 20	0 30	0 30	0 30	0 20
			Max	-	-	-	0 9	1 4	0 9	0 8	0 9	0 8	1 1	0 8	1 2	0 9	1 3	1 0	1 0	1 2	0 8

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-28 を引用

2.7.4.4.1.3 FSN-013P-03 試験及び FSN-013P-04 試験の併合

2.7.4.4.1.3.1 24 週投与

投与 6 周期終了時点までの Primary Safety Population を対象とした、血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量を表 2.7.4-210 に示す。

血圧（収縮期、拡張期）、脈拍数及び体温については試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-210 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Baseline Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Systolic Blood Pressure (mmHg)	Value	FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155
			Mean	107 8	107 0	107 7	108 1	108 4	109 0	107 9	108 6	108 0
			SD	12 07	10 61	11 26	10 61	10 76	11 19	11 17	10 72	11 23
			Min	86	86	85	84	88	82	86	84	83
			Q1	99 0	100 0	99 0	100 0	100 0	100 0	100 0	101 0	100 0
			Median	106 0	106 0	107 0	106 0	107 0	108 0	107 0	106 0	107 0
			Q3	115 5	113 0	116 0	115 0	116 0	116 5	115 0	117 0	116 0
			Max	145	143	134	138	141	138	140	149	142
	Change from Baseline	FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155
			Mean	-	-	-	0 2	0 4	1 1	0 2	0 6	0 1
			SD	-	-	-	8 87	9 80	9 56	10 84	8 68	9 98
			Min	-	-	-	-29	-25	-24	-33	-30	-31
			Q1	-	-	-	-6 0	-6 0	-4 5	-7 0	-4 0	-6 0
			Median	-	-	-	0 5	1 0	1 0	1 0	0 0	1 0
			Q3	-	-	-	6 0	6 0	7 0	7 0	7 0	6 0
			Max	-	-	-	26	38	30	31	21	27

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_3_1.sas / Output: t_4_4_3_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: advs

表 2.7.4-210 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Baseline Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Diastolic Blood Pressure (mmHg)	Value	FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155
			Mean	66.1	66.4	66.0	67.1	67.0	68.0	66.9	67.6	67.0
			SD	9.85	9.32	8.75	8.70	9.09	8.90	8.92	9 36	9.24
			Min	50	42	46	46	49	44	50	45	43
			Q1	59.0	60.0	60.0	61.0	60.0	63.0	61.0	62.0	60.0
			Median	64.0	66.0	65.5	67.0	66.0	67.0	66.0	68.0	67.0
			Q3	71.5	73.0	72.0	72.0	73.0	74.0	72.0	74.0	74.0
			Max	101	88	89	94	93	99	94	103	97
	Change from Baseline	FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155
			Mean	-	-	-	1.0	0 9	1.9	0.9	1.6	0.9
			SD	-	-	-	6.36	7.96	7.31	8.45	8 16	8.36
			Min	-	-	-	-19	-24	-16	-20	-23	-24
			Q1	-	-	-	-3.0	-4.0	-2.0	-6.0	-3.0	-4.0
			Median	-	-	-	1.0	1.0	1.5	2.0	3.0	1.0
			Q3	-	-	-	5.0	6.0	6.0	7.0	6.0	7.0
			Max	-	-	-	18	25	29	20	26	21

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name t_4_4_3_1.sas / Output t_4_4_3_1.rtf
Date of Table Generation 2023-02-20 8 51
Data Source advs

表 2.7.4-210 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Baseline Period					
				Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Pulse Rate (beats/min)	Value	FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155
			Mean	70.8	69.6	73.5	70.2	71.0	71.5	69.8	72.0	70.8
			SD	10.71	10.37	11.00	10.63	10.21	10.50	10.12	10.37	10.66
			Min	38	41	45	41	47	45	42	42	40
			Q1	63.0	63.0	66.0	63.0	63.0	64.0	62.0	66.0	64.0
			Median	71.0	69.0	73.0	70.0	71.0	71.0	70.0	72.0	71.0
			Q3	78.0	75.5	82.0	76.0	78.0	78.0	78.0	79.0	78.0
			Max	104	104	100	100	104	102	98	98	110
	Change from Baseline	FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155
			Mean	-	-	-	-3.3	-2.4	-1.9	-3.6	-1.6	-2.8
			SD	-	-	-	8.23	9.20	9.71	8.89	9.07	9.24
			Min	-	-	-	-32	-28	-24	-34	-25	-32
			Q1	-	-	-	-8.0	-8.0	-7.0	-9.0	-7.0	-7.0
			Median	-	-	-	-4.0	-2.0	-2.0	-3.0	-1.0	-2.0
			Q3	-	-	-	2.0	3.0	4.0	2.0	4.0	3.0
			Max	-	-	-	23	19	27	18	19	29

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8.
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10.

Program Name t_4_4_3_1.sas / Output t_4_4_3_1.rtf
Date of Table Generation 2023-02-20 8 51
Data Source advs

表 2.7.4-210 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

				Baseline Observation Period			Post-Baseline Period					
Parameter	Value	Treatment	Statistic	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8 / Discontinuation	Visit 9	Visit 10 / Discontinuation
Temperature (C)	Value	FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155
			Mean	36 41	36 41	36 54	36 55	36 54	36 52	36 50	36 55	36 53
			SD	0 424	0 369	0 372	0 373	0 400	0 398	0 404	0 386	0 410
			Min	35 0	35 1	35 4	35 2	35 1	35 4	35 0	35 2	35 0
			Q1	36 20	36 20	36 30	36 30	36 30	36 20	36 30	36 30	36 20
			Median	36 50	36 50	36 60	36 60	36 60	36 60	36 60	36 60	36 60
			Q3	36 70	36 70	36 80	36 80	36 80	36 80	36 80	36 80	36 80
			Max	37 1	37 2	37 3	37 4	37 4	37 3	37 4	37 3	37 5
	Change from Baseline	FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155
			Mean	-	-	-	0 01	0 00	-0 02	-0 03	0 01	-0 01
			SD	-	-	-	0 401	0 463	0 429	0 457	0 410	0 441
			Min	-	-	-	-1 1	-1 5	-1 1	-1 6	-1 5	-1 3
			Q1	-	-	-	-0 20	-0 20	-0 30	-0 30	-0 20	-0 20
			Median	-	-	-	0 00	0 00	0 00	-0 10	0 00	0 00
			Q3	-	-	-	0 30	0 30	0 20	0 20	0 30	0 30
			Max	-	-	-	1 1	1 3	1 4	1 3	1 2	1 1

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 10 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

Program Name: t_4_4_3_1.sas / Output: t_4_4_3_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: advs

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-72 を引用

2.7.4.4.1.3.2 52 週投与

投与 13 周期終了時点までの Primary Safety Population 及び Secondary Safety Population を対象とした、血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量を表 2.7.4-211 に示す。

Primary Safety Population 及び Secondary Safety Population において、血圧（収縮期、拡張期）、脈拍数及び体温については試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Administration Period													Follow-up Period	
				Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Systolic Blood Pressure (mmHg)	Value	Primary FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	107 8	107 0	107 7	108 1	108 4	109 0	107 9	108 6	108 0	108 2	108 2	107 6	106 5	107 2	107 4	109 0	108 8	110 0
			SD	12 07	10 61	11 26	10 61	10 76	11 19	11 17	10 72	11 23	11 12	10 74	11 07	10 37	10 16	10 77	11 39	10 93	11 20
			Min	86	86	85	84	88	82	86	84	83	86	86	85	85	84	85	88	83	73
			Q1	99 0	100 0	99 0	100 0	100 0	100 0	100 0	101 0	100 0	100 0	100 0	100 0	99 0	100 0	100 0	101 0	100 0	103 0
			Median	106 0	106 0	107 0	106 0	107 0	108 0	107 0	106 0	107 0	107 0	106 0	107 0	106 0	106 0	106 0	108 0	108 0	109 0
			Q3	115 5	113 0	116 0	115 0	116 0	116 5	115 0	117 0	116 0	116 0	114 0	115 0	112 0	114 0	113 0	118 0	117 0	118 0
			Max	145	143	134	138	141	138	140	149	142	138	139	133	130	139	146	140	154	138
		Secondary FSN-013 Pooled	n	311	311	311	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	107 5	107 3	107 7	108 2	107 6	108 5	107 5	108 0	107 1	107 9	107 9	107 6	106 5	107 2	107 4	108 9	108 5	109 5
			SD	11 10	10 68	10 54	10 24	10 42	10 78	10 76	10 54	11 07	10 66	10 41	11 07	10 37	10 16	10 77	11 19	10 61	11 42
			Min	86	84	85	84	84	82	86	84	83	86	86	85	85	84	85	77	78	73
			Q1	99 0	99 0	100 0	101 0	100 0	100 0	100 0	101 0	99 0	100 0	100 0	100 0	99 0	100 0	100 0	101 0	101 0	102 0
			Median	106 0	106 0	107 0	106 0	106 0	107 0	106 0	106 0	106 0	107 0	106 0	107 0	106 0	106 0	106 0	107 0	108 0	108 0
			Q3	114 0	113 0	115 0	114 0	114 0	116 0	115 0	115 0	114 0	115 0	114 0	115 0	112 0	114 0	113 0	116 0	115 0	118 0
			Max	147	144	140	146	144	152	146	149	147	138	139	133	130	139	146	158	154	149

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 3 1.sas / Output: t 4 4 3 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

				Baseline Observation Period			Post-Administration Period													Follow-up Period	
Parameter	Value	Treatment	Statistic	Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Systolic Blood Pressure (mmHg)	Change from Baseline	Primary FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	-	-	-	0 2	0 4	1 1	0 2	0 6	0 1	0 2	0 2	-0 5	-1 6	-1 0	-0 7	1 0	0 9	2 1
			SD	-	-	-	8 87	9 80	9 56	10 84	8 68	9 98	9 43	9 63	10 31	10 75	9 66	10 64	9 99	10 08	10 07
			Min	-	-	-	-29	-25	-24	-33	-30	-31	-28	-22	-31	-38	-27	-32	-28	-21	-19
			Q1	-	-	-	-6 0	-6 0	-4 5	-7 0	-4 0	-6 0	-5 0	-5 0	-8 0	-7 0	-7 0	-8 0	-5 0	-5 0	-4 0
			Median	-	-	-	0 5	1 0	1 0	1 0	0 0	1 0	-0 5	0 0	1 0	-1 5	0 0	0 0	0 0	1 0	1 0
			Q3	-	-	-	6 0	6 0	7 0	7 0	7 0	6 0	5 0	7 0	6 0	5 0	5 0	7 0	7 0	8 0	7 0
			Max	-	-	-	26	38	30	31	21	27	33	32	28	30	27	25	30	23	38
		Secondary FSN-013 Pooled	n	-	-	-	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	-	-	-	0 5	-0 2	0 7	-0 2	0 2	-0 6	0 3	0 3	-0 5	-1 6	-1 0	-0 7	1 0	0 7	1 8
			SD	-	-	-	9 05	9 77	9 03	10 26	9 11	10 06	9 11	10 18	10 31	10 75	9 66	10 64	10 13	9 75	10 08
			Min	-	-	-	-29	-30	-25	-33	-30	-35	-28	-31	-31	-38	-27	-32	-28	-22	-30
			Q1	-	-	-	-5 0	-7 0	-4 0	-7 0	-6 0	-6 0	-5 0	-5 0	-8 0	-7 0	-7 0	-8 0	-6 0	-6 0	-5 0
			Median	-	-	-	0 0	1 0	0 0	0 0	0 0	0 0	0 0	0 0	1 0	-1 5	0 0	0 0	1 0	1 0	1 0
			Q3	-	-	-	6 0	6 0	6 0	6 5	7 0	6 0	5 0	6 0	6 0	5 0	5 0	7 0	8 0	7 0	8 0
			Max	-	-	-	27	38	30	31	25	27	33	32	28	30	27	25	35	30	38

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 3 1.sas / Output: t 4 4 3 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Administration Period												Follow-up Period	
				Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Diastolic Blood Pressure (mmHg)	Value	Primary FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	66 1	66 4	66 0	67 1	67 0	68 0	66 9	67 6	67 0	67 0	66 6	67 1	66 9	67 1	67 1	68 4	68 2	68 9
			SD	9 85	9 32	8 75	8 70	9 09	8 90	8 92	9 36	9 24	9 65	8 73	8 74	8 38	8 60	9 18	8 66	8 15	8 40
			Min	50	42	46	46	49	44	50	45	43	43	49	45	50	42	46	52	51	48
			Q1	59 0	60 0	60 0	61 0	60 0	63 0	61 0	62 0	60 0	60 0	61 0	61 0	61 0	62 0	61 0	62 0	62 0	63 0
			Median	64 0	66 0	65 5	67 0	66 0	67 0	66 0	68 0	67 0	66 0	66 0	66 0	66 0	66 0	66 0	67 0	68 0	68 0
			Q3	71 5	73 0	72 0	72 0	73 0	74 0	72 0	74 0	74 0	73 0	71 0	72 0	72 0	72 0	71 0	75 0	73 0	74 0
			Max	101	88	89	94	93	99	94	103	97	94	93	97	94	92	103	88	95	94
		Secondary FSN-013 Pooled	n	311	311	311	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	66 5	66 8	66 1	66 9	67 4	67 7	66 8	67 4	66 8	67 1	66 7	67 1	66 9	67 1	67 1	68 4	68 2	68 7
			SD	9 84	9 47	9 10	8 65	8 89	9 03	8 90	9 26	9 37	9 44	8 87	8 74	8 38	8 60	9 18	9 06	8 40	9 10
			Min	47	42	44	46	49	44	49	45	43	43	49	45	50	42	46	46	48	43
			Q1	59 0	60 0	60 0	61 0	61 0	62 0	61 0	61 0	60 0	60 0	60 0	61 0	61 0	62 0	61 0	62 0	63 0	62 0
			Median	66 0	66 0	66 0	67 0	67 0	67 0	66 0	67 0	66 0	66 0	66 0	66 0	66 0	66 0	66 0	67 0	68 0	68 0
			Q3	73 0	73 0	72 0	72 0	73 0	74 0	72 0	73 0	73 0	73 0	72 0	72 0	72 0	72 0	71 0	75 0	74 0	74 0
			Max	101	98	90	94	98	99	95	103	102	94	93	97	94	92	103	94	103	96

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 3 1.sas / Output: t 4 4 3 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Administration Period													Follow-up Period	
				Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Diastolic Blood Pressure (mmHg)	Change from Baseline	Primary FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	-	-	-	1 0	0 9	1 9	0 9	1 6	0 9	0 9	0 5	0 9	0 6	0 8	0 6	2 3	2 1	2 7
			SD	-	-	-	6 36	7 96	7 31	8 45	8 16	8 36	8 78	7 39	8 58	9 13	7 99	8 86	7 71	8 59	7 62
			Min	-	-	-	-19	-24	-16	-20	-23	-24	-32	-32	-20	-22	-24	-33	-25	-24	-21
			Q1	-	-	-	-3 0	-4 0	-2 0	-6 0	-3 0	-4 0	-4 0	-3 0	-5 0	-5 0	-3 0	-5 0	-3 0	-4 0	-2 0
			Median	-	-	-	1 0	1 0	1 5	2 0	3 0	1 0	1 0	0 0	1 0	1 0	2 0	1 0	2 0	2 0	2 5
			Q3	-	-	-	5 0	6 0	6 0	7 0	6 0	7 0	6 0	5 0	6 0	7 0	6 0	6 0	8 0	8 0	8 0
			Max	-	-	-	18	25	29	20	26	21	24	17	26	31	19	21	23	28	20
		Secondary FSN-013 Pooled	n	-	-	-	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	-	-	-	0 7	1 2	1 6	0 7	1 3	0 8	1 3	0 9	0 9	0 6	0 8	0 6	2 3	2 0	2 5
			SD	-	-	-	6 93	8 04	7 38	8 49	8 19	8 33	8 66	7 96	8 58	9 13	7 99	8 86	8 23	8 68	8 12
			Min	-	-	-	-26	-27	-18	-32	-23	-29	-32	-32	-20	-22	-24	-33	-27	-24	-25
			Q1	-	-	-	-3 0	-4 0	-3 0	-5 0	-4 0	-4 0	-3 0	-3 0	-5 0	-5 0	-3 0	-5 0	-2 0	-4 0	-3 0
			Median	-	-	-	1 0	1 0	1 0	1 0	2 0	1 0	1 0	0 5	1 0	1 0	2 0	1 0	2 0	2 0	2 0
			Q3	-	-	-	5 0	6 0	6 0	6 0	6 0	6 0	6 0	6 0	6 0	7 0	6 0	6 0	8 0	8 0	8 0
			Max	-	-	-	20	25	29	26	26	21	29	26	26	31	19	21	31	28	26

