表2.7.4.7－110　各評価時点でのC-SSRS評価結果：プラセボ対照二重盲検期間（海外試験_ISS）

Visit	Category Item	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=110)	80 mg (N=112)	100 mg (N=27)	All NBI-98854 (N=254)	Placebo (N=178)
Any Suicidal Ideation or Suicidal Behavior Post-Baseline		n (%)	1(20.0)	6(5.5)	2(1.8)	0	9(3.5)	6(3.4)
Screening								
Lifetime History		n	5	110	112	27	254	178
	Suicidal Ideation[b]	n (%)	2(40.0)	41(37.3)	34(30.4)	6(22.2)	83(32.7)	54(30.3)
	Item 1	n (%)	2(40.0)	40(36.4)	32(28.6)	6(22.2)	80(31.5)	52(29.2)
	Item 2	n (%)	2(40.0)	36(32.7)	32(28.6)	4(14.8)	74(29.1)	47(26.4)
	Item 3	n (%)	2(40.0)	26(23.6)	27(24.1)	3(11.1)	58(22.8)	34(19.1)
	Item 4	n (%)	2(40.0)	21(19.1)	25(22.3)	3(11.1)	51(20.1)	28(15.7)
	Item 5	n (%)	2(40.0)	22(20.0)	29(25.9)	3(11.1)	56(22.0)	29(16.3)
	Suicidal Behavior[c]	n (%)	2(40.0)	36(32.7)	38(33.9)	6(22.2)	82(32.3)	47(26.4)
	Item 6	n (%)	1(20.0)	6(5.5)	12(10.7)	0	19(7.5)	14(7.9)
	Item 7	n (%)	0	4(3.6)	9(8.0)	1(3.7)	14(5.5)	11(6.2)
	Item 8	n (%)	0	10(9.1)	8(7.1)	1(3.7)	19(7.5)	11(6.2)
	Item 9	n (%)	2(40.0)	32(29.1)	37(33.0)	5(18.5)	76(29.9)	43(24.2)
	Item 10	n (%)	0	0	0	0	0	0
	Suicidal Ideation or Behavior	n (%)	2(40.0)	49(44.5)	44(39.3)	8(29.6)	103(40.6)	65(36.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
[b] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[c] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[d] From baseline on, C-SSRS evaluated suicidality from the last visit.

表2.7.4.7－110　各評価時点でのC-SSRS評価結果：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=110)	80 mg (N=112)	100 mg (N=27)	All NBI-98854 (N=254)	Placebo (N=178)
Past 3 Months		n	5	109	112	27	253	178
	Suicidal Ideation[b]	n (%)	1(20.0)	8(7.3)	2(1.8)	1(3.7)	12(4.7)	5(2.8)
	Item 1	n (%)	1(20.0)	8(7.3)	2(1.8)	1(3.7)	12(4.7)	5(2.8)
	Item 2	n (%)	0	4(3.7)	1(0.9)	0	5(2.0)	2(1.1)
	Item 3	n (%)	0	2(1.8)	0	0	2(0.8)	1(0.6)
	Item 4	n (%)	0	0	0	0	0	0
	Item 5	n (%)	0	0	0	0	0	0
	Suicidal Behavior[c]	n (%)	0	0	0	0	0	0
	Item 6	n (%)	0	0	0	0	0	0
	Item 7	n (%)	0	0	0	0	0	0
	Item 8	n (%)	0	0	0	0	0	0
	Item 9	n (%)	0	0	0	0	0	0
	Item 10	n (%)	0	0	0	0	0	0
	Suicidal Ideation or Behavior	n (%)	1(20.0)	8(7.3)	2(1.8)	1(3.7)	12(4.7)	5(2.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
[b] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[c] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[d] From baseline on, C-SSRS evaluated suicidality from the last visit.

表2.7.4.7－110　各評価時点でのC-SSRS評価結果：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=110)	80 mg (N=112)	100 mg (N=27)	All NBI-98854 (N=254)	Placebo (N=178)
Baseline[d]		n	5	110	112	27	254	178
	Suicidal Ideation[b]	n (%)	0	6(5.5)	1(0.9)	0	7(2.8)	1(0.6)
	Item 1	n (%)	0	5(4.5)	1(0.9)	0	6(2.4)	1(0.6)
	Item 2	n (%)	0	1(0.9)	0	0	1(0.4)	1(0.6)
	Item 3	n (%)	0	0	0	0	0	0
	Item 4	n (%)	0	0	0	0	0	0
	Item 5	n (%)	0	0	0	0	0	0
	Suicidal Behavior[c]	n (%)	0	0	0	0	0	0
	Item 6	n (%)	0	0	0	0	0	0
	Item 7	n (%)	0	0	0	0	0	0
	Item 8	n (%)	0	0	0	0	0	0
	Item 9	n (%)	0	0	0	0	0	0
	Item 10	n (%)	0	0	0	0	0	0
	Suicidal Ideation or Behavior	n (%)	0	6(5.5)	1(0.9)	0	7(2.8)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
[b] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[c] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[d] From baseline on, C-SSRS evaluated suicidality from the last visit.

表2.7.4.7－110 各評価時点でのC-SSRS評価結果：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=110)	80 mg (N=112)	100 mg (N=27)	All NBI-98854 (N=254)	Placebo (N=178)
Week 2		n	5	104	109	25	243	171
	Suicidal Ideation[b]	n (%)	1(20.0)	6(5.8)	0	0	7(2.9)	2(1.2)
	Item 1	n (%)	1(20.0)	6(5.8)	0	0	7(2.9)	2(1.2)
	Item 2	n (%)	0	0	0	0	0	2(1.2)
	Item 3	n (%)	0	0	0	0	0	0
	Item 4	n (%)	0	0	0	0	0	0
	Item 5	n (%)	0	0	0	0	0	0
	Suicidal Behavior[c]	n (%)	0	0	0	0	0	0
	Item 6	n (%)	0	0	0	0	0	0
	Item 7	n (%)	0	0	0	0	0	0
	Item 8	n (%)	0	0	0	0	0	0
	Item 9	n (%)	0	0	0	0	0	0
	Item 10	n (%)	0	0	0	0	0	0
	Suicidal Ideation or Behavior	n (%)	1(20.0)	6(5.8)	0	0	7(2.9)	2(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
[b] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[c] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[d] From baseline on, C-SSRS evaluated suicidality from the last visit.

表2.7.4.7－110　各評価時点でのC-SSRS評価結果：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=110)	80 mg (N=112)	100 mg (N=27)	All NBI-98854 (N=254)	Placebo (N=178)
Week 4		n	4	100	105	24	233	166
	Suicidal Ideation[b]	n (%)	0	3(3.0)	0	0	3(1.3)	6(3.6)
	Item 1	n (%)	0	3(3.0)	0	0	3(1.3)	5(3.0)
	Item 2	n (%)	0	0	0	0	0	5(3.0)
	Item 3	n (%)	0	0	0	0	0	1(0.6)
	Item 4	n (%)	0	0	0	0	0	0
	Item 5	n (%)	0	0	0	0	0	0
	Suicidal Behavior[c]	n (%)	0	0	0	0	0	0
	Item 6	n (%)	0	0	0	0	0	0
	Item 7	n (%)	0	0	0	0	0	0
	Item 8	n (%)	0	0	0	0	0	0
	Item 9	n (%)	0	0	0	0	0	0
	Item 10	n (%)	0	0	0	0	0	0
	Suicidal Ideation or Behavior	n (%)	0	3(3.0)	0	0	3(1.3)	6(3.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
[b] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[c] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[d] From baseline on, C-SSRS evaluated suicidality from the last visit.

表2.7.4.7－110　各評価時点でのC-SSRS評価結果：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=110)	80 mg (N=112)	100 mg (N=27)	All NBI-98854 (N=254)	Placebo (N=178)
Week 6		n	4	96	101	21	222	159
	Suicidal Ideation[b]	n (%)	0	2(2.1)	0	0	2(0.9)	1(0.6)
	Item 1	n (%)	0	2(2.1)	0	0	2(0.9)	1(0.6)
	Item 2	n (%)	0	0	0	0	0	1(0.6)
	Item 3	n (%)	0	0	0	0	0	0
	Item 4	n (%)	0	0	0	0	0	0
	Item 5	n (%)	0	0	0	0	0	0
	Suicidal Behavior[c]	n (%)	0	0	0	0	0	0
	Item 6	n (%)	0	0	0	0	0	0
	Item 7	n (%)	0	0	0	0	0	0
	Item 8	n (%)	0	0	0	0	0	0
	Item 9	n (%)	0	0	0	0	0	0
	Item 10	n (%)	0	0	0	0	0	0
	Suicidal Ideation or Behavior	n (%)	0	2(2.1)	0	0	2(0.9)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
[b] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[c] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[d] From baseline on, C-SSRS evaluated suicidality from the last visit.

5.3.5.3－2 Table 1.4.10.1より引用

表2.7.4.7－111　各評価時点での自殺念慮スコア最大値のシフトテーブル：プラセボ対照二重盲検期間（海外試験_ISS）

Treatment Group[a]	Total Non-missing	Baseline Score	Maximum Suicidal Ideation Score (Day 1 through Week 6) 0	1	2	3	4	5
Placebo	175	0	169 (96.6)	1 (0.6)	3 (1.7)	1 (0.6)	0	0
		1	0	0	0	0	0	0
		2	0	0	1 (0.6)	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
<40 mg	5	0	4 (80.0)	0	0	1 (20.0)	0	0
		1	0	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
40 mg	109	0	99 (90.8)	4 (3.7)	0	0	0	0
		1	3 (2.8)	2 (1.8)	0	0	0	0
		2	1 (0.9)	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
80 mg	112	0	110 (98.2)	0	0	0	0	1 (0.9)
		1	1 (0.9)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0

[a] 40 mg row includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg row includes doses of 75 mg and 80 mg NBI-98854.
Note: Suicidal Ideation Items: 0=No suicidal ideation, 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
Excludes subjects missing either a baseline score or a score between baseline and Week 6.

表 2.7.4.7－111　各評価時点での自殺念慮スコア最大値のシフトテーブル：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Treatment Group[a]	Total Non-missing	Baseline Score	Maximum Suicidal Ideation Score (Day 1 through Week 6) 0	1	2	3	4	5
100 mg	26	0	26 (100.0)	0	0	0	0	0
		1	0	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
All NBI-98854	252	0	239 (94.8)	4 (1.6)	0	1 (0.4)	0	1 (0.4)
		1	4 (1.6)	2 (0.8)	0	0	0	0
		2	1 (0.4)	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0

[a] 40 mg row includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg row includes doses of 75 mg and 80 mg NBI-98854.
Note: Suicidal Ideation Items: 0=No suicidal ideation, 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
Excludes subjects missing either a baseline score or a score between baseline and Week 6.

5.3.5.3－2 Table 1.4.10.3より引用

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-22	Placebo	Y	Y	Y	Y	N	N	Y	N	Y		Y
				PAST 3 MONTHS	201[redacted]	-22	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	15	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	Placebo	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	40	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	40 mg	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	71	40 mg	N	N				N	N	N	N	N	Y
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-50	Placebo	Y	Y	N	Y	Y	N	N	Y	Y		N
				PAST 3 MONTHS	201[redacted]	-50	Placebo	Y	Y	N	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	Placebo	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	41	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	40 mg	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	69	40 mg	Y	Y	Y	Y	N	N	N	N	N	N	N
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-16	Placebo	Y	Y	Y	Y	Y	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-16	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	15	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	30	Placebo	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y		WEEK 6		201[redacted]	37	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	40 mg	N	N				N	N	N	N	N	N
			WEEK 10		201[redacted]	72	40 mg	Y	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	85	40 mg	N	N				N	N	N	N	N	N
			WEEK 14		201[redacted]	98	40 mg	Y	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	113	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-15	40 mg	Y	Y	Y	Y	N	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-15	40 mg	Y	Y	N	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	Y	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	40 mg	Y	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	40 mg	Y	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	45	40 mg	Y	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	59	40 mg	Y	N				N	N	N	N	N	N
			WEEK 10		201[redacted]	73	40 mg	Y	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	87	40 mg	Y	N				N	N	N	N	N	N
			WEEK 14		201[redacted]	98	40 mg	Y	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	40 mg	Y	N				N	N	N	N	N	N
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-22	Placebo	Y	Y	Y	N	N	N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-22	Placebo	Y	Y	Y	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 2		201[redacted]	14	Placebo	Y	Y	N	N	N	N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y		WEEK 4		201[redacted]	28	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 6		201[redacted]	40	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	Y	N				N	N	N	N	N	N
			WEEK 10		201[redacted]	70	40 mg	Y	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	40 mg	N	N				N	N	N	N	N	N
			WEEK 14		201[redacted]	98	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	110	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-63	Placebo	Y	Y	Y	Y	Y	Y	Y	Y	Y		N
				PAST 3 MONTHS	201[redacted]	-63	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	16	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 4		201[redacted]	30	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 6		201[redacted]	37	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 8		201[redacted]	57	40 mg	Y	N				N	N	N	N	N	N
			WEEK 10		201[redacted]	72	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	87	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 14		201[redacted]	101	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	109	40 mg	Y	N				N	N	N	N	N	N
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-15	40 mg	Y	Y	Y	N	N	N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-15	40 mg	Y	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y		WEEK 2		201[redacted]	14	40 mg	Y	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	27	40 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-59	40 mg	Y	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-59	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	40 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	29	40 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	43	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	60	40 mg	Y	N				N	N	N	N	N	N
[redacted]	Y		SCREENING	LIFETIME	201[redacted]	-12	<40 mg	Y	Y	Y	Y	Y	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-12	<40 mg	Y	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	<40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	22	<40 mg	Y	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	28	<40 mg	Y	Y	Y	N	N	N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-15	Placebo	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-15	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	Placebo	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 4		201[redacted]	28	Placebo	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	Placebo	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	63	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-9	Placebo	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-9	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 6		201[redacted]	43	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	57	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	85	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	40 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	40 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	168	40 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	196	40 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	224	40 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	252	40 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	280	40 mg	N	N				N	N	N	N	N	N
			WEEK 44		201[redacted]	308	40 mg	N	N				N	N	N	N	N	N
			WEEK 48		201[redacted]	336	40 mg	N	N				N	N	N	N	N	N
			WEEK 52		201[redacted]	364	40 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-37	80 mg	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-37	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	22	80 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	118	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	80 mg	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 24		201[redacted]	168	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	196	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	224	80 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	252	80 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	279	80 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-37	Placebo	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-37	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	17	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	Placebo	N	Y	Y	N	N	N	N	N	N	N	N
			WEEK 6		201[redacted]	44	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	80 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 12		201[redacted]	84	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	80 mg	Y	Y	Y	N	N	N	N	N	N	N	N
			WEEK 20		201[redacted]	141	80 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	170	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	197	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	227	80 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	251	80 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	279	80 mg	N	N				N	N	N	N	N	N
			WEEK 44		201[redacted]	314	80 mg	N	N				N	N	N	N	N	N
			WEEK 48		201[redacted]	339	80 mg	N	N				N	N	N	N	N	N
			WEEK 52		201[redacted]	364	80 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-85	40 mg	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-85	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	12	40 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	27	40 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	82	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	40 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	40 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	168	40 mg	Y	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 28		201[redacted]	197	40 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	223	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-15	80 mg	N	N				N	N	N	N		Y
				PAST 3 MONTHS	201[redacted]	-15	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	13	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	27	80 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	49	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	63	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	80 mg	Y	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	80 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	166	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	194	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	224	80 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	251	80 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	280	80 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-7	80 mg	Y	Y	N	Y	Y	Y	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-7	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	1	80 mg	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	28	80 mg	Y	Y	Y	Y	Y	N	N	N	Y	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-13	40 mg	Y	Y	Y	Y	Y	N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-13	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	18	40 mg	Y	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	25	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-24	Placebo	N	Y	Y	Y	N	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-24	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	12	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	Placebo	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	46	Placebo	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	56	40 mg	Y	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-15	Placebo	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-15	Placebo	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	32	Placebo	Y	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	Placebo	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	80 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 20		201[redacted]	140	80 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	168	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	196	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	231	80 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	252	80 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	277	80 mg	N	N				N	N	N	N	N	N
			WEEK 44		201[redacted]	308	80 mg	N	N				N	N	N	N	N	N
			WEEK 48		201[redacted]	336	80 mg	N	N				N	N	N	N	N	N
			WEEK 52		201[redacted]	364	80 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-15	80 mg	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-15	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	80 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	80 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	168	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	196	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	226	80 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 36		201[redacted]	252	80 mg	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	280	80 mg	Y	Y	N	N	Y	N	N	N	Y	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-36	80 mg	Y	Y	Y	Y	Y	N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-36	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	80 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	43	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	57	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	85	80 mg	Y	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	113	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	141	80 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	169	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	197	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	225	80 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	253	80 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	281	80 mg	N	N				N	N	N	N	N	N
			WEEK 44		201[redacted]	309	80 mg	N	N				N	N	N	N	N	N
			WEEK 48		201[redacted]	337	80 mg	Y	N				N	N	N	N	N	N
			WEEK 52		201[redacted]	365	80 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-16	40 mg	Y	Y	Y	N	N	N	N	N	N		N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	SCREENING	PAST 3 MONTHS	201[redacted]	-16	40 mg	Y	Y	Y	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	12	40 mg	Y	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	27	40 mg	Y	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	41	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	83	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	111	40 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	139	40 mg	Y	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	172	40 mg	Y	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	209	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 32		201[redacted]	223	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 36		201[redacted]	251	40 mg	Y	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	279	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 44		201[redacted]	307	40 mg	Y	N				N	N	N	N	N	N
			WEEK 48		201[redacted]	336	40 mg	N	N				N	N	N	N	N	N
			WEEK 52		201[redacted]	363	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-15	80 mg	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-15	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	80 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	END OF TREATMENT		201[redacted]	47	80 mg	Y	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-17	40 mg	Y	Y	Y	Y	Y	N	Y	N	Y		N
				PAST 3 MONTHS	201[redacted]	-17	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	Y	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	40 mg	Y	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	33	40 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-16	40 mg	Y	Y	Y	N	N	N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-16	40 mg	Y	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	40 mg	Y	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	40 mg	Y	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	40 mg	Y	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	Y	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 16		201[redacted]	112	40 mg	Y	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	126	40 mg	N	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-13	Placebo	Y	Y	Y	Y	Y	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-13	Placebo	Y	N				N	N	N	N		N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	DAY -1		201[redacted]	-1	Placebo	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	Placebo	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	Placebo	Y	Y	N	N	N	N	N	N	N	N	N
			WEEK 6		201[redacted]	42	Placebo	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	64	80 mg	Y	Y	Y	N	N	N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-34	80 mg	N	N				N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-34	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	80 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	111	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	80 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	168	80 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	196	80 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	224	80 mg	Y	Y	Y	Y		N	Y	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-27	40 mg	N	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-27	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	Y	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 2		201[redacted]	14	40 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	29	40 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	42	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	112	40 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	139	40 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	167	40 mg	N	N				N	N	N	N	N	N
			WEEK 28		201[redacted]	196	40 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	223	40 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	253	40 mg	Y	N				N	N	N	N	N	N
[redacted]	Y	Y	SCREENING	LIFETIME	201[redacted]	-47	40 mg	Y	Y	Y	Y	Y	N	N	Y	Y		Y
				PAST 3 MONTHS	201[redacted]	-47	40 mg	Y	Y	Y	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 2		201[redacted]	14	40 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	40 mg	N	N				N	N	N	N	N	N
			WEEK 6		201[redacted]	39	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	40 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	114	40 mg	Y	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	140	40 mg	N	N				N	N	N	N	N	N
			WEEK 24		201[redacted]	168	40 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]	Y	Y	WEEK 28		201[redacted]	196	40 mg	N	N				N	N	N	N	N	N
			WEEK 32		201[redacted]	226	40 mg	N	N				N	N	N	N	N	N
			WEEK 36		201[redacted]	252	40 mg	N	N				N	N	N	N	N	N
			WEEK 40		201[redacted]	281	40 mg	N	N				N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-19	80 mg	Y	N				N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-19	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	18	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	52	80 mg	Y	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	89	80 mg	N	N				N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-29	40 mg	Y	Y	N	N	Y	Y	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-29	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	Y	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	27	40 mg	Y	N				N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-31	40 mg	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y
				PAST 3 MONTHS	201[redacted]	-31	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	27	40 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	55	40 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	82	40 mg	Y	Y	Y	Y	Y	N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]		Y	WEEK 16		201[redacted]	117	40 mg	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	133	40 mg	N	N				N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-15	40 mg	Y	Y	Y	Y	Y	Y	N	Y	Y		Y
				PAST 3 MONTHS	201[redacted]	-15	40 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	40 mg	Y	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	56	40 mg	Y	Y	Y	Y	N	N	N	N	N	N	N
			WEEK 12		201[redacted]	83	40 mg	N	N				N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-19	80 mg	Y	Y	N	N	N	N	N	N	Y		Y
				PAST 3 MONTHS	201[redacted]	-19	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-2	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	27	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	53	80 mg	N	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	87	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	109	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	137	80 mg	N	N				N	N	N	N	N	N
			END OF TREATMENT		201[redacted]	153	80 mg	Y	Y	N	N	N	N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-21	40 mg	Y	Y	Y	Y	Y	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-21	40 mg	Y	Y	Y	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	40 mg	Y	Y	N	N	N	N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

表2.7.4.7－112 自殺念慮又は自殺企図が認められた被験者の一覧：
プラセボ対照二重盲検期間・長期投与期間・長期投与終了後観察期間（海外試験_ISS）（続き）

Subject	Study Pool[a] CS	Study Pool[a] LTE	Visit	Timepoint	Visit Date	Study Day[b]	Treatment Group[c]	Suicidal Ideation[d] 1	2	3	4	5	Suicidal Behavior[e] 6	7	8	9	10	Self-Injurous Behavior w/o Suicidal Intent
[redacted]		Y	END OF TREATMENT		201[redacted]	28	40 mg	Y	Y	N	N	N	N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-25	80 mg	Y	Y	Y	Y	Y	N	N	N	Y		N
				PAST 3 MONTHS	201[redacted]	-25	80 mg	Y	Y	N	N	N	N	N	N	N		N
			DAY -1		201[redacted]	-1	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	28	80 mg	N	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	49	80 mg	Y	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	79	80 mg	N	N				N	N	N	N	N	N
			WEEK 16		201[redacted]	105	80 mg	N	N				N	N	N	N	N	N
			WEEK 20		201[redacted]	133	80 mg	N	N				N	N	N	N	N	N
[redacted]		Y	SCREENING	LIFETIME	201[redacted]	-27	80 mg	Y	N				N	N	N	N		N
				PAST 3 MONTHS	201[redacted]	-27	80 mg	N	N				N	N	N	N		N
			DAY -1		201[redacted]	-7	80 mg	N	N				N	N	N	N	N	N
			WEEK 4		201[redacted]	23	80 mg	Y	N				N	N	N	N	N	N
			WEEK 8		201[redacted]	51	80 mg	Y	N				N	N	N	N	N	N
			WEEK 12		201[redacted]	84	80 mg	N	N				N	N	N	N	N	N

CS=Controlled Study Pool, LT=Long-Term Exposure Study Pool.
[a] Applies to Phase 2/3 studies only.
[b] Study Day=Study day relative to the date of first administration of study drug.
[c] 40 mg includes doses of 40 mg and 50 mg NBI-98854 and 80 mg includes doses of 75 mg and 80 mg NBI-98854.
[d] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[e] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.

5.3.5.3－2 Table 1.4.10.6より引用

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Any Suicidal Ideation or Suicidal Behavior Post-Baseline		n (%)	14(7.0)	14(6.1)	14(6.7)	28(6.5)
Screening						
Lifetime History		n	200	230	210	430
	Suicidal Ideation[c]	n (%)	66(33.0)	76(33.0)	69(32.9)	142(33.0)
	Item 1	n (%)	64(32.0)	71(30.9)	65(31.0)	135(31.4)
	Item 2	n (%)	58(29.0)	66(28.7)	60(28.6)	124(28.8)
	Item 3	n (%)	44(22.0)	49(21.3)	43(20.5)	93(21.6)
	Item 4	n (%)	36(18.0)	40(17.4)	34(16.2)	76(17.7)
	Item 5	n (%)	39(19.5)	44(19.1)	38(18.1)	83(19.3)
	Suicidal Behavior[d]	n (%)	58(29.0)	67(29.1)	61(29.0)	125(29.1)
	Item 6	n (%)	13(6.5)	17(7.4)	12(5.7)	30(7.0)
	Item 7	n (%)	6(3.0)	11(4.8)	8(3.8)	17(4.0)
	Item 8	n (%)	18(9.0)	15(6.5)	12(5.7)	33(7.7)
	Item 9	n (%)	53(26.5)	63(27.4)	57(27.1)	116(27.0)
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	77(38.5)	93(40.4)	86(41.0)	170(39.5)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Past 3 Months		n	199	230	210	429
	Suicidal Ideation[c]	n (%)	10(5.0)	5(2.2)	5(2.4)	15(3.5)
	Item 1	n (%)	10(5.0)	5(2.2)	5(2.4)	15(3.5)
	Item 2	n (%)	6(3.0)	3(1.3)	3(1.4)	9(2.1)
	Item 3	n (%)	3(1.5)	0	0	3(0.7)
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	10(5.0)	5(2.2)	5(2.4)	15(3.5)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Baseline[e]		n	200	230	210	430
	Suicidal Ideation[c]	n (%)	10(5.0)	2(0.9)	2(1.0)	12(2.8)
	Item 1	n (%)	9(4.5)	2(0.9)	2(1.0)	11(2.6)
	Item 2	n (%)	3(1.5)	0	0	3(0.7)
	Item 3	n (%)	1(0.5)	0	0	1(0.2)
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	10(5.0)	2(0.9)	2(1.0)	12(2.8)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113 各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 2		n	113	73	68	186
	Suicidal Ideation[c]	n (%)	5(4.4)	0	0	5(2.7)
	Item 1	n (%)	5(4.4)	0	0	5(2.7)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	5(4.4)	0	0	5(2.7)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 4		n	144	187	171	331
	Suicidal Ideation[c]	n (%)	4(2.8)	1(0.5)	1(0.6)	5(1.5)
	Item 1	n (%)	4(2.8)	1(0.5)	1(0.6)	5(1.5)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	4(2.8)	1(0.5)	1(0.6)	5(1.5)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 6		n	101	66	61	167
	Suicidal Ideation[c]	n (%)	2(2.0)	0	0	2(1.2)
	Item 1	n (%)	2(2.0)	0	0	2(1.2)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	2(2.0)	0	0	2(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 8		n	159	207	187	366
	Suicidal Ideation[c]	n (%)	3(1.9)	4(1.9)	4(2.1)	7(1.9)
	Item 1	n (%)	3(1.9)	4(1.9)	4(2.1)	7(1.9)
	Item 2	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
	Item 3	n (%)	1(0.6)	0	0	1(0.3)
	Item 4	n (%)	1(0.6)	0	0	1(0.3)
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	3(1.9)	4(1.9)	4(2.1)	7(1.9)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 10		n	31	0	0	31
	Suicidal Ideation[c]	n (%)	1(3.2)	0	0	1(3.2)
	Item 1	n (%)	1(3.2)	0	0	1(3.2)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(3.2)	0	0	1(3.2)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 12		n	141	197	179	338
	Suicidal Ideation[c]	n (%)	3(2.1)	2(1.0)	2(1.1)	5(1.5)
	Item 1	n (%)	3(2.1)	2(1.0)	2(1.1)	5(1.5)
	Item 2	n (%)	2(1.4)	0	0	2(0.6)
	Item 3	n (%)	1(0.7)	0	0	1(0.3)
	Item 4	n (%)	1(0.7)	0	0	1(0.3)
	Item 5	n (%)	1(0.7)	0	0	1(0.3)
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	3(2.1)	2(1.0)	2(1.1)	5(1.5)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 14		n	30	0	0	30
	Suicidal Ideation[c]	n (%)	1(3.3)	0	0	1(3.3)
	Item 1	n (%)	1(3.3)	0	0	1(3.3)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(3.3)	0	0	1(3.3)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 16		n	134	187	170	321
	Suicidal Ideation[c]	n (%)	3(2.2)	1(0.5)	1(0.6)	4(1.2)
	Item 1	n (%)	3(2.2)	1(0.5)	1(0.6)	4(1.2)
	Item 2	n (%)	0	1(0.5)	1(0.6)	1(0.3)
	Item 3	n (%)	0	1(0.5)	1(0.6)	1(0.3)
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	3(2.2)	1(0.5)	1(0.6)	4(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 20		n	99	177	162	276
	Suicidal Ideation[c]	n (%)	1(1.0)	1(0.6)	1(0.6)	2(0.7)
	Item 1	n (%)	1(1.0)	1(0.6)	1(0.6)	2(0.7)
	Item 2	n (%)	0	1(0.6)	1(0.6)	1(0.4)
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(1.0)	1(0.6)	1(0.6)	2(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 24		n	93	156	146	249
	Suicidal Ideation[c]	n (%)	2(2.2)	1(0.6)	1(0.7)	3(1.2)
	Item 1	n (%)	2(2.2)	1(0.6)	1(0.7)	3(1.2)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	2(2.2)	1(0.6)	1(0.7)	3(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 28		n	88	146	138	234
	Suicidal Ideation[c]	n (%)	1(1.1)	0	0	1(0.4)
	Item 1	n (%)	1(1.1)	0	0	1(0.4)
	Item 2	n (%)	1(1.1)	0	0	1(0.4)
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(1.1)	0	0	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 32		n	79	134	126	213
	Suicidal Ideation[c]	n (%)	1(1.3)	1(0.7)	1(0.8)	2(0.9)
	Item 1	n (%)	1(1.3)	1(0.7)	1(0.8)	2(0.9)
	Item 2	n (%)	1(1.3)	1(0.7)	1(0.8)	2(0.9)
	Item 3	n (%)	0	1(0.7)	1(0.8)	1(0.5)
	Item 4	n (%)	0	1(0.7)	1(0.8)	1(0.5)
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	1(0.7)	1(0.8)	1(0.5)
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	1(0.7)	1(0.8)	1(0.5)
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(1.3)	1(0.7)	1(0.8)	2(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 36		n	75	121	114	196
	Suicidal Ideation[c]	n (%)	2(2.7)	0	0	2(1.0)
	Item 1	n (%)	2(2.7)	0	0	2(1.0)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	2(2.7)	0	0	2(1.0)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 40		n	73	107	101	180
	Suicidal Ideation[c]	n (%)	1(1.4)	0	0	1(0.6)
	Item 1	n (%)	1(1.4)	0	0	1(0.6)
	Item 2	n (%)	1(1.4)	0	0	1(0.6)
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(1.4)	0	0	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 44		n	70	95	90	165
	Suicidal Ideation[c]	n (%)	1(1.4)	0	0	1(0.6)
	Item 1	n (%)	1(1.4)	0	0	1(0.6)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(1.4)	0	0	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 48		n	68	88	84	156
	Suicidal Ideation[c]	n (%)	1(1.5)	1(1.1)	1(1.2)	2(1.3)
	Item 1	n (%)	1(1.5)	1(1.1)	1(1.2)	2(1.3)
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	1(1.5)	1(1.1)	1(1.2)	2(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

表 2.7.4.7－113　各評価時点での C-SSRS 評価結果：MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Visit	Category Item	Statistic	NBI-98854 Dose[a] 40 mg (N=200)	80 mg (N=230)	80 mg Only[b] (N=210)	All NBI-98854 (N=430)
Week 52		n	67	84	80	151
	Suicidal Ideation[c]	n (%)	0	0	0	0
	Item 1	n (%)	0	0	0	0
	Item 2	n (%)	0	0	0	0
	Item 3	n (%)	0	0	0	0
	Item 4	n (%)	0	0	0	0
	Item 5	n (%)	0	0	0	0
	Suicidal Behavior[d]	n (%)	0	0	0	0
	Item 6	n (%)	0	0	0	0
	Item 7	n (%)	0	0	0	0
	Item 8	n (%)	0	0	0	0
	Item 9	n (%)	0	0	0	0
	Item 10	n (%)	0	0	0	0
	Suicidal Ideation Or Behavior	n (%)	0	0	0	0

[a] 40 mg column includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
[c] Suicidal Ideation Items: 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent.
[d] Suicidal Behavior Items: 6=Preparatory acts or behavior, 7=Aborted attempt, 8=Interrupted attempt, 9=Non-fatal suicide attempt, 10=Completed suicide.
[e] From baseline on, C-SSRS evaluated suicidality from the last visit.