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

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Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Administration Period												Follow-up Period	
				Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Pulse Rate (beats/min)	Value	Primary FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	70 8	69 6	73 5	70 2	71 0	71 5	69 8	72 0	70 8	72 2	70 1	71 7	71 3	72 3	72 2	71 8	72 7	73 4
			SD	10 71	10 37	11 00	10 63	10 21	10 50	10 12	10 37	10 66	10 82	10 78	10 78	11 11	10 76	11 41	11 13	11 14	11 45
			Min	38	41	45	41	47	45	42	42	40	40	43	42	38	41	39	40	45	41
			Q1	63 0	63 0	66 0	63 0	63 0	64 0	62 0	66 0	64 0	65 0	62 0	65 0	64 0	64 0	66 0	64 0	65 0	66 0
			Median	71 0	69 0	73 0	70 0	71 0	71 0	70 0	72 0	71 0	71 0	69 0	70 0	71 0	72 0	73 0	71 0	73 0	73 0
			Q3	78 0	75 5	82 0	76 0	78 0	78 0	78 0	79 0	78 0	80 0	76 0	78 0	79 0	78 0	78 0	79 0	80 0	81 0
			Max	104	104	100	100	104	102	98	98	110	107	114	113	109	102	103	106	105	108
		Secondary FSN-013 Pooled	n	311	311	311	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	71 5	70 3	73 1	70 6	71 3	72 0	70 6	72 5	71 7	72 6	70 6	71 7	71 3	72 3	72 2	72 0	73 3	73 3
			SD	10 79	10 42	10 79	10 99	10 35	10 57	10 20	10 89	11 35	10 68	10 47	10 78	11 11	10 76	11 41	11 70	11 38	10 85
			Min	38	41	40	41	47	45	42	42	40	40	43	42	38	41	39	40	45	41
			Q1	64 0	64 0	66 0	64 0	63 0	64 0	64 0	65 0	64 0	66 0	64 0	65 0	64 0	64 0	66 0	64 0	65 0	66 0
			Median	72 0	69 0	72 0	70 0	70 0	71 0	70 0	72 0	71 0	71 0	70 0	70 0	71 0	72 0	73 0	70 0	72 0	72 0
			Q3	78 0	76 0	80 0	77 0	78 0	78 0	78 0	79 0	78 0	79 0	76 0	78 0	79 0	78 0	78 0	79 0	81 0	81 0
			Max	104	107	102	116	104	102	104	112	113	107	114	113	109	102	103	117	108	108

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 3 1.sas / Output: t 4 4 3 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Administration Period													Follow-up Period	
				Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Pulse Rate (beats/min)	Change from Baseline	Primary FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	-	-	-	-3 3	-2 4	-1 9	-3 6	-1 6	-2 8	-1 2	-3 3	-1 8	-2 2	-1 1	-1 4	-1 7	-1 0	-0 2
			SD	-	-	-	8 23	9 20	9 71	8 89	9 07	9 24	8 75	8 51	8 60	9 17	8 59	8 96	8 83	8 62	9 55
			Min	-	-	-	-32	-28	-24	-34	-25	-32	-23	-32	-25	-31	-25	-28	-29	-26	-30
			Q1	-	-	-	-8 0	-8 0	-7 0	-9 0	-7 0	-7 0	-7 0	-9 0	-7 0	-8 0	-6 0	-8 0	-7 0	-7 0	-7 0
			Median	-	-	-	-4 0	-2 0	-2 0	-3 0	-1 0	-2 0	-1 0	-3 0	-2 0	-2 0	-1 0	0 0	-2 0	-1 0	0 0
			Q3	-	-	-	2 0	3 0	4 0	2 0	4 0	3 0	5 0	1 0	4 0	4 0	4 0	5 0	3 0	5 0	5 0
			Max	-	-	-	23	19	27	18	19	29	25	22	27	20	23	19	22	18	26
		Secondary FSN-013 Pooled	n	-	-	-	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	-	-	-	-2 4	-1 9	-1 2	-2 5	-0 6	-1 4	-0 9	-2 9	-1 8	-2 2	-1 1	-1 4	-1 1	0 1	0 1
			SD	-	-	-	8 65	8 77	9 15	8 92	9 18	9 05	8 71	8 29	8 60	9 17	8 59	8 96	8 78	9 08	8 90
			Min	-	-	-	-32	-28	-24	-34	-26	-32	-23	-32	-25	-31	-25	-28	-29	-29	-30
			Q1	-	-	-	-7 0	-7 0	-7 0	-7 0	-7 0	-6 0	-6 0	-8 0	-7 0	-8 0	-6 0	-8 0	-7 0	-6 0	-5 0
			Median	-	-	-	-3 0	-2 0	-1 0	-2 5	0 0	-1 0	-1 0	-3 0	-2 0	-2 0	-1 0	0 0	-1 0	0 0	1 0
			Q3	-	-	-	3 0	4 0	4 0	3 0	5 0	4 0	5 0	3 0	4 0	4 0	4 0	5 0	4 0	6 0	5 0
			Max	-	-	-	27	19	27	25	25	29	25	22	27	20	23	19	30	29	26

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 3 1.sas / Output: t 4 4 3 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period			Post-Administration Period												Follow-up Period	
				Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Temperature (C)	Value	Primary FSN-013 Pooled	n	160	160	160	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	36 41	36 41	36 54	36 55	36 54	36 52	36 50	36 55	36 53	36 53	36 46	36 49	36 47	36 50	36 50	36 45	36 46	36 42
			SD	0 424	0 369	0 372	0 373	0 400	0 398	0 404	0 386	0 410	0 410	0 408	0 435	0 417	0 386	0 452	0 422	0 383	0 430
			Min	35 0	35 1	35 4	35 2	35 1	35 4	35 0	35 2	35 0	35 1	35 0	35 3	35 2	35 2	35 1	35 1	35 2	35 1
			Q1	36 20	36 20	36 30	36 30	36 30	36 20	36 30	36 30	36 20	36 30	36 30	36 20	36 20	36 30	36 20	36 30	36 20	36 20
			Median	36 50	36 50	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 50	36 60	36 50	36 60	36 60	36 50	36 50	36 50
			Q3	36 70	36 70	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 70	36 80	36 80	36 80	36 80	36 80	36 70	36 70
			Max	37 1	37 2	37 3	37 4	37 4	37 3	37 4	37 3	37 5	37 3	37 2	37 3	37 4	37 2	37 4	37 2	37 3	37 3
		Secondary FSN-013 Pooled	n	311	311	311	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	36 46	36 44	36 56	36 56	36 55	36 54	36 52	36 56	36 53	36 54	36 48	36 49	36 47	36 50	36 50	36 49	36 51	36 46
			SD	0 382	0 363	0 363	0 358	0 388	0 381	0 367	0 376	0 380	0 386	0 391	0 435	0 417	0 386	0 452	0 402	0 379	0 408
			Min	35 0	35 0	35 4	35 2	35 1	35 4	35 0	35 2	35 0	35 1	35 0	35 3	35 2	35 2	35 1	35 1	35 2	35 0
			Q1	36 20	36 20	36 30	36 30	36 30	36 30	36 35	36 30	36 30	36 30	36 30	36 20	36 20	36 30	36 20	36 30	36 30	36 20
			Median	36 50	36 50	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 60	36 55	36 60	36 50	36 60	36 60	36 50	36 60	36 50
			Q3	36 70	36 70	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 80	36 70	36 80	36 80	36 80	36 80	36 80	36 80	36 70
			Max	37 1	37 2	37 3	37 4	37 4	37 3	37 4	37 3	37 5	37 3	37 2	37 3	37 4	37 2	37 4	37 4	37 3	37 3

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04.

Program Name: t 4 4 3 1.sas / Output: t 4 4 3 1.rtf
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Data Source: advs

表 2.7.4-211 血圧（収縮期、拡張期）、脈拍数及び体温の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.3.1 Summary of Vital Signs (SAS)

				Baseline Observation Period			Post-Administration Period													Follow-up Period	
Parameter	Value	Treatment	Statistic	Cycle -2 (Visit 2)	Cycle -1 (Visit 3)	Cycle -1 (Visit 4)	Cycle 1[b]	Cycle 2[b]	Cycle 3[b]	Cycle 4[b]	Cycle 5[b]	Cycle 6[b]	Cycle 7[c]	Cycle 8[c]	Cycle 9[a]	Cycle 10[a]	Cycle 11[a]	Cycle 12[a]	End of Treatment[b] (Visit 17/ Discontinuation)	Follow-up[b] (Visit 18)	Follow-up[b] (Visit 19)
Temperature (C)	Change from Baseline	Primary FSN-013 Pooled	n	-	-	-	158	157	156	159	153	155	150	149	147	146	145	141	153	155	154
			Mean	-	-	-	0 01	0 00	-0 02	-0 03	0 01	-0 01	0 00	-0 07	-0 04	-0 05	-0 02	-0 03	-0 09	-0 08	-0 12
			SD	-	-	-	0 401	0 463	0 429	0 457	0 410	0 441	0 437	0 449	0 474	0 456	0 420	0 496	0 482	0 417	0 448
			Min	-	-	-	-1 1	-1 5	-1 1	-1 6	-1 5	-1 3	-1 6	-1 5	-1 4	-1 3	-1 1	-1 3	-1 7	-1 4	-1 2
			Q1	-	-	-	-0 20	-0 20	-0 30	-0 30	-0 20	-0 20	-0 20	-0 30	-0 30	-0 40	-0 30	-0 30	-0 40	-0 30	-0 40
			Median	-	-	-	0 00	0 00	0 00	-0 10	0 00	0 00	0 00	0 00	-0 10	-0 05	0 00	-0 10	0 00	-0 10	-0 10
			Q3	-	-	-	0 30	0 30	0 20	0 20	0 30	0 30	0 20	0 20	0 30	0 20	0 20	0 30	0 20	0 20	0 20
			Max	-	-	-	1 1	1 3	1 4	1 3	1 2	1 1	1 7	1 2	1 3	1 0	1 1	1 3	1 2	1 1	1 2
		Secondary FSN-013 Pooled	n	-	-	-	309	306	303	304	293	293	217	216	147	146	145	141	301	305	303
			Mean	-	-	-	0 00	-0 02	-0 03	-0 04	0 00	-0 03	-0 02	-0 08	-0 04	-0 05	-0 02	-0 03	-0 08	-0 06	-0 11
			SD	-	-	-	0 373	0 418	0 401	0 411	0 390	0 423	0 431	0 417	0 474	0 456	0 420	0 496	0 437	0 412	0 422
			Min	-	-	-	-1 1	-1 5	-1 1	-1 6	-1 5	-1 3	-1 6	-1 5	-1 4	-1 3	-1 1	-1 3	-1 7	-1 4	-1 2
			Q1	-	-	-	-0 20	-0 30	-0 30	-0 30	-0 20	-0 30	-0 30	-0 30	-0 30	-0 40	-0 30	-0 30	-0 30	-0 30	-0 40
			Median	-	-	-	0 00	0 00	0 00	-0 10	0 00	0 00	0 00	0 00	-0 10	-0 05	0 00	-0 10	-0 10	-0 10	-0 10
			Q3	-	-	-	0 20	0 20	0 20	0 20	0 20	0 20	0 20	0 20	0 30	0 20	0 20	0 30	0 20	0 20	0 20
			Max	-	-	-	1 1	1 3	1 4	1 3	1 3	1 1	1 7	1 2	1 3	1 0	1 1	1 3	1 2	1 2	1 2

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for subjects in the FSN-013 groups of both studies and only subjects in the Placebo group who were switched to FSN-013 in FSN-013P-03 study

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 11 to Visit 17 for FSN-013P-03 and FSN-013P-04

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Date of Table Generation: 2023-09-22 21:04
Data Source: advs

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07）表 6-74 を引用

2.7.4.4.1.4 FSN-013P-02 試験

バイタルサイン（収縮期血圧、拡張期血圧、脈拍）の評価時点ごとの要約統計量を表 2.7.4-212～表 2.7.4-214 に示す。

試験期間を通じてバイタルサイン（収縮期血圧、拡張期血圧、脈拍）に特記すべき変動は認められなかった。

表 2.7.4-212 バイタルサイン（血圧、脈拍）全体（FSN-013P-02 試験）（安全性解析対象集団）

観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
収縮期血圧 (mmHg)							
スクリーニング	42	107.8	9.22	8.6	90	106.0	132
前観察期	41	108.8	9.32	8.6	90	108.0	126
投薬期1	42	110.0	8.96	8.1	94	110.0	128
投薬期2	42	106.7	7.92	7.4	91	107.0	122
投薬期3	40	105.6	7.76	7.3	92	106.0	118
後観察期	42	105.5	9.92	9.4	88	105.5	129
Follow Up	42	111.4	9.21	8.3	94	109.5	129
拡張期血圧 (mmHg)							
スクリーニング	42	65.4	8.18	12.5	40	66.5	84
前観察期	41	67.4	7.12	10.6	55	67.0	88
投薬期1	42	65.9	6.18	9.4	54	65.0	81
投薬期2	42	65.3	6.39	9.8	53	64.5	78
投薬期3	40	64.8	5.98	9.2	56	64.0	77
後観察期	42	64.8	7.49	11.6	53	63.5	87
Follow Up	42	67.2	7.35	10.9	52	66.0	82
脈拍 (回/分)							
スクリーニング	42	70.5	10.32	14.6	49	69.0	97
前観察期	41	72.6	9.59	13.2	54	74.0	99
投薬期1	42	70.6	10.78	15.3	50	70.5	99
投薬期2	42	69.5	7.65	11.0	52	71.5	82
投薬期3	40	71.8	8.99	12.5	52	72.0	90
後観察期	42	69.9	8.76	12.5	55	69.5	98
Follow Up	42	72.4	7.75	10.7	51	73.0	87

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-48 を引用

表 2.7.4-213 バイタルサイン（血圧、脈拍）周期投与群（FSN-013P-02 試験）（安全性解析対象集団）

観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
収縮期血圧 (mmHg)							
スクリーニング	20	109.7	8.87	8.1	97	111.5	132
前観察期	20	110.3	8.75	7.9	93	108.5	125
投薬期1	20	110.2	7.82	7.1	99	110.0	128
投薬期2	20	105.0	6.77	6.5	91	105.0	117
投薬期3	19	107.2	7.76	7.2	94	107.0	118
後観察期	20	107.4	9.35	8.7	92	108.0	129
Follow Up	20	112.7	7.96	7.1	100	112.5	129
拡張期血圧 (mmHg)							
スクリーニング	20	65.3	8.98	13.8	40	68.0	77
前観察期	20	68.6	6.49	9.5	57	67.5	81
投薬期1	20	65.3	7.03	10.8	54	64.5	81
投薬期2	20	65.4	6.78	10.4	54	65.0	78
投薬期3	19	65.4	6.03	9.2	56	65.0	75
後観察期	20	65.2	8.42	12.9	53	64.0	87
Follow Up	20	67.1	8.61	12.8	52	66.0	82
脈拍 (回/分)							
スクリーニング	20	70.3	11.54	16.4	49	68.0	92
前観察期	20	71.9	10.61	14.8	54	73.5	99
投薬期1	20	71.2	12.04	16.9	50	69.5	99
投薬期2	20	71.2	7.61	10.7	52	72.5	82
投薬期3	19	71.7	8.12	11.3	59	72.0	86
後観察期	20	70.1	10.01	14.3	57	69.5	98
Follow Up	20	71.2	8.63	12.1	51	73.0	85

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-49 を引用

表 2.7.4-214 バイタルサイン（血圧、脈拍）連続投与群（FSN-013P-02 試験）（安全性解析対象集団）

観察時点	例数	平均値	標準偏差	変動係数 (%)	最小値	中央値	最大値
収縮期血圧 (mmHg)							
スクリーニング	22	106.1	9.42	8.9	90	105.5	128
前観察期	21	107.3	9.82	9.1	90	107.0	126
投薬期1	22	109.9	10.08	9.2	94	109.5	128
投薬期2	22	108.3	8.70	8.0	91	108.0	122
投薬期3	21	104.2	7.67	7.4	92	106.0	118
後観察期	22	103.9	10.35	10.0	88	101.0	123
Follow Up	22	110.2	10.26	9.3	94	106.5	128
拡張期血圧 (mmHg)							
スクリーニング	22	65.5	7.58	11.6	54	65.5	84
前観察期	21	66.3	7.67	11.6	55	66.0	88
投薬期1	22	66.5	5.40	8.1	58	66.5	79
投薬期2	22	65.3	6.18	9.5	53	64.5	77
投薬期3	21	64.3	6.04	9.4	56	64.0	77
後観察期	22	64.5	6.71	10.4	53	63.0	80
Follow Up	22	67.2	6.19	9.2	56	66.5	76
脈拍 (回/分)							
スクリーニング	22	70.8	9.34	13.2	51	69.0	97
前観察期	21	73.4	8.69	11.8	58	75.0	91
投薬期1	22	70.0	9.74	13.9	50	72.5	86
投薬期2	22	68.0	7.54	11.1	54	69.5	79
投薬期3	21	71.9	9.91	13.8	52	72.0	90
後観察期	22	69.7	7.69	11.0	55	70.0	82
Follow Up	22	73.5	6.87	9.3	62	73.0	87

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-50 を引用

2.7.4.4.1.5 FSN-013P-05 試験

バイタルサインの測定値及びベースラインからの変化量の要約統計量を表 2.7.4-215 に示す。

バイタルサイン（収縮期血圧、拡張期血圧、脈拍数、体温）には、FSN-013 群、EE/DRSP フレックス投与群とも、治験期間を通じて特記すべき変動は認められなかった。

表 2.7.4-215 バイタルサインの測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
収縮期血圧 (mmHg)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	104.5 (11.51)	111.8 (11.23)		
		CV	11.0	10.0		
		中央値	102.0	110.0		
		Q1 - Q3	98.0 - 109.0	104.0 - 116.0		
		最小値 - 最大値	88 - 138	92 - 139		
	Visit 3	被験者数	45	41	45	41
		平均値 (標準偏差)	104.4 (9.94)	108.5 (9.89)	-0.2 (7.86)	-3.4 (7.34)
		CV	9.5	9.1	-5054.4	-218.1
		中央値	102.0	107.0	-1.0	-3.0
		Q1 - Q3	99.0 - 109.0	102.0 - 110.0	-6.0 - 7.0	-8.0 - 1.0
		最小値 - 最大値	88 - 139	90 - 134	-16 - 13	-26 - 10
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	105.0 (8.50)	109.5 (10.19)	0.5 (7.60)	-1.8 (7.44)
		CV	8.1	9.3	1671.1	-407.6
		中央値	104.0	108.0	3.0	-1.5
		Q1 - Q3	100.0 - 108.0	103.0 - 113.5	-6.0 - 7.0	-7.0 - 1.5
		最小値 - 最大値	92 - 134	85 - 139	-16 - 13	-16 - 17
	Visit 5	被験者数	44	38	44	38
		平均値 (標準偏差)	103.1 (9.47)	110.4 (11.57)	-1.5 (10.16)	-1.2 (8.44)
		CV	9.2	10.5	-698.2	-712.7
		中央値	101.0	108.0	-1.5	-1.0
		Q1 - Q3	97.5 - 109.0	102.0 - 116.0	-7.0 - 7.0	-7.0 - 4.0
		最小値 - 最大値	84 - 136	92 - 144	-32 - 18	-22 - 15
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	104.3 (9.66)	111.2 (10.31)	-0.2 (8.20)	-0.9 (7.74)
		CV	9.3	9.3	-4101.8	-836.5
		中央値	102.0	110.0	-1.0	0.0
		Q1 - Q3	98.0 - 109.0	104.0 - 116.5	-4.0 - 5.0	-5.0 - 4.0
		最小値 - 最大値	86 - 138	90 - 138	-19 - 17	-22 - 14
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	105.8 (8.66)	112.3 (12.65)	1.3 (9.37)	0.5 (7.60)
		CV	8.2	11.3	714.7	1640.6
		中央値	106.0	110.0	3.0	0.0
		Q1 - Q3	100.0 - 111.0	102.0 - 119.0	-5.0 - 7.0	-5.0 - 5.0
		最小値 - 最大値	83 - 133	94 - 146	-22 - 21	-12 - 17
	Visit 8	被験者数	45	41	45	41
		平均値 (標準偏差)	107.4 (12.53)	109.3 (12.57)	2.9 (9.51)	-2.5 (8.49)
		CV	11.7	11.5	329.2	-341.4
		中央値	105.0	108.0	3.0	-1.0
		Q1 - Q3	100.0 - 115.0	101.0 - 115.0	-2.0 - 8.0	-8.0 - 3.0
		最小値 - 最大値	84 - 142	86 - 135	-18 - 24	-22 - 10

表 2.7.4-215 バイタルサインの測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
拡張期血圧 (mmHg)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	64.6 (9.02)	68.4 (9.99)		
		CV	14.0	14.6		
		中央値	64.0	67.0		
		Q1 - Q3	58.0 - 70.0	61.0 - 74.0		
		最小値 - 最大値	47 - 87	49 - 88		
	Visit 3	被験者数	45	41	45	41
		平均値 (標準偏差)	63.0 (8.52)	65.9 (8.99)	-1.5 (5.06)	-2.6 (7.38)
		CV	13.5	13.7	-329.8	-288.0
		中央値	63.0	66.0	-2.0	-2.0
		Q1 - Q3	57.0 - 69.0	59.0 - 71.0	-5.0 - 2.0	-6.0 - 1.0
		最小値 - 最大値	46 - 83	51 - 84	-10 - 10	-17 - 21
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	64.9 (7.91)	66.9 (8.35)	0.4 (6.52)	-1.1 (6.65)
		CV	12.2	12.5	1594.9	-618.3
		中央値	63.5	65.5	-0.5	0.0
		Q1 - Q3	60.0 - 69.0	60.0 - 72.0	-3.5 - 4.0	-4.0 - 2.0
		最小値 - 最大値	52 - 88	52 - 84	-14 - 18	-18 - 12
	Visit 5	被験者数	44	38	44	38
		平均値 (標準偏差)	64.7 (7.23)	67.3 (9.89)	0.3 (8.04)	-0.9 (7.58)
		CV	11.2	14.7	3214.1	-872.5
		中央値	66.0	67.0	0.0	-0.5
		Q1 - Q3	59.5 - 70.0	60.0 - 73.0	-6.0 - 8.0	-6.0 - 5.0
		最小値 - 最大値	49 - 82	50 - 89	-16 - 15	-18 - 14
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	63.7 (7.65)	69.0 (9.45)	-0.8 (6.05)	0.7 (7.25)
		CV	12.0	13.7	-715.9	1115.2
		中央値	64.0	68.0	-1.0	0.0
		Q1 - Q3	58.0 - 70.0	62.0 - 75.5	-6.0 - 2.0	-2.0 - 5.5
		最小値 - 最大値	50 - 82	50 - 94	-12 - 17	-20 - 14
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	66.6 (7.93)	71.4 (10.51)	2.0 (7.56)	3.0 (8.49)
		CV	11.9	14.7	369.7	283.0
		中央値	67.0	70.0	2.0	4.0
		Q1 - Q3	62.0 - 70.0	63.0 - 79.0	-4.0 - 7.0	-1.0 - 7.0
		最小値 - 最大値	46 - 88	51 - 89	-13 - 21	-18 - 26
	Visit 8	被験者数	45	41	45	41
		平均値 (標準偏差)	67.7 (10.51)	66.8 (10.79)	3.1 (8.35)	-1.7 (8.28)
		CV	15.5	16.2	268.2	-499.5
		中央値	67.0	62.0	2.0	0.0
		Q1 - Q3	62.0 - 74.0	58.0 - 71.0	-3.0 - 9.0	-7.0 - 2.0
		最小値 - 最大値	44 - 104	53 - 93	-16 - 19	-18 - 16

表 2.7.4-215 バイタルサインの測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
脈拍数 (bpm)	Visit 2 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	66.0 (8.06)	68.1 (9.83)		
		CV	12.2	14.4		
		中央値	65.0	66.0		
		Q1 - Q3	60.0 - 71.0	60.0 - 75.0		
		最小値 - 最大値	54 - 88	51 - 90		
	Visit 3	被験者数	45	41	45	41
		平均値 (標準偏差)	71.7 (10.51)	70.0 (10.14)	5.7 (7.31)	2.0 (8.25)
		CV	14.6	14.5	128.6	417.8
		中央値	70.0	69.0	6.0	2.0
		Q1 - Q3	64.0 - 79.0	63.0 - 79.0	0.0 - 10.0	-2.0 - 8.0
		最小値 - 最大値	51 - 92	51 - 93	-10 - 20	-25 - 22
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	67.9 (9.98)	67.6 (8.89)	1.8 (7.57)	-0.8 (7.50)
		CV	14.7	13.2	432.8	-937.6
		中央値	67.0	66.0	1.0	-1.0
		Q1 - Q3	61.5 - 72.0	60.0 - 74.0	-3.0 - 6.0	-7.0 - 4.0
		最小値 - 最大値	50 - 88	51 - 86	-15 - 24	-16 - 15
	Visit 5	被験者数	44	38	44	38
		平均値 (標準偏差)	68.6 (9.93)	71.2 (10.43)	2.5 (7.66)	2.8 (8.98)
		CV	14.5	14.6	311.9	315.9
		中央値	66.5	72.0	0.5	2.5
		Q1 - Q3	60.0 - 76.0	62.0 - 80.0	-3.5 - 7.5	-2.0 - 6.0
		最小値 - 最大値	53 - 89	55 - 91	-8 - 19	-20 - 25
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	67.4 (11.21)	68.5 (10.71)	1.4 (7.53)	0.8 (6.98)
		CV	16.6	15.6	537.9	846.0
		中央値	66.0	66.0	1.0	0.0
		Q1 - Q3	60.0 - 74.0	60.0 - 75.5	-4.0 - 6.0	-4.5 - 6.0
		最小値 - 最大値	47 - 93	54 - 98	-12 - 20	-13 - 14
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	68.1 (8.14)	70.3 (11.51)	2.0 (7.21)	2.3 (7.78)
		CV	12.0	16.4	356.7	342.9
		中央値	68.0	68.0	1.0	0.0
		Q1 - Q3	61.0 - 74.0	62.0 - 79.0	-1.0 - 5.0	-2.0 - 8.0
		最小値 - 最大値	52 - 88	46 - 103	-14 - 16	-15 - 23
	Visit 8	被験者数	45	41	45	41
		平均値 (標準偏差)	70.1 (8.19)	70.6 (9.18)	4.0 (7.93)	2.5 (8.92)
		CV	11.7	13.0	196.0	355.0
		中央値	70.0	71.0	5.0	2.0
		Q1 - Q3	64.0 - 77.0	65.0 - 77.0	0.0 - 9.0	-6.0 - 9.0
		最小値 - 最大値	52 - 84	46 - 95	-12 - 24	-13 - 30

表 2.7.4-215 バイタルサインの測定値及びベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）（続き）

検査項目	評価期間		測定値		変化量	
			FSN-013群	ヤーズフレックス配合錠群	FSN-013群	ヤーズフレックス配合錠群
(単位)			N=45	N=41	N=45	N=41
体温	Visit 2 (ベースライン)	被験者数	45	41		
(C)		平均値 (標準偏差)	36.44 (0.365)	36.40 (0.304)		
		CV	1.0	0.8		
		中央値	36.50	36.40		
		Q1 - Q3	36.20 - 36.70	36.20 - 36.50		
		最小値 - 最大値	35.5 - 37.0	35.7 - 37.0		
	Visit 3	被験者数	45	41	45	41
		平均値 (標準偏差)	36.54 (0.373)	36.54 (0.356)	0.10 (0.288)	0.13 (0.311)
		CV	1.0	1.0	294.6	231.9
		中央値	36.60	36.60	0.10	0.10
		Q1 - Q3	36.30 - 36.80	36.40 - 36.80	-0.10 - 0.20	-0.10 - 0.30
		最小値 - 最大値	35.6 - 37.2	35.7 - 37.1	-0.6 - 0.9	-0.8 - 0.7
	Visit 4	被験者数	44	40	44	40
		平均値 (標準偏差)	36.58 (0.340)	36.55 (0.397)	0.13 (0.365)	0.15 (0.311)
		CV	0.9	1.1	281.8	204.1
		中央値	36.60	36.65	0.10	0.10
		Q1 - Q3	36.40 - 36.85	36.35 - 36.90	-0.10 - 0.40	-0.10 - 0.40
		最小値 - 最大値	35.6 - 37.2	35.7 - 37.2	-0.8 - 0.9	-0.5 - 0.9
	Visit 5	被験者数	44	38	44	38
		平均値 (標準偏差)	36.53 (0.418)	36.48 (0.367)	0.08 (0.406)	0.06 (0.303)
		CV	1.1	1.0	483.2	500.2
		中央値	36.60	36.55	0.10	0.10
		Q1 - Q3	36.25 - 36.80	36.30 - 36.70	-0.10 - 0.30	-0.20 - 0.30
		最小値 - 最大値	35.2 - 37.1	35.6 - 37.1	-0.9 - 1.0	-0.5 - 0.6
	Visit 6/中止時	被験者数	45	40	45	40
		平均値 (標準偏差)	36.59 (0.373)	36.50 (0.349)	0.15 (0.340)	0.08 (0.290)
		CV	1.0	1.0	228.0	351.4
		中央値	36.70	36.50	0.10	0.10
		Q1 - Q3	36.40 - 36.80	36.20 - 36.80	0.00 - 0.40	-0.05 - 0.25
		最小値 - 最大値	35.4 - 37.2	35.9 - 37.1	-0.8 - 0.7	-0.7 - 0.6
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	36.46 (0.411)	36.48 (0.414)	0.02 (0.412)	0.07 (0.303)
		CV	1.1	1.1	2320.1	414.6
		中央値	36.60	36.60	0.00	0.10
		Q1 - Q3	36.30 - 36.80	36.30 - 36.80	-0.20 - 0.20	0.00 - 0.30
		最小値 - 最大値	35.4 - 37.0	35.4 - 37.1	-1.0 - 1.1	-0.8 - 0.5
	Visit 8	被験者数	45	41	45	41
		平均値 (標準偏差)	36.56 (0.364)	36.44 (0.409)	0.12 (0.362)	0.03 (0.319)
		CV	1.0	1.1	313.6	934.4
		中央値	36.60	36.50	0.10	0.00
		Q1 - Q3	36.30 - 36.80	36.30 - 36.80	-0.10 - 0.30	-0.20 - 0.20
		最小値 - 最大値	35.5 - 37.1	35.4 - 37.1	-0.5 - 1.3	-0.7 - 0.8

引用元：FSN-013P-05（資料番号 5.3.4.2-01）表 15.4-16 を引用

2.7.4.4.1.6 海外 ISS

第 III 相試験及び第 II 相試験の統合データでの、血圧（収縮期及び拡張期）、心拍数、体重並びに BMI のベースラインから試験終了までの変化量を表 2.7.4-216 に示す。なお、試験終了とは、MIT-Es0001-C202 試験では第 3 周期終了、MIT-Es0001-C201 及び Es-C02 試験では第 6 周期終了、MIT-Es0001-C301 及び MIT-Es0001-C302 試験では第 13 周期終了とする。

全体として、収縮期血圧、拡張期血圧及び心拍数に特記すべき変化は認められなかった。

表 2.7.4-216 血圧（収縮期及び拡張期）、心拍数、体重並びに BMI のベースラインから試験終了までの変化量（海外 ISS、第 III 相及び第 II 相試験）（安全性解析対象集団）

Phase 3 and 2 Studies (N=3790)*		
Vital Sign Time Point Statistic	Value	Change from Baseline
Systolic Blood Pressure (mmHg)		
Baseline		
n	3790	
Mean (SD)	113.8 (10.42)	
Median	114	
Q1, Q3	107, 120	
Min, Max	73, 143	
End of Study		
n	3148	3148
Mean (SD)	114.0 (10.44)	0.0 (10.54)
Median	114	0
Q1, Q3	107, 121	-6, 6
Min, Max	73, 164	-42, 46
Diastolic Blood Pressure (mmHg)		
Baseline		
n	3790	
Mean (SD)	72.5 (7.69)	
Median	72	
Q1, Q3	67, 78	
Min, Max	43, 96	
End of Study		
n	3148	3148
Mean (SD)	72.9 (7.69)	0.5 (7.96)
Median	72	0
Q1, Q3	68, 78	-5, 6
Min, Max	41, 106	-34, 30

表 2.7.4-216 血圧（収縮期及び拡張期）、心拍数、体重並びに BMI のベースラインから試験終了までの変化量（海外 ISS、第 III 相及び第 II 相試験）（安全性解析対象集団）（続き）

Phase 3 and 2 Studies (N=3790)*		
Vital Sign Time Point Statistic	Value	Change from Baseline
Heart Rate (beats/min)		
Baseline		
n	3790	
Mean (SD)	74.6 (9.69)	
Median	74	
Q1, Q3	68, 80	
Min, Max	46, 117	
End of Study		
n	3147	3147
Mean (SD)	74.3 (9.46)	-0.2 (9.94)
Median	74	0
Q1, Q3	68, 80	-6, 6
Min, Max	40, 128	-49, 40
Weight (kg)		
Baseline		
n	3790	
Mean (SD)	67.13 (13.052)	
Median	65.0	
Q1, Q3	57.7, 74.9	
Min, Max	35.0, 148.8	
End of Study		
n	3148	3148
Mean (SD)	67.20 (13.385)	0.87 (4.103)
Median	64.8	0.5
Q1, Q3	57.6, 74.4	-1.0, 2.7
Min, Max	35.6, 144.5	-19.1, 38.2

表 2.7.4-216 血圧（収縮期及び拡張期）、心拍数、体重並びに BMI のベースラインから試験終了までの変化量（海外 ISS、第 III 相及び第 II 相試験）（安全性解析対象集団）（続き）

Phase 3 and 2 Studies (N=3790)*		
Vital Sign Time Point Statistic	Value	Change from Baseline
Body Mass Index (kg/m^2)		
Baseline		
n	3790	
Mean (SD)	24.62 (4.456)	
Median	23.6	
Q1, Q3	21.2, 27.5	
Min, Max	14.3, 48.4	
End of Study		
n	3148	3148
Mean (SD)	24.62 (4.613)	0.32 (1.493)
Median	23.6	0.2
Q1, Q3	21.1, 27.3	-0.4, 1.0
Min, Max	14.7, 47.0	-6.8, 13.2

N = number of subjects; Q1 = lower quartile; Q3 = upper quartile; SD = standard deviation

The baseline value for each assessment was defined as the last measurement taken prior to the first administration of the study drug.