5.3.5.3－3 Table 1.4.10.2 より引用

表 2.7.4.7－114　各評価時点での自殺念慮スコア最大値のシフトテーブル：
MT-5199 長期投与期間（海外試験_120-Day Safety Update）

Treatment Group[a]	Total Non-missing	Baseline Score	Maximum Suicidal Ideation Score (Day 1 through Week 48) 0	1	2	3	4	5
40 mg	198	0	179 (90.4)	4 (2.0)	3 (1.5)	0	1 (0.5)	1 (0.5)
		1	3 (1.5)	4 (2.0)	0	0	0	0
		2	1 (0.5)	0	1 (0.5)	0	0	0
		3	1 (0.5)	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
80 mg	228	0	212 (93.0)	6 (2.6)	3 (1.3)	2 (0.9)	1 (0.4)	2 (0.9)
		1	2 (0.9)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
80 mg Only[b]	208	0	192 (92.3)	6 (2.9)	3 (1.4)	2 (1.0)	1 (0.5)	2 (1.0)
		1	2 (1.0)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0

[a] 40 mg row includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg row who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 row.
Note: Suicidal Ideation Items: 0=No suicidal ideation, 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent. Excludes subjects missing baseline score or a score post baseline to Wk 48.
Wk 48=Week 48

表 2.7.4.7－114　各評価時点での自殺念慮スコア最大値のシフトテーブル：
MT-5199 長期投与期間（海外試験_120-Day Safety Update）（続き）

Treatment Group[a]	Total Non-missing	Baseline Score	Maximum Suicidal Ideation Score (Day 1 through Week 48)					
			0	1	2	3	4	5
All NBI-98854	426	0	391 (91.8)	10 (2.3)	6 (1.4)	2 (0.5)	2 (0.5)	3 (0.7)
		1	5 (1.2)	4 (0.9)	0	0	0	0
		2	1 (0.2)	0	1 (0.2)	0	0	0
		3	1 (0.2)	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0

[a] 40 mg row includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg row who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 row.
Note: Suicidal Ideation Items: 0=No suicidal ideation, 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent. Excludes subjects missing baseline score or a score post baseline to Wk 48.
Wk 48=Week 48

5.3.5.3－3 Table 1.4.10.4 より引用（一部改変）

表 2.7.4.7－115　各評価時点での自殺念慮スコア最大値のシフトテーブル：
MT-5199 長期投与終了後観察期間（海外試験__120-Day Safety Update）

Treatment Group[a]	Total Non-missing	Week 48 Score	Maximum Suicidal Ideation Score (After Week 48 through Week 52)					
			0	1	2	3	4	5
40 mg	67	0	66 (98.5)	0	0	0	0	0
		1	1 (1.5)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
80 mg	84	0	83 (98.8)	0	0	0	0	0
		1	1 (1.2)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0
80 mg Only[b]	80	0	79 (98.8)	0	0	0	0	0
		1	1 (1.3)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0

[a] 40 mg row includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg row who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 row.
Note: Suicidal Ideation Items: 0=No suicidal ideation, 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent. Excludes subjects missing scores at either Wk 48 or between Wk 48 and Wk 52.
Wk 48=Week 48, Wk 52=Week 52

表 2.7.4.7－115　各評価時点での自殺念慮スコア最大値のシフトテーブル：
MT-5199 長期投与終了後観察期間（海外試験__120-Day Safety Update）（続き）

Treatment Group[a]	Total Non-missing	Week 48 Score	Maximum Suicidal Ideation Score (After Week 48 through Week 52) 0	1	2	3	4	5
All NBI-98854	151	0	149 (98.7)	0	0	0	0	0
		1	2 (1.3)	0	0	0	0	0
		2	0	0	0	0	0	0
		3	0	0	0	0	0	0
		4	0	0	0	0	0	0
		5	0	0	0	0	0	0

[a] 40 mg row includes doses of 40 mg and 50 mg.
[b] Subjects in the NBI-98854 80 mg row who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 row.
Note: Suicidal Ideation Items: 0=No suicidal ideation, 1=Wish to be dead, 2=Non-specific active suicidal thoughts, 3=Active suicidal ideation with any methods (not plan) without intent to act, 4=Active suicidal ideation with some intent to act, without specific plan, 5=Active suicidal ideation with specific plan and intent. Excludes subjects missing scores at either Wk 48 or between Wk 48 and Wk 52.
Wk 48=Week 48, Wk 52=Week 52

5.3.5.3－3 Table 1.4.10.5 より引用（一部改変）

表 2.7.4.7－116　各評価時点での BARS 包括スコア及び BARS 合計スコア，並びに各スコアのベースラインからの変化量：
プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
BARS Global Score	Baseline	n	85	84	169	84				
		Mean	0.4	0.4	0.4	0.5				
		SD	0.8	0.8	0.8	1.0				
		Median	0.0	0.0	0.0	0.0				
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)				
	Week 2	n	82	79	161	84	82	79	161	84
		Mean	0.5	0.4	0.5	0.4	0.1	0.1	0.1	-0.2
		SD	1.0	0.9	1.0	0.8	0.8	0.7	0.8	0.5
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 4)	(0, 4)	(0, 4)	(0, 4)	(-2, 4)	(-2, 4)	(-2, 4)	(-3, 1)
	Week 4	n	77	70	147	80	77	70	147	80
		Mean	0.4	0.5	0.5	0.3	-0.1	0.1	0.0	-0.2
		SD	0.8	0.9	0.8	0.8	0.6	0.8	0.7	0.6
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)	(-2, 2)	(-3, 4)	(-3, 4)	(-3, 1)
	Week 6	n	70	60	130	80	70	60	130	80
		Mean	0.3	0.5	0.4	0.3	-0.1	0.2	0.0	-0.2
		SD	0.6	1.0	0.8	0.7	0.6	0.9	0.8	0.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)	(-2, 1)	(-3, 4)	(-3, 4)	(-4, 1)

BARS: Barnes Akathisia Rating Scale

表 2.7.4.7－116　各評価時点での BARS 包括スコア及び BARS 合計スコア，並びに各スコアのベースラインからの変化量：
プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
BARS Total Score	Baseline	n	85	84	169	84				
		Mean	0.9	0.9	0.9	0.9				
		SD	1.5	1.5	1.5	1.5				
		Median	0.0	0.0	0.0	0.0				
		(Min, Max)	(0, 7)	(0, 6)	(0, 7)	(0, 7)				
	Week 2	n	82	79	161	84	82	79	161	84
		Mean	1.0	0.8	0.9	0.6	0.1	-0.1	0.0	-0.3
		SD	1.6	1.5	1.6	1.2	1.3	0.9	1.1	0.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 6)	(0, 6)	(0, 6)	(-3, 6)	(-4, 2)	(-4, 6)	(-4, 2)
	Week 4	n	77	70	147	80	77	70	147	80
		Mean	0.7	1.0	0.9	0.5	-0.2	0.1	0.0	-0.4
		SD	1.2	1.6	1.4	1.1	1.1	1.2	1.2	1.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 5)	(0, 6)	(0, 6)	(0, 6)	(-4, 3)	(-4, 5)	(-4, 5)	(-4, 1)
	Week 6	n	70	60	130	80	70	60	130	80
		Mean	0.5	0.9	0.7	0.5	-0.4	0.0	-0.2	-0.4
		SD	1.0	1.4	1.2	1.1	1.3	1.2	1.3	1.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 4)	(0, 6)	(0, 6)	(0, 6)	(-5, 3)	(-5, 3)	(-5, 3)	(-5, 2)

BARS: Barnes Akathisia Rating Scale

5.3.5.1－1 Table 14.3.5.1.2.1 より引用

表 2.7.4.7－117　各評価時点での BARS 包括スコア及び BARS 合計スコア，並びに各スコアのベースラインからの変化量：
MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
BARS Global Score	Baseline	n	126	123	84	249				
		Mean	0.5	0.5	0.3	0.5				
		SD	0.8	0.9	0.7	0.9				
		Median	0.0	0.0	0.0	0.0				
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)				
	Week 2	n	82	79	59	161	82	79	59	161
		Mean	0.5	0.4	0.4	0.5	0.1	0.1	0.1	0.1
		SD	1.0	0.9	0.8	1.0	0.8	0.7	0.8	0.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 4)	(0, 4)	(0, 4)	(0, 4)	(-2, 4)	(-2, 4)	(-2, 4)	(-2, 4)
	Week 4	n	77	70	50	147	77	70	50	147
		Mean	0.4	0.5	0.5	0.5	-0.1	0.1	0.2	0.0
		SD	0.8	0.9	0.9	0.8	0.6	0.8	0.9	0.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)	(-2, 2)	(-3, 4)	(-3, 4)	(-3, 4)
	Week 6	n	70	60	40	130	70	60	40	130
		Mean	0.3	0.5	0.5	0.4	-0.1	0.2	0.2	0.0
		SD	0.6	1.0	1.0	0.8	0.6	0.9	0.9	0.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)	(-2, 1)	(-3, 4)	(-2, 4)	(-3, 4)
	Week 8	n	105	93	55	198	105	93	55	198
		Mean	0.3	0.4	0.3	0.3	-0.2	-0.1	0.0	-0.1
		SD	0.7	0.8	0.7	0.7	0.6	0.9	0.8	0.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)	(-2, 2)	(-4, 4)	(-3, 4)	(-4, 4)
	Week 16	n	94	73	43	167	94	73	43	167
		Mean	0.2	0.4	0.3	0.3	-0.2	-0.2	0.0	-0.2
		SD	0.6	0.8	0.7	0.7	0.7	1.1	0.9	0.9
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 4)	(0, 4)	(0, 4)	(-3, 2)	(-4, 4)	(-4, 4)	(-4, 4)

BARS: Barnes Akathisia Rating Scale

表 2.7.4.7－117　各評価時点での BARS 包括スコア及び BARS 合計スコア，並びに各スコアのベースラインからの変化量：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
BARS Global Score	Week 24	n	86	65	39	151	86	65	39	151
		Mean	0.2	0.4	0.3	0.3	-0.1	-0.1	0.1	-0.1
		SD	0.5	0.9	0.8	0.7	0.6	1.0	0.9	0.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 4)	(0, 4)	(0, 4)	(-2, 1)	(-4, 4)	(-3, 4)	(-4, 4)
	Week 32	n	82	58	35	140	82	58	35	140
		Mean	0.2	0.4	0.3	0.3	-0.1	-0.1	0.0	-0.1
		SD	0.5	0.9	0.7	0.7	0.6	0.9	0.8	0.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 3)	(0, 3)	(0, 3)	(-2, 2)	(-3, 3)	(-3, 3)	(-3, 3)
	Week 40	n	71	55	33	126	71	55	33	126
		Mean	0.2	0.4	0.4	0.3	-0.1	-0.1	0.1	-0.1
		SD	0.5	0.8	0.8	0.7	0.6	0.9	0.9	0.7
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 3)	(0, 3)	(0, 3)	(-2, 1)	(-3, 3)	(-3, 3)	(-3, 3)
	Week 48	n	67	50	29	117	67	50	29	117
		Mean	0.1	0.3	0.2	0.2	-0.1	-0.2	-0.1	-0.2
		SD	0.4	0.8	0.7	0.6	0.6	1.0	1.0	0.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 3)	(0, 3)	(0, 3)	(-2, 1)	(-4, 3)	(-4, 3)	(-4, 3)
	Week 52	n	66	49	28	115	66	49	28	115
		Mean	0.2	0.5	0.5	0.3	-0.1	-0.1	0.2	-0.1
		SD	0.6	1.0	1.0	0.8	0.7	0.9	0.8	0.8
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 3)	(0, 3)	(0, 3)	(0, 3)	(-2, 3)	(-3, 3)	(-1, 3)	(-3, 3)

BARS: Barnes Akathisia Rating Scale

表 2.7.4.7－117　各評価時点での BARS 包括スコア及び BARS 合計スコア，並びに各スコアのベースラインからの変化量：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
BARS Total Score	Baseline	n	126	123	84	249				
		Mean	0.9	0.9	0.8	0.9				
		SD	1.4	1.6	1.5	1.5				
		Median	0.0	0.0	0.0	0.0				
		(Min, Max)	(0, 7)	(0, 7)	(0, 7)	(0, 7)				
	Week 2	n	82	79	59	161	82	79	59	161
		Mean	1.0	0.8	0.7	0.9	0.1	-0.1	-0.1	0.0
		SD	1.6	1.5	1.4	1.6	1.3	0.9	1.0	1.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 6)	(0, 5)	(0, 6)	(-3, 6)	(-4, 2)	(-4, 2)	(-4, 6)
	Week 4	n	77	70	50	147	77	70	50	147
		Mean	0.7	1.0	1.0	0.9	-0.2	0.1	0.2	0.0
		SD	1.2	1.6	1.7	1.4	1.1	1.2	1.3	1.2
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 5)	(0, 6)	(0, 5)	(0, 6)	(-4, 3)	(-4, 5)	(-4, 5)	(-4, 5)
	Week 6	n	70	60	40	130	70	60	40	130
		Mean	0.5	0.9	0.8	0.7	-0.4	0.0	0.1	-0.2
		SD	1.0	1.4	1.2	1.2	1.3	1.2	1.0	1.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 4)	(0, 6)	(0, 4)	(0, 6)	(-5, 3)	(-5, 3)	(-3, 3)	(-5, 3)
	Week 8	n	105	93	55	198	105	93	55	198
		Mean	0.6	0.7	0.5	0.6	-0.3	-0.3	-0.2	-0.3
		SD	1.1	1.4	1.1	1.3	1.2	1.2	1.2	1.2
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 5)	(0, 6)	(0, 5)	(0, 6)	(-5, 3)	(-5, 3)	(-5, 3)	(-5, 3)
	Week 16	n	94	73	43	167	94	73	43	167
		Mean	0.5	0.6	0.4	0.5	-0.3	-0.4	-0.3	-0.3
		SD	1.1	1.2	0.8	1.1	1.4	1.3	1.2	1.4
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 5)	(0, 6)	(0, 3)	(0, 6)	(-5, 5)	(-5, 3)	(-5, 2)	(-5, 5)

BARS: Barnes Akathisia Rating Scale

表 2.7.4.7－117　各評価時点での BARS 包括スコア及び BARS 合計スコア，並びに各スコアのベースラインからの変化量：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
BARS Total Score	Week 24	n	86	65	39	151	86	65	39	151
		Mean	0.5	0.6	0.5	0.6	-0.2	-0.4	-0.2	-0.3
		SD	1.0	1.2	0.9	1.1	1.4	1.3	1.4	1.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 6)	(0, 3)	(0, 6)	(-5, 6)	(-5, 3)	(-5, 3)	(-5, 6)
	Week 32	n	82	58	35	140	82	58	35	140
		Mean	0.4	0.7	0.5	0.5	-0.3	-0.2	-0.1	-0.3
		SD	1.0	1.3	1.0	1.2	1.4	1.0	1.0	1.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 6)	(0, 3)	(0, 6)	(-5, 6)	(-3, 2)	(-3, 2)	(-5, 6)
	Week 40	n	71	55	33	126	71	55	33	126
		Mean	0.3	0.7	0.7	0.5	-0.4	-0.3	0.0	-0.3
		SD	0.9	1.3	1.2	1.1	1.3	1.2	1.3	1.3
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 6)	(0, 4)	(0, 6)	(-5, 6)	(-3, 3)	(-3, 3)	(-5, 6)
	Week 48	n	67	50	29	117	67	50	29	117
		Mean	0.4	0.6	0.4	0.5	-0.3	-0.4	-0.3	-0.4
		SD	1.0	1.4	0.9	1.2	1.4	1.3	1.5	1.4
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 6)	(0, 3)	(0, 6)	(-5, 6)	(-6, 2)	(-6, 2)	(-6, 6)
	Week 52	n	66	49	28	115	66	49	28	115
		Mean	0.4	0.9	0.9	0.6	-0.3	-0.1	0.1	-0.2
		SD	0.9	1.8	1.7	1.4	1.1	1.1	1.1	1.1
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 5)	(0, 6)	(0, 6)	(0, 6)	(-4, 3)	(-3, 2)	(-2, 2)	(-4, 3)

BARS: Barnes Akathisia Rating Scale

5.3.5.1－1 Table 14.3.5.1.2.2 より引用

表 2.7.4.7－118　各評価時点での SAS 包括スコア及びベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
SAS Global Score	Baseline	n	85	84	169	84				
		Mean	2.8	3.2	3.0	3.3				
		SD	3.5	4.0	3.7	3.6				
		Median	2.0	2.0	2.0	2.0				
		(Min, Max)	(0, 16)	(0, 18)	(0, 18)	(0, 17)				
	Week 2	n	81	79	160	84	81	79	160	84
		Mean	2.6	3.9	3.2	3.0	-0.1	0.6	0.2	-0.3
		SD	3.1	4.6	4.0	3.6	1.6	2.0	1.8	1.6
		Median	2.0	2.0	2.0	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 18)	(0, 18)	(0, 16)	(-6, 7)	(-4, 9)	(-6, 9)	(-5, 9)
	Week 4	n	76	70	146	80	76	70	146	80
		Mean	2.5	3.4	3.0	2.6	-0.1	0.4	0.1	-0.4
		SD	3.2	4.2	3.7	3.4	2.1	2.4	2.3	1.7
		Median	1.0	2.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 18)	(0, 18)	(0, 16)	(-7, 7)	(-5, 9)	(-7, 9)	(-5, 8)
	Week 6	n	70	59	129	80	70	59	129	80
		Mean	2.3	3.3	2.8	2.6	-0.2	0.1	-0.1	-0.5
		SD	2.7	4.2	3.5	3.4	2.4	2.3	2.3	2.2
		Median	1.0	2.0	2.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 11)	(0, 18)	(0, 18)	(0, 16)	(-11, 7)	(-6, 12)	(-11, 12)	(-6, 9)

SAS: Simpson-Angus extrapyramidal side effects scale

5.3.5.1－1 Table 14.3.5.1.1.1 より引用

表 2.7.4.7－119　各評価時点での SAS 包括スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
SAS Global Score	Baseline	n	126	123	84	249				
		Mean	2.9	3.2	3.0	3.0				
		SD	3.5	3.7	3.5	3.6				
		Median	2.0	2.0	2.0	2.0				
		(Min, Max)	(0, 17)	(0, 18)	(0, 17)	(0, 18)				
	Week 2	n	81	79	59	160	81	79	59	160
		Mean	2.6	3.9	3.4	3.2	-0.1	0.6	0.5	0.2
		SD	3.1	4.6	4.3	4.0	1.6	2.0	1.9	1.8
		Median	2.0	2.0	2.0	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 18)	(0, 17)	(0, 18)	(-6, 7)	(-4, 9)	(-4, 9)	(-6, 9)
	Week 4	n	76	70	50	146	76	70	50	146
		Mean	2.5	3.4	3.1	3.0	-0.1	0.4	0.4	0.1
		SD	3.2	4.2	3.8	3.7	2.1	2.4	2.7	2.3
		Median	1.0	2.0	1.5	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 18)	(0, 15)	(0, 18)	(-7, 7)	(-5, 9)	(-5, 9)	(-7, 9)
	Week 6	n	70	59	39	129	70	59	39	129
		Mean	2.3	3.3	2.4	2.8	-0.2	0.1	-0.2	-0.1
		SD	2.7	4.2	3.7	3.5	2.4	2.3	2.6	2.3
		Median	1.0	2.0	1.0	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 11)	(0, 18)	(0, 18)	(0, 18)	(-11, 7)	(-6, 12)	(-6, 12)	(-11, 12)
	Week 8	n	105	93	55	198	105	93	55	198
		Mean	2.3	2.8	2.2	2.6	-0.4	-0.4	-0.7	-0.4
		SD	3.4	3.8	3.3	3.6	2.9	2.5	2.6	2.7
		Median	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 17)	(0, 18)	(0, 18)	(0, 18)	(-14, 14)	(-9, 12)	(-7, 12)	(-14, 14)
	Week 16	n	93	73	43	166	93	73	43	166
		Mean	2.1	3.3	2.9	2.6	-0.6	0.2	0.1	-0.2
		SD	2.9	4.9	5.3	3.9	2.6	4.2	4.9	3.4
		Median	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 15)	(0, 27)	(0, 27)	(0, 27)	(-13, 8)	(-9, 27)	(-5, 27)	(-13, 27)

SAS: Simpson-Angus extrapyramidal side effects scale

表 2.7.4.7－119　各評価時点での SAS 包括スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
SAS Global Score	Week 24	n	86	65	39	151	86	65	39	151
		Mean	2.0	3.1	2.9	2.5	-0.6	0.2	0.1	-0.2
		SD	3.1	4.4	4.8	3.7	2.8	3.4	3.9	3.1
		Median	1.0	2.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 18)	(0, 18)	(0, 18)	(-13, 11)	(-4, 18)	(-4, 18)	(-13, 18)
	Week 32	n	82	57	34	139	82	57	34	139
		Mean	2.4	2.6	2.1	2.5	-0.1	0.1	-0.2	-0.1
		SD	4.0	3.6	3.1	3.8	3.7	2.7	2.7	3.3
		Median	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 22)	(0, 16)	(0, 12)	(0, 22)	(-14, 20)	(-5, 12)	(-5, 12)	(-14, 20)
	Week 40	n	71	54	32	125	71	54	32	125
		Mean	2.6	2.3	1.6	2.5	0.1	-0.1	-0.5	0.0
		SD	5.1	3.5	2.7	4.5	4.8	2.5	2.3	4.0
		Median	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 31)	(0, 16)	(0, 14)	(0, 31)	(-13, 29)	(-5, 8)	(-5, 8)	(-13, 29)
	Week 48	n	66	49	28	115	66	49	28	115
		Mean	2.3	2.0	0.9	2.2	-0.3	-0.2	-0.9	-0.3
		SD	3.6	3.1	1.0	3.4	3.1	2.3	1.8	2.8
		Median	1.0	1.0	0.5	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 16)	(0, 16)	(0, 3)	(0, 16)	(-15, 11)	(-6, 7)	(-6, 2)	(-15, 11)
	Week 52	n	66	49	28	115	66	49	28	115
		Mean	2.6	2.4	2.1	2.5	0.1	0.2	0.2	0.1
		SD	3.6	3.6	3.2	3.6	3.1	2.2	2.2	2.7
		Median	1.0	1.0	0.5	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 16)	(0, 16)	(0, 13)	(0, 16)	(-12, 8)	(-3, 7)	(-3, 7)	(-12, 8)

SAS: Simpson-Angus extrapyramidal side effects scale

5.3.5.1－1 Table 14.3.5.1.1.2 より引用

表 2.7.4.7－120　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
Positive Scale	Baseline	n	55	54	109	53				
		Mean	11.7	11.2	11.5	11.6				
		SD	4.0	3.0	3.5	3.4				
		Median	11.0	11.0	11.0	12.0				
		(Min, Max)	(7, 31)	(7, 20)	(7, 31)	(7, 19)				
	Week 6	n	46	39	85	52	46	39	85	52
		Mean	11.8	11.5	11.7	11.2	0.2	0.0	0.1	-0.5
		SD	3.4	3.6	3.5	3.4	2.5	1.3	2.1	1.8
		Median	12.0	11.0	12.0	11.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 21)	(7, 21)	(7, 21)	(7, 22)	(-4, 13)	(-3, 4)	(-4, 13)	(-6, 5)

PANSS: Positive and Negative Syndrome Scale

表 2.7.4.7－120　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
Negative Scale	Baseline	n	55	54	109	53				
		Mean	16.3	15.9	16.1	17.0				
		SD	4.8	5.1	4.9	4.2				
		Median	16.0	16.0	16.0	17.0				
		(Min, Max)	(7, 29)	(7, 29)	(7, 29)	(7, 25)				
	Week 6	n	46	39	85	52	46	39	85	52
		Mean	16.2	16.1	16.2	16.5	0.4	-0.1	0.2	-0.5
		SD	4.2	5.1	4.6	4.7	2.2	2.8	2.5	2.5
		Median	17.0	17.0	17.0	17.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 27)	(7, 29)	(7, 29)	(7, 24)	(-6, 8)	(-12, 5)	(-12, 8)	(-6, 5)

PANSS: Positive and Negative Syndrome Scale

表 2.7.4.7－120　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
General Psychopathology Scale	Baseline	n	55	54	109	53				
		Mean	29.2	27.1	28.2	28.6				
		SD	6.8	6.4	6.6	5.2				
		Median	29.0	27.0	28.0	29.0				
		(Min, Max)	(16, 60)	(16, 45)	(16, 60)	(17, 37)				
	Week 6	n	46	39	85	52	46	39	85	52
		Mean	29.4	28.2	28.9	27.9	0.5	0.5	0.5	-0.8
		SD	6.7	6.5	6.6	5.5	5.6	3.3	4.7	3.4
		Median	30.0	27.0	29.0	28.0	0.0	0.0	0.0	0.0
		(Min, Max)	(16, 45)	(18, 44)	(16, 45)	(16, 45)	(-11, 23)	(-6, 13)	(-11, 23)	(-9, 9)

PANSS: Positive and Negative Syndrome Scale

表 2.7.4.7－120　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
Composite scale	Baseline	n	55	54	109	53				
		Mean	-4.6	-4.6	-4.6	-5.4				
		SD	5.2	5.8	5.4	5.1				
		Median	-4.0	-4.0	-4.0	-5.0				
		(Min, Max)	(-22, 4)	(-22, 4)	(-22, 4)	(-15, 5)				
	Week 6	n	46	39	85	52	46	39	85	52
		Mean	-4.4	-4.6	-4.5	-5.3	-0.2	0.1	0.0	0.0
		SD	4.6	5.9	5.2	5.0	2.8	2.9	2.8	2.9
		Median	-4.0	-4.0	-4.0	-5.0	0.0	0.0	0.0	0.0
		(Min, Max)	(-17, 4)	(-22, 3)	(-22, 4)	(-14, 5)	(-6, 10)	(-4, 14)	(-6, 14)	(-7, 8)