* The ISS Safety Population includes 3,575 subjects with confirmed exposure to E4/DRSP 15/3 mg and 215 subjects for whom neither exposure nor non-exposure could be confirmed. All 215 subjects were included in Phase 3 studies.

Integrated Summary of Safety（資料番号 5.3.5.3-int02）Table 14.2.3.2 より作成

2.7.4.4.2 体重及び BMI

2.7.4.4.2.1 FSN-013P-03 試験

2.7.4.4.2.1.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、体重の測定値及びベースラインからの変化量を表 2.7.4-217 に示す。

投与 6 周期終了時点までの体重に特記すべき異常変動は認められなかった。

表 2.7.4-217 体重の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
Weight (kg)	Value	FSN-013	n	81	80	81	1
			Mean	54 50	54 34	54 57	55 30
			SD	8 440	8 489	8 960	-
			Min	37 9	37 1	37 0	55 3
			Q1	48 70	48 35	47 80	55 30
			Median	53 40	53 35	53 60	55 30
			Q3	59 10	59 15	60 70	55 30
			Max	79 1	76 8	77 3	55 3
		Placebo	n	79	78	79	1
			Mean	55 10	55 34	55 50	62 20
			SD	6 660	6 732	6 834	-
			Min	42 1	41 7	42 1	62 2
			Q1	49 90	49 80	50 50	62 20
			Median	55 20	55 10	54 80	62 20
			Q3	59 50	59 60	60 20	62 20
			Max	83 6	82 2	83 5	62 2
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-0 20	0 08	0 60
			SD	-	0 993	1 732	-
			Min	-	-2 3	-3 9	0 6
			Q1	-	-0 85	-1 10	0 60
			Median	-	-0 40	-0 20	0 60
			Q3	-	0 35	1 20	0 60
			Max	-	2 6	4 6	0 6
		Placebo	n	-	78	79	1
			Mean	-	0 24	0 41	1 40
			SD	-	0 976	1 608	-
			Min	-	-2 6	-4 5	1 4
			Q1	-	-0 30	-0 60	1 40
			Median	-	0 20	0 40	1 40
			Q3	-	0 80	1 20	1 40
			Max	-	2 6	6 2	1 4

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 17 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-39 を引用

2.7.4.4.2.1.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、体重の測定値及びベースラインからの変化量を表 2.7.4-218 に示す。

投与 13 周期終了時点までの体重に特記すべき異常変動は認められなかった。

表 2.7.4-218 体重の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
Weight (kg)	Value	FSN-013	n	81	80	81	75	77
			Mean	54 50	54 34	54 57	54 70	54 74
			SD	8 440	8 489	8 960	9 303	9 124
			Min	37 9	37 1	37 0	37 0	36 7
			Q1	48 70	48 35	47 80	47 90	48 20
			Median	53 40	53 35	53 60	53 40	54 20
			Q3	59 10	59 15	60 70	61 10	58 60
			Max	79 1	76 8	77 3	77 2	78 6
		Placebo	n	79	78	79	71	74
			Mean	55 10	55 34	55 50	54 67	54 80
			SD	6 660	6 732	6 834	7 075	7 309
			Min	42 1	41 7	42 1	40 9	39 9
			Q1	49 90	49 80	50 50	49 50	49 10
			Median	55 20	55 10	54 80	54 00	53 90
			Q3	59 50	59 60	60 20	58 40	59 50
			Max	83 6	82 2	83 5	82 3	83 9
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-0 20	0 08	0 13	0 31
			SD	-	0 993	1 732	2 172	2 546
			Min	-	-2 3	-3 9	-4 9	-8 9
			Q1	-	-0 85	-1 10	-1 80	-1 20
			Median	-	-0 40	-0 20	0 10	0 00
			Q3	-	0 35	1 20	1 30	1 80
			Max	-	2 6	4 6	5 2	5 8
		Placebo	n	-	78	79	71	74
			Mean	-	0 24	0 41	-0 47	-0 36
			SD	-	0 976	1 608	1 902	2 293
			Min	-	-2 6	-4 5	-4 2	-5 4
			Q1	-	-0 30	-0 60	-1 90	-1 90
			Median	-	0 20	0 40	-0 70	-0 45
			Q3	-	0 80	1 20	0 80	1 20
			Max	-	2 6	6 2	3 9	5 5

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 9 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-29 を引用

2.7.4.4.2.2 FSN-013P-04 試験

2.7.4.4.2.2.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、体重の測定値及びベースラインからの変化量を表 2.7.4-219 に示す。

投与 6 周期終了時点までの体重に特記すべき異常変動は認められなかった。

表 2.7.4-219 体重の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
Weight (kg)	Value	FSN-013	n	79	78	78	78
			Mean	54 31	54 20	54 37	54 18
			SD	6 444	6 573	6 589	6 745
			Min	40 7	40 3	39 5	40 5
			Q1	49 80	50 10	50 00	49 00
			Median	53 40	53 50	53 95	54 00
			Q3	58 50	59 00	59 00	58 30
			Max	68 4	67 6	67 9	68 2
		Placebo	n	83	82	80	83
			Mean	55 43	55 50	55 50	55 53
			SD	7 836	7 980	8 193	8 025
			Min	40 4	40 7	40 8	41 3
			Q1	49 40	49 10	49 75	49 20
			Median	54 80	54 40	54 45	54 30
			Q3	60 80	60 30	60 15	60 30
			Max	80 7	82 2	84 6	85 9
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0 18	-0 01	-0 16
			SD	-	1 044	1 462	1 855
			Min	-	-2 1	-3 4	-5 2
			Q1	-	-0 90	-1 20	-0 90
			Median	-	-0 25	-0 05	-0 25
			Q3	-	0 20	0 60	0 90
			Max	-	3 2	4 7	4 8
		Placebo	n	-	82	80	83
			Mean	-	0 05	0 26	0 10
			SD	-	0 877	1 622	1 794
			Min	-	-3 3	-7 2	-5 9
			Q1	-	-0 40	-0 60	-0 90
			Median	-	0 10	0 35	0 00
			Q3	-	0 60	1 20	1 00
			Max	-	2 0	3 9	5 5

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-38 を引用

2.7.4.4.2.2.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、体重の測定値及びベースラインからの変化量を表 2.7.4-220 に示す。

投与 13 周期終了時点までの体重に特記すべき異常変動は認められなかった。

表 2.7.4-220 体重の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
Weight (kg)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	54.31	54.20	54.37	54.18	53.60	53.81
			SD	6.444	6.573	6.589	6.745	6.667	6.889
			Min	40.7	40.3	39.5	40.5	40.7	41.5
			Q1	49.80	50.10	50.00	49.00	48.00	48.10
			Median	53.40	53.50	53.95	54.00	53.30	54.00
			Q3	58.50	59.00	59.00	58.30	57.70	57.80
			Max	68.4	67.6	67.9	68.2	67.9	69.4
		Placebo	n	83	82	80	83	74	76
			Mean	55.43	55.50	55.50	55.53	54.34	54.65
			SD	7.836	7.980	8.193	8.025	7.748	7.926
			Min	40.4	40.7	40.8	41.3	39.6	39.8
			Q1	49.40	49.10	49.75	49.20	48.80	48.65
			Median	54.80	54.40	54.45	54.30	53.75	54.25
			Q3	60.80	60.30	60.15	60.30	59.40	59.60
			Max	80.7	82.2	84.6	85.9	78.0	76.5
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-0.18	-0.01	-0.16	-0.60	-0.47
			SD	-	1.044	1.462	1.855	2.252	2.764
			Min	-	-2.1	-3.4	-5.2	-8.3	-14.3
			Q1	-	-0.90	-1.20	-0.90	-2.00	-2.05
			Median	-	-0.25	-0.05	-0.25	-0.50	-0.15
			Q3	-	0.20	0.60	0.90	0.50	1.35
			Max	-	3.2	4.7	4.8	4.7	4.8
		Placebo	n	-	82	80	83	74	76
			Mean	-	0.05	0.26	0.10	-0.46	-0.24
			SD	-	0.877	1.622	1.794	2.475	2.275
			Min	-	-3.3	-7.2	-5.9	-8.3	-5.2
			Q1	-	-0.40	-0.60	-0.90	-1.70	-1.60
			Median	-	0.10	0.35	0.00	-0.80	-0.60
			Q3	-	0.60	1.20	1.00	1.00	0.65
			Max	-	2.0	3.9	5.5	9.0	9.7

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-29 を引用

2.7.4.4.2.3 FSN-013P-03 試験及び FSN-013P-04 試験の併合

2.7.4.4.2.3.1 24 週投与

投与 6 周期終了時点までの Primary Safety Population を対象とした、体重の測定値及びベースラインからの変化量を表 2.7.4-221 に示す。

体重に特記すべき異常変動は認められなかった。

表 2.7.4-221 体重の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.4.1 Summary of Weight (SAS)

				Baseline Observation Period	Post-Baseline Period		
Parameter	Value	Treatment	Statistic	Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
Weight (kg)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	54 40	54 27	54 47	54 19
			SD	7 498	7 580	7 862	6 703
			Min	37 9	37 1	37 0	40 5
			Q1	49 40	49 00	48 70	49 00
			Median	53 40	53 45	53 60	54 10
			Q3	58 60	59 00	59 30	58 30
			Max	79 1	76 8	77 3	68 2
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-0 19	0 04	-0 15
			SD	-	1 016	1 601	1 845
			Min	-	-2 3	-3 9	-5 2
			Q1	-	-0 90	-1 20	-0 90
			Median	-	-0 35	-0 10	-0 20
			Q3	-	0 20	1 00	0 90
			Max	-	3 2	4 7	4 8

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Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_4_1.sas / Output: t_4_4_4_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: advs

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-73 を引用

2.7.4.4.2.3.2 52 週投与

投与 13 周期終了時点までの Primary Safety Population 及び Secondary Safety Population を対象とした、体重の測定値及びベースラインからの変化量を表 2.7.4-222 に示す。

Primary Safety Population 及び Secondary Safety Population において、体重については試験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-222 体重の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.4.1 Summary of Weight (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period					
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 4[b)]	Cycle 6[d)]	Cycle 8[c)]	Cycle 10[d)]	End of Treatment[b)] (Visit 17/ Discontinuation)
Weight (kg)	Value	Primary FSN-013 Pooled	n	160	158	159	78	75	71	153
			Mean	54 40	54 27	54 47	54 18	54 70	53 60	54 28
			SD	7 498	7 580	7 862	6 745	9 303	6 667	8 078
			Min	37 9	37 1	37 0	40 5	37 0	40 7	36 7
			Q1	49 40	49 00	48 70	49 00	47 90	48 00	48 20
			Median	53 40	53 45	53 60	54 00	53 40	53 30	54 00
			Q3	58 60	59 00	59 30	58 30	61 10	57 70	58 50
			Max	79 1	76 8	77 3	68 2	77 2	67 9	78 6
		Secondary FSN-013 Pooled	n	311	158	304	78	75	71	302
			Mean	54 70	54 27	54 49	54 18	54 70	53 60	54 50
			SD	7 324	7 580	7 634	6 745	9 303	6 667	7 850
			Min	37 9	37 1	37 0	40 5	37 0	40 7	36 7
			Q1	49 60	49 00	49 15	49 00	47 90	48 00	48 40
			Median	53 90	53 45	53 70	54 00	53 40	53 30	54 00
			Q3	59 10	59 00	58 95	58 30	61 10	57 70	59 30
			Max	83 6	76 8	82 3	68 2	77 2	67 9	83 9

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for FSN-013 group of FSN-013P-03 study only.
d) : Includes data for FSN-013 group of FSN-013P-04 study only.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 9 to Visit 17 of FSN-013P-03 and subjects who discontinued from visit 11 to Visit 17 of FSN-013P-04.

Program Name: t 4 4 4 1.sas / Output: t 4 4 4 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

表 2.7.4-222 体重の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）（続き）

Table 4.4.4.1 Summary of Weight (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period					
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 4[b)]	Cycle 6[d)]	Cycle 8[c)]	Cycle 10[d)]	End of Treatment[b)] (Visit 17/ Discontinuation)
Weight (kg)	Change from Baseline	Primary FSN-013 Pooled	n	-	158	159	78	75	71	153
			Mean	-	-0 19	0 04	-0 16	0 13	-0 60	-0 08
			SD	-	1 016	1 601	1 855	2 172	2 252	2 677
			Min	-	-2 3	-3 9	-5 2	-4 9	-8 3	-14 3
			Q1	-	-0 90	-1 20	-0 90	-1 80	-2 00	-1 40
			Median	-	-0 35	-0 10	-0 25	0 10	-0 50	0 00
			Q3	-	0 20	1 00	0 90	1 30	0 50	1 60
			Max	-	3 2	4 7	4 8	5 2	4 7	5 8
		Secondary FSN-013 Pooled	n	-	158	304	78	75	71	302
			Mean	-	-0 19	-0 20	-0 16	0 13	-0 60	-0 18
			SD	-	1 016	1 926	1 855	2 172	2 252	2 483
			Min	-	-2 3	-8 3	-5 2	-4 9	-8 3	-14 3
			Q1	-	-0 90	-1 30	-0 90	-1 80	-2 00	-1 60
			Median	-	-0 35	-0 40	-0 25	0 10	-0 50	-0 25
			Q3	-	0 20	1 00	0 90	1 30	0 50	1 40
			Max	-	3 2	9 0	4 8	5 2	4 7	9 7

Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ.
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013.
a) : Includes data for only FSN-013 groups of both studies.
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies.
c) : Includes data for FSN-013 group of FSN-013P-03 study only.
d) : Includes data for FSN-013 group of FSN-013P-04 study only.

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively.
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively.
Visit 17/Discontinuation includes subjects who discontinued from Visit 9 to Visit 17 of FSN-013P-03 and subjects who discontinued from visit 11 to Visit 17 of FSN-013P-04.

Program Name: t 4 4 4 1.sas / Output: t 4 4 4 1.rtf
Date of Table Generation: 2023-09-22 21:04
Data Source: advs

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（52 週）（資料番号 5.3.5.3-int07）表 6-75 を引用

2.7.4.4.2.4 FSN-013P-02 試験

身長、体重、BMI の評価時点ごとの要約統計量を表 2.7.4-223 に示す。

試験期間を通じて体重、BMI に特記すべき異常変動は認められなかった。

表 2.7.4-223 身長、体重、BMI の評価時点ごとの要約統計量（FSN-013P-02 試験）（安全性解析対象集団）

検査項目	観察時点		全体 (N = 42)	周期投与群 (N = 20)	連続投与群 (N = 22)
身長 (cm)	スクリーニング	例数	42	20	22
		平均値	156.59	156.82	156.39
		標準偏差	5.512	5.869	5.297
		変動係数 (%)	3.5	3.7	3.4
		最小値	143.2	143.2	146.2
		中央値	156.65	158.00	155.80
		最大値	170.5	166.6	170.5
体重 (kg)	スクリーニング	例数	42	20	22
		平均値	50.50	50.57	50.44
		標準偏差	4.817	4.075	5.501
		変動係数 (%)	9.5	8.1	10.9
		最小値	41.5	45.6	41.5
		中央値	50.55	50.10	51.30
		最大値	62.2	62.2	59.4
	後観察期	例数	42	20	22
		平均値	50.60	50.95	50.28
		標準偏差	5.471	4.464	6.340
		変動係数 (%)	10.8	8.8	12.6
		最小値	39.5	44.1	39.5
		中央値	50.95	50.95	51.50
		最大値	61.5	60.4	61.5
BMI (kg/m^2)	スクリーニング	例数	42	20	22
		平均値	20.56	20.55	20.57
		標準偏差	1.751	1.573	1.936
		変動係数 (%)	8.5	7.7	9.4
		最小値	18.5	18.5	18.5
		中央値	20.55	20.55	20.70
		最大値	24.3	24.3	23.6
	後観察期	例数	42	20	22
		平均値	20.58	20.69	20.49
		標準偏差	1.968	1.615	2.276
		変動係数 (%)	9.6	7.8	11.1
		最小値	16.8	17.7	16.8
		中央値	21.00	20.95	21.05
		最大値	24.2	23.3	24.2

引用元：FSN-013P-02（資料番号 5.3.4.1-01）表 14.4-61 を引用

2.7.4.4.2.5 FSN-013P-05 試験

身長・体重・BMI の要約統計量及び体重・BMI のベースラインからの変化量の要約統計量を表 2.7.4-224 に示す。

体重、BMI には、FSN-013 群、EE/DRSP フレックス投与群とも、治験期間を通じて特記すべき異常変動は認められなかった。

表 2.7.4-224 身長・体重・BMI の要約統計量及び体重・BMI のベースラインからの変化量の要約統計量（FSN-013P-05 試験）（安全性解析対象集団）

検査項目 (単位)	評価期間		測定値 FSN-013群 N=45	測定値 ヤーズフレックス配合錠群 N=41	変化量 FSN-013群 N=45	変化量 ヤーズフレックス配合錠群 N=41
身長 (cm)	Visit 1	被験者数	45	41		
		平均値 (標準偏差)	161.49 (4.763)	160.47 (4.804)		
		CV	2.9	3.0		
		中央値	162.30	159.90		
		Q1 - Q3	158.00 - 164.80	156.80 - 164.30		
		最小値 - 最大値	152.8 - 173.0	151.5 - 169.5		
体重 (kg)	Visit 3 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	54.19 (5.892)	53.73 (7.956)		
		CV	10.9	14.8		
		中央値	54.40	53.10		
		Q1 - Q3	49.70 - 57.30	48.00 - 58.20		
		最小値 - 最大値	42.6 - 71.0	40.2 - 70.8		
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	53.80 (6.551)	53.56 (8.002)	-0.39 (1.521)	-0.18 (1.621)
		CV	12.2	14.9	-386.6	-910.7
		中央値	53.20	53.00	-0.70	0.00
		Q1 - Q3	49.00 - 57.30	47.80 - 58.70	-1.40 - 0.50	-0.60 - 0.70
		最小値 - 最大値	42.6 - 73.0	41.0 - 71.8	-3.8 - 2.5	-6.3 - 3.0
BMI (kg/m^2)	Visit 3 (ベースライン)	被験者数	45	41		
		平均値 (標準偏差)	20.72 (1.921)	20.81 (2.931)		
		CV	9.3	14.1		
		中央値	20.90	20.70		
		Q1 - Q3	19.50 - 22.00	19.00 - 22.10		
		最小値 - 最大値	17.5 - 26.0	16.2 - 28.9		
	Visit 7	被験者数	45	41	45	41
		平均値 (標準偏差)	20.56 (2.174)	20.75 (3.016)	-0.16 (0.589)	-0.06 (0.599)
		CV	10.6	14.5	-368.2	-982.5
		中央値	20.10	20.90	-0.30	0.00
		Q1 - Q3	19.00 - 21.70	18.80 - 22.30	-0.50 - 0.20	-0.20 - 0.30
		最小値 - 最大値	17.5 - 26.9	15.3 - 29.0	-1.6 - 0.9	-2.2 - 1.1

引用元：FSN-013P-05（資料番号 5.3.4.2-01）表 15.4-17 を引用

2.7.4.4.2.6 海外 ISS

第 III 相試験及び第 II 相試験の統合データで、ベースラインから試験終了までの変化量における体重の平均値（標準偏差）［+0.87 kg（4.103）］及び BMI の平均値（標準偏差）［+0.32 kg/m^2（1.493）］にごくわずかな変化が認められた（表 2.7.4-216）。

2.7.4.4.3 心機能への影響

2.7.4.4.3.1 12 誘導心電図

2.7.4.4.3.1.1 FSN-013P-03 試験

2.7.4.4.3.1.1.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、12 誘導心電図の異常の有無を表 2.7.4-225 に、心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、補正 QT（QTc）間隔［Bazett 補正法で補正した QTc（QTcB）及び Fridericia 補正法で補正した QTc（QTcF）］の測定値及びベースラインからの変化量を表 2.7.4-226 に示す。

12 誘導心電図の異常の有無は FSN-013 群及びプラセボ群で大差はなく、心拍数や各波間隔（PR、RR、QRS、QT、QTcB 及び QTcF）の平均変化量に特記すべき異常変動は認められなかった。

表 2.7.4-225 12 誘導心電図の異常の有無［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Treatment	Period	Analysis Visit	n	Normal n (%)	Abnormal n (%)
FSN-013	Baseline Observation Period	Visit3	81	77 (95.1)	4 (4.9)
	Comparative Period	Visit5	80	75 (93.8)	5 (6.3)
		Visit 8 / Discontinuation	81	76 (93.8)	5 (6.2)
	Extension Period	Visit 17 / Discontinuation	1	1 (100.0)	0 (0.0)
Placebo	Baseline Observation Period	Visit3	79	79 (100.0)	0 (0.0)
	Comparative Period	Visit5	78	77 (98.7)	1 (1.3)
		Visit 8 / Discontinuation	79	79 (100.0)	0 (0.0)
	Extension Period	Visit 17 / Discontinuation	1	1 (100.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 17 / Discontinuation : Discontinued subjects from Visit 9 to Visit 10

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-40 を引用

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
ECG Mean Heart Rate (beats/min)	Value	FSN-013	n	81	80	81	1
			Mean	62 9	62 2	62 0	61 0
			SD	8 60	8 39	8 62	-
			Min	42	41	41	61
			Q1	58 0	57 0	56 0	61 0
			Median	63 0	61 5	62 0	61 0
			Q3	68 0	68 0	67 0	61 0
			Max	87	80	84	61
		Placebo	n	79	78	79	1
			Mean	65 0	65 8	65 5	64 0
			SD	8 30	7 82	9 42	-
			Min	48	51	45	64
			Q1	58 0	61 0	60 0	64 0
			Median	64 0	66 0	64 0	64 0
			Q3	71 0	71 0	70 0	64 0
			Max	86	88	93	64
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-0 6	-0 9	0 0
			SD	-	7 23	7 38	-
			Min	-	-27	-20	0
			Q1	-	-4 0	-5 0	0 0
			Median	-	0 0	-1 0	0 0
			Q3	-	3 0	4 0	0 0
			Max	-	19	26	0
		Placebo	n	-	78	79	1
			Mean	-	0 8	0 5	7 0
			SD	-	5 86	8 20	-
			Min	-	-17	-20	7
			Q1	-	-4 0	-4 0	7 0
			Median	-	0 0	1 0	7 0
			Q3	-	5 0	5 0	7 0
			Max	-	16	28	7

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
PR Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	1
			Mean	152.5	151.0	152.1	153.0
			SD	20.86	20.36	20.42	-
			Min	120	108	108	153
			Q1	139.0	136.0	140.0	153.0
			Median	146.0	148.0	147.0	153.0
			Q3	166.0	164.0	164.0	153.0
			Max	222	205	197	153
		Placebo	n	79	78	79	1
			Mean	150.2	151.0	150.7	150.0
			SD	17.01	18.43	17.90	-
			Min	116	111	110	150
			Q1	138.0	136.0	137.0	150.0
			Median	148.0	151.0	150.0	150.0
			Q3	163.0	164.0	163.0	150.0
			Max	188	208	190	150
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-1.6	-0.4	33.0
			SD	-	11.01	11.24	-
			Min	-	-32	-26	33
			Q1	-	-7.0	-7.0	33.0
			Median	-	-2.5	0.0	33.0
			Q3	-	6.0	5.0	33.0
			Max	-	36	38	33
		Placebo	n	-	78	79	1
			Mean	-	0.9	0.5	-5.0
			SD	-	10.66	11.56	-
			Min	-	-30	-39	-5
			Q1	-	-6.0	-6.0	-5.0
			Median	-	-0.5	2.0	-5.0
			Q3	-	6.0	8.0	-5.0
			Max	-	36	24	-5

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
RR Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	1
			Mean	970.1	982.0	984.4	980.0
			SD	133.16	138.63	140.75	-
			Min	690	750	714	980
			Q1	882.0	882.0	890.0	980.0
			Median	960.0	975.0	968.0	980.0
			Q3	1040.0	1056.5	1068.0	980.0
			Max	1424	1472	1452	980
		Placebo	n	79	78	79	1
			Mean	937.6	923.2	934.6	944.0
			SD	117.56	111.39	131.98	-
			Min	701	684	647	944
			Q1	845.0	851.0	850.0	944.0
			Median	938.0	908.5	937.0	944.0
			Q3	1033.0	979.0	1006.0	944.0
			Max	1250	1176	1346	944
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	10.4	14.3	3.0
			SD	-	103.21	110.85	-
			Min	-	-264	-340	3
			Q1	-	-58.0	-56.0	3.0
			Median	-	0.0	19.0	3.0
			Q3	-	61.0	97.0	3.0
			Max	-	310	288	3
		Placebo	n	-	78	79	1
			Mean	-	-13.1	-3.0	-104.0
			SD	-	81.02	107.80	-
			Min	-	-193	-279	-104
			Q1	-	-78.0	-70.0	-104.0
			Median	-	-6.5	-14.0	-104.0
			Q3	-	54.0	59.0	-104.0
			Max	-	182	275	-104

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
QRS Duration, Aggregate (msec)	Value	FSN-013	n	81	80	81	1
			Mean	89.4	88.8	88.8	93.0
			SD	10.86	10.31	11.23	-
			Min	63	53	56	93
			Q1	84.0	83.5	84.0	93.0
			Median	90.0	90.0	88.0	93.0
			Q3	96.0	94.5	94.0	93.0
			Max	114	113	116	93
		Placebo	n	79	78	79	1
			Mean	88.0	87.4	87.0	96.0
			SD	10.25	10.05	11.67	-
			Min	60	53	46	96
			Q1	80.0	82.0	78.0	96.0
			Median	90.0	88.5	89.0	96.0
			Q3	96.0	94.0	96.0	96.0
			Max	111	107	109	96
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-1.0	-0.7	4.0
			SD	-	4.64	6.16	-
			Min	-	-13	-20	4
			Q1	-	-3.0	-4.0	4.0
			Median	-	-1.0	-1.0	4.0
			Q3	-	2.0	2.0	4.0
			Max	-	10	30	4
		Placebo	n	-	78	79	1
			Mean	-	-0.7	-1.0	3.0
			SD	-	4.18	6.13	-
			Min	-	-11	-40	3
			Q1	-	-3.0	-3.0	3.0
			Median	-	0.0	0.0	3.0
			Q3	-	2.0	3.0	3.0
			Max	-	12	13	3

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
QT Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	1
			Mean	415 5	411 6	412 9	390 0
			SD	29 58	27 24	27 67	-
			Min	348	368	360	390
			Q1	396 0	390 0	393 0	390 0
			Median	412 0	406 5	412 0	390 0
			Q3	437 0	428 5	428 0	390 0
			Max	490	494	492	390
		Placebo	n	79	78	79	1
			Mean	408 3	402 0	403 3	409 0
			SD	25 59	30 49	28 85	-
			Min	349	352	348	409
			Q1	388 0	380 0	382 0	409 0
			Median	408 0	399 0	402 0	409 0
			Q3	425 0	418 0	420 0	409 0
			Max	474	536	475	409
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-4 3	-2 6	5 0
			SD	-	21 79	22 62	-
			Min	-	-48	-68	5
			Q1	-	-20 0	-20 0	5 0
			Median	-	-5 5	0 0	5 0
			Q3	-	9 0	12 0	5 0
			Max	-	65	64	5
		Placebo	n	-	78	79	1
			Mean	-	-6 1	-5 1	-20 0
			SD	-	21 99	22 20	-
			Min	-	-52	-55	-20
			Q1	-	-19 0	-20 0	-20 0
			Median	-	-7 5	-6 0	-20 0
			Q3	-	3 0	10 0	-20 0
			Max	-	114	60	-20

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
QTcB Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	1
			Mean	423.1	417.0	417.7	394.0
			SD	17.87	21.20	18.82	-
			Min	377	364	362	394
			Q1	412.0	408.0	411.0	394.0
			Median	422.0	415.0	418.0	394.0
			Q3	437.0	428.0	427.0	394.0
			Max	459	494	462	394
		Placebo	n	79	78	79	1
			Mean	422.8	419.2	418.5	421.0
			SD	16.50	21.06	16.89	-
			Min	386	389	380	421
			Q1	410.0	404.0	406.0	421.0
			Median	423.0	417.0	420.0	421.0
			Q3	432.0	429.0	431.0	421.0
			Max	459	527	453	421
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-6.2	-5.4	4.0
			SD	-	17.33	14.23	-
			Min	-	-47	-53	4
			Q1	-	-16.5	-14.0	4.0
			Median	-	-6.0	-5.0	4.0
			Q3	-	6.5	3.0	4.0
			Max	-	39	26	4
		Placebo	n	-	78	79	1
			Mean	-	-3.7	-4.4	2.0
			SD	-	19.11	14.61	-
			Min	-	-42	-34	2
			Q1	-	-13.0	-16.0	2.0
			Median	-	-5.0	-5.0	2.0
			Q3	-	2.0	4.0	2.0
			Max	-	130	35	2

表 2.7.4-226 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 17 / Discontinuation
QTcF Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	1
			Mean	420.4	415.1	415.8	393.0
			SD	18.17	19.16	17.38	-
			Min	384	370	367	393
			Q1	408.0	404.5	406.0	393.0
			Median	418.0	412.0	415.0	393.0
			Q3	434.0	425.5	426.0	393.0
			Max	463	492	467	393
		Placebo	n	79	78	79	1
			Mean	417.7	413.2	413.1	417.0
			SD	15.88	21.72	16.83	-
			Min	382	379	376	417
			Q1	406.0	398.0	402.0	417.0
			Median	417.0	410.5	414.0	417.0
			Q3	427.0	424.0	426.0	417.0
			Max	459	530	451	417
	Change from Baseline	FSN-013	n	-	80	81	1
			Mean	-	-5.6	-4.6	5.0
			SD	-	15.67	13.41	-
			Min	-	-46	-44	5
			Q1	-	-15.0	-12.0	5.0
			Median	-	-6.0	-4.0	5.0
			Q3	-	5.0	4.0	5.0
			Max	-	45	29	5
		Placebo	n	-	78	79	1
			Mean	-	-4.4	-4.7	-5.0
			SD	-	18.30	13.40	-
			Min	-	-33	-33	-5
			Q1	-	-13.0	-16.0	-5.0
			Median	-	-6.0	-4.0	-5.0
			Q3	-	1.0	4.0	-5.0
			Max	-	125	27	-5
[redacted]							

引用元：FSN-013P-03 試験（継続投与期）（資料番号 5.3.5.2-dys01）表 14-41 を引用

2.7.4.4.3.1.1.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、12 誘導心電図の異常の有無を表 2.7.4-227 に、心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、補正 QT（QTc）間隔［Bazett 補正法で補正した QTc（QTcB）及び Fridericia 補正法で補正した QTc（QTcF）］の測定値及びベースラインからの変化量を表 2.7.4-228 に示す。

投与 13 周期終了時点までに 12 誘導心電図検査に異常が認められた全ての被験者において、12 誘導心電図検査の異常を治験薬との因果関係が「関連あり」である TEAE として報告されたのは、FSN-013 群のみで 2 例（PT 別で、心電図 QT 延長が 1 例に 1 件、心電図 T 波逆転が 1 例に 1 件）認められたが、いずれの TEAE も重症度は軽度であり、いずれも試験終了までに回復が認められた。心拍数や各波間隔（PR、RR、QRS、QT、QTcB 及び QTcF）の平均変化量に特記すべき異常変動は認められなかった。

表 2.7.4-227 12 誘導心電図の異常の有無［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Treatment	Period	Analysis Visit	n	Normal n (%)	Abnormal n (%)
FSN-013	Baseline Observation Period	Visit3	81	77 (95.1)	4 (4.9)
	Comparative Period	Visit5	80	75 (93.8)	5 (6.3)
		Visit 8 / Discontinuation	81	76 (93.8)	5 (6.2)
	Extension Period	Visit12	75	70 (93.3)	5 (6.7)
		Visit 17 / Discontinuation	77	76 (98.7)	1 (1.3)
Placebo	Baseline Observation Period	Visit3	79	79 (100.0)	0 (0.0)
	Comparative Period	Visit5	78	77 (98.7)	1 (1.3)
		Visit 8 / Discontinuation	79	79 (100.0)	0 (0.0)
	Extension Period	Visit12	70	70 (100.0)	0 (0.0)
		Visit 17 / Discontinuation	74	74 (100.0)	0 (0.0)

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8

Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 9 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-30 を引用

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
ECG Mean Heart Rate (beats/min)	Value	FSN-013	n	81	80	81	75	77
			Mean	62.9	62.2	62.0	61.8	63.7
			SD	8.60	8.39	8.62	8.79	7.83
			Min	42	41	41	44	40
			Q1	58.0	57.0	56.0	56.0	58.0
			Median	63.0	61.5	62.0	62.0	63.0
			Q3	68.0	68.0	67.0	67.0	70.0
			Max	87	80	84	86	82
		Placebo	n	79	78	79	70	74
			Mean	65.0	65.8	65.5	64.2	64.6
			SD	8.30	7.82	9.42	8.82	8.34
			Min	48	51	45	46	46
			Q1	58.0	61.0	60.0	58.0	58.0
			Median	64.0	66.0	64.0	63.0	64.0
			Q3	71.0	71.0	70.0	69.0	69.0
			Max	86	88	93	90	93
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-0.6	-0.9	-0.9	1.1
			SD	-	7.23	7.38	6.60	7.40
			Min	-	-27	-20	-21	-23
			Q1	-	-4.0	-5.0	-5.0	-3.0
			Median	-	0.0	-1.0	0.0	1.0
			Q3	-	3.0	4.0	4.0	6.0
			Max	-	19	26	15	18
		Placebo	n	-	78	79	70	74
			Mean	-	0.8	0.5	-0.7	-0.4
			SD	-	5.86	8.20	7.60	6.99
			Min	-	-17	-20	-16	-16
			Q1	-	-4.0	-4.0	-6.0	-4.0
			Median	-	0.0	1.0	-1.5	1.0
			Q3	-	5.0	5.0	3.0	4.0
			Max	-	16	28	21	17