PANSS: Positive and Negative Syndrome Scale

5.3.5.1－1 Table 14.3.5.1.3.1 より引用

表 2.7.4.7－121　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
Positive Scale	Baseline	n	82	79	50	161				
		Mean	11.7	11.4	11.1	11.6				
		SD	3.9	3.1	3.2	3.5				
		Median	11.0	11.0	11.0	11.0				
		(Min, Max)	(7, 31)	(7, 20)	(7, 20)	(7, 31)				
	Week 6	n	46	39	21	85	46	39	21	85
		Mean	11.8	11.5	11.2	11.7	0.2	0.0	0.0	0.1
		SD	3.4	3.6	4.2	3.5	2.5	1.3	1.6	2.1
		Median	12.0	11.0	10.0	12.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 21)	(7, 21)	(7, 21)	(7, 21)	(-4, 13)	(-3, 4)	(-3, 4)	(-4, 13)
	Week 16	n	60	52	27	112	60	52	27	112
		Mean	11.6	10.7	10.4	11.2	0.0	-0.6	-0.6	-0.3
		SD	3.7	2.9	3.2	3.4	2.1	2.1	1.3	2.1
		Median	11.0	10.5	10.0	11.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 23)	(7, 19)	(7, 19)	(7, 23)	(-7, 6)	(-6, 6)	(-4, 2)	(-7, 6)
	Week 32	n	52	43	23	95	52	43	23	95
		Mean	11.7	11.0	10.7	11.4	-0.2	-0.5	-0.6	-0.3
		SD	4.0	3.2	3.6	3.7	2.4	2.5	2.8	2.5
		Median	11.0	11.0	11.0	11.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 25)	(7, 19)	(7, 19)	(7, 25)	(-7, 9)	(-10, 5)	(-10, 5)	(-10, 9)
	Week 48	n	42	35	17	77	42	35	17	77
		Mean	11.8	11.3	10.0	11.6	0.2	-0.1	-0.7	0.1
		SD	4.0	4.3	3.3	4.1	3.0	3.4	1.9	3.2
		Median	11.5	11.0	10.0	11.0	0.0	0.0	-1.0	0.0
		(Min, Max)	(7, 23)	(7, 27)	(7, 17)	(7, 27)	(-4, 12)	(-6, 14)	(-4, 3)	(-6, 14)

PANSS: Positive and Negative Syndrome Scale

表 2.7.4.7－121　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
Negative Scale	Baseline	n	82	79	50	161				
		Mean	16.7	16.1	15.1	16.4				
		SD	4.5	5.0	4.6	4.7				
		Median	16.0	16.0	15.5	16.0				
		(Min, Max)	(7, 29)	(7, 29)	(7, 25)	(7, 29)				
	Week 6	n	46	39	21	85	46	39	21	85
		Mean	16.2	16.1	15.0	16.2	0.4	-0.1	0.2	0.2
		SD	4.2	5.1	5.0	4.6	2.2	2.8	2.5	2.5
		Median	17.0	17.0	14.0	17.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 27)	(7, 29)	(7, 23)	(7, 29)	(-6, 8)	(-12, 5)	(-5, 5)	(-12, 8)
	Week 16	n	60	52	27	112	60	52	27	112
		Mean	16.2	16.5	15.3	16.3	-0.4	0.5	0.3	0.0
		SD	4.6	5.2	5.7	4.9	3.1	2.8	2.6	3.0
		Median	16.0	17.0	17.0	17.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 27)	(7, 30)	(7, 27)	(7, 30)	(-10, 8)	(-6, 8)	(-6, 5)	(-10, 8)
	Week 32	n	52	43	23	95	52	43	23	95
		Mean	16.8	17.1	16.1	16.9	0.0	0.6	0.8	0.3
		SD	5.0	4.9	5.3	5.0	3.2	3.8	3.3	3.5
		Median	17.0	19.0	18.0	17.0	0.0	0.0	0.0	0.0
		(Min, Max)	(7, 27)	(7, 28)	(7, 24)	(7, 28)	(-8, 8)	(-8, 11)	(-6, 8)	(-8, 11)
	Week 48	n	42	35	17	77	42	35	17	77
		Mean	17.2	17.7	16.1	17.5	0.5	1.0	1.1	0.7
		SD	5.8	5.7	6.0	5.7	3.5	3.1	3.1	3.3
		Median	18.0	19.0	17.0	18.0	0.0	1.0	1.0	1.0
		(Min, Max)	(7, 30)	(7, 31)	(7, 27)	(7, 31)	(-8, 8)	(-6, 7)	(-6, 7)	(-8, 8)

PANSS: Positive and Negative Syndrome Scale

表 2.7.4.7－121　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
General Psychopathology Scale	Baseline	n	82	79	50	161				
		Mean	29.1	27.5	27.2	28.3				
		SD	6.1	6.2	6.3	6.2				
		Median	29.0	28.0	27.5	29.0				
		(Min, Max)	(16, 60)	(16, 45)	(16, 37)	(16, 60)				
	Week 6	n	46	39	21	85	46	39	21	85
		Mean	29.4	28.2	28.4	28.9	0.5	0.5	0.9	0.5
		SD	6.7	6.5	6.4	6.6	5.6	3.3	3.7	4.7
		Median	30.0	27.0	29.0	29.0	0.0	0.0	0.0	0.0
		(Min, Max)	(16, 45)	(18, 44)	(18, 44)	(16, 45)	(-11, 23)	(-6, 13)	(-6, 13)	(-11, 23)
	Week 16	n	60	52	27	112	60	52	27	112
		Mean	28.4	28.4	27.8	28.4	-0.6	0.6	0.1	0.0
		SD	6.1	7.3	7.5	6.6	5.4	5.0	4.9	5.3
		Median	29.0	29.0	29.0	29.0	0.0	0.0	0.0	0.0
		(Min, Max)	(16, 40)	(16, 45)	(16, 42)	(16, 45)	(-17, 10)	(-9, 18)	(-9, 8)	(-17, 18)
	Week 32	n	52	43	23	95	52	43	23	95
		Mean	28.6	28.4	28.9	28.5	-0.5	0.7	1.1	0.0
		SD	7.7	7.0	8.0	7.3	6.6	5.1	4.8	6.0
		Median	28.5	29.0	30.0	29.0	0.0	1.0	1.0	0.0
		(Min, Max)	(16, 51)	(16, 42)	(16, 42)	(16, 51)	(-17, 18)	(-9, 12)	(-9, 12)	(-17, 18)
	Week 48	n	42	35	17	77	42	35	17	77
		Mean	30.0	28.4	28.0	29.3	0.9	0.9	1.1	0.9
		SD	8.2	8.2	8.7	8.2	8.0	7.0	6.1	7.5
		Median	28.5	28.0	28.0	28.0	-1.0	0.0	0.0	0.0
		(Min, Max)	(18, 51)	(16, 49)	(17, 43)	(16, 51)	(-9, 29)	(-9, 24)	(-9, 14)	(-9, 29)

PANSS: Positive and Negative Syndrome Scale

表 2.7.4.7－121　各評価時点での PANSS 陽性症状スコア，陰性症状スコア，全般的精神症状スコア及び Composite scale スコア，並びに各スコアのベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
Composite scale	Baseline	n	82	79	50	161				
		Mean	-4.9	-4.7	-4.0	-4.8				
		SD	5.1	5.6	5.0	5.3				
		Median	-4.0	-4.0	-3.5	-4.0				
		(Min, Max)	(-22, 4)	(-22, 5)	(-18, 4)	(-22, 5)				
	Week 6	n	46	39	21	85	46	39	21	85
		Mean	-4.4	-4.6	-3.8	-4.5	-0.2	0.1	-0.2	0.0
		SD	4.6	5.9	5.1	5.2	2.8	2.9	2.1	2.8
		Median	-4.0	-4.0	-2.0	-4.0	0.0	0.0	0.0	0.0
		(Min, Max)	(-17, 4)	(-22, 3)	(-15, 3)	(-22, 4)	(-6, 10)	(-4, 14)	(-4, 5)	(-6, 14)
	Week 16	n	60	52	27	112	60	52	27	112
		Mean	-4.6	-5.8	-4.9	-5.1	0.4	-1.1	-1.0	-0.3
		SD	5.0	5.3	5.0	5.2	3.1	3.3	2.9	3.3
		Median	-4.0	-5.5	-4.0	-5.0	0.0	-1.0	0.0	0.0
		(Min, Max)	(-17, 5)	(-23, 2)	(-20, 1)	(-23, 5)	(-6, 11)	(-9, 9)	(-6, 6)	(-9, 11)
	Week 32	n	52	43	23	95	52	43	23	95
		Mean	-5.1	-6.1	-5.4	-5.6	-0.2	-1.1	-1.3	-0.6
		SD	5.3	4.8	4.9	5.1	3.0	4.1	4.7	3.5
		Median	-5.0	-6.0	-5.0	-6.0	0.0	-1.0	-1.0	0.0
		(Min, Max)	(-17, 5)	(-21, 1)	(-15, 1)	(-21, 5)	(-6, 7)	(-14, 7)	(-14, 6)	(-14, 7)
	Week 48	n	42	35	17	77	42	35	17	77
		Mean	-5.5	-6.4	-6.1	-5.9	-0.3	-1.1	-1.8	-0.7
		SD	6.1	4.6	5.2	5.5	3.3	3.2	3.6	3.3
		Median	-5.0	-6.0	-8.0	-5.0	0.0	-1.0	-2.0	-1.0
		(Min, Max)	(-21, 7)	(-20, 1)	(-17, 1)	(-21, 7)	(-9, 7)	(-7, 8)	(-7, 6)	(-9, 8)

PANSS: Positive and Negative Syndrome Scale

5.3.5.1－1 Table 14.3.5.1.3.2 より引用

表 2.7.4.7－122　各評価時点での JCDSS 合計スコア及びベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
JCDSS Total Score	Baseline	n	55	54	109	53				
		Mean	2.8	2.7	2.8	2.4				
		SD	2.3	2.6	2.5	2.6				
		Median	2.0	2.0	2.0	2.0				
		(Min, Max)	(0, 9)	(0, 9)	(0, 9)	(0, 9)				
	Week 2	n	54	51	105	53	54	51	105	53
		Mean	2.7	3.1	2.9	2.4	0.0	0.3	0.1	0.0
		SD	2.7	3.2	2.9	3.0	2.4	1.7	2.1	1.5
		Median	2.0	2.0	2.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 11)	(0, 14)	(0, 14)	(0, 13)	(-5, 10)	(-3, 8)	(-5, 10)	(-4, 4)
	Week 4	n	50	46	96	52	50	46	96	52
		Mean	3.0	3.3	3.1	2.2	0.1	0.4	0.3	-0.2
		SD	2.9	3.4	3.1	2.7	2.5	3.0	2.8	1.4
		Median	2.0	2.5	2.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 12)	(0, 17)	(0, 17)	(0, 10)	(-5, 11)	(-4, 16)	(-5, 16)	(-4, 5)
	Week 6	n	46	40	86	52	46	40	86	52
		Mean	2.8	2.8	2.8	2.3	0.0	0.1	0.1	-0.1
		SD	3.3	2.6	3.0	3.0	3.3	2.2	2.9	1.7
		Median	2.5	2.0	2.0	1.0	-1.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 10)	(0, 14)	(0, 14)	(-5, 13)	(-7, 4)	(-7, 13)	(-4, 5)

JCDSS: The Japanese version of the Calgary Depression Scale for Schizophrenics

5.3.5.1－1 Table 14.3.5.1.4.1 より引用

表 2.7.4.7－123　各評価時点での JCDSS 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
JCDSS Total Score	Baseline	n	82	79	50	161				
		Mean	2.7	2.6	2.9	2.6				
		SD	2.4	2.6	2.7	2.5				
		Median	2.0	2.0	2.0	2.0				
		(Min, Max)	(0, 9)	(0, 9)	(0, 9)	(0, 9)				
	Week 2	n	54	51	33	105	54	51	33	105
		Mean	2.7	3.1	3.5	2.9	0.0	0.3	0.5	0.1
		SD	2.7	3.2	3.3	2.9	2.4	1.7	2.1	2.1
		Median	2.0	2.0	3.0	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 11)	(0, 14)	(0, 14)	(0, 14)	(-5, 10)	(-3, 8)	(-3, 8)	(-5, 10)
	Week 4	n	50	46	28	96	50	46	28	96
		Mean	3.0	3.3	3.8	3.1	0.1	0.4	0.7	0.3
		SD	2.9	3.4	3.6	3.1	2.5	3.0	3.6	2.8
		Median	2.0	2.5	4.0	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 12)	(0, 17)	(0, 17)	(0, 17)	(-5, 11)	(-4, 16)	(-4, 16)	(-5, 16)
	Week 6	n	46	40	22	86	46	40	22	86
		Mean	2.8	2.8	2.9	2.8	0.0	0.1	-0.1	0.1
		SD	3.3	2.6	2.3	3.0	3.3	2.2	2.7	2.9
		Median	2.5	2.0	2.0	2.0	-1.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 10)	(0, 8)	(0, 14)	(-5, 13)	(-7, 4)	(-7, 4)	(-7, 13)
	Week 8	n	68	62	33	130	68	62	33	130
		Mean	2.4	2.8	3.1	2.6	0.0	0.2	0.0	0.1
		SD	2.9	3.2	3.2	3.0	2.5	2.2	2.5	2.3
		Median	1.0	2.0	2.0	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 10)	(0, 13)	(0, 10)	(0, 13)	(-8, 9)	(-8, 5)	(-8, 5)	(-8, 9)
	Week 12	n	66	55	27	121	66	55	27	121
		Mean	2.1	3.1	3.7	2.6	-0.3	0.6	0.8	0.1
		SD	2.9	3.8	4.5	3.3	2.4	3.0	3.7	2.8
		Median	1.0	2.0	2.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 14)	(0, 20)	(0, 20)	(0, 20)	(-7, 10)	(-6, 11)	(-6, 11)	(-7, 11)

JCDSS: The Japanese version of the Calgary Depression Scale for Schizophrenics

表 2.7.4.7－123　各評価時点での JCDSS 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
JCDSS Total Score	Week 16	n	60	52	27	112	60	52	27	112
		Mean	1.9	3.4	4.2	2.6	-0.5	0.8	1.3	0.1
		SD	2.3	4.5	5.4	3.5	1.8	3.5	4.4	2.8
		Median	1.0	1.0	2.0	1.0	0.0	0.0	1.0	0.0
		(Min, Max)	(0, 11)	(0, 23)	(0, 23)	(0, 23)	(-6, 4)	(-8, 14)	(-8, 14)	(-8, 14)
	Week 20	n	59	49	26	108	59	49	26	108
		Mean	1.9	2.8	3.8	2.3	-0.5	0.1	0.9	-0.2
		SD	2.5	4.2	5.1	3.4	2.1	3.1	3.9	2.6
		Median	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 11)	(0, 18)	(0, 18)	(0, 18)	(-7, 5)	(-8, 11)	(-8, 11)	(-8, 11)
	Week 24	n	56	48	26	104	56	48	26	104
		Mean	2.0	2.8	3.0	2.4	-0.3	0.0	0.0	-0.1
		SD	3.1	3.3	3.5	3.2	2.7	2.7	3.3	2.7
		Median	1.0	1.0	1.5	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 12)	(0, 12)	(0, 12)	(0, 12)	(-7, 9)	(-7, 9)	(-7, 9)	(-7, 9)
	Week 28	n	55	45	25	100	55	45	25	100
		Mean	2.2	3.0	3.9	2.5	-0.1	0.3	0.8	0.1
		SD	2.9	4.3	5.0	3.6	2.8	3.3	3.9	3.0
		Median	1.0	1.0	2.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 11)	(0, 18)	(0, 18)	(0, 18)	(-6, 10)	(-8, 10)	(-8, 10)	(-8, 10)
	Week 32	n	52	43	23	95	52	43	23	95
		Mean	1.9	2.5	3.3	2.2	-0.4	0.0	0.5	-0.2
		SD	2.6	3.5	4.1	3.0	2.2	3.3	4.1	2.7
		Median	1.0	1.0	1.0	1.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 10)	(0, 13)	(0, 13)	(0, 13)	(-7, 5)	(-9, 10)	(-9, 10)	(-9, 10)
	Week 36	n	49	41	22	90	49	41	22	90
		Mean	1.4	3.2	4.0	2.2	-0.9	0.6	1.1	-0.2
		SD	2.3	3.6	4.3	3.1	2.1	3.5	4.4	2.9
		Median	0.0	1.0	2.0	1.0	-1.0	0.0	0.0	0.0
		(Min, Max)	(0, 10)	(0, 13)	(0, 13)	(0, 13)	(-8, 5)	(-7, 12)	(-7, 12)	(-8, 12)

JCDSS: The Japanese version of the Calgary Depression Scale for Schizophrenics

表 2.7.4.7－123　各評価時点での JCDSS 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
JCDSS Total Score	Week 40	n	46	40	21	86	46	40	21	86
		Mean	1.3	2.7	3.5	2.0	-0.9	0.0	0.5	-0.5
		SD	2.1	3.5	4.4	2.9	2.1	3.1	3.7	2.6
		Median	1.0	1.5	2.0	1.0	-1.0	0.0	0.0	0.0
		(Min, Max)	(0, 10)	(0, 14)	(0, 14)	(0, 14)	(-7, 5)	(-6, 11)	(-6, 11)	(-7, 11)
	Week 44	n	42	36	17	78	42	36	17	78
		Mean	1.6	2.5	2.4	2.0	-0.6	0.1	0.0	-0.3
		SD	2.5	4.3	3.7	3.4	2.2	3.5	3.2	2.9
		Median	1.0	1.0	0.0	1.0	-1.0	0.0	0.0	-0.5
		(Min, Max)	(0, 10)	(0, 21)	(0, 13)	(0, 21)	(-7, 6)	(-6, 15)	(-6, 10)	(-7, 15)
	Week 48	n	42	35	17	77	42	35	17	77
		Mean	2.0	2.0	2.3	2.0	-0.2	-0.3	-0.1	-0.2
		SD	3.7	2.7	3.5	3.3	3.4	2.3	2.9	3.0
		Median	0.0	1.0	1.0	1.0	-1.0	0.0	0.0	-1.0
		(Min, Max)	(0, 16)	(0, 12)	(0, 12)	(0, 16)	(-8, 13)	(-4, 9)	(-3, 9)	(-8, 13)
	Week 52	n	42	35	17	77	42	35	17	77
		Mean	1.1	2.3	3.1	1.7	-1.1	0.1	0.7	-0.6
		SD	1.7	2.8	3.6	2.3	1.9	2.0	2.5	2.1
		Median	0.0	1.0	2.0	1.0	-1.0	0.0	0.0	0.0
		(Min, Max)	(0, 6)	(0, 11)	(0, 11)	(0, 11)	(-6, 4)	(-4, 6)	(-4, 6)	(-6, 6)

JCDSS: The Japanese version of the Calgary Depression Scale for Schizophrenics

5.3.5.1－1 Table 14.3.5.1.4.2 より引用

表 2.7.4.7－124　各評価時点での MADRS-J 合計スコア及びベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
MADRS-J Total Score	Baseline	n	30	30	60	31				
		Mean	5.9	5.9	5.9	5.2				
		SD	4.2	3.9	4.0	4.0				
		Median	6.5	5.0	6.0	4.0				
		(Min, Max)	(0, 12)	(0, 13)	(0, 13)	(0, 12)				
	Week 2	n	28	28	56	31	28	28	56	31
		Mean	7.2	6.5	6.9	5.6	1.5	0.8	1.2	0.4
		SD	6.4	5.6	5.9	4.5	5.4	5.2	5.3	2.7
		Median	6.5	5.0	6.0	5.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 25)	(0, 18)	(0, 25)	(0, 14)	(-6, 17)	(-12, 13)	(-12, 17)	(-5, 6)
	Week 4	n	27	24	51	28	27	24	51	28
		Mean	6.0	7.0	6.5	5.6	0.4	1.2	0.8	0.9
		SD	5.5	6.0	5.7	5.7	4.7	4.9	4.8	4.6
		Median	6.0	6.0	6.0	2.5	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 24)	(0, 26)	(0, 26)	(0, 19)	(-10, 15)	(-4, 14)	(-10, 15)	(-7, 9)
	Week 6	n	24	20	44	28	24	20	44	28
		Mean	6.3	7.0	6.6	5.1	0.7	0.8	0.7	0.3
		SD	6.1	6.1	6.0	5.2	4.5	5.3	4.8	4.6
		Median	3.5	5.5	4.5	2.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 22)	(0, 20)	(0, 22)	(0, 15)	(-8, 11)	(-12, 11)	(-12, 11)	(-8, 9)

MADRS-J: The Japanese version of the Montgomery–Asberg Depression Rating Scale

5.3.5.1－1 Table 14.3.5.1.5.1 より引用

表 2.7.4.7－125　各評価時点での MADRS-J 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
MADRS-J Total Score	Baseline	n	44	44	34	88				
		Mean	5.4	5.6	6.0	5.5				
		SD	4.1	3.9	4.0	3.9				
		Median	6.0	4.5	5.5	5.0				
		(Min, Max)	(0, 12)	(0, 13)	(0, 13)	(0, 13)				
	Week 2	n	28	28	26	56	28	28	26	56
		Mean	7.2	6.5	6.7	6.9	1.5	0.8	0.8	1.2
		SD	6.4	5.6	5.7	5.9	5.4	5.2	5.3	5.3
		Median	6.5	5.0	5.0	6.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 25)	(0, 18)	(0, 18)	(0, 25)	(-6, 17)	(-12, 13)	(-12, 13)	(-12, 17)
	Week 4	n	27	24	22	51	27	24	22	51
		Mean	6.0	7.0	7.3	6.5	0.4	1.2	1.3	0.8
		SD	5.5	6.0	6.1	5.7	4.7	4.9	5.1	4.8
		Median	6.0	6.0	6.0	6.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 24)	(0, 26)	(0, 26)	(0, 26)	(-10, 15)	(-4, 14)	(-4, 14)	(-10, 15)
	Week 6	n	24	20	18	44	24	20	18	44
		Mean	6.3	7.0	7.3	6.6	0.7	0.8	0.8	0.7
		SD	6.1	6.1	6.4	6.0	4.5	5.3	5.6	4.8
		Median	3.5	5.5	6.0	4.5	0.0	0.0	0.5	0.0
		(Min, Max)	(0, 22)	(0, 20)	(0, 20)	(0, 22)	(-8, 11)	(-12, 11)	(-12, 11)	(-12, 11)
	Week 8	n	37	31	22	68	37	31	22	68
		Mean	5.8	7.5	9.0	6.6	0.7	1.6	2.6	1.1
		SD	6.1	6.9	7.1	6.5	5.5	4.9	5.4	5.2
		Median	3.0	6.0	7.5	4.5	0.0	0.0	1.0	0.0
		(Min, Max)	(0, 19)	(0, 29)	(0, 29)	(0, 29)	(-10, 13)	(-5, 16)	(-5, 16)	(-10, 16)
	Week 12	n	34	26	20	60	34	26	20	60
		Mean	5.4	8.6	10.4	6.8	0.4	3.2	4.1	1.6
		SD	6.5	10.2	10.9	8.4	6.1	9.0	9.9	7.5
		Median	2.5	4.5	5.5	4.0	0.0	1.0	2.0	0.0
		(Min, Max)	(0, 24)	(0, 40)	(0, 40)	(0, 40)	(-10, 17)	(-10, 28)	(-10, 28)	(-10, 28)

MADRS-J: The Japanese version of the Montgomery–Asberg Depression Rating Scale

表 2.7.4.7－125　各評価時点での MADRS-J 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
MADRS-J Total Score	Week 16	n	34	21	16	55	34	21	16	55
		Mean	6.0	10.3	11.2	7.7	1.0	4.6	4.4	2.3
		SD	6.4	9.8	9.7	8.1	6.8	9.4	9.6	8.0
		Median	3.5	5.0	10.0	5.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 19)	(0, 30)	(0, 30)	(0, 30)	(-11, 15)	(-8, 22)	(-8, 22)	(-11, 22)
	Week 20	n	33	18	13	51	33	18	13	51
		Mean	7.5	9.7	9.5	8.3	2.4	4.1	2.6	3.0
		SD	8.4	10.6	10.3	9.2	7.4	10.2	9.6	8.5
		Median	5.0	6.5	9.0	5.0	0.0	1.5	0.0	0.0
		(Min, Max)	(0, 35)	(0, 37)	(0, 37)	(0, 37)	(-11, 26)	(-7, 29)	(-7, 29)	(-11, 29)
	Week 24	n	30	17	13	47	30	17	13	47
		Mean	6.2	9.6	9.5	7.4	1.2	3.8	2.7	2.1
		SD	7.4	10.8	10.3	8.8	6.4	10.1	9.5	7.9
		Median	2.5	7.0	8.0	5.0	0.0	0.0	-1.0	0.0
		(Min, Max)	(0, 23)	(0, 36)	(0, 36)	(0, 36)	(-11, 16)	(-6, 28)	(-6, 28)	(-11, 28)
	Week 28	n	30	16	12	46	30	16	12	46
		Mean	6.9	9.0	9.2	7.6	1.9	3.1	2.2	2.3
		SD	7.8	11.2	10.4	9.0	6.2	10.2	9.2	7.8
		Median	4.0	4.5	6.5	4.0	0.0	-0.5	-0.5	0.0
		(Min, Max)	(0, 27)	(0, 35)	(0, 35)	(0, 35)	(-10, 17)	(-6, 27)	(-6, 27)	(-10, 27)
	Week 32	n	30	15	12	45	30	15	12	45
		Mean	5.5	7.7	9.2	6.2	0.5	1.7	2.2	0.9
		SD	7.2	9.4	10.0	8.0	6.3	7.8	8.7	6.8
		Median	3.0	5.0	8.5	3.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 26)	(0, 32)	(0, 32)	(0, 32)	(-11, 14)	(-8, 24)	(-8, 24)	(-11, 24)
	Week 36	n	28	15	12	43	28	15	12	43
		Mean	6.1	7.7	9.5	6.7	1.2	1.7	2.5	1.4
		SD	7.2	10.0	10.4	8.2	6.6	8.4	9.3	7.2
		Median	3.5	5.0	8.0	4.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 24)	(0, 34)	(0, 34)	(0, 34)	(-11, 17)	(-8, 26)	(-8, 26)	(-11, 26)

MADRS-J: The Japanese version of the Montgomery–Asberg Depression Rating Scale

表 2.7.4.7－125　各評価時点での MADRS-J 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
MADRS-J Total Score	Week 40	n	25	15	12	40	25	15	12	40
		Mean	5.8	8.3	10.2	6.7	1.0	2.3	3.2	1.5
		SD	7.2	9.9	10.3	8.3	7.2	8.2	9.1	7.5
		Median	3.0	5.0	7.5	3.0	0.0	0.0	1.0	0.0
		(Min, Max)	(0, 25)	(0, 34)	(0, 34)	(0, 34)	(-11, 18)	(-8, 26)	(-8, 26)	(-11, 26)
	Week 44	n	25	15	12	40	25	15	12	40
		Mean	5.6	9.7	11.8	7.2	0.8	3.7	4.8	1.9
		SD	7.7	10.2	10.4	8.8	6.8	8.0	8.6	7.3
		Median	2.0	6.0	9.5	3.5	0.0	0.0	1.5	0.0
		(Min, Max)	(0, 26)	(0, 33)	(0, 33)	(0, 33)	(-11, 18)	(-4, 25)	(-4, 25)	(-11, 25)
	Week 48	n	25	15	12	40	25	15	12	40
		Mean	5.2	8.2	9.9	6.3	0.4	2.2	2.9	1.1
		SD	6.1	9.9	10.4	7.7	5.4	8.2	9.1	6.5
		Median	2.0	5.0	7.0	3.5	0.0	0.0	-0.5	0.0
		(Min, Max)	(0, 18)	(0, 31)	(0, 31)	(0, 31)	(-11, 10)	(-7, 23)	(-7, 23)	(-11, 23)
	Week 52	n	24	14	11	38	24	14	11	38
		Mean	6.2	9.9	11.7	7.5	1.7	4.0	4.8	2.5
		SD	7.2	12.7	13.9	9.6	6.4	11.1	12.5	8.4
		Median	3.5	5.0	7.0	4.0	1.5	0.5	0.0	1.0
		(Min, Max)	(0, 21)	(0, 42)	(0, 42)	(0, 42)	(-10, 15)	(-8, 30)	(-8, 30)	(-10, 30)

MADRS-J: The Japanese version of the Montgomery–Asberg Depression Rating Scale

5.3.5.1－1 Table 14.3.5.1.5.2 より引用

表 2.7.4.7－126　各評価時点での YMRS 合計スコア及びベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
YMRS Total Score	Baseline	n	30	30	60	31				
		Mean	1.3	1.4	1.4	1.1				
		SD	1.9	1.7	1.8	1.9				
		Median	0.0	1.0	1.0	0.0				
		(Min, Max)	(0, 7)	(0, 6)	(0, 7)	(0, 8)				
	Week 6	n	24	20	44	28	24	20	44	28
		Mean	0.3	1.8	1.0	0.8	-0.6	0.0	-0.3	-0.3
		SD	0.6	3.1	2.3	1.8	1.2	2.2	1.7	1.6
		Median	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 13)	(0, 13)	(0, 8)	(-3, 2)	(-2, 7)	(-3, 7)	(-7, 2)