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
PR Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	75	77
			Mean	152.5	151.0	152.1	151.7	151.2
			SD	20.86	20.36	20.42	19.61	20.41
			Min	120	108	108	115	106
			Q1	139.0	136.0	140.0	138.0	137.0
			Median	146.0	148.0	147.0	146.0	146.0
			Q3	166.0	164.0	164.0	161.0	164.0
			Max	222	205	197	198	205
		Placebo	n	79	78	79	70	74
			Mean	150.2	151.0	150.7	150.8	148.7
			SD	17.01	18.43	17.90	19.72	20.56
			Min	116	111	110	116	113
			Q1	138.0	136.0	137.0	139.0	133.0
			Median	148.0	151.0	150.0	148.0	145.0
			Q3	163.0	164.0	163.0	163.0	164.0
			Max	188	208	190	198	208
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-1.6	-0.4	-1.9	-1.8
			SD	-	11.01	11.24	9.23	13.23
			Min	-	-32	-26	-30	-42
			Q1	-	-7.0	-7.0	-6.0	-8.0
			Median	-	-2.5	0.0	-2.0	-2.0
			Q3	-	6.0	5.0	4.0	4.0
			Max	-	36	38	16	60
		Placebo	n	-	78	79	70	74
			Mean	-	0.9	0.5	0.5	-1.5
			SD	-	10.66	11.56	11.81	12.90
			Min	-	-30	-39	-27	-21
			Q1	-	-6.0	-6.0	-6.0	-7.0
			Median	-	-0.5	2.0	0.5	-4.0
			Q3	-	6.0	8.0	8.0	1.0
			Max	-	36	24	30	77

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
RR Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	75	77
			Mean	970.1	982.0	984.4	988.6	956.3
			SD	133.16	138.63	140.75	143.39	126.78
			Min	690	750	714	698	732
			Q1	882.0	882.0	890.0	896.0	862.0
			Median	960.0	975.0	968.0	968.0	950.0
			Q3	1040.0	1056.5	1068.0	1070.0	1041.0
			Max	1424	1472	1452	1358	1517
		Placebo	n	79	78	79	70	74
			Mean	937.6	923.2	934.6	951.7	941.2
			SD	117.56	111.39	131.98	128.02	114.01
			Min	701	684	647	664	648
			Q1	845.0	851.0	850.0	866.0	868.0
			Median	938.0	908.5	937.0	951.0	941.0
			Q3	1033.0	979.0	1006.0	1034.0	1021.0
			Max	1250	1176	1346	1304	1304
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	10.4	14.3	13.9	-18.4
			SD	-	103.21	110.85	97.42	106.84
			Min	-	-264	-340	-268	-257
			Q1	-	-58.0	-56.0	-53.0	-96.0
			Median	-	0.0	19.0	0.0	-16.0
			Q3	-	61.0	97.0	94.0	54.0
			Max	-	310	288	240	269
		Placebo	n	-	78	79	70	74
			Mean	-	-13.1	-3.0	12.0	3.8
			SD	-	81.02	107.80	103.21	99.26
			Min	-	-193	-279	-265	-190
			Q1	-	-78.0	-70.0	-42.0	-73.0
			Median	-	-6.5	-14.0	15.0	-16.5
			Q3	-	54.0	59.0	79.0	66.0
			Max	-	182	275	254	254

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
QRS Duration, Aggregate (msec)	Value	FSN-013	n	81	80	81	75	77
			Mean	89.4	88.8	88.8	89.1	89.4
			SD	10.86	10.31	11.23	9.60	9.96
			Min	63	53	56	63	50
			Q1	84.0	83.5	84.0	84.0	84.0
			Median	90.0	90.0	88.0	89.0	90.0
			Q3	96.0	94.5	94.0	96.0	95.0
			Max	114	113	116	110	112
		Placebo	n	79	78	79	70	74
			Mean	88.0	87.4	87.0	87.5	87.5
			SD	10.25	10.05	11.67	9.63	10.48
			Min	60	53	46	60	46
			Q1	80.0	82.0	78.0	80.0	81.0
			Median	90.0	88.5	89.0	88.0	88.0
			Q3	96.0	94.0	96.0	93.0	93.0
			Max	111	107	109	106	107
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-1.0	-0.7	-0.9	-0.7
			SD	-	4.64	6.16	6.28	5.52
			Min	-	-13	-20	-22	-22
			Q1	-	-3.0	-4.0	-4.0	-4.0
			Median	-	-1.0	-1.0	-1.0	-1.0
			Q3	-	2.0	2.0	2.0	1.0
			Max	-	10	30	24	19
		Placebo	n	-	78	79	70	74
			Mean	-	-0.7	-1.0	-1.3	-1.3
			SD	-	4.18	6.13	4.81	5.26
			Min	-	-11	-40	-17	-24
			Q1	-	-3.0	-3.0	-4.0	-4.0
			Median	-	0.0	0.0	-1.0	-1.0
			Q3	-	2.0	3.0	2.0	2.0
			Max	-	12	13	13	11

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
QT Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	75	77
			Mean	415.5	411.6	412.9	415.9	409.5
			SD	29.58	27.24	27.67	29.90	28.67
			Min	348	368	360	362	353
			Q1	396.0	390.0	393.0	392.0	391.0
			Median	412.0	406.5	412.0	413.0	402.0
			Q3	437.0	428.5	428.0	435.0	426.0
			Max	490	494	492	509	486
		Placebo	n	79	78	79	70	74
			Mean	408.3	402.0	403.3	404.8	404.7
			SD	25.59	30.49	28.85	26.62	25.08
			Min	349	352	348	352	358
			Q1	388.0	380.0	382.0	387.0	382.0
			Median	408.0	399.0	402.0	404.0	406.0
			Q3	425.0	418.0	420.0	426.0	421.0
			Max	474	536	475	461	490
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-4.3	-2.6	-0.5	-6.9
			SD	-	21.79	22.62	20.91	23.20
			Min	-	-48	-68	-51	-63
			Q1	-	-20.0	-20.0	-12.0	-18.0
			Median	-	-5.5	0.0	-2.0	-6.0
			Q3	-	9.0	12.0	14.0	10.0
			Max	-	65	64	54	54
		Placebo	n	-	78	79	70	74
			Mean	-	-6.1	-5.1	-3.7	-3.6
			SD	-	21.99	22.20	18.45	20.09
			Min	-	-52	-55	-51	-48
			Q1	-	-19.0	-20.0	-17.0	-18.0
			Median	-	-7.5	-6.0	-0.5	-6.0
			Q3	-	3.0	10.0	11.0	8.0
			Max	-	114	60	38	50

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
QTcB Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	75	77
			Mean	423.1	417.0	417.7	419.7	420.0
			SD	17.87	21.20	18.82	19.02	20.28
			Min	377	364	362	371	368
			Q1	412.0	408.0	411.0	407.0	409.0
			Median	422.0	415.0	418.0	419.0	417.0
			Q3	437.0	428.0	427.0	433.0	437.0
			Max	459	494	462	463	467
		Placebo	n	79	78	79	70	74
			Mean	422.8	419.2	418.5	416.2	418.1
			SD	16.50	21.06	16.89	16.15	14.91
			Min	386	389	380	380	377
			Q1	410.0	404.0	406.0	408.0	407.0
			Median	423.0	417.0	420.0	414.0	419.5
			Q3	432.0	429.0	431.0	427.0	428.0
			Max	459	527	453	466	457
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-6.2	-5.4	-3.3	-3.0
			SD	-	17.33	14.23	14.60	15.17
			Min	-	-47	-53	-38	-52
			Q1	-	-16.5	-14.0	-14.0	-14.0
			Median	-	-6.0	-5.0	-1.0	-2.0
			Q3	-	6.5	3.0	8.0	7.0
			Max	-	39	26	30	36
		Placebo	n	-	78	79	70	74
			Mean	-	-3.7	-4.4	-6.3	-4.8
			SD	-	19.11	14.61	12.64	11.95
			Min	-	-42	-34	-33	-36
			Q1	-	-13.0	-16.0	-15.0	-13.0
			Median	-	-5.0	-5.0	-7.0	-5.5
			Q3	-	2.0	4.0	2.0	3.0
			Max	-	130	35	26	28

表 2.7.4-228 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-03 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		Extension Period	
				Visit 3	Visit 5	Visit 8 / Discontinuation	Visit 12	Visit 17 / Discontinuation
QTcF Interval, Aggregate (msec)	Value	FSN-013	n	81	80	81	75	77
			Mean	420 4	415 1	415 8	418 3	416 2
			SD	18 17	19 16	17 38	18 55	19 81
			Min	384	370	367	383	368
			Q1	408 0	404 5	406 0	404 0	406 0
			Median	418 0	412 0	415 0	418 0	413 0
			Q3	434 0	425 5	426 0	431 0	427 0
			Max	463	492	467	467	468
		Placebo	n	79	78	79	70	74
			Mean	417 7	413 2	413 1	412 1	413 6
			SD	15 88	21 72	16 83	15 56	14 69
			Min	382	379	376	376	380
			Q1	406 0	398 0	402 0	401 0	404 0
			Median	417 0	410 5	414 0	412 0	413 0
			Q3	427 0	424 0	426 0	420 0	425 0
			Max	459	530	451	457	449
	Change from Baseline	FSN-013	n	-	80	81	75	77
			Mean	-	-5 6	-4 6	-2 4	-4 4
			SD	-	15 67	13 41	14 01	14 50
			Min	-	-46	-44	-37	-50
			Q1	-	-15 0	-12 0	-12 0	-12 0
			Median	-	-6 0	-4 0	-1 0	-2 0
			Q3	-	5 0	4 0	7 0	4 0
			Max	-	45	29	27	34
		Placebo	n	-	78	79	70	74
			Mean	-	-4 4	-4 7	-5 5	-4 2
			SD	-	18 30	13 40	10 07	11 13
			Min	-	-33	-33	-30	-39
			Q1	-	-13 0	-16 0	-11 0	-12 0
			Median	-	-6 0	-4 0	-5 5	-5 0
			Q3	-	1 0	4 0	1 0	5 0
			Max	-	125	27	14	20

Visit 8 / Discontinuation : Visit 8 and Discontinued subjects until Visit 8
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 9 to Visit 17

引用元：FSN-013P-03 試験（継続投与期）（52 週）（資料番号 5.3.5.2-dys02）表 14-31 を引用

2.7.4.4.3.1.2 FSN-013P-04 試験

2.7.4.4.3.1.2.1 24 週投与

投与 6 周期終了時点までの安全性解析対象集団を対象とした、12 誘導心電図の異常の有無を表 2.7.4-229 に、心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量を表 2.7.4-230 に示す。

12 誘導心電図の異常の有無は FSN-013 群及びプラセボ群で大差はなく、心拍数や各波間隔（PR、RR、QRS、QT、QTcB 及び QTcF）の平均変化量に特記すべき異常変動は認められなかった。

表 2.7.4-229 12 誘導心電図の異常の有無［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Treatment	Period	Analysis Visit	n	Normal n (%)	Abnormal n (%)
FSN-013	Baseline Observation Period	Visit3	79	78 (98.7)	1 (1.3)
	Comparative Period	Visit5	78	76 (97.4)	2 (2.6)
		Visit 8	78	77 (98.7)	1 (1.3)
		Visit 10 / Discontinuation	78	78 (100.0)	0 (0.0)
Placebo	Baseline Observation Period	Visit3	83	82 (98.8)	1 (1.2)
	Comparative Period	Visit5	82	81 (98.8)	1 (1.2)
		Visit 8	80	79 (98.8)	1 (1.3)
		Visit 10 / Discontinuation	83	83 (100.0)	0 (0.0)

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-39 を引用

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
ECG Mean Heart Rate (beats/min)	Value	FSN-013	n	79	78	78	78
			Mean	65.1	64.4	65.4	66.4
			SD	8.50	8.88	8.69	9.23
			Min	47	48	47	48
			Q1	59.0	58.0	60.0	61.0
			Median	64.0	65.0	65.0	66.0
			Q3	71.0	69.0	72.0	72.0
			Max	90	90	86	90
		Placebo	n	83	82	80	83
			Mean	64.8	64.3	64.3	63.9
			SD	8.53	7.26	7.73	8.20
			Min	49	48	45	47
			Q1	60.0	60.0	59.0	59.0
			Median	64.0	64.0	64.0	63.0
			Q3	70.0	69.0	69.0	69.0
			Max	94	86	82	85
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0.7	0.3	1.2
			SD	-	6.05	6.88	7.52
			Min	-	-15	-21	-23
			Q1	-	-4.0	-4.0	-3.0
			Median	-	-1.5	1.0	1.5
			Q3	-	2.0	4.0	5.0
			Max	-	30	21	25
		Placebo	n	-	82	80	83
			Mean	-	-0.7	-0.6	-1.0
			SD	-	7.86	7.62	9.12
			Min	-	-28	-26	-28
			Q1	-	-5.0	-5.0	-6.0
			Median	-	0.5	0.0	-1.0
			Q3	-	5.0	4.5	4.0
			Max	-	13	15	17

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
PR Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78
			Mean	150.9	150.7	148.1	147.7
			SD	19.87	19.14	18.75	17.83
			Min	110	113	100	112
			Q1	136.0	137.0	134.0	132.0
			Median	147.0	149.0	146.0	145.0
			Q3	165.0	164.0	164.0	163.0
			Max	200	214	192	188
		Placebo	n	83	82	80	83
			Mean	154.6	152.0	154.3	153.6
			SD	21.49	21.05	20.39	17.99
			Min	110	106	112	116
			Q1	142.0	138.0	142.0	143.0
			Median	151.0	150.0	152.0	152.0
			Q3	168.0	158.0	160.0	162.0
			Max	224	215	211	222
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-0.5	-3.0	-3.5
			SD	-	10.17	8.14	9.57
			Min	-	-24	-24	-27
			Q1	-	-7.0	-8.0	-8.0
			Median	-	-1.5	-3.5	-4.0
			Q3	-	5.0	2.0	2.0
			Max	-	30	20	37
		Placebo	n	-	82	80	83
			Mean	-	-2.1	1.0	-1.0
			SD	-	14.56	11.34	15.38
			Min	-	-50	-23	-70
			Q1	-	-9.0	-6.0	-6.0
			Median	-	-4.0	0.0	0.0
			Q3	-	4.0	6.5	5.0
			Max	-	63	48	35

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
RR Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78
			Mean	936 0	948 3	933 2	920 5
			SD	118 79	128 98	131 21	129 61
			Min	667	667	693	662
			Q1	845 0	870 0	826 0	832 0
			Median	934 0	922 5	918 5	909 0
			Q3	1020 0	1033 0	1000 0	985 0
			Max	1277	1250	1277	1234
		Placebo	n	83	82	80	83
			Mean	939 9	943 3	945 3	954 1
			SD	119 96	107 71	116 85	123 26
			Min	641	698	732	706
			Q1	862 0	865 0	866 0	870 0
			Median	938 0	937 0	935 0	951 0
			Q3	1003 0	994 0	1016 5	1017 0
			Max	1220	1250	1322	1273
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	11 9	-3 2	-12 7
			SD	-	88 73	99 05	104 35
			Min	-	-390	-248	-377
			Q1	-	-29 0	-60 0	-69 0
			Median	-	21 5	-12 0	-20 5
			Q3	-	60 0	55 0	37 0
			Max	-	212	342	308
		Placebo	n	-	82	80	83
			Mean	-	5 5	6 3	14 2
			SD	-	104 35	100 95	127 23
			Min	-	-180	-208	-220
			Q1	-	-81 0	-66 0	-70 0
			Median	-	-6 5	2 0	16 0
			Q3	-	76 0	71 5	70 0
			Max	-	293	322	431

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
QRS Duration, Aggregate (msec)	Value	FSN-013	n	79	78	78	78
			Mean	89.7	88.6	89.2	89.0
			SD	9.21	9.94	9.53	9.60
			Min	66	63	74	72
			Q1	83.0	82.0	82.0	82.0
			Median	88.0	87.0	88.0	88.5
			Q3	96.0	97.0	97.0	96.0
			Max	112	107	117	110
		Placebo	n	83	82	80	83
			Mean	90.0	89.3	88.7	89.0
			SD	11.43	9.69	10.34	10.16
			Min	63	66	56	60
			Q1	84.0	84.0	83.0	83.0
			Median	90.0	89.5	89.0	90.0
			Q3	96.0	96.0	95.5	96.0
			Max	127	108	112	118
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-1.2	-0.6	-0.9
			SD	-	3.37	4.25	4.80
			Min	-	-10	-10	-14
			Q1	-	-4.0	-3.0	-4.0
			Median	-	-2.0	-1.0	-0.5
			Q3	-	1.0	2.0	2.0
			Max	-	9	17	14
		Placebo	n	-	82	80	83
			Mean	-	-0.7	-1.0	-1.0
			SD	-	7.65	7.86	7.10
			Min	-	-33	-38	-35
			Q1	-	-3.0	-4.0	-4.0
			Median	-	0.0	0.0	0.0
			Q3	-	3.0	3.0	3.0
			Max	-	22	26	22