YMRS: Young Mania Rating Scale

5.3.5.1－1 Table 14.3.5.1.6.1 より引用

表 2.7.4.7－127　各評価時点での YMRS 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
YMRS Total Score	Baseline	n	44	44	34	88				
		Mean	1.6	1.0	1.4	1.3				
		SD	2.1	1.6	1.6	1.9				
		Median	1.0	0.0	1.0	0.0				
		(Min, Max)	(0, 8)	(0, 6)	(0, 6)	(0, 8)				
	Week 6	n	24	20	18	44	24	20	18	44
		Mean	0.3	1.8	1.9	1.0	-0.6	0.0	-0.1	-0.3
		SD	0.6	3.1	3.3	2.3	1.2	2.2	2.3	1.7
		Median	0.0	0.5	0.5	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 13)	(0, 13)	(0, 13)	(-3, 2)	(-2, 7)	(-2, 7)	(-3, 7)
	Week 16	n	34	21	16	55	34	21	16	55
		Mean	0.8	1.2	1.6	1.0	-0.5	-0.1	-0.2	-0.4
		SD	1.9	2.1	2.3	2.0	1.8	2.6	2.9	2.1
		Median	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 8)	(0, 9)	(0, 9)	(0, 9)	(-7, 4)	(-4, 9)	(-4, 9)	(-7, 9)
	Week 32	n	30	15	12	45	30	15	12	45
		Mean	0.3	0.9	1.0	0.5	-0.7	-0.4	-0.7	-0.6
		SD	0.7	1.2	1.3	0.9	1.5	1.6	1.6	1.5
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 2)	(0, 3)	(0, 3)	(0, 3)	(-6, 2)	(-4, 2)	(-4, 2)	(-6, 2)
	Week 48	n	25	15	12	40	25	15	12	40
		Mean	0.9	0.7	0.8	0.8	-0.2	-0.7	-0.8	-0.4
		SD	3.2	1.0	1.1	2.6	3.6	1.7	1.9	3.0
		Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		(Min, Max)	(0, 16)	(0, 3)	(0, 3)	(0, 16)	(-5, 16)	(-4, 2)	(-4, 2)	(-5, 16)

YMRS: Young Mania Rating Scale

5.3.5.1－1 Table 14.3.5.1.6.2 より引用

表 2.7.4.7－128　各評価時点での MMSE-J 合計スコア及びベースラインからの変化量：プラセボ対照二重盲検期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)	40 mg (N=85)	80 mg (N=84)	All MT-5199 (N=169)	Placebo (N=84)
MMSE-J Total Score	Baseline	n	85	84	169	84				
		Mean	26.6	26.8	26.7	26.1				
		SD	3.6	3.8	3.7	3.6				
		Median	28.0	28.0	28.0	27.0				
		(Min, Max)	(16, 30)	(6, 30)	(6, 30)	(15, 30)				
	Week 6	n	70	59	129	80	70	59	129	80
		Mean	27.1	27.2	27.2	26.9	0.3	0.6	0.4	0.7
		SD	3.8	4.2	4.0	3.3	2.0	2.1	2.1	2.0
		Median	29.0	29.0	29.0	28.0	0.0	1.0	0.0	0.5
		(Min, Max)	(16, 30)	(6, 30)	(6, 30)	(16, 30)	(-5, 6)	(-5, 7)	(-5, 7)	(-5, 5)

MMSE-J: Mini Mental State Examination-Japanese

5.3.5.1－1 Table 14.3.5.1.7.1 より引用

表 2.7.4.7－129　各評価時点での MMSE-J 合計スコア及びベースラインからの変化量：MT-5199 長期投与期間（MT-5199-J02 試験）

			Absolute				Change from baseline			
			MT-5199				MT-5199			
Parameter	Analysis visit	Statistics	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)	40 mg (N=126)	80 mg (N=123)	80 mg (no dose reduction) (N=84)	All MT-5199 (N=249)
MMSE-J Total Score	Baseline	n	126	123	84	249				
		Mean	26.6	26.5	26.7	26.5				
		SD	3.7	3.7	3.2	3.7				
		Median	28.0	28.0	28.0	28.0				
		(Min, Max)	(15, 30)	(6, 30)	(18, 30)	(6, 30)				
	Week 6	n	70	59	39	129	70	59	39	129
		Mean	27.1	27.2	27.8	27.2	0.3	0.6	0.3	0.4
		SD	3.8	4.2	3.1	4.0	2.0	2.1	2.0	2.1
		Median	29.0	29.0	29.0	29.0	0.0	1.0	1.0	0.0
		(Min, Max)	(16, 30)	(6, 30)	(19, 30)	(6, 30)	(-5, 6)	(-5, 7)	(-5, 5)	(-5, 7)
	Week 12	n	99	79	47	178	99	79	47	178
		Mean	27.3	27.6	27.7	27.4	0.7	0.9	1.1	0.8
		SD	4.0	3.1	2.9	3.6	2.2	2.4	2.2	2.3
		Median	29.0	29.0	29.0	29.0	0.0	1.0	1.0	0.0
		(Min, Max)	(13, 30)	(18, 30)	(20, 30)	(13, 30)	(-6, 6)	(-9, 7)	(-4, 7)	(-9, 7)
	Week 28	n	83	60	37	143	83	60	37	143
		Mean	27.2	27.6	27.6	27.4	0.5	0.9	1.0	0.6
		SD	3.9	3.6	3.7	3.8	2.6	2.4	2.5	2.5
		Median	29.0	30.0	30.0	29.0	1.0	0.0	0.0	0.0
		(Min, Max)	(12, 30)	(18, 30)	(19, 30)	(12, 30)	(-11, 6)	(-7, 7)	(-5, 7)	(-11, 7)
	Week 48	n	66	50	29	116	66	50	29	116
		Mean	27.0	28.2	28.2	27.5	0.5	0.9	0.7	0.7
		SD	4.0	2.8	3.0	3.5	2.6	2.0	2.1	2.3
		Median	29.0	29.0	29.0	29.0	0.5	0.0	0.0	0.0
		(Min, Max)	(11, 30)	(17, 30)	(17, 30)	(11, 30)	(-12, 6)	(-4, 5)	(-4, 5)	(-12, 6)

MMSE-J: Mini Mental State Examination-Japanese

5.3.5.1－1 Table 14.3.5.1.7.2 より引用

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Any System Organ Class		38 (74.5)	41 (75.9)	79 (75.2)	22 (45.8)	16 (47.1)	26 (86.7)	42 (65.6)	15 (41.7)
Infections and infestations	感染症および寄生虫症	7 (13.7)	4 (7.4)	11 (10.5)	4 (8.3)	3 (8.8)	5 (16.7)	8 (12.5)	3 (8.3)
Nasopharyngitis	上咽頭炎	4 (7.8)	3 (5.6)	7 (6.7)	3 (6.3)	2 (5.9)	1 (3.3)	3 (4.7)	3 (8.3)
Pneumonia	肺炎	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	1 (2.9)	1 (3.3)	2 (3.1)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Influenza	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Periodontitis	歯周炎	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Upper respiratory tract infection	上気道感染	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	1 (1.9)	1 (1.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin papilloma	皮膚乳頭腫	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blepharal papilloma	眼瞼乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	4 (7.8)	1 (1.9)	5 (4.8)	2 (4.2)	2 (5.9)	3 (10.0)	5 (7.8)	0 (0.0)
Decreased appetite	食欲減退	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	1 (2.9)	1 (3.3)	2 (3.1)	0 (0.0)
Dehydration	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.1)	0 (0.0)
Diabetes mellitus	糖尿病	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperuricaemia	高尿酸血症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polydipsia	多飲症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (2.0)	0 (0.0)	1 (1.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Psychiatric disorders	精神障害	15 (29.4)	11 (20.4)	26 (24.8)	2 (4.2)	2 (5.9)	5 (16.7)	7 (10.9)	3 (8.3)
Insomnia	不眠症	2 (3.9)	4 (7.4)	6 (5.7)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	1 (2.8)
Schizophrenia	統合失調症	7 (13.7)	0 (0.0)	7 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Anxiety	不安	1 (2.0)	4 (7.4)	5 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	3 (10.0)	3 (4.7)	1 (2.8)
Disinhibition	脱抑制	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	1 (1.9)	1 (1.0)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Panic attack	パニック発作	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Depressive symptom	抑うつ症状	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somatic symptom disorder	身体症状症	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Nervous system disorders	神経系障害	14 (27.5)	27 (50.0)	41 (39.0)	5 (10.4)	6 (17.6)	11 (36.7)	17 (26.6)	1 (2.8)
Somnolence	傾眠	7 (13.7)	14 (25.9)	21 (20.0)	2 (4.2)	3 (8.8)	7 (23.3)	10 (15.6)	0 (0.0)
Akathisia	アカシジア	3 (5.9)	4 (7.4)	7 (6.7)	1 (2.1)	1 (2.9)	1 (3.3)	2 (3.1)	0 (0.0)
Headache	頭痛	1 (2.0)	3 (5.6)	4 (3.8)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	1 (2.8)
Tremor	振戦	0 (0.0)	2 (3.7)	2 (1.9)	0 (0.0)	0 (0.0)	3 (10.0)	3 (4.7)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	2 (3.7)	2 (1.9)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Drooling	よだれ	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	1 (2.0)	1 (1.9)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia	感覚鈍麻	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Seizure	痙攣発作	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Eye disorders	眼障害	1 (2.0)	1 (1.9)	2 (1.9)	2 (4.2)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Blepharitis	眼瞼炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	2 (3.9)	0 (0.0)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deafness neurosensory	感音性難聴	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	心臓障害	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	動悸	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Hypertension	高血圧	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1 (2.0)	2 (3.7)	3 (2.9)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.1)	1 (2.8)
Asthma	喘息	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Gastrointestinal disorders	胃腸障害	5 (9.8)	14 (25.9)	19 (18.1)	6 (12.5)	3 (8.8)	6 (20.0)	9 (14.1)	1 (2.8)
Salivary hypersecretion	流涎過多	3 (5.9)	6 (11.1)	9 (8.6)	1 (2.1)	0 (0.0)	3 (10.0)	3 (4.7)	0 (0.0)
Constipation	便秘	1 (2.0)	0 (0.0)	1 (1.0)	1 (2.1)	1 (2.9)	1 (3.3)	2 (3.1)	0 (0.0)
Nausea	悪心	0 (0.0)	3 (5.6)	3 (2.9)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	下痢	1 (2.0)	1 (1.9)	2 (1.9)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry mouth	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.1)	0 (0.0)
Dysphagia	嚥下障害	1 (2.0)	1 (1.9)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastritis	胃炎	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Toothache	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Hepatic steatosis	脂肪肝	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	5 (9.8)	4 (7.4)	9 (8.6)	3 (6.3)	1 (2.9)	2 (6.7)	3 (4.7)	2 (5.6)
Urticaria	蕁麻疹	2 (3.9)	2 (3.7)	4 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	湿疹	1 (2.0)	1 (1.9)	2 (1.9)	2 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Alopecia areata	円形脱毛症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry skin	皮膚乾燥	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	3 (5.9)	2 (3.7)	5 (4.8)	2 (4.2)	1 (2.9)	3 (10.0)	4 (6.3)	3 (8.3)
Back pain	背部痛	2 (3.9)	1 (1.9)	3 (2.9)	0 (0.0)	1 (2.9)	1 (3.3)	2 (3.1)	2 (5.6)
Neck pain	頚部痛	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Posture abnormal	姿勢異常	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Renal and urinary disorders	腎および尿路障害	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	1 (2.8)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Polyuria	多尿	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	5 (9.8)	7 (13.0)	12 (11.4)	0 (0.0)	5 (14.7)	4 (13.3)	9 (14.1)	2 (5.6)
Malaise	倦怠感	2 (3.9)	3 (5.6)	5 (4.8)	0 (0.0)	3 (8.8)	1 (3.3)	4 (6.3)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (3.7)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	口渇	2 (3.9)	0 (0.0)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Asthenia	無力症	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Oedema peripheral	末梢性浮腫	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Pyrexia	発熱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Investigations	臨床検査	3 (5.9)	1 (1.9)	4 (3.8)	0 (0.0)	1 (2.9)	1 (3.3)	2 (3.1)	1 (2.8)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	1 (3.3)	2 (3.1)	1 (2.8)
Weight increased	体重増加	1 (2.0)	1 (1.9)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－130　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	2 (3.9)	1 (1.9)	3 (2.9)	3 (6.3)	1 (2.9)	1 (3.3)	2 (3.1)	0 (0.0)
Fall	転倒	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Head injury	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Contusion	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Heat illness	熱中症	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.3.1.1 より引用

表 2.7.4.7－131　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65				>=65			
		MT-5199				MT-5199			
		40 mg (N=51) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=105) n(%)	Placebo (N=48) n(%)	40 mg (N=34) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=64) n(%)	Placebo (N=36) n(%)
Any AESI		27 (52.9)	35 (64.8)	62 (59.0)	10 (20.8)	9 (26.5)	18 (60.0)	27 (42.2)	5 (13.9)
Somnolence	傾眠関連有害事象	10 (19.6)	16 (29.6)	26 (24.8)	2 (4.2)	6 (17.6)	8 (26.7)	14 (21.9)	0 (0.0)
Somnolence	傾眠	7 (13.7)	14 (25.9)	21 (20.0)	2 (4.2)	3 (8.8)	7 (23.3)	10 (15.6)	0 (0.0)
Malaise	倦怠感	2 (3.9)	3 (5.6)	5 (4.8)	0 (0.0)	3 (8.8)	1 (3.3)	4 (6.3)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (3.7)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	4 (7.8)	4 (7.4)	8 (7.6)	4 (8.3)	1 (2.9)	3 (10.0)	4 (6.3)	2 (5.6)
Urticaria	蕁麻疹	2 (3.9)	2 (3.7)	4 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	湿疹	1 (2.0)	1 (1.9)	2 (1.9)	2 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Blister	水疱	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Dermatitis	皮膚炎	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－131　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=51) n(%)	<65 MT-5199 80 mg (N=54) n(%)	<65 All MT-5199 (N=105) n(%)	<65 Placebo (N=48) n(%)	>=65 MT-5199 40 mg (N=34) n(%)	>=65 MT-5199 80 mg (N=30) n(%)	>=65 All MT-5199 (N=64) n(%)	>=65 Placebo (N=36) n(%)
Parkinsonism	パーキンソニズム関連有害事象	3 (5.9)	11 (20.4)	14 (13.3)	1 (2.1)	2 (5.9)	7 (23.3)	9 (14.1)	0 (0.0)
Salivary hypersecretion	流涎過多	3 (5.9)	6 (11.1)	9 (8.6)	1 (2.1)	0 (0.0)	3 (10.0)	3 (4.7)	0 (0.0)
Tremor	振戦	0 (0.0)	2 (3.7)	2 (1.9)	0 (0.0)	0 (0.0)	3 (10.0)	3 (4.7)	0 (0.0)
Drooling	よだれ	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	5 (9.8)	0 (0.0)	5 (4.8)	0 (0.0)	1 (2.9)	3 (10.0)	4 (6.3)	1 (2.8)
Depression	うつ病	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	3 (10.0)	3 (4.7)	1 (2.8)
Depressed mood	抑うつ気分	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Depressive symptom	抑うつ症状	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Akathisia	アカシジア関連有害事象	3 (5.9)	6 (11.1)	9 (8.6)	1 (2.1)	1 (2.9)	2 (6.7)	3 (4.7)	0 (0.0)
Akathisia	アカシジア	3 (5.9)	4 (7.4)	7 (6.7)	1 (2.1)	1 (2.9)	1 (3.3)	2 (3.1)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	1 (2.0)	4 (7.4)	5 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	1 (2.0)	4 (7.4)	5 (4.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－131　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=51) n(%)	<65 MT-5199 80 mg (N=54) n(%)	<65 All MT-5199 (N=105) n(%)	<65 Placebo (N=48) n(%)	>=65 MT-5199 40 mg (N=34) n(%)	>=65 MT-5199 80 mg (N=30) n(%)	>=65 All MT-5199 (N=64) n(%)	>=65 Placebo (N=36) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	10 (19.6)	2 (3.7)	12 (11.4)	1 (2.1)	1 (2.9)	4 (13.3)	5 (7.8)	2 (5.6)
Schizophrenia	統合失調症	7 (13.7)	0 (0.0)	7 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Depression	うつ病	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	3 (10.0)	3 (4.7)	1 (2.8)
Bipolar disorder	双極性障害	0 (0.0)	1 (1.9)	1 (1.0)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Depressed mood	抑うつ気分	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (1.9)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (1.6)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)
Depressive symptom	抑うつ症状	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	1 (2.0)	1 (1.9)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害	1 (2.0)	1 (1.9)	2 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	2 (3.9)	0 (0.0)	2 (1.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Hepatic steatosis	脂肪肝	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	1 (2.0)	2 (3.7)	3 (2.9)	1 (2.1)	0 (0.0)	2 (6.7)	2 (3.1)	1 (2.8)
Dizziness	浮動性めまい	0 (0.0)	2 (3.7)	2 (1.9)	1 (2.1)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Fall	転倒	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.6)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.3.1.2 より引用

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Any System Organ Class		71 (93.4)	71 (94.7)	45 (91.8)	142 (94.0)	42 (84.0)	45 (93.8)	32 (91.4)	87 (88.8)
Infections and infestations	感染症および寄生虫症	31 (40.8)	23 (30.7)	15 (30.6)	54 (35.8)	15 (30.0)	17 (35.4)	14 (40.0)	32 (32.7)
Nasopharyngitis	上咽頭炎	20 (26.3)	15 (20.0)	10 (20.4)	35 (23.2)	10 (20.0)	8 (16.7)	5 (14.3)	18 (18.4)
Cystitis	膀胱炎	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Pneumonia	肺炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	2 (4.0)	2 (4.2)	2 (5.7)	4 (4.1)
Bronchitis	気管支炎	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Influenza	インフルエンザ	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Upper respiratory tract infection	上気道感染	2 (2.6)	1 (1.3)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cellulitis	蜂巣炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Conjunctivitis	結膜炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Folliculitis	毛包炎	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	胃腸炎	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis externa	外耳炎	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periodontitis	歯周炎	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pharyngitis	咽頭炎	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Gingivitis	歯肉炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	帯状疱疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Mastitis	乳腺炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal vestibulitis	鼻前庭炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis media	中耳炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Subcutaneous abscess	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Tonsillitis	扁桃炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary tract infection	尿路感染	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal infection	腟感染	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Varicella	水痘	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Eczema impetiginous	膿痂疹性湿疹	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin candida	皮膚カンジダ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Nail infection	爪感染	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Acarodermatitis	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Cystitis bacterial	細菌性膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Infected dermal cyst	感染性皮膚嚢腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial vulvovaginitis	細菌性外陰腟炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin papilloma	皮膚乳頭腫	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	代謝および栄養障害	10 (13.2)	5 (6.7)	2 (4.1)	15 (9.9)	6 (12.0)	7 (14.6)	6 (17.1)	13 (13.3)
Decreased appetite	食欲減退	1 (1.3)	2 (2.7)	0 (0.0)	3 (2.0)	4 (8.0)	2 (4.2)	1 (2.9)	6 (6.1)
Dehydration	脱水	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	1 (2.0)	3 (6.3)	3 (8.6)	4 (4.1)
Hyperuricaemia	高尿酸血症	2 (2.6)	1 (1.3)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Increased appetite	食欲亢進	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Dyslipidaemia	脂質異常症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Type 2 diabetes mellitus	２型糖尿病	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Electrolyte imbalance	電解質失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hypokalaemia	低カリウム血症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypouricaemia	低尿酸血症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marasmus	マラスムス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Polydipsia	多飲症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hyperlipidaemia	高脂血症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Psychiatric disorders	精神障害	42 (55.3)	35 (46.7)	24 (49.0)	77 (51.0)	10 (20.0)	22 (45.8)	16 (45.7)	32 (32.7)
Schizophrenia	統合失調症	18 (23.7)	9 (12.0)	4 (8.2)	27 (17.9)	3 (6.0)	4 (8.3)	1 (2.9)	7 (7.1)
Insomnia	不眠症	9 (11.8)	10 (13.3)	7 (14.3)	19 (12.6)	1 (2.0)	6 (12.5)	5 (14.3)	7 (7.1)
Depression	うつ病	6 (7.9)	5 (6.7)	4 (8.2)	11 (7.3)	0 (0.0)	5 (10.4)	5 (14.3)	5 (5.1)
Anxiety	不安	4 (5.3)	5 (6.7)	5 (10.2)	9 (6.0)	1 (2.0)	4 (8.3)	2 (5.7)	5 (5.1)
Suicidal ideation	自殺念慮	4 (5.3)	3 (4.0)	2 (4.1)	7 (4.6)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	2 (4.0)	1 (2.1)	1 (2.9)	3 (3.1)
Suicide attempt	自殺企図	3 (3.9)	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Bipolar disorder	双極性障害	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Middle insomnia	中期不眠症	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bruxism	歯ぎしり	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delirium	譫妄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Disinhibition	脱抑制	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Flat affect	感情の平板化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)	1 (2.9)	2 (2.0)
Hallucination, auditory	幻聴	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Agitation	激越	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Hypomania	軽躁	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Neurosis	神経症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abulia	無為	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Abnormal behaviour	異常行動	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somatic hallucination	体感幻覚	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Nervous system disorders	神経系障害	33 (43.4)	47 (62.7)	28 (57.1)	80 (53.0)	18 (36.0)	22 (45.8)	16 (45.7)	40 (40.8)
Somnolence	傾眠	13 (17.1)	20 (26.7)	12 (24.5)	33 (21.9)	6 (12.0)	8 (16.7)	6 (17.1)	14 (14.3)
Tremor	振戦	2 (2.6)	9 (12.0)	3 (6.1)	11 (7.3)	3 (6.0)	7 (14.6)	6 (17.1)	10 (10.2)
Akathisia	アカシジア	7 (9.2)	11 (14.7)	7 (14.3)	18 (11.9)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Headache	頭痛	4 (5.3)	7 (9.3)	4 (8.2)	11 (7.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Dizziness	浮動性めまい	4 (5.3)	5 (6.7)	4 (8.2)	9 (6.0)	0 (0.0)	2 (4.2)	2 (5.7)	2 (2.0)
Parkinsonism	パーキンソニズム	2 (2.6)	2 (2.7)	1 (2.0)	4 (2.6)	3 (6.0)	1 (2.1)	1 (2.9)	4 (4.1)
Extrapyramidal disorder	錐体外路障害	1 (1.3)	3 (4.0)	1 (2.0)	4 (2.6)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Drooling	よだれ	0 (0.0)	2 (2.7)	1 (2.0)	2 (1.3)	2 (4.0)	1 (2.1)	1 (2.9)	3 (3.1)
Tardive dyskinesia	遅発性ジスキネジア	3 (3.9)	1 (1.3)	1 (2.0)	4 (2.6)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hypoaesthesia	感覚鈍麻	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Bradykinesia	運動緩慢	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Dyskinesia	ジスキネジア	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Dysarthria	構語障害	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dystonia	ジストニア	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Seizure	痙攣発作	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Coordination abnormal	協調運動異常	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Hypersomnia	過眠症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Neuralgia	神経痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Radial nerve palsy	橈骨神経麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Sciatica	坐骨神経痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Stupor	昏迷	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intercostal neuralgia	肋間神経痛	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Vagus nerve disorder	迷走神経障害	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Eye disorders	眼障害	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	2 (4.0)	4 (8.3)	2 (5.7)	6 (6.1)
Blepharitis	眼瞼炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Cataract	白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Eye discharge	眼脂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Eye pain	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Deafness neurosensory	感音性難聴	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Vertigo	回転性めまい	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Cardiac disorders	心臓障害	3 (3.9)	4 (5.3)	3 (6.1)	7 (4.6)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Palpitations	動悸	2 (2.6)	1 (1.3)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradycardia	徐脈	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Sinus bradycardia	洞性徐脈	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tachycardia	頻脈	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Vascular disorders	血管障害	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	2 (4.0)	2 (4.2)	1 (2.9)	4 (4.1)
Hypertension	高血圧	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	2 (4.0)	1 (2.1)	0 (0.0)	3 (3.1)
Hypotension	低血圧	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Deep vein thrombosis	深部静脈血栓症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	7 (9.2)	5 (6.7)	0 (0.0)	12 (7.9)	1 (2.0)	7 (14.6)	4 (11.4)	8 (8.2)
Asthma	喘息	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	2 (4.2)	1 (2.9)	2 (2.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Dyspnoea	呼吸困難	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleural effusion	胸水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Upper respiratory tract inflammation	上気道の炎症	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Cough	咳嗽	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Interstitial lung disease	間質性肺疾患	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleurisy	胸膜炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	湿性咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Pulmonary embolism	肺塞栓症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory failure	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough variant asthma	咳喘息	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Gastrointestinal disorders	胃腸障害	24 (31.6)	31 (41.3)	15 (30.6)	55 (36.4)	15 (30.0)	20 (41.7)	13 (37.1)	35 (35.7)
Salivary hypersecretion	流涎過多	6 (7.9)	13 (17.3)	5 (10.2)	19 (12.6)	3 (6.0)	8 (16.7)	5 (14.3)	11 (11.2)
Constipation	便秘	5 (6.6)	2 (2.7)	1 (2.0)	7 (4.6)	4 (8.0)	7 (14.6)	4 (11.4)	11 (11.2)
Dysphagia	嚥下障害	2 (2.6)	3 (4.0)	2 (4.1)	5 (3.3)	3 (6.0)	2 (4.2)	1 (2.9)	5 (5.1)
Diarrhoea	下痢	3 (3.9)	3 (4.0)	2 (4.1)	6 (4.0)	3 (6.0)	0 (0.0)	0 (0.0)	3 (3.1)
Nausea	悪心	2 (2.6)	5 (6.7)	4 (8.2)	7 (4.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	4 (5.3)	2 (2.7)	2 (4.1)	6 (4.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Vomiting	嘔吐	1 (1.3)	4 (5.3)	1 (2.0)	5 (3.3)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Abdominal discomfort	腹部不快感	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Dental caries	齲歯	1 (1.3)	2 (2.7)	0 (0.0)	3 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Abdominal pain	腹痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Dry mouth	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.3)	2 (5.7)	3 (3.1)
Gastritis	胃炎	1 (1.3)	2 (2.7)	2 (4.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	歯痛	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Abdominal distension	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aphthous ulcer	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eructation	おくび	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorder	胃腸障害	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingival bleeding	歯肉出血	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hypoaesthesia oral	口の感覚鈍麻	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal pruritus	肛門そう痒症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Hepatobiliary disorders	肝胆道系障害	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hepatic steatosis	脂肪肝	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	16 (21.1)	13 (17.3)	8 (16.3)	29 (19.2)	7 (14.0)	10 (20.8)	6 (17.1)	17 (17.3)
Eczema	湿疹	3 (3.9)	2 (2.7)	2 (4.1)	5 (3.3)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Urticaria	蕁麻疹	3 (3.9)	2 (2.7)	1 (2.0)	5 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.3)	3 (8.6)	4 (4.1)
Dermatitis contact	接触皮膚炎	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Dry skin	皮膚乾燥	2 (2.6)	1 (1.3)	0 (0.0)	3 (2.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Pruritus	そう痒症	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	2 (4.2)	2 (5.7)	2 (2.0)
Hyperkeratosis	過角化	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Rash	発疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Alopecia areata	円形脱毛症	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Hyperhidrosis	多汗症	0 (0.0)	2 (2.7)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhage subcutaneous	皮下出血	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ingrowing nail	嵌入爪	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Skin fissures	皮膚亀裂	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin ulcer	皮膚潰瘍	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	19 (25.0)	14 (18.7)	9 (18.4)	33 (21.9)	8 (16.0)	9 (18.8)	7 (20.0)	17 (17.3)
Back pain	背部痛	6 (7.9)	3 (4.0)	1 (2.0)	9 (6.0)	1 (2.0)	3 (6.3)	3 (8.6)	4 (4.1)
Arthralgia	関節痛	1 (1.3)	4 (5.3)	3 (6.1)	5 (3.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Osteoarthritis	変形性関節症	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	1 (2.0)	3 (6.3)	2 (5.7)	4 (4.1)
Muscular weakness	筋力低下	1 (1.3)	2 (2.7)	2 (4.1)	3 (2.0)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Pain in extremity	四肢痛	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	2 (4.2)	2 (5.7)	2 (2.0)
Myalgia	筋肉痛	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Musculoskeletal pain	筋骨格痛	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neck pain	頚部痛	0 (0.0)	3 (4.0)	2 (4.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Posture abnormal	姿勢異常	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Intervertebral disc protrusion	椎間板突出	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoporosis	骨粗鬆症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Periarthritis	関節周囲炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Tenosynovitis	腱鞘炎	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mastication disorder	咀嚼障害	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Temporomandibular joint syndrome	顎関節症候群	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Trigger finger	弾発指	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Extremity contracture	四肢拘縮	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot deformity	足変形	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Renal and urinary disorders	腎および尿路障害	2 (2.6)	1 (1.3)	0 (0.0)	3 (2.0)	2 (4.0)	3 (6.3)	3 (8.6)	5 (5.1)
Dysuria	排尿困難	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Neurogenic bladder	神経因性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Nocturia	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Polyuria	多尿	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal glycosuria	腎性糖尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Urinary incontinence	尿失禁	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention	尿閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Bladder prolapse	膀胱脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal discharge	膣分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Prostatomegaly	前立腺腫大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	13 (17.1)	11 (14.7)	7 (14.3)	24 (15.9)	14 (28.0)	14 (29.2)	8 (22.9)	28 (28.6)
Malaise	倦怠感	6 (7.9)	5 (6.7)	4 (8.2)	11 (7.3)	4 (8.0)	5 (10.4)	1 (2.9)	9 (9.2)
Thirst	口渇	4 (5.3)	0 (0.0)	0 (0.0)	4 (2.6)	3 (6.0)	2 (4.2)	1 (2.9)	5 (5.1)
Fatigue	疲労	0 (0.0)	3 (4.0)	2 (4.1)	3 (2.0)	2 (4.0)	1 (2.1)	1 (2.9)	3 (3.1)
Pyrexia	発熱	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	2 (4.0)	2 (4.2)	1 (2.9)	4 (4.1)
Feeling abnormal	異常感	0 (0.0)	2 (2.7)	1 (2.0)	2 (1.3)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Asthenia	無力症	0 (0.0)	2 (2.7)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	死亡	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Calcinosis	石灰沈着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Chest discomfort	胸部不快感	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Discomfort	不快感	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	熱感	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Oedema peripheral	末梢性浮腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Propulsive gait	突進性歩行	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Investigations	臨床検査	17 (22.4)	8 (10.7)	5 (10.2)	25 (16.6)	5 (10.0)	7 (14.6)	5 (14.3)	12 (12.2)
Weight decreased	体重減少	6 (7.9)	4 (5.3)	2 (4.1)	10 (6.6)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Weight increased	体重増加	4 (5.3)	3 (4.0)	2 (4.1)	7 (4.6)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)	5 (10.4)	4 (11.4)	7 (7.1)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	2 (2.7)	2 (4.1)	2 (1.3)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Blood creatinine increased	血中クレアチニン増加	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood pressure increased	血圧上昇	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Liver function test increased	肝機能検査値上昇	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Blood triglycerides increased	血中トリグリセリド増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood uric acid increased	血中尿酸増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	13 (17.1)	12 (16.0)	7 (14.3)	25 (16.6)	8 (16.0)	10 (20.8)	8 (22.9)	18 (18.4)
Contusion	挫傷	4 (5.3)	3 (4.0)	1 (2.0)	7 (4.6)	1 (2.0)	4 (8.3)	3 (8.6)	5 (5.1)
Fall	転倒	1 (1.3)	2 (2.7)	2 (4.1)	3 (2.0)	1 (2.0)	5 (10.4)	4 (11.4)	6 (6.1)
Skin abrasion	皮膚擦過傷	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Sedation complication	鎮静合併症	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Thermal burn	熱傷	1 (1.3)	2 (2.7)	1 (2.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Animal bite	動物咬傷	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ankle fracture	足関節部骨折	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Concussion	脳振盪	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femoral neck fracture	大腿骨頚部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Femur fracture	大腿骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Foot fracture	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Fractured sacrum	仙骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Hand fracture	手骨折	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Intentional overdose	企図的過量投与	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint dislocation	関節脱臼	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ligament sprain	靱帯捻挫	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Road traffic accident	交通事故	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－132　年齢区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Face injury	顔面損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Wound	創傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Tooth fracture	歯牙破折	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid injury	眼瞼損傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin wound	皮膚創傷	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.3.2.1 より引用

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Any AESI		56 (73.7)	66 (88.0)	41 (83.7)	122 (80.8)	32 (64.0)	42 (87.5)	29 (82.9)	74 (75.5)
Somnolence	傾眠関連有害事象	20 (26.3)	25 (33.3)	15 (30.6)	45 (29.8)	12 (24.0)	15 (31.3)	7 (20.0)	27 (27.6)
Somnolence	傾眠	13 (17.1)	20 (26.7)	12 (24.5)	33 (21.9)	6 (12.0)	8 (16.7)	6 (17.1)	14 (14.3)
Malaise	倦怠感	6 (7.9)	5 (6.7)	4 (8.2)	11 (7.3)	4 (8.0)	5 (10.4)	1 (2.9)	9 (9.2)
Fatigue	疲労	0 (0.0)	3 (4.0)	2 (4.1)	3 (2.0)	2 (4.0)	1 (2.1)	1 (2.9)	3 (3.1)
Sedation complication	鎮静合併症	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Asthenia	無力症	0 (0.0)	2 (2.7)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Hypersomnia	過眠症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Hypersensitivity	過敏症関連有害事象	16 (21.1)	10 (13.3)	7 (14.3)	26 (17.2)	7 (14.0)	8 (16.7)	7 (20.0)	15 (15.3)
Eczema	湿疹	3 (3.9)	2 (2.7)	2 (4.1)	5 (3.3)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Stomatitis	口内炎	4 (5.3)	2 (2.7)	2 (4.1)	6 (4.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Urticaria	蕁麻疹	3 (3.9)	2 (2.7)	1 (2.0)	5 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	接触皮膚炎	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Pruritus	そう痒症	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	2 (4.2)	2 (5.7)	2 (2.0)
Rash	発疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Conjunctivitis	結膜炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Dermatitis	皮膚炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Blister	水疱	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Dermatitis atopic	アトピー性皮膚炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Erythema	紅斑	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Parkinsonism	パーキンソニズム関連有害事象	12 (15.8)	28 (37.3)	10 (20.4)	40 (26.5)	12 (24.0)	22 (45.8)	15 (42.9)	34 (34.7)
Salivary hypersecretion	流涎過多	6 (7.9)	13 (17.3)	5 (10.2)	19 (12.6)	3 (6.0)	8 (16.7)	5 (14.3)	11 (11.2)
Tremor	振戦	2 (2.6)	9 (12.0)	3 (6.1)	11 (7.3)	3 (6.0)	7 (14.6)	6 (17.1)	10 (10.2)
Parkinsonism	パーキンソニズム	2 (2.6)	2 (2.7)	1 (2.0)	4 (2.6)	3 (6.0)	1 (2.1)	1 (2.9)	4 (4.1)
Extrapyramidal disorder	錐体外路障害	1 (1.3)	3 (4.0)	1 (2.0)	4 (2.6)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Drooling	よだれ	0 (0.0)	2 (2.7)	1 (2.0)	2 (1.3)	2 (4.0)	1 (2.1)	1 (2.9)	3 (3.1)
Bradykinesia	運動緩慢	1 (1.3)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Muscle rigidity	筋固縮	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	15 (19.7)	11 (14.7)	8 (16.3)	26 (17.2)	4 (8.0)	8 (16.7)	7 (20.0)	12 (12.2)
Depression	うつ病	6 (7.9)	5 (6.7)	4 (8.2)	11 (7.3)	0 (0.0)	5 (10.4)	5 (14.3)	5 (5.1)
Suicidal ideation	自殺念慮	4 (5.3)	3 (4.0)	2 (4.1)	7 (4.6)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Suicide attempt	自殺企図	3 (3.9)	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Middle insomnia	中期不眠症	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Depressive symptom	抑うつ症状	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac events	心血管系及びQT間隔延長関連有害事象	3 (3.9)	0 (0.0)	0 (0.0)	3 (2.0)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Death	死亡	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Long QT syndrome	ＱＴ延長症候群	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Hyperprolactinemia	高プロラクチン血症関連有害事象	1 (1.3)	1 (1.3)	1 (2.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Menstruation irregular	不規則月経	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Akathisia	アカシジア関連有害事象	8 (10.5)	15 (20.0)	8 (16.3)	23 (15.2)	4 (8.0)	4 (8.3)	3 (8.6)	8 (8.2)
Akathisia	アカシジア	7 (9.2)	11 (14.7)	7 (14.3)	18 (11.9)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Extrapyramidal disorder	錐体外路障害	1 (1.3)	3 (4.0)	1 (2.0)	4 (2.6)	1 (2.0)	1 (2.1)	1 (2.9)	2 (2.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	2 (4.0)	1 (2.1)	1 (2.9)	3 (3.1)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Anxiety	不安	4 (5.3)	5 (6.7)	5 (10.2)	9 (6.0)	1 (2.0)	4 (8.3)	2 (5.7)	5 (5.1)
Anxiety	不安	4 (5.3)	5 (6.7)	5 (10.2)	9 (6.0)	1 (2.0)	4 (8.3)	2 (5.7)	5 (5.1)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	29 (38.2)	18 (24.0)	11 (22.4)	47 (31.1)	6 (12.0)	11 (22.9)	8 (22.9)	17 (17.3)
Schizophrenia	統合失調症	18 (23.7)	9 (12.0)	4 (8.2)	27 (17.9)	3 (6.0)	4 (8.3)	1 (2.9)	7 (7.1)
Depression	うつ病	6 (7.9)	5 (6.7)	4 (8.2)	11 (7.3)	0 (0.0)	5 (10.4)	5 (14.3)	5 (5.1)
Suicidal ideation	自殺念慮	4 (5.3)	3 (4.0)	2 (4.1)	7 (4.6)	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)
Suicide attempt	自殺企図	3 (3.9)	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Bipolar disorder	双極性障害	2 (2.6)	1 (1.3)	1 (2.0)	3 (2.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Depressed mood	抑うつ気分	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Depressive symptom	抑うつ症状	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Dysphagia	嚥下障害関連有害事象	2 (2.6)	3 (4.0)	2 (4.1)	5 (3.3)	3 (6.0)	2 (4.2)	1 (2.9)	5 (5.1)
Dysphagia	嚥下障害	2 (2.6)	3 (4.0)	2 (4.1)	5 (3.3)	3 (6.0)	2 (4.2)	1 (2.9)	5 (5.1)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－133　年齢区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<65 MT-5199 40 mg (N=76) n(%)	<65 MT-5199 80 mg (N=75) n(%)	<65 MT-5199 80 mg (no dose reduction) (N=49) n(%)	<65 All MT-5199 (N=151) n(%)	>=65 MT-5199 40 mg (N=50) n(%)	>=65 MT-5199 80 mg (N=48) n(%)	>=65 MT-5199 80 mg (no dose reduction) (N=35) n(%)	>=65 All MT-5199 (N=98) n(%)
Hepatotoxicity	肝障害関連有害事象	5 (6.6)	1 (1.3)	1 (2.0)	6 (4.0)	0 (0.0)	2 (4.2)	1 (2.9)	2 (2.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Liver function test increased	肝機能検査値上昇	2 (2.6)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	5 (6.6)	7 (9.3)	6 (12.2)	12 (7.9)	2 (4.0)	6 (12.5)	5 (14.3)	8 (8.2)
Dizziness	浮動性めまい	4 (5.3)	5 (6.7)	4 (8.2)	9 (6.0)	0 (0.0)	2 (4.2)	2 (5.7)	2 (2.0)
Fall	転倒	1 (1.3)	2 (2.7)	2 (4.1)	3 (2.0)	1 (2.0)	5 (10.4)	4 (11.4)	6 (6.1)
Hypotension	低血圧	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.7)	0 (0.0)	1 (2.1)	1 (2.9)	1 (1.0)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)
Cognitive disorder	認知機能低下関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.0)	1 (2.1)	0 (0.0)	3 (3.1)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.1)	0 (0.0)	2 (2.0)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.3.2.2 より引用

表 2.7.4.7－134　年齢区分ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	<65 years (N=213) n (%)	≥65 years (N=41) n (%)	<65 years (N=144) n (%)	≥65 years (N=34) n (%)	<65 years (N=348) n (%)	≥65 years (N=79) n (%)
At Least 1 AE	97 (45.5)	14 (34.1)	59 (41.0)	12 (35.3)	213 (61.2)	46 (58.2)
At Least 1 SAE	7 (3.3)	5 (12.2)	5 (3.5)	1 (2.9)	42 (12.1)	12 (15.2)
At Least 1 AE Leading to Study Discontinuation	8 (3.8)	2 (4.9)	6 (4.2)	2 (5.9)	42 (12.1)	16 (20.3)
At Least 1 AE Leading to Dose Reduction	7 (3.3)	0	3 (2.1)	1 (2.9)	22 (6.3)	4 (5.1)

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is only counted once for that category.

5.3.5.3－2 Table 98 より引用（一部改変）

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
Any Adverse Event	n (%)	2(40.0)	43(45.3)	46(50.0)	6(28.6)	97(45.5)	59(41.0)
血液およびリンパ系障害	n (%)	0	0	1(1.1)	0	1(0.5)	0
白血球減少症	n (%)	0	0	1(1.1)	0	1(0.5)	0
心臓障害	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
徐脈	n (%)	0	1(1.1)	0	0	1(0.5)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.7)
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(0.7)
トゥレット病	n (%)	0	0	0	0	0	1(0.7)
耳および迷路障害	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
耳鳴	n (%)	0	1(1.1)	0	0	1(0.5)	0
耳痛	n (%)	0	0	0	0	0	1(0.7)
眼障害	n (%)	0	0	0	1(4.8)	1(0.5)	1(0.7)
霧視	n (%)	0	0	0	1(4.8)	1(0.5)	0
結膜出血	n (%)	0	0	0	0	0	1(0.7)
胃腸障害	n (%)	0	14(14.7)	7(7.6)	1(4.8)	22(10.3)	16(11.1)
口内乾燥	n (%)	0	7(7.4)	0	1(4.8)	8(3.8)	3(2.1)
嘔吐	n (%)	0	2(2.1)	4(4.3)	0	6(2.8)	1(0.7)
悪心	n (%)	0	2(2.1)	2(2.2)	0	4(1.9)	4(2.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
流涎過多	n (%)	0	0	2(2.2)	1(4.8)	3(1.4)	0
便秘	n (%)	0	2(2.1)	0	0	2(0.9)	1(0.7)
嚥下障害	n (%)	0	2(2.1)	0	0	2(0.9)	0
腹部圧痛	n (%)	0	1(1.1)	0	0	1(0.5)	0
下痢	n (%)	0	1(1.1)	0	0	1(0.5)	2(1.4)
消化不良	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
びらん性胃炎	n (%)	0	0	1(1.1)	0	1(0.5)	0
メレナ	n (%)	0	1(1.1)	0	0	1(0.5)	0
口腔知覚不全	n (%)	0	1(1.1)	0	0	1(0.5)	0
臍ヘルニア	n (%)	0	1(1.1)	0	0	1(0.5)	0
上腹部痛	n (%)	0	0	0	0	0	1(0.7)
排便回数増加	n (%)	0	0	0	0	0	1(0.7)
胃食道逆流性疾患	n (%)	0	0	0	0	0	2(1.4)
歯肉炎	n (%)	0	0	0	0	0	1(0.7)
舌痛	n (%)	0	0	0	0	0	1(0.7)
歯痛	n (%)	0	0	0	0	0	1(0.7)
全身障害および投与局所様態	n (%)	0	7(7.4)	3(3.3)	2(9.5)	12(5.6)	5(3.5)
疲労	n (%)	0	4(4.2)	3(3.3)	2(9.5)	9(4.2)	3(2.1)
歩行障害	n (%)	0	1(1.1)	0	1(4.8)	2(0.9)	0
末梢性浮腫	n (%)	0	2(2.1)	0	0	2(0.9)	0
空腹	n (%)	0	1(1.1)	0	0	1(0.5)	0
易刺激性	n (%)	0	1(1.1)	0	0	1(0.5)	2(1.4)
疼痛	n (%)	0	1(1.1)	0	0	1(0.5)	0
口渇	n (%)	0	1(1.1)	0	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
肝胆道系障害	n (%)	0	0	1(1.1)	0	1(0.5)	0
急性肝炎	n (%)	0	0	1(1.1)	0	1(0.5)	0
黄疸	n (%)	0	0	1(1.1)	0	1(0.5)	0
感染症および寄生虫症	n (%)	0	9(9.5)	2(2.2)	2(9.5)	13(6.1)	10(6.9)
尿路感染	n (%)	0	4(4.2)	0	1(4.8)	5(2.3)	5(3.5)
鼻咽頭炎	n (%)	0	1(1.1)	1(1.1)	0	2(0.9)	1(0.7)
上気道感染	n (%)	0	0	1(1.1)	1(4.8)	2(0.9)	1(0.7)
ダニ皮膚炎	n (%)	0	1(1.1)	0	0	1(0.5)	0
体部白癬	n (%)	0	1(1.1)	0	0	1(0.5)	0
せつ	n (%)	0	1(1.1)	0	0	1(0.5)	0
ウイルス性胃腸炎	n (%)	0	1(1.1)	0	0	1(0.5)	0
インフルエンザ	n (%)	0	1(1.1)	0	0	1(0.5)	0
副鼻腔炎	n (%)	0	1(1.1)	0	0	1(0.5)	0
外陰腟真菌感染	n (%)	0	1(1.1)	0	0	1(0.5)	0
気管支炎	n (%)	0	0	0	0	0	1(0.7)
耳感染	n (%)	0	0	0	0	0	1(0.7)
ウイルス感染	n (%)	0	0	0	0	0	1(0.7)
傷害、中毒および処置合併症	n (%)	0	3(3.2)	4(4.3)	1(4.8)	8(3.8)	2(1.4)
動物咬傷	n (%)	0	0	1(1.1)	0	1(0.5)	0
節足動物咬傷	n (%)	0	0	0	1(4.8)	1(0.5)	1(0.7)
第２度熱傷	n (%)	0	0	1(1.1)	0	1(0.5)	0
転倒・転落	n (%)	0	0	1(1.1)	0	1(0.5)	0
関節損傷	n (%)	0	1(1.1)	0	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
四肢損傷	n (%)	0	0	1(1.1)	0	1(0.5)	0
筋挫傷	n (%)	0	1(1.1)	0	0	1(0.5)	0
交通事故	n (%)	0	1(1.1)	0	0	1(0.5)	0
むち打ち損傷	n (%)	0	1(1.1)	0	0	1(0.5)	0
足骨折	n (%)	0	0	0	0	0	1(0.7)
臨床検査	n (%)	1(20.0)	5(5.3)	9(9.8)	1(4.8)	16(7.5)	4(2.8)
血中ブドウ糖増加	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	0
体重増加	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	1(0.7)
血中クレアチニン増加	n (%)	0	1(1.1)	1(1.1)	0	2(0.9)	0
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	2(2.2)	0	2(0.9)	0
血中クレアチンホスホキナーゼ増加	n (%)	0	1(1.1)	0	0	1(0.5)	0
血中トリグリセリド増加	n (%)	0	0	0	1(4.8)	1(0.5)	0
血中尿素増加	n (%)	0	1(1.1)	0	0	1(0.5)	0
尿中結晶陽性	n (%)	0	0	1(1.1)	0	1(0.5)	0
尿中ブドウ糖陽性	n (%)	0	0	1(1.1)	0	1(0.5)	0
グリコヘモグロビン増加	n (%)	0	0	1(1.1)	0	1(0.5)	1(0.7)
握力低下	n (%)	0	1(1.1)	0	0	1(0.5)	0
ヘマトクリット減少	n (%)	0	0	1(1.1)	0	1(0.5)	0
ヘモグロビン減少	n (%)	0	0	1(1.1)	0	1(0.5)	0
肝酵素上昇	n (%)	1(20.0)	0	0	0	1(0.5)	0
便潜血陽性	n (%)	0	0	1(1.1)	0	1(0.5)	0
赤血球数減少	n (%)	0	0	1(1.1)	0	1(0.5)	0
赤血球数増加	n (%)	0	0	1(1.1)	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
血中カリウム増加	n (%)	0	0	0	0	0	1(0.7)
好中球数増加	n (%)	0	0	0	0	0	1(0.7)
白血球数増加	n (%)	0	0	0	0	0	1(0.7)
代謝および栄養障害	n (%)	0	2(2.1)	5(5.4)	0	7(3.3)	5(3.5)
食欲減退	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	2(1.4)
食欲亢進	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	1(0.7)
低ナトリウム血症	n (%)	0	0	1(1.1)	0	1(0.5)	0
異常体重減少	n (%)	0	0	0	0	0	1(0.7)
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(0.7)
低血糖症	n (%)	0	0	0	0	0	1(0.7)
筋骨格系および結合組織障害	n (%)	0	9(9.5)	5(5.4)	1(4.8)	15(7.0)	4(2.8)
関節痛	n (%)	0	3(3.2)	2(2.2)	0	5(2.3)	1(0.7)
背部痛	n (%)	0	2(2.1)	1(1.1)	0	3(1.4)	0
筋力低下	n (%)	0	2(2.1)	0	0	2(0.9)	0
筋肉痛	n (%)	0	0	1(1.1)	1(4.8)	2(0.9)	0
関節炎	n (%)	0	1(1.1)	0	0	1(0.5)	0
四肢不快感	n (%)	0	1(1.1)	0	0	1(0.5)	0
筋痙縮	n (%)	0	0	1(1.1)	0	1(0.5)	0
顎関節症候群	n (%)	0	1(1.1)	0	0	1(0.5)	0
関節腫脹	n (%)	0	0	0	0	0	1(0.7)
筋骨格硬直	n (%)	0	0	0	0	0	1(0.7)
四肢痛	n (%)	0	0	0	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
神経系障害	n (%)	0	17(17.9)	16(17.4)	3(14.3)	36(16.9)	13(9.0)
傾眠	n (%)	0	9(9.5)	2(2.2)	1(4.8)	12(5.6)	4(2.8)
頭痛	n (%)	0	4(4.2)	4(4.3)	1(4.8)	9(4.2)	3(2.1)
アカシジア	n (%)	0	3(3.2)	3(3.3)	0	6(2.8)	1(0.7)
ジスキネジー	n (%)	0	0	3(3.3)	0	3(1.4)	0
鎮静	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	1(0.7)
浮動性めまい	n (%)	0	2(2.1)	0	0	2(0.9)	3(2.1)
よだれ	n (%)	0	0	2(2.2)	0	2(0.9)	0
振戦	n (%)	0	0	2(2.2)	0	2(0.9)	0
平衡障害	n (%)	0	0	1(1.1)	0	1(0.5)	0
注意力障害	n (%)	0	1(1.1)	0	0	1(0.5)	0
ジストニー	n (%)	0	0	1(1.1)	0	1(0.5)	0
感覚鈍麻	n (%)	0	0	1(1.1)	0	1(0.5)	0
ミオクローヌス	n (%)	0	1(1.1)	0	0	1(0.5)	0
睡眠の質低下	n (%)	0	1(1.1)	0	0	1(0.5)	0
失神	n (%)	0	0	0	1(4.8)	1(0.5)	0
咬舌	n (%)	0	1(1.1)	0	0	1(0.5)	0
痙攣	n (%)	0	0	0	0	0	1(0.7)
片頭痛	n (%)	0	0	0	0	0	1(0.7)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(0.7)
精神障害	n (%)	2(40.0)	14(14.7)	10(10.9)	0	26(12.2)	14(9.7)
自殺念慮	n (%)	0	4(4.2)	1(1.1)	0	5(2.3)	4(2.8)
不眠症	n (%)	0	2(2.1)	2(2.2)	0	4(1.9)	1(0.7)
不安	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	0
パニック発作	n (%)	1(20.0)	0	1(1.1)	0	2(0.9)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
双極１型障害	n (%)	0	1(1.1)	0	0	1(0.5)	0
歯ぎしり	n (%)	0	1(1.1)	0	0	1(0.5)	0
抑うつ気分	n (%)	1(20.0)	0	0	0	1(0.5)	0
うつ病	n (%)	0	0	1(1.1)	0	1(0.5)	2(1.4)
抑うつ症状	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
ディスフェミア	n (%)	0	1(1.1)	0	0	1(0.5)	0
敵意	n (%)	0	1(1.1)	0	0	1(0.5)	0
軽躁	n (%)	0	1(1.1)	0	0	1(0.5)	0
精神状態変化	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
神経過敏	n (%)	0	0	1(1.1)	0	1(0.5)	0
妄想症	n (%)	0	1(1.1)	0	0	1(0.5)	0
精神運動制止遅滞	n (%)	0	1(1.1)	0	0	1(0.5)	0
精神病性障害	n (%)	0	0	1(1.1)	0	1(0.5)	2(1.4)
落ち着きのなさ	n (%)	0	1(1.1)	0	0	1(0.5)	0
統合失調症	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
自殺企図	n (%)	0	0	1(1.1)	0	1(0.5)	0
激越	n (%)	0	0	0	0	0	1(0.7)
躁病	n (%)	0	0	0	0	0	1(0.7)
統合失調感情障害	n (%)	0	0	0	0	0	1(0.7)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.7)
睡眠障害	n (%)	0	0	0	0	0	1(0.7)
腎および尿路障害	n (%)	0	0	0	0	0	1(0.7)
糖尿	n (%)	0	0	0	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
生殖系および乳房障害	n (%)	0	0	1(1.1)	0	1(0.5)	2(1.4)
月経過多	n (%)	0	0	1(1.1)	0	1(0.5)	0
腟出血	n (%)	0	0	0	0	0	2(1.4)
呼吸器、胸郭および縦隔障害	n (%)	0	0	2(2.2)	0	2(0.9)	2(1.4)
鼻閉	n (%)	0	0	2(2.2)	0	2(0.9)	0
慢性閉塞性肺疾患	n (%)	0	0	0	0	0	1(0.7)
咳嗽	n (%)	0	0	0	0	0	1(0.7)
皮膚および皮下組織障害	n (%)	0	2(2.1)	2(2.2)	0	4(1.9)	4(2.8)
網状皮斑	n (%)	0	1(1.1)	0	0	1(0.5)	0
そう痒症	n (%)	0	1(1.1)	0	0	1(0.5)	2(1.4)
発疹	n (%)	0	0	1(1.1)	0	1(0.5)	1(0.7)
斑状丘疹状皮疹	n (%)	0	0	1(1.1)	0	1(0.5)	0
多汗症	n (%)	0	0	0	0	0	1(0.7)
外科および内科処置	n (%)	0	0	0	0	0	1(0.7)
鼓膜切開	n (%)	0	0	0	0	0	1(0.7)
血管障害	n (%)	0	1(1.1)	3(3.3)	0	4(1.9)	1(0.7)
血腫	n (%)	0	0	1(1.1)	0	1(0.5)	0
ほてり	n (%)	0	0	1(1.1)	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	 40 mg (N=95)	 80 mg (N=92)	 100 mg (N=21)	All NBI-98854 (N=213)	 Placebo (N=144)
高血圧	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
低血圧	n (%)	0	0	1(1.1)	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	 40 mg (N=15)	 80 mg (N=20)	 100 mg (N=6)	All NBI-98854 (N=41)	 Placebo (N=34)
Any Adverse Event	n (%)	0	5(33.3)	7(35.0)	2(33.3)	14(34.1)	12(35.3)
胃腸障害	n (%)	0	0	0	0	0	5(14.7)
便秘	n (%)	0	0	0	0	0	4(11.8)
下痢	n (%)	0	0	0	0	0	1(2.9)
全身障害および投与局所様態	n (%)	0	3(20.0)	2(10.0)	0	5(12.2)	2(5.9)
胸痛	n (%)	0	1(6.7)	0	0	1(2.4)	0
疲労	n (%)	0	1(6.7)	0	0	1(2.4)	0
歩行障害	n (%)	0	1(6.7)	0	0	1(2.4)	0
末梢性浮腫	n (%)	0	1(6.7)	0	0	1(2.4)	1(2.9)
発熱	n (%)	0	0	1(5.0)	0	1(2.4)	1(2.9)
突然死	n (%)	0	0	1(5.0)	0	1(2.4)	0
感染症および寄生虫症	n (%)	0	1(6.7)	1(5.0)	1(16.7)	3(7.3)	4(11.8)
鼻咽頭炎	n (%)	0	0	0	1(16.7)	1(2.4)	0
急性腎盂腎炎	n (%)	0	1(6.7)	0	0	1(2.4)	0
尿路感染	n (%)	0	0	1(5.0)	0	1(2.4)	3(8.8)
口腔ヘルペス	n (%)	0	0	0	0	0	1(2.9)
傷害、中毒および処置合併症	n (%)	0	2(13.3)	0	0	2(4.9)	1(2.9)
転倒・転落	n (%)	0	2(13.3)	0	0	2(4.9)	0
処置による疼痛	n (%)	0	0	0	0	0	1(2.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	 40 mg (N=15)	 80 mg (N=20)	 100 mg (N=6)	All NBI-98854 (N=41)	 Placebo (N=34)
臨床検査	n (%)	0	0	1(5.0)	0	1(2.4)	2(5.9)
血圧上昇	n (%)	0	0	1(5.0)	0	1(2.4)	0
血中ビリルビン増加	n (%)	0	0	0	0	0	1(2.9)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	0	0	0	1(2.9)
肝酵素上昇	n (%)	0	0	0	0	0	1(2.9)
代謝および栄養障害	n (%)	0	1(6.7)	0	0	1(2.4)	0
食欲減退	n (%)	0	1(6.7)	0	0	1(2.4)	0
筋骨格系および結合組織障害	n (%)	0	0	1(5.0)	0	1(2.4)	1(2.9)
関節痛	n (%)	0	0	1(5.0)	0	1(2.4)	0
滑液包炎	n (%)	0	0	0	0	0	1(2.9)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(2.9)
口腔乳頭腫	n (%)	0	0	0	0	0	1(2.9)
神経系障害	n (%)	0	0	3(15.0)	0	3(7.3)	3(8.8)
傾眠	n (%)	0	0	2(10.0)	0	2(4.9)	0
頭痛	n (%)	0	0	1(5.0)	0	1(2.4)	1(2.9)
浮動性めまい	n (%)	0	0	0	0	0	1(2.9)
感覚鈍麻	n (%)	0	0	0	0	0	1(2.9)
精神障害	n (%)	0	0	2(10.0)	0	2(4.9)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－135　年齢区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	 40 mg (N=15)	 80 mg (N=20)	 100 mg (N=6)	All NBI-98854 (N=41)	 Placebo (N=34)
うつ病	n (%)	0	0	1(5.0)	0	1(2.4)	0
統合失調感情障害	n (%)	0	0	1(5.0)	0	1(2.4)	0
腎および尿路障害	n (%)	0	0	0	0	0	2(5.9)
血尿	n (%)	0	0	0	0	0	1(2.9)
尿閉	n (%)	0	0	0	0	0	1(2.9)
呼吸器、胸郭および縦隔障害	n (%)	0	1(6.7)	0	1(16.7)	2(4.9)	0
慢性閉塞性肺疾患	n (%)	0	1(6.7)	0	1(16.7)	2(4.9)	0
皮膚および皮下組織障害	n (%)	0	0	0	0	0	1(2.9)
ケラトアカントーマ	n (%)	0	0	0	0	0	1(2.9)
乾癬	n (%)	0	0	0	0	0	1(2.9)
外科および内科処置	n (%)	0	0	1(5.0)	0	1(2.4)	0
抜歯	n (%)	0	0	1(5.0)	0	1(2.4)	0
血管障害	n (%)	0	0	0	0	0	1(2.9)
ほてり	n (%)	0	0	0	0	0	1(2.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.2より引用（一部改変）