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
QT Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78
			Mean	406.6	403.7	401.3	399.3
			SD	29.63	25.49	25.15	26.09
			Min	354	348	360	348
			Q1	387.0	386.0	380.0	382.0
			Median	406.0	401.0	398.0	401.0
			Q3	423.0	420.0	416.0	414.0
			Max	556	500	482	460
		Placebo	n	83	82	80	83
			Mean	408.9	403.1	405.7	407.6
			SD	25.17	22.44	26.52	26.50
			Min	344	348	346	346
			Q1	392.0	388.0	389.0	392.0
			Median	413.0	402.0	405.0	403.0
			Q3	422.0	416.0	422.0	426.0
			Max	471	457	486	488
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-2.9	-5.4	-7.4
			SD	-	22.58	23.95	24.82
			Min	-	-136	-150	-140
			Q1	-	-10.0	-15.0	-18.0
			Median	-	2.0	-6.0	-5.5
			Q3	-	10.0	6.0	8.0
			Max	-	26	50	56
		Placebo	n	-	82	80	83
			Mean	-	-5.1	-2.6	-1.3
			SD	-	19.00	20.84	23.23
			Min	-	-42	-55	-68
			Q1	-	-20.0	-16.5	-16.0
			Median	-	-7.0	-3.0	-2.0
			Q3	-	5.0	10.0	17.0
			Max	-	47	49	52

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
QTcB Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78
			Mean	421.6	416.3	417.1	417.7
			SD	24.64	23.97	23.63	17.84
			Min	370	347	373	364
			Q1	410.0	404.0	402.0	406.0
			Median	423.0	416.5	418.0	418.0
			Q3	432.0	428.0	429.0	430.0
			Max	540	544	543	461
		Placebo	n	83	82	80	83
			Mean	423.0	416.1	418.1	418.4
			SD	18.88	16.82	14.45	17.28
			Min	372	372	366	370
			Q1	413.0	406.0	410.0	410.0
			Median	425.0	414.5	421.0	417.0
			Q3	433.0	429.0	428.0	430.0
			Max	470	456	453	469
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-5.2	-4.4	-4.5
			SD	-	17.15	20.94	22.07
			Min	-	-110	-131	-139
			Q1	-	-14.0	-11.0	-11.0
			Median	-	-6.5	-2.5	-4.0
			Q3	-	5.0	4.0	5.0
			Max	-	24	81	53
		Placebo	n	-	82	80	83
			Mean	-	-6.8	-4.6	-4.6
			SD	-	16.08	16.75	17.65
			Min	-	-49	-54	-50
			Q1	-	-16.0	-14.0	-15.0
			Median	-	-6.0	-5.5	-2.0
			Q3	-	5.0	6.0	9.0
			Max	-	27	44	25

表 2.7.4-230 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（24 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period		
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation
QTcF Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78
			Mean	416 4	411 9	411 6	411 2
			SD	23 25	20 70	20 15	16 20
			Min	372	358	372	366
			Q1	405 0	404 0	400 0	402 0
			Median	415 0	410 5	409 5	413 0
			Q3	425 0	420 0	419 0	421 0
			Max	534	529	522	444
		Placebo	n	83	82	80	83
			Mean	418 1	411 6	413 8	414 6
			SD	17 05	15 51	15 42	16 63
			Min	365	373	359	377
			Q1	410 0	402 0	404 0	405 0
			Median	417 0	411 5	414 0	415 0
			Q3	430 0	420 0	424 5	424 0
			Max	455	449	444	460
	Change from Baseline	FSN-013	n	-	78	78	78
			Mean	-	-4 4	-4 7	-5 6
			SD	-	16 86	19 48	20 43
			Min	-	-119	-137	-140
			Q1	-	-11 0	-12 0	-11 0
			Median	-	-4 0	-3 5	-4 0
			Q3	-	5 0	3 0	3 0
			Max	-	22	58	26
		Placebo	n	-	82	80	83
			Mean	-	-6 2	-3 9	-3 5
			SD	-	12 95	14 59	14 30
			Min	-	-40	-36	-47
			Q1	-	-14 0	-15 0	-13 0
			Median	-	-7 0	-3 5	-3 0
			Q3	-	2 0	3 0	6 0
			Max	-	29	43	28

引用元：FSN-013P-04 試験（継続投与期）（資料番号 5.3.5.2-end01）表 14-40 を引用

2.7.4.4.3.1.2.2 52 週投与

投与 13 周期終了時点までの安全性解析対象集団を対象とした、12 誘導心電図の異常の有無を表 2.7.4-231 に、心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、補正 QT（QTc）間隔［Bazett 補正法で補正した QTc（QTcB）及び Fridericia 補正法で補正した QTc（QTcF）］の測定値及びベースラインからの変化量を表 2.7.4-232 に示す。

投与 13 周期終了時点までに、FSN-013 群及びプラセボ群で、12 誘導心電図検査に異常があった被験者は認められたが、治験薬と因果関係ありと判定された有害事象はなく、心拍数や各波間隔（PR、RR、QRS、QT、QTcB 及び QTcF）の平均変化量に特記すべき異常変動は認められなかった。

表 2.7.4-231 12 誘導心電図の異常の有無［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Treatment	Period	Analysis Visit	n	Normal n (%)	Abnormal n (%)
FSN-013	Baseline Observation Period	Visit3	79	78 (98.7)	1 (1.3)
	Comparative Period	Visit5	78	76 (97.4)	2 (2.6)
		Visit 8	78	77 (98.7)	1 (1.3)
		Visit 10 / Discontinuation	78	78 (100.0)	0 (0.0)
	Extension Period	Visit 14	71	69 (97.2)	2 (2.8)
		Visit 17 / Discontinuation	76	75 (98.7)	1 (1.3)
Placebo	Baseline Observation Period	Visit3	83	82 (98.8)	1 (1.2)
	Comparative Period	Visit5	82	81 (98.8)	1 (1.2)
		Visit 8	80	79 (98.8)	1 (1.3)
		Visit 10 / Discontinuation	83	83 (100.0)	0 (0.0)
	Extension Period	Visit 14	74	74 (100.0)	0 (0.0)
		Visit 17 / Discontinuation	76	76 (100.0)	0 (0.0)

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10.
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17.
引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-30 を引用

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
ECG Mean Heart Rate (beats/min)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	65.1	64.4	65.4	66.4	66.1	66.2
			SD	8.50	8.88	8.69	9.23	8.75	9.73
			Min	47	48	47	48	45	47
			Q1	59.0	58.0	60.0	61.0	60.0	58.0
			Median	64.0	65.0	65.0	66.0	66.0	67.0
			Q3	71.0	69.0	72.0	72.0	72.0	73.0
			Max	90	90	86	90	90	94
		Placebo	n	83	82	80	83	74	76
			Mean	64.8	64.3	64.3	63.9	65.0	64.4
			SD	8.53	7.26	7.73	8.20	7.15	8.37
			Min	49	48	45	47	48	49
			Q1	60.0	60.0	59.0	59.0	60.0	59.0
			Median	64.0	64.0	64.0	63.0	64.5	64.0
			Q3	70.0	69.0	69.0	69.0	70.0	68.0
			Max	94	86	82	85	81	106
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-0.7	0.3	1.2	0.8	0.9
			SD	-	6.05	6.88	7.52	6.17	6.45
			Min	-	-15	-21	-23	-20	-21
			Q1	-	-4.0	-4.0	-3.0	-3.0	-3.0
			Median	-	-1.5	1.0	1.5	2.0	1.0
			Q3	-	2.0	4.0	5.0	5.0	5.0
			Max	-	30	21	25	14	20
		Placebo	n	-	82	80	83	74	76
			Mean	-	-0.7	-0.6	-1.0	-0.2	-0.7
			SD	-	7.86	7.62	9.12	8.44	8.15
			Min	-	-28	-26	-28	-21	-18
			Q1	-	-5.0	-5.0	-6.0	-6.0	-6.5
			Median	-	0.5	0.0	-1.0	0.5	0.5
			Q3	-	5.0	4.5	4.0	6.0	5.0
			Max	-	13	15	17	17	25

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
PR Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	150 9	150 7	148 1	147 7	150 1	147 4
			SD	19 87	19 14	18 75	17 83	18 41	19 16
			Min	110	113	100	112	122	106
			Q1	136 0	137 0	134 0	132 0	134 0	132 0
			Median	147 0	149 0	146 0	145 0	148 0	144 0
			Q3	165 0	164 0	164 0	163 0	164 0	161 0
			Max	200	214	192	188	194	202
		Placebo	n	83	82	80	83	74	76
			Mean	154 6	152 0	154 3	153 6	151 4	151 7
			SD	21 49	21 05	20 39	17 99	18 82	18 95
			Min	110	106	112	116	104	104
			Q1	142 0	138 0	142 0	143 0	142 0	140 0
			Median	151 0	150 0	152 0	152 0	148 0	149 0
			Q3	168 0	158 0	160 0	162 0	158 0	158 5
			Max	224	215	211	222	210	208
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-0 5	-3 0	-3 5	-2 5	-4 1
			SD	-	10 17	8 14	9 57	9 90	9 33
			Min	-	-24	-24	-27	-28	-26
			Q1	-	-7 0	-8 0	-8 0	-8 0	-9 0
			Median	-	-1 5	-3 5	-4 0	-4 0	-4 0
			Q3	-	5 0	2 0	2 0	0 0	0 0
			Max	-	30	20	37	38	22
		Placebo	n	-	82	80	83	74	76
			Mean	-	-2 1	1 0	-1 0	-2 0	-1 9
			SD	-	14 56	11 34	15 38	13 54	17 02
			Min	-	-50	-23	-70	-68	-68
			Q1	-	-9 0	-6 0	-6 0	-8 0	-8 0
			Median	-	-4 0	0 0	0 0	-3 5	-2 0
			Q3	-	4 0	6 5	5 0	4 0	6 0
			Max	-	63	48	35	34	60

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
RR Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	936 0	948 3	933 2	920 5	923 7	924 0
			SD	118 79	128 98	131 21	129 61	129 15	136 40
			Min	667	667	693	662	667	638
			Q1	845 0	870 0	826 0	832 0	831 0	823 5
			Median	934 0	922 5	918 5	909 0	909 0	894 5
			Q3	1020 0	1033 0	1000 0	985 0	1005 0	1026 5
			Max	1277	1250	1277	1234	1333	1257
		Placebo	n	83	82	80	83	74	76
			Mean	939 9	943 3	945 3	954 1	932 6	947 7
			SD	119 96	107 71	116 85	123 26	104 83	113 95
			Min	641	698	732	706	741	566
			Q1	862 0	865 0	866 0	870 0	857 0	882 0
			Median	938 0	937 0	935 0	951 0	924 5	937 0
			Q3	1003 0	994 0	1016 5	1017 0	993 0	1021 5
			Max	1220	1250	1322	1273	1248	1213
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	11 9	-3 2	-12 7	-9 1	-9 3
			SD	-	88 73	99 05	104 35	88 81	92 36
			Min	-	-390	-248	-377	-193	-222
			Q1	-	-29 0	-60 0	-69 0	-64 0	-74 5
			Median	-	21 5	-12 0	-20 5	-21 0	-15 5
			Q3	-	60 0	55 0	37 0	44 0	46 5
			Max	-	212	342	308	206	334
		Placebo	n	-	82	80	83	74	76
			Mean	-	5 5	6 3	14 2	-2 6	11 1
			SD	-	104 35	100 95	127 23	115 48	108 50
			Min	-	-180	-208	-220	-276	-209
			Q1	-	-81 0	-66 0	-70 0	-80 0	-69 0
			Median	-	-6 5	2 0	16 0	-11 5	-0 5
			Q3	-	76 0	71 5	70 0	94 0	109 0
			Max	-	293	322	431	253	245

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
QRS Duration, Aggregate (msec)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	89 7	88 6	89 2	89 0	88 4	88 8
			SD	9 21	9 94	9 53	9 60	12 40	9 97
			Min	66	63	74	72	20	63
			Q1	83 0	82 0	82 0	82 0	82 0	82 0
			Median	88 0	87 0	88 0	88 5	89 0	88 0
			Q3	96 0	97 0	97 0	96 0	97 0	97 0
			Max	112	107	117	110	112	110
		Placebo	n	83	82	80	83	74	76
			Mean	90 0	89 3	88 7	89 0	88 7	87 8
			SD	11 43	9 69	10 34	10 16	9 68	8 92
			Min	63	66	56	60	68	66
			Q1	84 0	84 0	83 0	83 0	83 0	82 0
			Median	90 0	89 5	89 0	90 0	88 0	88 0
			Q3	96 0	96 0	95 5	96 0	96 0	94 0
			Max	127	108	112	118	112	113
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-1 2	-0 6	-0 9	-1 8	-1 2
			SD	-	3 37	4 25	4 80	9 00	5 02
			Min	-	-10	-10	-14	-64	-17
			Q1	-	-4 0	-3 0	-4 0	-4 0	-4 0
			Median	-	-2 0	-1 0	-0 5	-2 0	-2 0
			Q3	-	1 0	2 0	2 0	2 0	1 0
			Max	-	9	17	14	14	22
		Placebo	n	-	82	80	83	74	76
			Mean	-	-0 7	-1 0	-1 0	-1 4	-2 1
			SD	-	7 65	7 86	7 10	6 69	7 51
			Min	-	-33	-38	-35	-31	-34
			Q1	-	-3 0	-4 0	-4 0	-4 0	-5 5
			Median	-	0 0	0 0	0 0	-2 0	0 0
			Q3	-	3 0	3 0	3 0	2 0	1 5
			Max	-	22	26	22	22	20

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
QT Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	406.6	403.7	401.3	399.3	400.4	400.1
			SD	29.63	25.49	25.15	26.09	26.99	27.50
			Min	354	348	360	348	346	341
			Q1	387.0	386.0	380.0	382.0	380.0	380.5
			Median	406.0	401.0	398.0	401.0	396.0	394.0
			Q3	423.0	420.0	416.0	414.0	418.0	420.0
			Max	556	500	482	460	506	468
		Placebo	n	83	82	80	83	74	76
			Mean	408.9	403.1	405.7	407.6	401.6	404.6
			SD	25.17	22.44	26.52	26.50	22.32	23.02
			Min	344	348	346	346	344	328
			Q1	392.0	388.0	389.0	392.0	388.0	394.0
			Median	413.0	402.0	405.0	403.0	403.0	404.0
			Q3	422.0	416.0	422.0	426.0	418.0	419.5
			Max	471	457	486	488	454	454
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-2.9	-5.4	-7.4	-6.9	-6.4
			SD	-	22.58	23.95	24.82	22.49	24.31
			Min	-	-136	-150	-140	-130	-130
			Q1	-	-10.0	-15.0	-18.0	-18.0	-16.0
			Median	-	2.0	-6.0	-5.5	-6.0	-6.5
			Q3	-	10.0	6.0	8.0	6.0	7.5
			Max	-	26	50	56	36	51
		Placebo	n	-	82	80	83	74	76
			Mean	-	-5.1	-2.6	-1.3	-6.9	-3.2
			SD	-	19.00	20.84	23.23	20.36	20.59
			Min	-	-42	-55	-68	-58	-42
			Q1	-	-20.0	-16.5	-16.0	-22.0	-18.5
			Median	-	-7.0	-3.0	-2.0	-7.5	-6.5
			Q3	-	5.0	10.0	17.0	4.0	13.0
			Max	-	47	49	52	48	48

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
QTcB Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	421 6	416 3	417 1	417 7	418 2	417 9
			SD	24 64	23 97	23 63	17 84	21 87	18 48
			Min	370	347	373	364	364	354
			Q1	410 0	404 0	402 0	406 0	408 0	405 5
			Median	423 0	416 5	418 0	418 0	420 0	421 0
			Q3	432 0	428 0	429 0	430 0	429 0	430 0
			Max	540	544	543	461	531	476
		Placebo	n	83	82	80	83	74	76
			Mean	423 0	416 1	418 1	418 4	416 9	416 8
			SD	18 88	16 82	14 45	17 28	18 91	17 92
			Min	372	372	366	370	372	361
			Q1	413 0	406 0	410 0	410 0	406 0	407 0
			Median	425 0	414 5	421 0	417 0	416 0	417 0
			Q3	433 0	429 0	428 0	430 0	430 0	429 0
			Max	470	456	453	469	467	460
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-5 2	-4 4	-4 5	-4 7	-4 1
			SD	-	17 15	20 94	22 07	17 41	19 64
			Min	-	-110	-131	-139	-115	-119
			Q1	-	-14 0	-11 0	-11 0	-10 0	-11 0
			Median	-	-6 5	-2 5	-4 0	-5 0	-0 5
			Q3	-	5 0	4 0	5 0	4 0	8 0
			Max	-	24	81	53	30	26
		Placebo	n	-	82	80	83	74	76
			Mean	-	-6 8	-4 6	-4 6	-6 8	-5 8
			SD	-	16 08	16 75	17 65	16 47	16 99
			Min	-	-49	-54	-50	-40	-58
			Q1	-	-16 0	-14 0	-15 0	-20 0	-15 0
			Median	-	-6 0	-5 5	-2 0	-7 5	-4 0
			Q3	-	5 0	6 0	9 0	6 0	5 0
			Max	-	27	44	25	34	26