表2.7.4.7－136　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=95)	80 mg (N=92)	100 mg (N=21)	All NBI-98854 (N=213)	Placebo (N=144)
Any Adverse Event of Special Interest	n (%)	1(20.0)	24(25.3)	18(19.6)	3(14.3)	46(21.6)	23(16.0)
アカシジア関連有害事象	n (%)	0	3(3.2)	3(3.3)	0	6(2.8)	1(0.7)
アカシジア	n (%)	0	3(3.2)	3(3.3)	0	6(2.8)	1(0.7)
不安	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	0
不安	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	0	1(4.8)	1(0.5)	1(0.7)
失神	n (%)	0	0	0	1(4.8)	1(0.5)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.7)
うつ病及び自殺関連有害事象	n (%)	1(20.0)	5(5.3)	3(3.3)	0	9(4.2)	6(4.2)
自殺念慮	n (%)	0	4(4.2)	1(1.1)	0	5(2.3)	4(2.8)
抑うつ気分	n (%)	1(20.0)	0	0	0	1(0.5)	0
うつ病	n (%)	0	0	1(1.1)	0	1(0.5)	2(1.4)
抑うつ症状	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
自殺企図	n (%)	0	0	1(1.1)	0	1(0.5)	0
嚥下障害関連有害事象	n (%)	0	2(2.1)	0	0	2(0.9)	0
嚥下障害	n (%)	0	2(2.1)	0	0	2(0.9)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	4(4.2)	3(3.3)	2(9.5)	9(4.2)	3(2.1)
疲労	n (%)	0	4(4.2)	3(3.3)	2(9.5)	9(4.2)	3(2.1)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－136　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=95)	80 mg (N=92)	100 mg (N=21)	All NBI-98854 (N=213)	Placebo (N=144)
肝障害関連有害事象	n (%)	0	0	1(1.1)	0	1(0.5)	0
急性肝炎	n (%)	0	0	1(1.1)	0	1(0.5)	0
低血圧関連有害事象	n (%)	0	2(2.1)	2(2.2)	1(4.8)	5(2.3)	3(2.1)
浮動性めまい	n (%)	0	2(2.1)	0	0	2(0.9)	3(2.1)
転倒・転落	n (%)	0	0	1(1.1)	0	1(0.5)	0
低血圧	n (%)	0	0	1(1.1)	0	1(0.5)	0
失神	n (%)	0	0	0	1(4.8)	1(0.5)	0
パーキンソニズム関連有害事象	n (%)	0	0	2(2.2)	0	2(0.9)	0
振戦	n (%)	0	0	2(2.2)	0	2(0.9)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	10(10.5)	4(4.3)	1(4.8)	15(7.0)	5(3.5)
傾眠	n (%)	0	9(9.5)	2(2.2)	1(4.8)	12(5.6)	4(2.8)
鎮静	n (%)	0	1(1.1)	2(2.2)	0	3(1.4)	1(0.7)
基礎疾患の悪化に関連する有害事象	n (%)	1(20.0)	10(10.5)	4(4.3)	0	15(7.0)	13(9.0)
自殺念慮	n (%)	0	4(4.2)	1(1.1)	0	5(2.3)	4(2.8)
双極１型障害	n (%)	0	1(1.1)	0	0	1(0.5)	0
抑うつ気分	n (%)	1(20.0)	0	0	0	1(0.5)	0
うつ病	n (%)	0	0	1(1.1)	0	1(0.5)	2(1.4)
抑うつ症状	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
敵意	n (%)	0	1(1.1)	0	0	1(0.5)	0
軽躁	n (%)	0	1(1.1)	0	0	1(0.5)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－136　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=5)	40 mg (N=95)	80 mg (N=92)	100 mg (N=21)	All NBI-98854 (N=213)	Placebo (N=144)
易刺激性	n (%)	0	1(1.1)	0	0	1(0.5)	2(1.4)
妄想症	n (%)	0	1(1.1)	0	0	1(0.5)	0
精神病性障害	n (%)	0	0	1(1.1)	0	1(0.5)	2(1.4)
統合失調症	n (%)	0	1(1.1)	0	0	1(0.5)	1(0.7)
自殺企図	n (%)	0	0	1(1.1)	0	1(0.5)	0
躁病	n (%)	0	0	0	0	0	1(0.7)
統合失調感情障害	n (%)	0	0	0	0	0	1(0.7)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.7)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－136　年齢区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Age Category: >=65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	40 mg (N=15)	80 mg (N=20)	100 mg (N=6)	All NBI-98854 (N=41)	Placebo (N=34)
Any Adverse Event of Special Interest	n (%)	0	4(26.7)	5(25.0)	0	9(22.0)	1(2.9)
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(6.7)	1(5.0)	0	2(4.9)	0
胸痛	n (%)	0	1(6.7)	0	0	1(2.4)	0
突然死	n (%)	0	0	1(5.0)	0	1(2.4)	0
うつ病及び自殺関連有害事象	n (%)	0	0	1(5.0)	0	1(2.4)	0
うつ病	n (%)	0	0	1(5.0)	0	1(2.4)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(6.7)	0	0	1(2.4)	0
疲労	n (%)	0	1(6.7)	0	0	1(2.4)	0
低血圧関連有害事象	n (%)	0	2(13.3)	0	0	2(4.9)	1(2.9)
転倒・転落	n (%)	0	2(13.3)	0	0	2(4.9)	0
浮動性めまい	n (%)	0	0	0	0	0	1(2.9)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	0	2(10.0)	0	2(4.9)	0
傾眠	n (%)	0	0	2(10.0)	0	2(4.9)	0
基礎疾患の悪化に関連する有害事象	n (%)	0	0	2(10.0)	0	2(4.9)	0
うつ病	n (%)	0	0	1(5.0)	0	1(2.4)	0
統合失調感情障害	n (%)	0	0	1(5.0)	0	1(2.4)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.2より引用（一部改変）

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
Any Adverse Event	n (%)	98(60.9)	115(61.5)	103(58.9)	213(61.2)
血液およびリンパ系障害	n (%)	2(1.2)	5(2.7)	5(2.9)	7(2.0)
貧血	n (%)	0	3(1.6)	3(1.7)	3(0.9)
好中球減少症	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
白血球増加症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
白血球減少症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
血小板血症	n (%)	1(0.6)	0	0	1(0.3)
心臓障害	n (%)	3(1.9)	2(1.1)	2(1.1)	5(1.4)
心房細動	n (%)	1(0.6)	0	0	1(0.3)
左脚ブロック	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
洞性頻脈	n (%)	1(0.6)	0	0	1(0.3)
頻脈	n (%)	1(0.6)	0	0	1(0.3)
先天性、家族性および遺伝性障害	n (%)	0	1(0.5)	1(0.6)	1(0.3)
弯足	n (%)	0	1(0.5)	1(0.6)	1(0.3)
耳および迷路障害	n (%)	3(1.9)	2(1.1)	2(1.1)	5(1.4)
耳鳴	n (%)	2(1.2)	0	0	2(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
耳介軟骨膜炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
耳痛	n (%)	0	1(0.5)	1(0.6)	1(0.3)
聴覚障害	n (%)	1(0.6)	0	0	1(0.3)
内分泌障害	n (%)	1(0.6)	0	0	1(0.3)
甲状腺機能低下症	n (%)	1(0.6)	0	0	1(0.3)
眼障害	n (%)	0	3(1.6)	3(1.7)	3(0.9)
核性白内障	n (%)	0	1(0.5)	1(0.6)	1(0.3)
複視	n (%)	0	1(0.5)	1(0.6)	1(0.3)
兎眼	n (%)	0	1(0.5)	1(0.6)	1(0.3)
黄斑浮腫	n (%)	0	1(0.5)	1(0.6)	1(0.3)
網膜静脈閉塞	n (%)	0	1(0.5)	1(0.6)	1(0.3)
胃腸障害	n (%)	28(17.4)	36(19.3)	28(16.0)	64(18.4)
下痢	n (%)	6(3.7)	9(4.8)	8(4.6)	15(4.3)
嘔吐	n (%)	7(4.3)	7(3.7)	5(2.9)	14(4.0)
便秘	n (%)	6(3.7)	6(3.2)	4(2.3)	12(3.4)
口内乾燥	n (%)	8(5.0)	2(1.1)	2(1.1)	10(2.9)
悪心	n (%)	4(2.5)	6(3.2)	6(3.4)	10(2.9)
流涎過多	n (%)	2(1.2)	6(3.2)	3(1.7)	8(2.3)
腹痛	n (%)	2(1.2)	4(2.1)	3(1.7)	6(1.7)
上腹部痛	n (%)	2(1.2)	3(1.6)	2(1.1)	5(1.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
嚥下障害	n (%)	3(1.9)	1(0.5)	1(0.6)	4(1.1)
歯痛	n (%)	1(0.6)	2(1.1)	1(0.6)	3(0.9)
結腸ポリープ	n (%)	2(1.2)	0	0	2(0.6)
消化不良	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
胃炎	n (%)	0	2(1.1)	1(0.6)	2(0.6)
胃食道逆流性疾患	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
痔核	n (%)	2(1.2)	0	0	2(0.6)
腹部膨満	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腹部圧痛	n (%)	1(0.6)	0	0	1(0.3)
細菌叢異常症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
憩室	n (%)	1(0.6)	0	0	1(0.3)
変色便	n (%)	1(0.6)	0	0	1(0.3)
食中毒	n (%)	0	1(0.5)	1(0.6)	1(0.3)
びらん性胃炎	n (%)	0	1(0.5)	0	1(0.3)
胃腸出血	n (%)	1(0.6)	0	0	1(0.3)
裂孔ヘルニア	n (%)	0	1(0.5)	1(0.6)	1(0.3)
メレナ	n (%)	1(0.6)	0	0	1(0.3)
食道食物嵌入	n (%)	1(0.6)	0	0	1(0.3)
食道狭窄	n (%)	1(0.6)	0	0	1(0.3)
食道炎	n (%)	1(0.6)	0	0	1(0.3)
臍ヘルニア	n (%)	1(0.6)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
全身障害および投与局所様態	n (%)	14(8.7)	19(10.2)	15(8.6)	33(9.5)
疲労	n (%)	11(6.8)	7(3.7)	7(4.0)	18(5.2)
胸痛	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
歩行障害	n (%)	2(1.2)	1(0.5)	0	3(0.9)
非心臓性胸痛	n (%)	1(0.6)	2(1.1)	1(0.6)	3(0.9)
末梢性浮腫	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
無力症	n (%)	1(0.6)	1(0.5)	0	2(0.6)
易刺激性	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
空腹	n (%)	1(0.6)	0	0	1(0.3)
倦怠感	n (%)	0	1(0.5)	1(0.6)	1(0.3)
疼痛	n (%)	0	1(0.5)	1(0.6)	1(0.3)
発熱	n (%)	0	1(0.5)	0	1(0.3)
口渇	n (%)	1(0.6)	0	0	1(0.3)
肝胆道系障害	n (%)	0	3(1.6)	3(1.7)	3(0.9)
胆石症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
肝不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
急性肝炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
黄疸	n (%)	0	1(0.5)	1(0.6)	1(0.3)
免疫系障害	n (%)	0	2(1.1)	2(1.1)	2(0.6)
過敏症	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
季節性アレルギー	n (%)	0	1(0.5)	1(0.6)	1(0.3)
感染症および寄生虫症	n (%)	27(16.8)	35(18.7)	30(17.1)	62(17.8)
尿路感染	n (%)	11(6.8)	8(4.3)	7(4.0)	19(5.5)
鼻咽頭炎	n (%)	4(2.5)	9(4.8)	8(4.6)	13(3.7)
気管支炎	n (%)	2(1.2)	5(2.7)	4(2.3)	7(2.0)
上気道感染	n (%)	4(2.5)	3(1.6)	3(1.7)	7(2.0)
蜂巣炎	n (%)	0	4(2.1)	3(1.7)	4(1.1)
胃腸炎	n (%)	0	3(1.6)	3(1.7)	3(0.9)
ウイルス性胃腸炎	n (%)	3(1.9)	0	0	3(0.9)
耳感染	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
インフルエンザ	n (%)	2(1.2)	0	0	2(0.6)
副鼻腔炎	n (%)	0	2(1.1)	1(0.6)	2(0.6)
皮下組織膿瘍	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
外陰腟真菌感染	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
四肢膿瘍	n (%)	0	1(0.5)	0	1(0.3)
軟部組織膿瘍	n (%)	0	1(0.5)	1(0.6)	1(0.3)
ダニ皮膚炎	n (%)	1(0.6)	0	0	1(0.3)
急性扁桃炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
体部白癬	n (%)	1(0.6)	0	0	1(0.3)
ブドウ球菌性蜂巣炎	n (%)	1(0.6)	0	0	1(0.3)
憩室炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
せつ	n (%)	1(0.6)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
咬傷感染	n (%)	0	1(0.5)	1(0.6)	1(0.3)
肺炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
股部白癬	n (%)	1(0.6)	0	0	1(0.3)
歯膿瘍	n (%)	0	1(0.5)	1(0.6)	1(0.3)
傷害、中毒および処置合併症	n (%)	11(6.8)	20(10.7)	16(9.1)	31(8.9)
転倒・転落	n (%)	1(0.6)	5(2.7)	4(2.3)	6(1.7)
擦過傷	n (%)	2(1.2)	2(1.1)	2(1.1)	4(1.1)
挫傷	n (%)	2(1.2)	1(0.5)	1(0.6)	3(0.9)
足骨折	n (%)	0	3(1.6)	2(1.1)	3(0.9)
関節脱臼	n (%)	0	2(1.1)	1(0.6)	2(0.6)
交通事故	n (%)	0	2(1.1)	2(1.1)	2(0.6)
皮膚裂傷	n (%)	0	2(1.1)	2(1.1)	2(0.6)
動物咬傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
節足動物咬傷	n (%)	0	1(0.5)	0	1(0.3)
第２度熱傷	n (%)	1(0.6)	0	0	1(0.3)
頚椎骨折	n (%)	0	1(0.5)	1(0.6)	1(0.3)
皮膚化学熱傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
異物による損傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
頭部損傷	n (%)	1(0.6)	0	0	1(0.3)
関節損傷	n (%)	1(0.6)	0	0	1(0.3)
関節捻挫	n (%)	1(0.6)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
四肢損傷	n (%)	0	1(0.5)	0	1(0.3)
四肢外傷性切断	n (%)	1(0.6)	0	0	1(0.3)
口腔内損傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋挫傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
膝蓋骨骨折	n (%)	0	1(0.5)	1(0.6)	1(0.3)
橈骨骨折	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腎損傷	n (%)	1(0.6)	0	0	1(0.3)
肋骨骨折	n (%)	0	1(0.5)	0	1(0.3)
引っかき傷	n (%)	1(0.6)	0	0	1(0.3)
皮下血腫	n (%)	0	1(0.5)	1(0.6)	1(0.3)
臨床検査	n (%)	17(10.6)	28(15.0)	23(13.1)	45(12.9)
体重増加	n (%)	2(1.2)	6(3.2)	6(3.4)	8(2.3)
体重減少	n (%)	3(1.9)	3(1.6)	2(1.1)	6(1.7)
γ－グルタミルトランスフェラーゼ増加	n (%)	2(1.2)	2(1.1)	2(1.1)	4(1.1)
血中クレアチンホスホキナーゼ増加	n (%)	2(1.2)	1(0.5)	1(0.6)	3(0.9)
血中クレアチニン増加	n (%)	1(0.6)	2(1.1)	1(0.6)	3(0.9)
血中プロラクチン増加	n (%)	2(1.2)	1(0.5)	0	3(0.9)
血中トリグリセリド増加	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
尿中ブドウ糖陽性	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
グリコヘモグロビン増加	n (%)	1(0.6)	2(1.1)	1(0.6)	3(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
ヘモグロビン減少	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
血中ブドウ糖増加	n (%)	0	2(1.1)	2(1.1)	2(0.6)
血中尿素増加	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
ヘマトクリット減少	n (%)	0	2(1.1)	2(1.1)	2(0.6)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
抗精神病薬濃度治療量以上	n (%)	0	1(0.5)	0	1(0.3)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
血中コレステロール増加	n (%)	0	1(0.5)	1(0.6)	1(0.3)
血中ブドウ糖減少	n (%)	0	1(0.5)	0	1(0.3)
尿中結晶陽性	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心電図ＱＴ延長	n (%)	0	1(0.5)	1(0.6)	1(0.3)
握力低下	n (%)	1(0.6)	0	0	1(0.3)
心拍数減少	n (%)	0	1(0.5)	1(0.6)	1(0.3)
便潜血陽性	n (%)	0	1(0.5)	1(0.6)	1(0.3)
血小板数減少	n (%)	0	1(0.5)	1(0.6)	1(0.3)
総蛋白減少	n (%)	0	1(0.5)	1(0.6)	1(0.3)
赤血球数減少	n (%)	0	1(0.5)	1(0.6)	1(0.3)
赤血球数増加	n (%)	0	1(0.5)	1(0.6)	1(0.3)
代謝および栄養障害	n (%)	7(4.3)	15(8.0)	12(6.9)	22(6.3)
食欲減退	n (%)	4(2.5)	3(1.6)	2(1.1)	7(2.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
低ナトリウム血症	n (%)	0	3(1.6)	2(1.1)	3(0.9)
糖尿病	n (%)	0	2(1.1)	2(1.1)	2(0.6)
食欲亢進	n (%)	0	2(1.1)	1(0.6)	2(0.6)
食欲不振	n (%)	1(0.6)	0	0	1(0.3)
食欲障害	n (%)	0	1(0.5)	1(0.6)	1(0.3)
脱水	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高血糖	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高カリウム血症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高トリグリセリド血症	n (%)	1(0.6)	0	0	1(0.3)
低アルブミン血症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
低カリウム血症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
低ナトリウム血症候群	n (%)	0	1(0.5)	1(0.6)	1(0.3)
代謝性アシドーシス	n (%)	0	1(0.5)	1(0.6)	1(0.3)
多飲症	n (%)	1(0.6)	0	0	1(0.3)
筋骨格系および結合組織障害	n (%)	15(9.3)	15(8.0)	10(5.7)	30(8.6)
背部痛	n (%)	5(3.1)	4(2.1)	4(2.3)	9(2.6)
関節痛	n (%)	2(1.2)	4(2.1)	3(1.7)	6(1.7)
四肢痛	n (%)	1(0.6)	4(2.1)	2(1.1)	5(1.4)
筋肉痛	n (%)	2(1.2)	1(0.5)	1(0.6)	3(0.9)
関節炎	n (%)	1(0.6)	1(0.5)	0	2(0.6)
頚部痛	n (%)	1(0.6)	1(0.5)	0	2(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
骨関節炎	n (%)	2(1.2)	0	0	2(0.6)
尾骨痛	n (%)	0	1(0.5)	1(0.6)	1(0.3)
関節腫脹	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋固縮	n (%)	0	1(0.5)	0	1(0.3)
筋痙縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋力低下	n (%)	1(0.6)	0	0	1(0.3)
骨減少症	n (%)	1(0.6)	0	0	1(0.3)
良性、悪性および詳細不明の新生物 （嚢胞およびポリープを含む）	n (%)	2(1.2)	3(1.6)	3(1.7)	5(1.4)
副腎腺腫	n (%)	0	1(0.5)	1(0.6)	1(0.3)
乳癌	n (%)	0	1(0.5)	1(0.6)	1(0.3)
脂肪腫	n (%)	1(0.6)	0	0	1(0.3)
肺新生物	n (%)	1(0.6)	0	0	1(0.3)
甲状腺新生物	n (%)	0	1(0.5)	1(0.6)	1(0.3)
神経系障害	n (%)	41(25.5)	41(21.9)	32(18.3)	82(23.6)
頭痛	n (%)	9(5.6)	16(8.6)	12(6.9)	25(7.2)
傾眠	n (%)	14(8.7)	5(2.7)	4(2.3)	19(5.5)
浮動性めまい	n (%)	6(3.7)	8(4.3)	8(4.6)	14(4.0)
アカシジア	n (%)	7(4.3)	1(0.5)	1(0.6)	8(2.3)
振戦	n (%)	4(2.5)	3(1.6)	1(0.6)	7(2.0)
ジスキネジー	n (%)	1(0.6)	4(2.1)	3(1.7)	5(1.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
鎮静	n (%)	2(1.2)	2(1.1)	2(1.1)	4(1.1)
失神	n (%)	3(1.9)	1(0.5)	0	4(1.1)
よだれ	n (%)	0	3(1.6)	3(1.7)	3(0.9)
平衡障害	n (%)	0	2(1.1)	1(0.6)	2(0.6)
ジストニー	n (%)	2(1.2)	0	0	2(0.6)
錐体外路障害	n (%)	0	2(1.1)	2(1.1)	2(0.6)
パーキンソニズム	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
遅発性ジスキネジー	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
歯車様固縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
注意力障害	n (%)	0	1(0.5)	1(0.6)	1(0.3)
構語障害	n (%)	0	1(0.5)	0	1(0.3)
顔面神経麻痺	n (%)	0	1(0.5)	1(0.6)	1(0.3)
感覚鈍麻	n (%)	1(0.6)	0	0	1(0.3)
企図振戦	n (%)	1(0.6)	0	0	1(0.3)
嗜眠	n (%)	0	1(0.5)	0	1(0.3)
片頭痛	n (%)	1(0.6)	0	0	1(0.3)
ミオクローヌス	n (%)	1(0.6)	0	0	1(0.3)
神経痛	n (%)	1(0.6)	0	0	1(0.3)
末梢性ニューロパチー	n (%)	0	1(0.5)	1(0.6)	1(0.3)
咬舌	n (%)	1(0.6)	0	0	1(0.3)
一過性脳虚血発作	n (%)	1(0.6)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
妊娠、産褥および周産期の状態	n (%)	0	1(0.5)	1(0.6)	1(0.3)
自然流産	n (%)	0	1(0.5)	1(0.6)	1(0.3)
精神障害	n (%)	37(23.0)	30(16.0)	24(13.7)	67(19.3)
自殺念慮	n (%)	9(5.6)	8(4.3)	8(4.6)	17(4.9)
うつ病	n (%)	8(5.0)	4(2.1)	3(1.7)	12(3.4)
不安	n (%)	4(2.5)	6(3.2)	3(1.7)	10(2.9)
不眠症	n (%)	4(2.5)	4(2.1)	3(1.7)	8(2.3)
統合失調症	n (%)	4(2.5)	3(1.6)	3(1.7)	7(2.0)
激越	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
落ち着きのなさ	n (%)	1(0.6)	2(1.1)	0	3(0.9)
抑うつ症状	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
躁病	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
精神状態変化	n (%)	2(1.2)	0	0	2(0.6)
妄想症	n (%)	2(1.2)	0	0	2(0.6)
精神運動制止遅滞	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
精神病性障害	n (%)	1(0.6)	1(0.5)	0	2(0.6)
自殺企図	n (%)	0	2(1.1)	2(1.1)	2(0.6)
アルコール症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
死別反応	n (%)	1(0.6)	0	0	1(0.3)
双極１型障害	n (%)	1(0.6)	0	0	1(0.3)
錯乱状態	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
抑うつ気分	n (%)	0	1(0.5)	1(0.6)	1(0.3)
ディスフェミア	n (%)	1(0.6)	0	0	1(0.3)
敵意	n (%)	1(0.6)	0	0	1(0.3)
軽躁	n (%)	1(0.6)	0	0	1(0.3)
リビドー減退	n (%)	1(0.6)	0	0	1(0.3)
気分動揺	n (%)	0	1(0.5)	0	1(0.3)
神経過敏	n (%)	0	1(0.5)	1(0.6)	1(0.3)
パニック発作	n (%)	1(0.6)	0	0	1(0.3)
統合失調感情障害	n (%)	1(0.6)	0	0	1(0.3)
自殺行為	n (%)	0	1(0.5)	1(0.6)	1(0.3)
トランス	n (%)	1(0.6)	0	0	1(0.3)
腎および尿路障害	n (%)	3(1.9)	3(1.6)	3(1.7)	6(1.7)
糖尿	n (%)	0	1(0.5)	1(0.6)	1(0.3)
血尿	n (%)	0	1(0.5)	1(0.6)	1(0.3)
頻尿	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腎嚢胞	n (%)	1(0.6)	0	0	1(0.3)
急性腎不全	n (%)	1(0.6)	0	0	1(0.3)
尿失禁	n (%)	1(0.6)	0	0	1(0.3)
生殖系および乳房障害	n (%)	2(1.2)	2(1.1)	2(1.1)	4(1.1)
良性前立腺肥大症	n (%)	1(0.6)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
乳房圧痛	n (%)	1(0.6)	0	0	1(0.3)
乳汁漏出症	n (%)	1(0.6)	0	0	1(0.3)
月経過多	n (%)	0	1(0.5)	1(0.6)	1(0.3)
精巣捻転	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腟分泌物	n (%)	1(0.6)	0	0	1(0.3)
呼吸器、胸郭および縦隔障害	n (%)	5(3.1)	22(11.8)	18(10.3)	27(7.8)
咳嗽	n (%)	2(1.2)	6(3.2)	4(2.3)	8(2.3)
鼻閉	n (%)	1(0.6)	4(2.1)	4(2.3)	5(1.4)
喘息	n (%)	1(0.6)	3(1.6)	2(1.1)	4(1.1)
呼吸困難	n (%)	1(0.6)	3(1.6)	2(1.1)	4(1.1)
慢性閉塞性肺疾患	n (%)	0	3(1.6)	3(1.7)	3(0.9)
口腔咽頭痛	n (%)	0	2(1.1)	1(0.6)	2(0.6)
アレルギー性鼻炎	n (%)	0	2(1.1)	2(1.1)	2(0.6)
アレルギー性副鼻腔炎	n (%)	1(0.6)	0	0	1(0.3)
慢性気管支炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
嚢胞性肺疾患	n (%)	0	1(0.5)	1(0.6)	1(0.3)
鼻出血	n (%)	1(0.6)	0	0	1(0.3)
胸水	n (%)	0	1(0.5)	1(0.6)	1(0.3)
気道うっ血	n (%)	0	1(0.5)	0	1(0.3)
副鼻腔うっ血	n (%)	0	1(0.5)	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
皮膚および皮下組織障害	n (%)	9(5.6)	7(3.7)	6(3.4)	16(4.6)
発疹	n (%)	2(1.2)	3(1.6)	2(1.1)	5(1.4)
過角化	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
斑状丘疹状皮疹	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
水疱	n (%)	1(0.6)	0	0	1(0.3)
アレルギー性皮膚炎	n (%)	1(0.6)	0	0	1(0.3)
そう痒症	n (%)	1(0.6)	0	0	1(0.3)
全身性皮疹	n (%)	1(0.6)	0	0	1(0.3)
丘疹	n (%)	0	1(0.5)	1(0.6)	1(0.3)
皮膚剥脱	n (%)	0	1(0.5)	1(0.6)	1(0.3)
皮膚病変	n (%)	0	1(0.5)	1(0.6)	1(0.3)
蕁麻疹	n (%)	1(0.6)	0	0	1(0.3)
社会環境	n (%)	1(0.6)	0	0	1(0.3)
社会的入院	n (%)	1(0.6)	0	0	1(0.3)
外科および内科処置	n (%)	2(1.2)	2(1.1)	2(1.1)	4(1.1)
抜歯	n (%)	2(1.2)	0	0	2(0.6)
四肢再接合手術	n (%)	0	1(0.5)	1(0.6)	1(0.3)
鼓膜切開	n (%)	0	1(0.5)	1(0.6)	1(0.3)
血管障害	n (%)	4(2.5)	9(4.8)	8(4.6)	13(3.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	All NBI-98854 (N=348)
高血圧	n (%)	2(1.2)	3(1.6)	2(1.1)	5(1.4)
血腫	n (%)	0	2(1.1)	2(1.1)	2(0.6)
ほてり	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
深部静脈血栓症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
本態性高血圧症	n (%)	1(0.6)	0	0	1(0.3)
低血圧	n (%)	0	1(0.5)	1(0.6)	1(0.3)
レイノー現象	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	All NBI-98854 (N=79)
Any Adverse Event	n (%)	19(52.8)	27(62.8)	23(59.0)	46(58.2)
血液およびリンパ系障害	n (%)	2(5.6)	0	0	2(2.5)
貧血	n (%)	1(2.8)	0	0	1(1.3)
好中球減少症	n (%)	1(2.8)	0	0	1(1.3)
心臓障害	n (%)	2(5.6)	3(7.0)	3(7.7)	5(6.3)
上室性不整脈	n (%)	1(2.8)	0	0	1(1.3)
心房細動	n (%)	0	1(2.3)	1(2.6)	1(1.3)
冠動脈疾患	n (%)	1(2.8)	0	0	1(1.3)
僧帽弁閉鎖不全症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
三尖弁閉鎖不全症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
心室性期外収縮	n (%)	0	1(2.3)	1(2.6)	1(1.3)
胃腸障害	n (%)	2(5.6)	6(14.0)	5(12.8)	8(10.1)
下痢	n (%)	0	2(4.7)	2(5.1)	2(2.5)
歯痛	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
便秘	n (%)	0	1(2.3)	0	1(1.3)
口内乾燥	n (%)	0	1(2.3)	1(2.6)	1(1.3)
胃食道逆流性疾患	n (%)	0	1(2.3)	1(2.6)	1(1.3)
悪心	n (%)	0	1(2.3)	1(2.6)	1(1.3)
歯の脱落	n (%)	1(2.8)	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	All NBI-98854 (N=79)
全身障害および投与局所様態	n (%)	4(11.1)	8(18.6)	5(12.8)	12(15.2)
無力症	n (%)	0	3(7.0)	0	3(3.8)
胸痛	n (%)	2(5.6)	1(2.3)	1(2.6)	3(3.8)
疲労	n (%)	2(5.6)	1(2.3)	1(2.6)	3(3.8)
歩行障害	n (%)	1(2.8)	0	0	1(1.3)
治癒不良	n (%)	1(2.8)	0	0	1(1.3)
易刺激性	n (%)	0	1(2.3)	1(2.6)	1(1.3)
末梢性浮腫	n (%)	1(2.8)	0	0	1(1.3)
発熱	n (%)	0	1(2.3)	1(2.6)	1(1.3)
突然死	n (%)	0	1(2.3)	1(2.6)	1(1.3)
感染症および寄生虫症	n (%)	5(13.9)	9(20.9)	9(23.1)	14(17.7)
尿路感染	n (%)	0	6(14.0)	6(15.4)	6(7.6)
急性副鼻腔炎	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
鼻咽頭炎	n (%)	2(5.6)	0	0	2(2.5)
ダニ皮膚炎	n (%)	1(2.8)	0	0	1(1.3)
気管支炎	n (%)	0	1(2.3)	1(2.6)	1(1.3)
眼感染	n (%)	1(2.8)	0	0	1(1.3)
胃腸炎	n (%)	0	1(2.3)	1(2.6)	1(1.3)
爪真菌症	n (%)	1(2.8)	0	0	1(1.3)
咽頭炎	n (%)	1(2.8)	0	0	1(1.3)
急性腎盂腎炎	n (%)	1(2.8)	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	All NBI-98854 (N=79)
上気道感染	n (%)	0	1(2.3)	1(2.6)	1(1.3)
傷害、中毒および処置合併症	n (%)	5(13.9)	1(2.3)	1(2.6)	6(7.6)
転倒・転落	n (%)	4(11.1)	0	0	4(5.1)
筋挫傷	n (%)	0	1(2.3)	1(2.6)	1(1.3)
熱傷	n (%)	1(2.8)	0	0	1(1.3)
臨床検査	n (%)	2(5.6)	6(14.0)	6(15.4)	8(10.1)
血圧上昇	n (%)	0	2(4.7)	2(5.1)	2(2.5)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(2.3)	1(2.6)	1(1.3)
血中ブドウ糖増加	n (%)	0	1(2.3)	1(2.6)	1(1.3)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	1(2.3)	1(2.6)	1(1.3)
ヘモグロビン減少	n (%)	0	1(2.3)	1(2.6)	1(1.3)
肝酵素上昇	n (%)	1(2.8)	0	0	1(1.3)
体重減少	n (%)	1(2.8)	0	0	1(1.3)
体重増加	n (%)	0	1(2.3)	1(2.6)	1(1.3)
代謝および栄養障害	n (%)	2(5.6)	1(2.3)	1(2.6)	3(3.8)
食欲不振	n (%)	1(2.8)	0	0	1(1.3)
耐糖能障害	n (%)	1(2.8)	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	All NBI-98854 (N=79)
食欲亢進	n (%)	0	1(2.3)	1(2.6)	1(1.3)
筋骨格系および結合組織障害	n (%)	3(8.3)	6(14.0)	6(15.4)	9(11.4)
関節痛	n (%)	0	2(4.7)	2(5.1)	2(2.5)
骨関節炎	n (%)	0	2(4.7)	2(5.1)	2(2.5)
背部痛	n (%)	1(2.8)	0	0	1(1.3)
滑液包炎	n (%)	1(2.8)	0	0	1(1.3)
椎間板変性症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
筋骨格系胸痛	n (%)	1(2.8)	0	0	1(1.3)
筋骨格痛	n (%)	0	1(2.3)	1(2.6)	1(1.3)
顎痛	n (%)	1(2.8)	0	0	1(1.3)
神経系障害	n (%)	5(13.9)	8(18.6)	5(12.8)	13(16.5)
傾眠	n (%)	1(2.8)	4(9.3)	2(5.1)	5(6.3)
浮動性めまい	n (%)	0	2(4.7)	2(5.1)	2(2.5)
鎮静	n (%)	0	2(4.7)	1(2.6)	2(2.5)
失神	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
健忘	n (%)	0	1(2.3)	1(2.6)	1(1.3)
平衡障害	n (%)	1(2.8)	0	0	1(1.3)
認知症	n (%)	1(2.8)	0	0	1(1.3)
脳症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
頭痛	n (%)	1(2.8)	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	All NBI-98854 (N=79)
一過性脳虚血発作	n (%)	0	1(2.3)	1(2.6)	1(1.3)
精神障害	n (%)	4(11.1)	5(11.6)	4(10.3)	9(11.4)
不安	n (%)	2(5.6)	1(2.3)	0	3(3.8)
うつ病	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
自殺念慮	n (%)	0	2(4.7)	2(5.1)	2(2.5)
抑うつ気分	n (%)	1(2.8)	0	0	1(1.3)
不眠症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
外傷後ストレス障害	n (%)	1(2.8)	0	0	1(1.3)
統合失調感情障害	n (%)	0	1(2.3)	1(2.6)	1(1.3)
統合失調症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
腎および尿路障害	n (%)	3(8.3)	3(7.0)	3(7.7)	6(7.6)
血尿	n (%)	2(5.6)	0	0	2(2.5)
排尿困難	n (%)	0	1(2.3)	1(2.6)	1(1.3)
腎結石症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
頻尿	n (%)	1(2.8)	0	0	1(1.3)
尿失禁	n (%)	0	1(2.3)	1(2.6)	1(1.3)
尿臭異常	n (%)	1(2.8)	0	0	1(1.3)
生殖系および乳房障害	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
良性前立腺肥大症	n (%)	0	1(2.3)	1(2.6)	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	All NBI-98854 (N=79)
前立腺炎	n (%)	1(2.8)	0	0	1(1.3)
呼吸器、胸郭および縦隔障害	n (%)	3(8.3)	5(11.6)	5(12.8)	8(10.1)
慢性閉塞性肺疾患	n (%)	2(5.6)	2(4.7)	2(5.1)	4(5.1)
咳嗽	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
鼻閉	n (%)	0	1(2.3)	1(2.6)	1(1.3)
胸膜線維症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
鼻漏	n (%)	1(2.8)	0	0	1(1.3)
副鼻腔うっ血	n (%)	1(2.8)	0	0	1(1.3)
くしゃみ	n (%)	0	1(2.3)	1(2.6)	1(1.3)
皮膚および皮下組織障害	n (%)	2(5.6)	0	0	2(2.5)
そう痒症	n (%)	2(5.6)	0	0	2(2.5)
外科および内科処置	n (%)	0	1(2.3)	1(2.6)	1(1.3)
抜歯	n (%)	0	1(2.3)	1(2.6)	1(1.3)
Unknown	n (%)	1(2.8)	0	0	1(1.3)
皮膚嚢腫	n (%)	1(2.8)	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－137 年齢区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	 80 mg (N=43)	 80 mg Only[b] (N=39)	 All NBI-98854 (N=79)
血管障害	n (%)	2(5.6)	5(11.6)	5(12.8)	7(8.9)
高血圧	n (%)	0	3(7.0)	3(7.7)	3(3.8)
深部静脈血栓症	n (%)	0	1(2.3)	1(2.6)	1(1.3)
ほてり	n (%)	0	1(2.3)	1(2.6)	1(1.3)
起立性低血圧	n (%)	1(2.8)	0	0	1(1.3)
末梢動脈閉塞性疾患	n (%)	1(2.8)	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.2より引用（一部改変）

表2.7.4.7－138　年齢区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	 All NBI-98854 (N=348)
Any Adverse Event of Special Interest	n (%)	58(36.0)	57(30.5)	46(26.3)	115(33.0)
アカシジア関連有害事象	n (%)	7(4.3)	1(0.5)	1(0.6)	8(2.3)
アカシジア	n (%)	7(4.3)	1(0.5)	1(0.6)	8(2.3)
不安	n (%)	4(2.5)	6(3.2)	3(1.7)	10(2.9)
不安	n (%)	4(2.5)	6(3.2)	3(1.7)	10(2.9)
心血管系及びQT間隔延長関連有害事象	n (%)	3(1.9)	5(2.7)	4(2.3)	8(2.3)
失神	n (%)	3(1.9)	1(0.5)	0	4(1.1)
胸痛	n (%)	1(0.6)	2(1.1)	2(1.1)	3(0.9)
心不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心電図QT延長	n (%)	0	1(0.5)	1(0.6)	1(0.3)
うつ病及び自殺関連有害事象	n (%)	17(10.6)	16(8.6)	15(8.6)	33(9.5)
自殺念慮	n (%)	9(5.6)	8(4.3)	8(4.6)	17(4.9)
うつ病	n (%)	8(5.0)	4(2.1)	3(1.7)	12(3.4)
抑うつ症状	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
自殺企図	n (%)	0	2(1.1)	2(1.1)	2(0.6)
抑うつ気分	n (%)	0	1(0.5)	1(0.6)	1(0.3)
自殺行為	n (%)	0	1(0.5)	1(0.6)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－138　年齢区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	 80 mg (N=187)	 80 mg Only[b] (N=175)	 All NBI-98854 (N=348)
嚥下障害関連有害事象	n (%)	3(1.9)	1(0.5)	1(0.6)	4(1.1)
嚥下障害	n (%)	3(1.9)	1(0.5)	1(0.6)	4(1.1)
食道食物嵌入	n (%)	1(0.6)	0	0	1(0.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	11(6.8)	10(5.3)	8(4.6)	21(6.0)
疲労	n (%)	11(6.8)	7(3.7)	7(4.0)	18(5.2)
無力症	n (%)	1(0.6)	1(0.5)	0	2(0.6)
嗜眠	n (%)	0	1(0.5)	0	1(0.3)
倦怠感	n (%)	0	1(0.5)	1(0.6)	1(0.3)
肝障害関連有害事象	n (%)	0	2(1.1)	2(1.1)	2(0.6)
肝不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
急性肝炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高プロラクチン血症関連有害事象	n (%)	3(1.9)	1(0.5)	0	4(1.1)
血中プロラクチン増加	n (%)	2(1.2)	1(0.5)	0	3(0.9)
乳汁漏出症	n (%)	1(0.6)	0	0	1(0.3)
低血圧関連有害事象	n (%)	9(5.6)	13(7.0)	12(6.9)	22(6.3)
浮動性めまい	n (%)	6(3.7)	8(4.3)	8(4.6)	14(4.0)
転倒・転落	n (%)	1(0.6)	5(2.7)	4(2.3)	6(1.7)
失神	n (%)	3(1.9)	1(0.5)	0	4(1.1)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－138　年齢区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	80 mg (N=187)	80 mg Only[b] (N=175)	All NBI-98854 (N=348)
低血圧	n (%)	0	1(0.5)	1(0.6)	1(0.3)
パーキンソニズム関連有害事象	n (%)	5(3.1)	5(2.7)	2(1.1)	10(2.9)
振戦	n (%)	4(2.5)	3(1.6)	1(0.6)	7(2.0)
パーキンソニズム	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
歯車様固縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋固縮	n (%)	0	1(0.5)	0	1(0.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	16(9.9)	7(3.7)	6(3.4)	23(6.6)
傾眠	n (%)	14(8.7)	5(2.7)	4(2.3)	19(5.5)
鎮静	n (%)	2(1.2)	2(1.1)	2(1.1)	4(1.1)
基礎疾患の悪化に関連する有害事象	n (%)	24(14.9)	22(11.8)	20(11.4)	46(13.2)
自殺念慮	n (%)	9(5.6)	8(4.3)	8(4.6)	17(4.9)
うつ病	n (%)	8(5.0)	4(2.1)	3(1.7)	12(3.4)
統合失調症	n (%)	4(2.5)	3(1.6)	3(1.7)	7(2.0)
抑うつ症状	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
易刺激性	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
躁病	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.6)
妄想症	n (%)	2(1.2)	0	0	2(0.6)
精神病性障害	n (%)	1(0.6)	1(0.5)	0	2(0.6)
自殺企図	n (%)	0	2(1.1)	2(1.1)	2(0.6)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－138　年齢区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: <65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=161)	80 mg (N=187)	80 mg Only[b] (N=175)	All NBI-98854 (N=348)
双極１型障害	n (%)	1(0.6)	0	0	1(0.3)
抑うつ気分	n (%)	0	1(0.5)	1(0.6)	1(0.3)
敵意	n (%)	1(0.6)	0	0	1(0.3)
軽躁	n (%)	1(0.6)	0	0	1(0.3)
気分動揺	n (%)	0	1(0.5)	0	1(0.3)
統合失調感情障害	n (%)	1(0.6)	0	0	1(0.3)
自殺行為	n (%)	0	1(0.5)	1(0.6)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－138　年齢区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	80 mg (N=43)	80 mg Only[b] (N=39)	All NBI-98854 (N=79)
Any Adverse Event of Special Interest	n (%)	12(33.3)	14(32.6)	10(25.6)	26(32.9)
不安	n (%)	2(5.6)	1(2.3)	0	3(3.8)
不安	n (%)	2(5.6)	1(2.3)	0	3(3.8)
心血管系及びQT間隔延長関連有害事象	n (%)	3(8.3)	3(7.0)	3(7.7)	6(7.6)
胸痛	n (%)	2(5.6)	1(2.3)	1(2.6)	3(3.8)
失神	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
突然死	n (%)	0	1(2.3)	1(2.6)	1(1.3)
うつ病及び自殺関連有害事象	n (%)	2(5.6)	2(4.7)	2(5.1)	4(5.1)
うつ病	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
自殺念慮	n (%)	0	2(4.7)	2(5.1)	2(2.5)
抑うつ気分	n (%)	1(2.8)	0	0	1(1.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	2(5.6)	4(9.3)	1(2.6)	6(7.6)
無力症	n (%)	0	3(7.0)	0	3(3.8)
疲労	n (%)	2(5.6)	1(2.3)	1(2.6)	3(3.8)
低血圧関連有害事象	n (%)	5(13.9)	3(7.0)	3(7.7)	8(10.1)
転倒・転落	n (%)	4(11.1)	0	0	4(5.1)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－138　年齢区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Age Category: >=65 Years

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=36)	80 mg (N=43)	80 mg Only[b] (N=39)	All NBI-98854 (N=79)
浮動性めまい	n (%)	0	2(4.7)	2(5.1)	2(2.5)
失神	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
起立性低血圧	n (%)	1(2.8)	0	0	1(1.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	1(2.8)	6(14.0)	3(7.7)	7(8.9)
傾眠	n (%)	1(2.8)	4(9.3)	2(5.1)	5(6.3)
鎮静	n (%)	0	2(4.7)	1(2.6)	2(2.5)
基礎疾患の悪化に関連する有害事象	n (%)	3(8.3)	3(7.0)	3(7.7)	6(7.6)
うつ病	n (%)	1(2.8)	1(2.3)	1(2.6)	2(2.5)
自殺念慮	n (%)	0	2(4.7)	2(5.1)	2(2.5)
抑うつ気分	n (%)	1(2.8)	0	0	1(1.3)
易刺激性	n (%)	0	1(2.3)	1(2.6)	1(1.3)
外傷後ストレス障害	n (%)	1(2.8)	0	0	1(1.3)
統合失調感情障害	n (%)	0	1(2.3)	1(2.6)	1(1.3)
統合失調症	n (%)	0	1(2.3)	1(2.6)	1(1.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.2より引用（一部改変）

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Any System Organ Class		23 (57.5)	40 (78.4)	63 (69.2)	16 (44.4)	31 (68.9)	27 (81.8)	58 (74.4)	21 (43.8)
Infections and infestations	感染症および寄生虫症	6 (15.0)	5 (9.8)	11 (12.1)	3 (8.3)	4 (8.9)	4 (12.1)	8 (10.3)	4 (8.3)
Nasopharyngitis	上咽頭炎	2 (5.0)	1 (2.0)	3 (3.3)	2 (5.6)	4 (8.9)	3 (9.1)	7 (9.0)	4 (8.3)
Pneumonia	肺炎	1 (2.5)	2 (3.9)	3 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Influenza	インフルエンザ	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periodontitis	歯周炎	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	上気道感染	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	1 (2.1)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Blepharal papilloma	眼瞼乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	2 (5.0)	1 (2.0)	3 (3.3)	1 (2.8)	4 (8.9)	3 (9.1)	7 (9.0)	1 (2.1)
Decreased appetite	食欲減退	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	1 (2.2)	1 (3.0)	2 (2.6)	0 (0.0)
Dehydration	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.1)	2 (2.6)	0 (0.0)
Diabetes mellitus	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hyperuricaemia	高尿酸血症	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polydipsia	多飲症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hyperlipidaemia	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Psychiatric disorders	精神障害	8 (20.0)	11 (21.6)	19 (20.9)	1 (2.8)	9 (20.0)	5 (15.2)	14 (17.9)	4 (8.3)
Insomnia	不眠症	1 (2.5)	2 (3.9)	3 (3.3)	0 (0.0)	1 (2.2)	3 (9.1)	4 (5.1)	1 (2.1)
Schizophrenia	統合失調症	3 (7.5)	0 (0.0)	3 (3.3)	0 (0.0)	4 (8.9)	0 (0.0)	4 (5.1)	1 (2.1)
Anxiety	不安	0 (0.0)	3 (5.9)	3 (3.3)	0 (0.0)	1 (2.2)	1 (3.0)	2 (2.6)	0 (0.0)
Depression	うつ病	1 (2.5)	3 (5.9)	4 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Disinhibition	脱抑制	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	1 (2.1)
Delusion	妄想	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Somatic symptom disorder	身体症状症	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Nervous system disorders	神経系障害	8 (20.0)	22 (43.1)	30 (33.0)	4 (11.1)	12 (26.7)	16 (48.5)	28 (35.9)	2 (4.2)
Somnolence	傾眠	5 (12.5)	10 (19.6)	15 (16.5)	2 (5.6)	5 (11.1)	11 (33.3)	16 (20.5)	0 (0.0)
Akathisia	アカシジア	1 (2.5)	2 (3.9)	3 (3.3)	1 (2.8)	3 (6.7)	3 (9.1)	6 (7.7)	0 (0.0)
Headache	頭痛	0 (0.0)	3 (5.9)	3 (3.3)	1 (2.8)	1 (2.2)	1 (3.0)	2 (2.6)	1 (2.1)
Tremor	振戦	0 (0.0)	2 (3.9)	2 (2.2)	0 (0.0)	0 (0.0)	3 (9.1)	3 (3.8)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	3 (5.9)	3 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Drooling	よだれ	1 (2.5)	1 (2.0)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Parkinsonism	パーキンソニズム	1 (2.5)	1 (2.0)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hypoaesthesia	感覚鈍麻	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Seizure	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Eye disorders	眼障害	1 (2.5)	2 (3.9)	3 (3.3)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Blepharitis	眼瞼炎	0 (0.0)	1 (2.0)	1 (1.1)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Ear and labyrinth disorders	耳および迷路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (2.6)	0 (0.0)
Deafness neurosensory	感音性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Cardiac disorders	心臓障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Palpitations	動悸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Vascular disorders	血管障害	1 (2.5)	0 (0.0)	1 (1.1)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	高血圧	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1 (2.5)	4 (7.8)	5 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Asthma	喘息	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Gastrointestinal disorders	胃腸障害	3 (7.5)	12 (23.5)	15 (16.5)	3 (8.3)	5 (11.1)	8 (24.2)	13 (16.7)	4 (8.3)
Salivary hypersecretion	流涎過多	2 (5.0)	5 (9.8)	7 (7.7)	1 (2.8)	1 (2.2)	4 (12.1)	5 (6.4)	0 (0.0)
Constipation	便秘	1 (2.5)	1 (2.0)	2 (2.2)	1 (2.8)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Nausea	悪心	0 (0.0)	2 (3.9)	2 (2.2)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	1 (2.1)
Diarrhoea	下痢	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	1 (2.1)
Dry mouth	口内乾燥	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Dysphagia	嚥下障害	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastritis	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Hepatobiliary disorders	肝胆道系障害	1 (2.5)	1 (2.0)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	1 (2.5)	3 (5.9)	4 (4.4)	3 (8.3)	5 (11.1)	3 (9.1)	8 (10.3)	2 (4.2)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	2 (6.1)	4 (5.1)	0 (0.0)
Eczema	湿疹	1 (2.5)	1 (2.0)	2 (2.2)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)
Alopecia areata	円形脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Blister	水疱	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Dry skin	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (2.5)	4 (7.8)	5 (5.5)	1 (2.8)	3 (6.7)	1 (3.0)	4 (5.1)	4 (8.3)
Back pain	背部痛	1 (2.5)	2 (3.9)	3 (3.3)	0 (0.0)	2 (4.4)	0 (0.0)	2 (2.6)	2 (4.2)
Neck pain	頚部痛	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Posture abnormal	姿勢異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Muscle spasms	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Renal and urinary disorders	腎および尿路障害	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	1 (2.1)
Hypertonic bladder	緊張性膀胱	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	4 (10.0)	4 (7.8)	8 (8.8)	0 (0.0)	6 (13.3)	7 (21.2)	13 (16.7)	2 (4.2)
Malaise	倦怠感	3 (7.5)	2 (3.9)	5 (5.5)	0 (0.0)	2 (4.4)	2 (6.1)	4 (5.1)	0 (0.0)
Fatigue	疲労	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Thirst	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	0 (0.0)	2 (2.6)	1 (2.1)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Discomfort	不快感	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	1 (2.1)
Pyrexia	発熱	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Investigations	臨床検査	2 (5.0)	1 (2.0)	3 (3.3)	0 (0.0)	2 (4.4)	1 (3.0)	3 (3.8)	1 (2.1)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	1 (2.1)
Weight increased	体重増加	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－139　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	2 (5.0)	0 (0.0)	2 (2.2)	2 (5.6)	1 (2.2)	2 (6.1)	3 (3.8)	1 (2.1)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (3.0)	2 (2.6)	0 (0.0)
Head injury	頭部損傷	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contusion	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	1 (2.1)
Heat illness	熱中症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Sedation complication	鎮静合併症	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.2.1.1 より引用

表 2.7.4.7－140　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Any AESI		17 (42.5)	29 (56.9)	46 (50.5)	7 (19.4)	19 (42.2)	24 (72.7)	43 (55.1)	8 (16.7)
Somnolence	傾眠関連有害事象	8 (20.0)	11 (21.6)	19 (20.9)	2 (5.6)	8 (17.8)	13 (39.4)	21 (26.9)	0 (0.0)
Somnolence	傾眠	5 (12.5)	10 (19.6)	15 (16.5)	2 (5.6)	5 (11.1)	11 (33.3)	16 (20.5)	0 (0.0)
Malaise	倦怠感	3 (7.5)	2 (3.9)	5 (5.5)	0 (0.0)	2 (4.4)	2 (6.1)	4 (5.1)	0 (0.0)
Fatigue	疲労	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Sedation complication	鎮静合併症	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	1 (2.5)	3 (5.9)	4 (4.4)	2 (5.6)	4 (8.9)	4 (12.1)	8 (10.3)	4 (8.3)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.4)	2 (6.1)	4 (5.1)	0 (0.0)
Eczema	湿疹	1 (2.5)	1 (2.0)	2 (2.2)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)
Blister	水疱	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－140 性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Parkinsonism	パーキンソニズム関連有害事象	4 (10.0)	10 (19.6)	14 (15.4)	1 (2.8)	1 (2.2)	8 (24.2)	9 (11.5)	0 (0.0)
Salivary hypersecretion	流涎過多	2 (5.0)	5 (9.8)	7 (7.7)	1 (2.8)	1 (2.2)	4 (12.1)	5 (6.4)	0 (0.0)
Tremor	振戦	0 (0.0)	2 (3.9)	2 (2.2)	0 (0.0)	0 (0.0)	3 (9.1)	3 (3.8)	0 (0.0)
Drooling	よだれ	1 (2.5)	1 (2.0)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Parkinsonism	パーキンソニズム	1 (2.5)	1 (2.0)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	3 (7.5)	3 (5.9)	6 (6.6)	0 (0.0)	3 (6.7)	0 (0.0)	3 (3.8)	1 (2.1)
Depression	うつ病	1 (2.5)	3 (5.9)	4 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Akathisia	アカシジア関連有害事象	1 (2.5)	4 (7.8)	5 (5.5)	1 (2.8)	3 (6.7)	4 (12.1)	7 (9.0)	0 (0.0)
Akathisia	アカシジア	1 (2.5)	2 (3.9)	3 (3.3)	1 (2.8)	3 (6.7)	3 (9.1)	6 (7.7)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	3 (5.9)	3 (3.3)	0 (0.0)	1 (2.2)	1 (3.0)	2 (2.6)	0 (0.0)
Anxiety	不安	0 (0.0)	3 (5.9)	3 (3.3)	0 (0.0)	1 (2.2)	1 (3.0)	2 (2.6)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－140　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male				Female			
		MT-5199				MT-5199			
		40 mg (N=40) n(%)	80 mg (N=51) n(%)	All MT-5199 (N=91) n(%)	Placebo (N=36) n(%)	40 mg (N=45) n(%)	80 mg (N=33) n(%)	All MT-5199 (N=78) n(%)	Placebo (N=48) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	5 (12.5)	4 (7.8)	9 (9.9)	0 (0.0)	6 (13.3)	2 (6.1)	8 (10.3)	3 (6.3)
Schizophrenia	統合失調症	3 (7.5)	0 (0.0)	3 (3.3)	0 (0.0)	4 (8.9)	0 (0.0)	4 (5.1)	1 (2.1)
Depression	うつ病	1 (2.5)	3 (5.9)	4 (4.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Bipolar disorder	双極性障害	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	1 (2.1)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Dysphagia	嚥下障害	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.0)	1 (1.3)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	1 (2.5)	1 (2.0)	2 (2.2)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	0 (0.0)	1 (1.3)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (2.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	1 (2.5)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	0 (0.0)	3 (5.9)	3 (3.3)	1 (2.8)	1 (2.2)	1 (3.0)	2 (2.6)	1 (2.1)
Dizziness	浮動性めまい	0 (0.0)	3 (5.9)	3 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (3.0)	2 (2.6)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.2.1.2 より引用