表 2.7.4-232 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量［FSN-013P-04 試験（継続投与期）］（安全性解析対象集団）（52 週）（続き）

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Comparative Period			Extension Period	
				Visit 3	Visit 5	Visit 8	Visit 10 / Discontinuation	Visit 14	Visit 17 / Discontinuation
QTcF Interval, Aggregate (msec)	Value	FSN-013	n	79	78	78	78	71	76
			Mean	416 4	411 9	411 6	411 2	412 0	411 6
			SD	23 25	20 70	20 15	16 20	19 90	16 84
			Min	372	358	372	366	374	358
			Q1	405 0	404 0	400 0	402 0	400 0	402 5
			Median	415 0	410 5	409 5	413 0	411 0	413 0
			Q3	425 0	420 0	419 0	421 0	420 0	422 0
			Max	534	529	522	444	522	461
		Placebo	n	83	82	80	83	74	76
			Mean	418 1	411 6	413 8	414 6	411 6	412 5
			SD	17 05	15 51	15 42	16 63	17 09	15 97
			Min	365	373	359	377	362	369
			Q1	410 0	402 0	404 0	405 0	402 0	401 5
			Median	417 0	411 5	414 0	415 0	411 0	412 5
			Q3	430 0	420 0	424 5	424 0	422 0	424 0
			Max	455	449	444	460	452	441
	Change from Baseline	FSN-013	n	-	78	78	78	71	76
			Mean	-	-4 4	-4 7	-5 6	-5 5	-5 0
			SD	-	16 86	19 48	20 43	16 86	19 08
			Min	-	-119	-137	-140	-120	-123
			Q1	-	-11 0	-12 0	-11 0	-11 0	-10 0
			Median	-	-4 0	-3 5	-4 0	-4 0	-3 0
			Q3	-	5 0	3 0	3 0	1 0	5 0
			Max	-	22	58	26	21	22
		Placebo	n	-	82	80	83	74	76
			Mean	-	-6 2	-3 9	-3 5	-6 8	-5 0
			SD	-	12 95	14 59	14 30	12 97	14 35
			Min	-	-40	-36	-47	-34	-47
			Q1	-	-14 0	-15 0	-13 0	-15 0	-12 0
			Median	-	-7 0	-3 5	-3 0	-8 0	-5 0
			Q3	-	2 0	3 0	6 0	0 0	3 0
			Max	-	29	43	28	39	26

Visit 10 / Discontinuation : Visit 10 and Discontinued subjects until Visit 10
Visit 17 / Discontinuation : Visit 17 and Discontinued subjects from Visit 11 to Visit 17

引用元：FSN-013P-04 試験（継続投与期）（52 週）（資料番号 5.3.5.2-end02）表 14-31 を引用

2.7.4.4.3.1.3 FSN-013P-03 試験及び FSN-013P-04 試験の併合

2.7.4.4.3.1.3.1 24 週投与

投与 6 周期終了時点までの Primary Safety Population を対象とした、心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量を表 2.7.4-233 に、12 誘導心電図の異常の有無を表 2.7.4-234 に、QTcB、QTcF の評価時点ごとの測定値及びベースラインからの変化量を表 2.7.4-235、表 2.7.4-236 に示す。

各波間隔（RR、QRS、QT、QTcB 及び QTcF）の平均変化量に特記すべき異常変動は認められなかった。QTcB 又は QTcF がベースライン時に正常であり、FSN-013 投与後に 480 msec、又は特に懸念すべき 500 msec を超える被験者の割合について、QTcB では認められなかった。QTcF では投与 1 周期後に 1 例 480 msec を超えた被験者が認められたが、投与 6 周期終了時点で QTcB 及び QTcF ともに 480 msec 及び 500 msec を超えた被験者は認められなかった。

表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

				Baseline Observation Period	Post-Baseline Period		
Parameter	Value	Treatment	Statistic	Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
ECG Mean Heart Rate (beats/min)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	64 0	63 3	63 7	66 3
			SD	8 59	8 68	8 79	9 19
			Min	42	41	41	48
			Q1	58 0	57 0	58 0	61 0
			Median	63 0	63 0	63 0	66 0
			Q3	70 0	68 0	71 0	72 0
			Max	90	90	86	90
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-0 6	-0 3	1 1
			SD	-	6 65	7 14	7 48
			Min	-	-27	-21	-23
			Q1	-	-4 0	-5 0	-3 0
			Median	-	-1 0	0 0	1 0
			Q3	-	3 0	4 0	5 0
			Max	-	30	26	25

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: adeg

表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
PR Interval, Aggregate (msec)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	151 7	150 8	150 1	147 8
			SD	20 33	19 70	19 66	17 72
			Min	110	108	100	112
			Q1	136 0	136 0	136 0	132 0
			Median	146 0	148 0	147 0	146 0
			Q3	165 5	164 0	164 0	163 0
			Max	222	214	197	188
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-1 1	-1 7	-3 1
			SD	-	10 59	9 90	10 36
			Min	-	-32	-26	-27
			Q1	-	-7 0	-8 0	-8 0
			Median	-	-2 0	-2 0	-4 0
			Q3	-	5 0	4 0	2 0
			Max	-	36	38	37

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: adeg

表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
RR Interval, Aggregate (msec)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	953 3	965 3	959 3	921 3
			SD	127 03	134 59	138 13	128 96
			Min	667	667	693	662
			Q1	857 0	877 0	848 0	832 0
			Median	952 5	952 0	943 0	909 0
			Q3	1030 5	1053 0	1033 0	985 0
			Max	1424	1472	1452	1234
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	11 1	5 7	-12 5
			SD	-	96 03	105 26	103 69
			Min	-	-390	-340	-377
			Q1	-	-44 0	-60 0	-69 0
			Median	-	9 5	-1 0	-20 0
			Q3	-	61 0	81 0	37 0
			Max	-	310	342	308

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: adeg

表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
QRS Duration, Aggregate (msec)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	89 6	88 7	89 0	89 1
			SD	10 05	10 10	10 40	9 55
			Min	63	53	56	72
			Q1	83 5	82 0	83 0	82 0
			Median	89 5	88 0	88 0	89 0
			Q3	96 0	96 0	96 0	96 0
			Max	114	113	117	110
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-1 1	-0 6	-0 8
			SD	-	4 06	5 29	4 80
			Min	-	-13	-20	-14
			Q1	-	-3 0	-4 0	-4 0
			Median	-	-1 0	-1 0	0 0
			Q3	-	1 0	2 0	2 0
			Max	-	10	30	14

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
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Data Source: adeg

表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
QT Interval, Aggregate (msec)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	411 1	407 7	407 2	399 2
			SD	29 84	26 60	27 01	25 95
			Min	348	348	360	348
			Q1	390 0	389 0	388 0	382 0
			Median	410 0	404 5	406 0	400 0
			Q3	428 0	422 0	424 0	414 0
			Max	556	500	492	460
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-3 6	-4 0	-7 2
			SD	-	22 12	23 25	24 70
			Min	-	-136	-150	-140
			Q1	-	-14 0	-18 0	-18 0
			Median	-	0 0	-4 0	-5 0
			Q3	-	10 0	8 0	8 0
			Max	-	65	64	56

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: adeg

表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
QTcB Interval, Aggregate (msec)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	422 4	416 7	417 4	417 4
			SD	21 42	22 54	21 25	17 92
			Min	370	347	362	364
			Q1	411 0	406 0	408 0	404 0
			Median	423 0	415 5	418 0	418 0
			Q3	435 0	428 0	428 0	430 0
			Max	540	544	543	461
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-5 7	-4 9	-4 4
			SD	-	17 19	17 79	21 95
			Min	-	-110	-131	-139
			Q1	-	-15 0	-13 0	-11 0
			Median	-	-6 5	-4 0	-4 0
			Q3	-	5 0	4 0	5 0
			Max	-	39	81	53

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
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表 2.7.4-233 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）（続き）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Baseline Period		
				Visit 3	Visit 5	Visit 8 / Discontinuation	End of week 24
QTcF Interval, Aggregate (msec)	Value	FSN-013 Pooled	n	160	158	159	79
			Mean	418 4	413 5	413 8	411 0
			SD	20 86	19 94	18 85	16 23
			Min	372	358	367	366
			Q1	406 5	404 0	402 0	400 0
			Median	417 0	411 5	413 0	413 0
			Q3	428 0	423 0	424 0	421 0
			Max	534	529	522	444
	Change from Baseline	FSN-013 Pooled	n	-	158	159	79
			Mean	-	-5 0	-4 6	-5 4
			SD	-	16 23	16 61	20 33
			Min	-	-119	-137	-140
			Q1	-	-12 0	-12 0	-11 0
			Median	-	-5 0	-4 0	-4 0
			Q3	-	5 0	3 0	4 0
			Max	-	45	58	26

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Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04

Program Name: t_4_4_5_1.sas / Output: t_4_4_5_1.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: adeg

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-74 を引用

表 2.7.4-234 12 誘導心電図の異常の有無（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.5.2 Frequency of Abnormality in 12-Lead ECG (SAS)

FSN-013 Pooled N=160							
Baseline Observation Period		Post-Baseline Period					
Visit3 n=160		Visit5 n=158		Visit 8 / Discontinuation n=159		End of week 24 n=79	
Normal n (%)	Abnormal n (%)	Normal n (%)	Abnormal n (%)	Normal n (%)	Abnormal n (%)	Normal n (%)	Abnormal n (%)
155 (96.9)	5 (3.1)	151 (95.6)	7 (4.4)	153 (96.2)	6 (3.8)	79 (100.0)	0 (0.0)

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Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04.
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04.

Program Name: t_4_4_5_2.sas / Output: t_4_4_5_2.rtf
Date of Table Generation: 2023-02-20 8:51
Data Source: adeg

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-75 を引用

表 2.7.4-235 QTcB の評価時点ごとの測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.5.3 Summary of Changes in QTcB (SAS)

Parameter (unit) Category	FSN-013 Pooled N=160		
	Visit 5	Visit 8 / Discontinuation	End of week 24
Categorical/Clinically significant Shifts (Normal Baseline Values) [n]:	151	152	77
QTcB >450 ms [n(%)]	2 (1.3)	4 (2.6)	0 (0.0)
QTcB >480 ms [n(%)]	0 (0.0)	0 (0.0)	0 (0.0)
QTcB >500 ms [n(%)]	0 (0.0)	0 (0.0)	0 (0.0)
Categorical/Clinically significant Shifts (Abnormal Baseline Values) [n]:	7	7	2
QTcB >450 ms [n(%)]	2 (28.6)	3 (42.9)	1 (50.0)
QTcB >480 ms [n(%)]	2 (28.6)	1 (14.3)	0 (0.0)
QTcB >500 ms [n(%)]	1 (14.3)	1 (14.3)	0 (0.0)

Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04.
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04.

Program Name: t_4_4_5_3.sas / Output: t_4_4_5_3.rtf
Date of Table Generation: 2023-02-20 8:52
Data Source: adeg

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-76 を引用

表 2.7.4-236 QTcF の評価時点ごとの測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population）（24 週）

Table 4.4.5.4 Summary of Changes in QTcF (SAS)

Parameter (unit) Category	FSN-013 Pooled N=160		
	Visit 5	Visit 8 / Discontinuation	End of week 24
Categorical/Clinically significant Shifts (Normal Baseline Values) [n]:	152	153	77
QTcF >450 ms [n(%)]	1 (0.7)	4 (2.6)	0 (0.0)
QTcF >480 ms [n(%)]	1 (0.7)	0 (0.0)	0 (0.0)
QTcF >500 ms [n(%)]	0 (0.0)	0 (0.0)	0 (0.0)
Categorical/Clinically significant Shifts (Abnormal Baseline Values) [n]:	6	6	2
QTcF >450 ms [n(%)]	2 (33.3)	3 (50.0)	0 (0.0)
QTcF >480 ms [n(%)]	1 (16.7)	1 (16.7)	0 (0.0)
QTcF >500 ms [n(%)]	1 (16.7)	1 (16.7)	0 (0.0)

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Visit 8/discontinuation includes Visit 8/discontinuation of FSN-013P-03 and Visit 8 of FSN-013P-04.
End of Week 24 includes Visit 17/discontinuation of FSN-013P-03 and Visit 10/discontinuation of FSN-013P-04.

Program Name: t_4_4_5_4.sas / Output: t_4_4_5_4.rtf
Date of Table Generation: 2023-02-20 8:52
Data Source: adeg

引用元：FSN-013P-03 試験及び FSN-013P-04 試験の併合（資料番号 5.3.5.3-int01）表 6-77 を引用

2.7.4.4.3.1.3.2 52 週投与

投与 13 周期終了時点までの Primary Safety Population 及び Secondary Safety Population を対象とした、心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量を表 2.7.4-237 に、12 誘導心電図の異常の有無を表 2.7.4-238 に、QTcB、QTcF の評価時点ごとの測定値及びベースラインからの変化量を表 2.7.4-239、表 2.7.4-240 に示す。

Primary Safety Population 及び Secondary Safety Population において、いずれも各波間隔（PR、RR、QRS、QT、QTcB 及び QTcF）の平均変化量に特記すべき異常変動は認められなかった。12 誘導心電図検査の異常を治験薬との因果関係が「関連あり」である TEAE として報告されたのは 2 例（PT 別で、心電図 QT 延長が 1 例に 1 件、心電図 T 波逆転が 1 例に 1 件）認められたが、いずれの TEAE も重症度は軽度であり、いずれも試験終了までに回復が認められた。また、Primary Safety Population 及び Secondary Safety Population において、QTcB 又は QTcF がベースライン時に正常であり、FSN-013 投与後に 480 msec、又は特に懸念すべき 500 msec を超える被験者は QTcB では認められなかったが、QTcF では FSN-013 の投与 1 周期（Cycle 1）に 480 msec を超えた被験者が 1 例認められた。なお、Primary Safety Population 及び Secondary Safety Population で、試験終了（Visit 17）又は中止時で QTcB 及び QTcF ともに 480 msec 及び 500 msec を超えた被験者は認められなかった。

表 2.7.4-237 心拍数、PR 間隔、RR 間隔、QRS 幅、QT 間隔、QTcB、QTcF の測定値及びベースラインからの変化量（FSN-013P-03 試験及び FSN-013P-04 試験の併合）（Primary Safety Population 及び Secondary Safety Population）（52 週）

Table 4.4.5.1 Summary of 12-Lead ECG (SAS)

Parameter	Value	Treatment	Statistic	Baseline Observation Period	Post-Administration Period					
				Cycle -1 (Visit 3)	Cycle 1[a)]	Cycle 4[b)]	Cycle 6[d)]	Cycle 8[c)]	Cycle 10[d)]	End of Treatment[b)] (Visit 17/ Discontinuation)
ECG Mean Heart Rate (beats/min)	Value	Primary FSN-013 Pooled	n	160	158	159	78	75	71	153
			Mean	64 0	63 3	63 7	66 4	61 8	66 1	64 9
			SD	8 59	8 68	8 79	9 23	8 79	8 75	8 89
			Min	42	41	41	48	44	45	40
			Q1	58 0	57 0	58 0	61 0	56 0	60 0	58 0
			Median	63 0	63 0	63 0	66 0	62 0	66 0	65 0
			Q3	70 0	68 0	71 0	72 0	67 0	72 0	71 0
			Max	90	90	86	90	86	90	94
		Secondary FSN-013 Pooled	n	311	158	303	78	75	71	302
			Mean	64 5	63 3	64 1	66 4	61 8	66 1	64 8
			SD	8 55	8 68	8 42	9 23	8 79	8 75	8 61
			Min	42	41	41	48	44	45	40
			Q1	58 0	57 0	59 0	61 0	56 0	60 0	58 0
			Median	64 0	63 0	64 0	66 0	62 0	66 0	64 0
			Q3	70 0	68 0	70 0	72 0	67 0	72 0	70 0
			Max	94	90	90	90	86	90	106

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Measurements below the lower limit of quantitation (LLOQ) or above the upper limit of quantitation (ULOQ) are substituted by the corresponding LLOQ/ULOQ
Primary Safety Analysis Population includes data of FSN-013 group only while Secondary Safety Analysis Population includes data of both FSN-013 group and subjects who switched from Placebo to FSN-013
a) : Includes data for only FSN-013 groups of both studies
b) : Includes data for subjects in the FSN-013 group and subjects in the Placebo group who were switched to FSN-013 in both studies
c) : Includes data for FSN-013 group of FSN-013P-03 study only
d) : Includes data for FSN-013 group of FSN-013P-04 study only

For FSN-013P-03 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 9 for subjects in the Placebo group who were switched to FSN-013, respectively
For FSN-013P-04 study, Cycle 1 corresponds to Visit 5 for FSN-013 group and Visit 11 for subjects in the Placebo group who were switched to FSN-013, respectively
Visit 17/Discontinuation includes subjects who discontinued from Visit 9 to Visit 17 of FSN-013P-03 and subjects who discontinued from visit 11 to Visit 17 of FSN-013P-04

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