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Any System Organ Class		50 (84.7)	63 (92.6)	43 (89.6)	113 (89.0)	63 (94.0)	53 (96.4)	34 (94.4)	116 (95.1)
Infections and infestations	感染症および寄生虫症	22 (37.3)	20 (29.4)	14 (29.2)	42 (33.1)	24 (35.8)	20 (36.4)	15 (41.7)	44 (36.1)
Nasopharyngitis	上咽頭炎	13 (22.0)	8 (11.8)	5 (10.4)	21 (16.5)	17 (25.4)	15 (27.3)	10 (27.8)	32 (26.2)
Cystitis	膀胱炎	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Pneumonia	肺炎	2 (3.4)	3 (4.4)	3 (6.3)	5 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bronchitis	気管支炎	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Influenza	インフルエンザ	0 (0.0)	2 (2.9)	2 (4.2)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Upper respiratory tract infection	上気道感染	2 (3.4)	1 (1.5)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cellulitis	蜂巣炎	1 (1.7)	1 (1.5)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Folliculitis	毛包炎	1 (1.7)	1 (1.5)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	胃腸炎	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Otitis externa	外耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Periodontitis	歯周炎	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Pharyngitis	咽頭炎	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	2 (2.9)	1 (2.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Gingivitis	歯肉炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Herpes zoster	帯状疱疹	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Mastitis	乳腺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Nasal vestibulitis	鼻前庭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Otitis media	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Subcutaneous abscess	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Tonsillitis	扁桃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Urinary tract infection	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Vaginal infection	腟感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Varicella	水痘	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Eczema impetiginous	膿痂疹性湿疹	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin candida	皮膚カンジダ	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Nail infection	爪感染	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Acarodermatitis	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Cystitis bacterial	細菌性膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Infected dermal cyst	感染性皮膚嚢腫	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial vulvovaginitis	細菌性外陰腟炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Metabolism and nutrition disorders	代謝および栄養障害	6 (10.2)	5 (7.4)	4 (8.3)	11 (8.7)	10 (14.9)	7 (12.7)	4 (11.1)	17 (13.9)
Decreased appetite	食欲減退	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	4 (6.0)	3 (5.5)	0 (0.0)	7 (5.7)
Dehydration	脱水	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	3 (5.5)	3 (8.3)	4 (3.3)
Hyperuricaemia	高尿酸血症	2 (3.4)	1 (1.5)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Increased appetite	食欲亢進	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Dyslipidaemia	脂質異常症	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Type 2 diabetes mellitus	２型糖尿病	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Electrolyte imbalance	電解質失調	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypokalaemia	低カリウム血症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypouricaemia	低尿酸血症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marasmus	マラスムス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Polydipsia	多飲症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Hyperlipidaemia	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Psychiatric disorders	精神障害	21 (35.6)	31 (45.6)	20 (41.7)	52 (40.9)	31 (46.3)	26 (47.3)	20 (55.6)	57 (46.7)
Schizophrenia	統合失調症	8 (13.6)	7 (10.3)	1 (2.1)	15 (11.8)	13 (19.4)	6 (10.9)	4 (11.1)	19 (15.6)
Insomnia	不眠症	5 (8.5)	7 (10.3)	4 (8.3)	12 (9.4)	5 (7.5)	9 (16.4)	8 (22.2)	14 (11.5)
Depression	うつ病	3 (5.1)	6 (8.8)	6 (12.5)	9 (7.1)	3 (4.5)	4 (7.3)	3 (8.3)	7 (5.7)
Anxiety	不安	0 (0.0)	5 (7.4)	4 (8.3)	5 (3.9)	5 (7.5)	4 (7.3)	3 (8.3)	9 (7.4)
Suicidal ideation	自殺念慮	3 (5.1)	1 (1.5)	0 (0.0)	4 (3.1)	3 (4.5)	2 (3.6)	2 (5.6)	5 (4.1)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Suicide attempt	自殺企図	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Bipolar disorder	双極性障害	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Middle insomnia	中期不眠症	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Bruxism	歯ぎしり	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Delirium	譫妄	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Disinhibition	脱抑制	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Flat affect	感情の平板化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.6)	1 (2.8)	2 (1.6)
Hallucination, auditory	幻聴	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Sleep disorder	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Agitation	激越	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Intentional self-injury	故意の自傷行為	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurosis	神経症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abulia	無為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Abnormal behaviour	異常行動	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somatic hallucination	体感幻覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Nervous system disorders	神経系障害	24 (40.7)	35 (51.5)	24 (50.0)	59 (46.5)	27 (40.3)	34 (61.8)	20 (55.6)	61 (50.0)
Somnolence	傾眠	6 (10.2)	12 (17.6)	8 (16.7)	18 (14.2)	13 (19.4)	16 (29.1)	10 (27.8)	29 (23.8)
Tremor	振戦	3 (5.1)	6 (8.8)	4 (8.3)	9 (7.1)	2 (3.0)	10 (18.2)	5 (13.9)	12 (9.8)
Akathisia	アカシジア	4 (6.8)	6 (8.8)	4 (8.3)	10 (7.9)	4 (6.0)	6 (10.9)	4 (11.1)	10 (8.2)
Headache	頭痛	0 (0.0)	5 (7.4)	2 (4.2)	5 (3.9)	4 (6.0)	3 (5.5)	3 (8.3)	7 (5.7)
Dizziness	浮動性めまい	1 (1.7)	4 (5.9)	4 (8.3)	5 (3.9)	3 (4.5)	3 (5.5)	2 (5.6)	6 (4.9)
Parkinsonism	パーキンソニズム	3 (5.1)	2 (2.9)	1 (2.1)	5 (3.9)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Extrapyramidal disorder	錐体外路障害	2 (3.4)	1 (1.5)	1 (2.1)	3 (2.4)	0 (0.0)	3 (5.5)	1 (2.8)	3 (2.5)
Drooling	よだれ	2 (3.4)	3 (4.4)	2 (4.2)	5 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tardive dyskinesia	遅発性ジスキネジア	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	3 (4.5)	1 (1.8)	1 (2.8)	4 (3.3)
Hypoaesthesia	感覚鈍麻	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Bradykinesia	運動緩慢	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	2 (3.6)	0 (0.0)	2 (1.6)
Dyskinesia	ジスキネジア	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	0 (0.0)	2 (1.6)
Dysarthria	構語障害	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Dystonia	ジストニア	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Seizure	痙攣発作	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Coordination abnormal	協調運動異常	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Neuralgia	神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Radial nerve palsy	橈骨神経麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Sciatica	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Stupor	昏迷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Intercostal neuralgia	肋間神経痛	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Cognitive disorder	認知障害	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vagus nerve disorder	迷走神経障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Reduced facial expression	表情減少	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Eye disorders	眼障害	2 (3.4)	3 (4.4)	1 (2.1)	5 (3.9)	1 (1.5)	2 (3.6)	1 (2.8)	3 (2.5)
Blepharitis	眼瞼炎	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cataract	白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Eye discharge	眼脂	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	2 (3.0)	1 (1.8)	0 (0.0)	3 (2.5)
Deafness neurosensory	感音性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Tinnitus	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Vertigo	回転性めまい	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Cardiac disorders	心臓障害	2 (3.4)	3 (4.4)	2 (4.2)	5 (3.9)	2 (3.0)	2 (3.6)	2 (5.6)	4 (3.3)
Palpitations	動悸	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Bradycardia	徐脈	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sinus bradycardia	洞性徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Tachycardia	頻脈	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Vascular disorders	血管障害	2 (3.4)	1 (1.5)	1 (2.1)	3 (2.4)	2 (3.0)	2 (3.6)	1 (2.8)	4 (3.3)
Hypertension	高血圧	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	0 (0.0)	3 (2.5)
Hypotension	低血圧	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Deep vein thrombosis	深部静脈血栓症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3 (5.1)	10 (14.7)	4 (8.3)	13 (10.2)	5 (7.5)	2 (3.6)	0 (0.0)	7 (5.7)
Asthma	喘息	0 (0.0)	3 (4.4)	1 (2.1)	3 (2.4)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	2 (2.9)	1 (2.1)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Dyspnoea	呼吸困難	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Pleural effusion	胸水	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Upper respiratory tract inflammation	上気道の炎症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Cough	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Interstitial lung disease	間質性肺疾患	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleurisy	胸膜炎	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	湿性咳嗽	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary embolism	肺塞栓症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory failure	呼吸不全	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Cough variant asthma	咳喘息	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Gastrointestinal disorders	胃腸障害	15 (25.4)	26 (38.2)	12 (25.0)	41 (32.3)	24 (35.8)	25 (45.5)	16 (44.4)	49 (40.2)
Salivary hypersecretion	流涎過多	3 (5.1)	11 (16.2)	4 (8.3)	14 (11.0)	6 (9.0)	10 (18.2)	6 (16.7)	16 (13.1)
Constipation	便秘	5 (8.5)	5 (7.4)	2 (4.2)	10 (7.9)	4 (6.0)	4 (7.3)	3 (8.3)	8 (6.6)
Dysphagia	嚥下障害	4 (6.8)	3 (4.4)	1 (2.1)	7 (5.5)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Diarrhoea	下痢	2 (3.4)	2 (2.9)	1 (2.1)	4 (3.1)	4 (6.0)	1 (1.8)	1 (2.8)	5 (4.1)
Nausea	悪心	0 (0.0)	2 (2.9)	2 (4.2)	2 (1.6)	2 (3.0)	3 (5.5)	2 (5.6)	5 (4.1)
Stomatitis	口内炎	3 (5.1)	1 (1.5)	1 (2.1)	4 (3.1)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Vomiting	嘔吐	0 (0.0)	4 (5.9)	0 (0.0)	4 (3.1)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Abdominal discomfort	腹部不快感	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Dental caries	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	2 (3.6)	0 (0.0)	4 (3.3)
Abdominal pain	腹痛	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Dry mouth	口内乾燥	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	2 (3.6)	1 (2.8)	2 (1.6)
Gastritis	胃炎	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Toothache	歯痛	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Abdominal distension	腹部膨満	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aphthous ulcer	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eructation	おくび	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Gastrointestinal disorder	胃腸障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Gingival bleeding	歯肉出血	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia oral	口の感覚鈍麻	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal pruritus	肛門そう痒症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hepatobiliary disorders	肝胆道系障害	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Hepatic steatosis	脂肪肝	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	10 (16.9)	14 (20.6)	9 (18.8)	24 (18.9)	13 (19.4)	9 (16.4)	5 (13.9)	22 (18.0)
Eczema	湿疹	3 (5.1)	2 (2.9)	1 (2.1)	5 (3.9)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.5)	2 (3.6)	1 (2.8)	5 (4.1)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	3 (4.4)	2 (4.2)	3 (2.4)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Dermatitis contact	接触皮膚炎	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	2 (3.6)	1 (2.8)	3 (2.5)
Dry skin	皮膚乾燥	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	0 (0.0)	3 (2.5)
Pruritus	そう痒症	2 (3.4)	2 (2.9)	2 (4.2)	4 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	1 (1.7)	1 (1.5)	0 (0.0)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Rash	発疹	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Alopecia areata	円形脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Hyperhidrosis	多汗症	0 (0.0)	2 (2.9)	1 (2.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Erythema	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Haemorrhage subcutaneous	皮下出血	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ingrowing nail	嵌入爪	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Skin exfoliation	皮膚剥脱	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Skin fissures	皮膚亀裂	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin ulcer	皮膚潰瘍	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	11 (18.6)	10 (14.7)	6 (12.5)	21 (16.5)	16 (23.9)	13 (23.6)	10 (27.8)	29 (23.8)
Back pain	背部痛	1 (1.7)	4 (5.9)	3 (6.3)	5 (3.9)	6 (9.0)	2 (3.6)	1 (2.8)	8 (6.6)
Arthralgia	関節痛	0 (0.0)	2 (2.9)	2 (4.2)	2 (1.6)	1 (1.5)	3 (5.5)	2 (5.6)	4 (3.3)
Osteoarthritis	変形性関節症	2 (3.4)	2 (2.9)	1 (2.1)	4 (3.1)	0 (0.0)	2 (3.6)	1 (2.8)	2 (1.6)
Muscular weakness	筋力低下	1 (1.7)	1 (1.5)	0 (0.0)	2 (1.6)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Pain in extremity	四肢痛	1 (1.7)	2 (2.9)	2 (4.2)	3 (2.4)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Myalgia	筋肉痛	3 (5.1)	0 (0.0)	0 (0.0)	3 (2.4)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Musculoskeletal pain	筋骨格痛	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Neck pain	頚部痛	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	2 (3.6)	2 (5.6)	2 (1.6)
Posture abnormal	姿勢異常	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Intervertebral disc protrusion	椎間板突出	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Osteoporosis	骨粗鬆症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Periarthritis	関節周囲炎	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Tenosynovitis	腱鞘炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	0 (0.0)	2 (1.6)
Mastication disorder	咀嚼障害	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Temporomandibular joint syndrome	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Trigger finger	弾発指	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Extremity contracture	四肢拘縮	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot deformity	足変形	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	3 (5.1)	3 (4.4)	2 (4.2)	6 (4.7)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Dysuria	排尿困難	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurogenic bladder	神経因性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Nocturia	夜間頻尿	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Renal glycosuria	腎性糖尿	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	尿失禁	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention	尿閉	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bladder prolapse	膀胱脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Vaginal discharge	膣分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Prostatomegaly	前立腺腫大	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	10 (16.9)	9 (13.2)	5 (10.4)	19 (15.0)	17 (25.4)	16 (29.1)	10 (27.8)	33 (27.0)
Malaise	倦怠感	6 (10.2)	3 (4.4)	2 (4.2)	9 (7.1)	4 (6.0)	7 (12.7)	3 (8.3)	11 (9.0)
Thirst	口渇	3 (5.1)	0 (0.0)	0 (0.0)	3 (2.4)	4 (6.0)	2 (3.6)	1 (2.8)	6 (4.9)
Fatigue	疲労	0 (0.0)	2 (2.9)	2 (4.2)	2 (1.6)	2 (3.0)	2 (3.6)	1 (2.8)	4 (3.3)
Pyrexia	発熱	1 (1.7)	1 (1.5)	0 (0.0)	2 (1.6)	2 (3.0)	2 (3.6)	2 (5.6)	4 (3.3)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	2 (3.6)	1 (2.8)	3 (2.5)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.6)	1 (2.8)	2 (1.6)
Death	死亡	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Calcinosis	石灰沈着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Chest discomfort	胸部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Discomfort	不快感	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	熱感	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Investigations	臨床検査	12 (20.3)	7 (10.3)	4 (8.3)	19 (15.0)	10 (14.9)	8 (14.5)	6 (16.7)	18 (14.8)
Weight decreased	体重減少	4 (6.8)	2 (2.9)	1 (2.1)	6 (4.7)	2 (3.0)	3 (5.5)	2 (5.6)	5 (4.1)
Weight increased	体重増加	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	4 (6.0)	3 (5.5)	2 (5.6)	7 (5.7)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1 (1.7)	2 (2.9)	1 (2.1)	3 (2.4)	1 (1.5)	3 (5.5)	3 (8.3)	4 (3.3)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	3 (4.4)	3 (6.3)	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood pressure increased	血圧上昇	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Liver function test increased	肝機能検査値上昇	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Blood triglycerides increased	血中トリグリセリド増加	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood uric acid increased	血中尿酸増加	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	10 (16.9)	8 (11.8)	5 (10.4)	18 (14.2)	11 (16.4)	14 (25.5)	10 (27.8)	25 (20.5)
Contusion	挫傷	1 (1.7)	3 (4.4)	1 (2.1)	4 (3.1)	4 (6.0)	4 (7.3)	3 (8.3)	8 (6.6)
Fall	転倒	1 (1.7)	5 (7.4)	4 (8.3)	6 (4.7)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Skin abrasion	皮膚擦過傷	3 (5.1)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	2 (3.6)	2 (5.6)	2 (1.6)
Sedation complication	鎮静合併症	2 (3.4)	1 (1.5)	0 (0.0)	3 (2.4)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Thermal burn	熱傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	2 (3.6)	1 (2.8)	3 (2.5)
Heat illness	熱中症	2 (3.4)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Animal bite	動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Ankle fracture	足関節部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Concussion	脳振盪	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femoral neck fracture	大腿骨頚部骨折	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femur fracture	大腿骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Foot fracture	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Fractured sacrum	仙骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Hand fracture	手骨折	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Joint dislocation	関節脱臼	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ligament sprain	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Road traffic accident	交通事故	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－141　性別ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Face injury	顔面損傷	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tooth fracture	歯牙破折	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid injury	眼瞼損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Skin wound	皮膚創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.2.2.1 より引用

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Any AESI		39 (66.1)	58 (85.3)	39 (81.3)	97 (76.4)	49 (73.1)	50 (90.9)	31 (86.1)	99 (81.1)
Somnolence	傾眠関連有害事象	12 (20.3)	15 (22.1)	9 (18.8)	27 (21.3)	20 (29.9)	25 (45.5)	13 (36.1)	45 (36.9)
Somnolence	傾眠	6 (10.2)	12 (17.6)	8 (16.7)	18 (14.2)	13 (19.4)	16 (29.1)	10 (27.8)	29 (23.8)
Malaise	倦怠感	6 (10.2)	3 (4.4)	2 (4.2)	9 (7.1)	4 (6.0)	7 (12.7)	3 (8.3)	11 (9.0)
Fatigue	疲労	0 (0.0)	2 (2.9)	2 (4.2)	2 (1.6)	2 (3.0)	2 (3.6)	1 (2.8)	4 (3.3)
Sedation complication	鎮静合併症	2 (3.4)	1 (1.5)	0 (0.0)	3 (2.4)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.6)	1 (2.8)	2 (1.6)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Hypersensitivity	過敏症関連有害事象	10 (16.9)	9 (13.2)	8 (16.7)	19 (15.0)	13 (19.4)	9 (16.4)	6 (16.7)	22 (18.0)
Eczema	湿疹	3 (5.1)	2 (2.9)	1 (2.1)	5 (3.9)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Stomatitis	口内炎	3 (5.1)	1 (1.5)	1 (2.1)	4 (3.1)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.5)	2 (3.6)	1 (2.8)	5 (4.1)
Dermatitis contact	接触皮膚炎	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	2 (3.6)	1 (2.8)	3 (2.5)
Pruritus	そう痒症	2 (3.4)	2 (2.9)	2 (4.2)	4 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Conjunctivitis	結膜炎	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Blister	水疱	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Erythema	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Skin exfoliation	皮膚剥脱	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Parkinsonism	パーキンソニズム関連有害事象	14 (23.7)	25 (36.8)	13 (27.1)	39 (30.7)	10 (14.9)	25 (45.5)	12 (33.3)	35 (28.7)
Salivary hypersecretion	流涎過多	3 (5.1)	11 (16.2)	4 (8.3)	14 (11.0)	6 (9.0)	10 (18.2)	6 (16.7)	16 (13.1)
Tremor	振戦	3 (5.1)	6 (8.8)	4 (8.3)	9 (7.1)	2 (3.0)	10 (18.2)	5 (13.9)	12 (9.8)
Parkinsonism	パーキンソニズム	3 (5.1)	2 (2.9)	1 (2.1)	5 (3.9)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Extrapyramidal disorder	錐体外路障害	2 (3.4)	1 (1.5)	1 (2.1)	3 (2.4)	0 (0.0)	3 (5.5)	1 (2.8)	3 (2.5)
Drooling	よだれ	2 (3.4)	3 (4.4)	2 (4.2)	5 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradykinesia	運動緩慢	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	2 (3.6)	0 (0.0)	2 (1.6)
Gait disturbance	歩行障害	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Muscle rigidity	筋固縮	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	8 (13.6)	10 (14.7)	8 (16.7)	18 (14.2)	11 (16.4)	9 (16.4)	7 (19.4)	20 (16.4)
Depression	うつ病	3 (5.1)	6 (8.8)	6 (12.5)	9 (7.1)	3 (4.5)	4 (7.3)	3 (8.3)	7 (5.7)
Suicidal ideation	自殺念慮	3 (5.1)	1 (1.5)	0 (0.0)	4 (3.1)	3 (4.5)	2 (3.6)	2 (5.6)	5 (4.1)
Suicide attempt	自殺企図	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Middle insomnia	中期不眠症	1 (1.7)	1 (1.5)	1 (2.1)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	0 (0.0)	2 (1.6)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Intentional self-injury	故意の自傷行為	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac events	心血管系及びQT間隔延長関連有害事象	2 (3.4)	1 (1.5)	1 (2.1)	3 (2.4)	2 (3.0)	0 (0.0)	0 (0.0)	2 (1.6)
Death	死亡	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Long QT syndrome	ＱＴ延長症候群	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Myocardial ischaemia	心筋虚血	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperprolactinemia	高プロラクチン血症関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	1 (2.8)	2 (1.6)
Galactorrhoea	乳汁漏出症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Akathisia	アカシジア関連有害事象	6 (10.2)	8 (11.8)	5 (10.4)	14 (11.0)	6 (9.0)	11 (20.0)	6 (16.7)	17 (13.9)
Akathisia	アカシジア	4 (6.8)	6 (8.8)	4 (8.3)	10 (7.9)	4 (6.0)	6 (10.9)	4 (11.1)	10 (8.2)
Extrapyramidal disorder	錐体外路障害	2 (3.4)	1 (1.5)	1 (2.1)	3 (2.4)	0 (0.0)	3 (5.5)	1 (2.8)	3 (2.5)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (0.8)
Anxiety	不安	0 (0.0)	5 (7.4)	4 (8.3)	5 (3.9)	5 (7.5)	4 (7.3)	3 (8.3)	9 (7.4)
Anxiety	不安	0 (0.0)	5 (7.4)	4 (8.3)	5 (3.9)	5 (7.5)	4 (7.3)	3 (8.3)	9 (7.4)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	13 (22.0)	15 (22.1)	8 (16.7)	28 (22.0)	22 (32.8)	14 (25.5)	11 (30.6)	36 (29.5)
Schizophrenia	統合失調症	8 (13.6)	7 (10.3)	1 (2.1)	15 (11.8)	13 (19.4)	6 (10.9)	4 (11.1)	19 (15.6)
Depression	うつ病	3 (5.1)	6 (8.8)	6 (12.5)	9 (7.1)	3 (4.5)	4 (7.3)	3 (8.3)	7 (5.7)
Suicidal ideation	自殺念慮	3 (5.1)	1 (1.5)	0 (0.0)	4 (3.1)	3 (4.5)	2 (3.6)	2 (5.6)	5 (4.1)
Suicide attempt	自殺企図	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Bipolar disorder	双極性障害	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	2 (3.0)	1 (1.8)	1 (2.8)	3 (2.5)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Intentional self-injury	故意の自傷行為	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Dysphagia	嚥下障害関連有害事象	4 (6.8)	3 (4.4)	1 (2.1)	7 (5.5)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Dysphagia	嚥下障害	4 (6.8)	3 (4.4)	1 (2.1)	7 (5.5)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－142　性別ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Male MT-5199 40 mg (N=59) n(%)	Male MT-5199 80 mg (N=68) n(%)	Male MT-5199 80 mg (no dose reduction) (N=48) n(%)	Male All MT-5199 (N=127) n(%)	Female MT-5199 40 mg (N=67) n(%)	Female MT-5199 80 mg (N=55) n(%)	Female MT-5199 80 mg (no dose reduction) (N=36) n(%)	Female All MT-5199 (N=122) n(%)
Hepatotoxicity	肝障害関連有害事象	2 (3.4)	2 (2.9)	1 (2.1)	4 (3.1)	3 (4.5)	1 (1.8)	1 (2.8)	4 (3.3)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Liver function test increased	肝機能検査値上昇	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hepatic steatosis	脂肪肝	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Hypotension	低血圧関連有害事象	2 (3.4)	8 (11.8)	7 (14.6)	10 (7.9)	5 (7.5)	5 (9.1)	4 (11.1)	10 (8.2)
Dizziness	浮動性めまい	1 (1.7)	4 (5.9)	4 (8.3)	5 (3.9)	3 (4.5)	3 (5.5)	2 (5.6)	6 (4.9)
Fall	転倒	1 (1.7)	5 (7.4)	4 (8.3)	6 (4.7)	1 (1.5)	2 (3.6)	2 (5.6)	3 (2.5)
Hypotension	低血圧	0 (0.0)	1 (1.5)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.8)	1 (2.8)	1 (0.8)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	1 (0.8)
Cognitive disorder	認知機能低下関連有害事象	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.5)	1 (1.8)	0 (0.0)	2 (1.6)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.8)	0 (0.0)	2 (1.6)
Cognitive disorder	認知障害	1 (1.7)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.2.2.2 より引用

表 2.7.4.7－143　性別ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Male (N=149) n (%)	Female (N=105) n (%)	Male (N=102) n (%)	Female (N=76) n (%)	Male (N=237) n (%)	Female (N=190) n (%)
At Least 1 AE	57 (38.3)	54 (51.4)	35 (34.3)	36 (47.4)	136 (57.4)	123 (64.7)
At Least 1 SAE	8 (5.4)	4 (3.8)	3 (2.9)	3 (3.9)	34 (14.3)	20 (10.5)
At Least 1 AE Leading to Study Discontinuation	5 (3.4)	5 (4.8)	5 (4.9)	3 (3.9)	29 (12.2)	29 (15.3)
At Least 1 AE Leading to Dose Reduction	3 (2.0)	4 (3.8)	0	4 (5.3)	14 (5.9)	12 (6.3)

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is only counted once for that category.

5.3.5.3－2 Table 97 より引用（一部改変）

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=66)	 80 mg (N=61)	 100 mg (N=18)	All NBI-98854 (N=149)	 Placebo (N=102)
Any Adverse Event	n (%)	2(50.0)	25(37.9)	24(39.3)	6(33.3)	57(38.3)	35(34.3)
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(1.0)
トゥレット病	n (%)	0	0	0	0	0	1(1.0)
耳および迷路障害	n (%)	0	1(1.5)	0	0	1(0.7)	0
耳鳴	n (%)	0	1(1.5)	0	0	1(0.7)	0
眼障害	n (%)	0	0	0	1(5.6)	1(0.7)	1(1.0)
霧視	n (%)	0	0	0	1(5.6)	1(0.7)	0
結膜出血	n (%)	0	0	0	0	0	1(1.0)
胃腸障害	n (%)	0	9(13.6)	2(3.3)	1(5.6)	12(8.1)	9(8.8)
口内乾燥	n (%)	0	4(6.1)	0	1(5.6)	5(3.4)	2(2.0)
嚥下障害	n (%)	0	2(3.0)	0	0	2(1.3)	0
悪心	n (%)	0	1(1.5)	1(1.6)	0	2(1.3)	2(2.0)
流涎過多	n (%)	0	0	1(1.6)	1(5.6)	2(1.3)	0
嘔吐	n (%)	0	1(1.5)	1(1.6)	0	2(1.3)	0
便秘	n (%)	0	1(1.5)	0	0	1(0.7)	1(1.0)
下痢	n (%)	0	1(1.5)	0	0	1(0.7)	2(2.0)
消化不良	n (%)	0	1(1.5)	0	0	1(0.7)	0
メレナ	n (%)	0	1(1.5)	0	0	1(0.7)	0
口腔知覚不全	n (%)	0	1(1.5)	0	0	1(0.7)	0
臍ヘルニア	n (%)	0	1(1.5)	0	0	1(0.7)	0
排便回数増加	n (%)	0	0	0	0	0	1(1.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a]					
		<40 mg (N=4)	40 mg (N=66)	80 mg (N=61)	100 mg (N=18)	All NBI-98854 (N=149)	Placebo (N=102)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(1.0)
舌痛	n (%)	0	0	0	0	0	1(1.0)
歯痛	n (%)	0	0	0	0	0	1(1.0)
全身障害および投与局所様態	n (%)	0	5(7.6)	3(4.9)	2(11.1)	10(6.7)	4(3.9)
疲労	n (%)	0	3(4.5)	2(3.3)	2(11.1)	7(4.7)	3(2.9)
末梢性浮腫	n (%)	0	2(3.0)	0	0	2(1.3)	0
歩行障害	n (%)	0	0	0	1(5.6)	1(0.7)	0
空腹	n (%)	0	1(1.5)	0	0	1(0.7)	0
突然死	n (%)	0	0	1(1.6)	0	1(0.7)	0
口渇	n (%)	0	1(1.5)	0	0	1(0.7)	0
易刺激性	n (%)	0	0	0	0	0	1(1.0)
肝胆道系障害	n (%)	0	0	1(1.6)	0	1(0.7)	0
急性肝炎	n (%)	0	0	1(1.6)	0	1(0.7)	0
黄疸	n (%)	0	0	1(1.6)	0	1(0.7)	0
感染症および寄生虫症	n (%)	0	3(4.5)	1(1.6)	2(11.1)	6(4.0)	6(5.9)
鼻咽頭炎	n (%)	0	0	1(1.6)	1(5.6)	2(1.3)	1(1.0)
ウイルス性胃腸炎	n (%)	0	1(1.5)	0	0	1(0.7)	0
インフルエンザ	n (%)	0	1(1.5)	0	0	1(0.7)	0
急性腎盂腎炎	n (%)	0	1(1.5)	0	0	1(0.7)	0
上気道感染	n (%)	0	0	0	1(5.6)	1(0.7)	1(1.0)
尿路感染	n (%)	0	0	0	0	0	4(3.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=66)	 80 mg (N=61)	 100 mg (N=18)	All NBI-98854 (N=149)	 Placebo (N=102)
傷害、中毒および処置合併症	n (%)	0	2(3.0)	2(3.3)	1(5.6)	5(3.4)	2(2.0)
転倒・転落	n (%)	0	2(3.0)	1(1.6)	0	3(2.0)	0
節足動物咬傷	n (%)	0	0	0	1(5.6)	1(0.7)	1(1.0)
四肢損傷	n (%)	0	0	1(1.6)	0	1(0.7)	0
足骨折	n (%)	0	0	0	0	0	1(1.0)
臨床検査	n (%)	1(25.0)	2(3.0)	4(6.6)	0	7(4.7)	3(2.9)
体重増加	n (%)	0	1(1.5)	1(1.6)	0	2(1.3)	1(1.0)
血中クレアチニン増加	n (%)	0	0	1(1.6)	0	1(0.7)	0
血中ブドウ糖増加	n (%)	0	0	1(1.6)	0	1(0.7)	0
尿中ブドウ糖陽性	n (%)	0	0	1(1.6)	0	1(0.7)	0
グリコヘモグロビン増加	n (%)	0	0	1(1.6)	0	1(0.7)	1(1.0)
握力低下	n (%)	0	1(1.5)	0	0	1(0.7)	0
ヘマトクリット減少	n (%)	0	0	1(1.6)	0	1(0.7)	0
ヘモグロビン減少	n (%)	0	0	1(1.6)	0	1(0.7)	0
肝酵素上昇	n (%)	1(25.0)	0	0	0	1(0.7)	0
赤血球数減少	n (%)	0	0	1(1.6)	0	1(0.7)	0
血中カリウム増加	n (%)	0	0	0	0	0	1(1.0)
代謝および栄養障害	n (%)	0	1(1.5)	3(4.9)	0	4(2.7)	3(2.9)
食欲亢進	n (%)	0	1(1.5)	1(1.6)	0	2(1.3)	1(1.0)
食欲減退	n (%)	0	0	1(1.6)	0	1(0.7)	1(1.0)
低ナトリウム血症	n (%)	0	0	1(1.6)	0	1(0.7)	0
異常体重減少	n (%)	0	0	0	0	0	1(1.0)
低血糖症	n (%)	0	0	0	0	0	1(1.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=66)	 80 mg (N=61)	 100 mg (N=18)	All NBI-98854 (N=149)	 Placebo (N=102)
筋骨格系および結合組織障害	n (%)	0	4(6.1)	2(3.3)	1(5.6)	7(4.7)	2(2.0)
背部痛	n (%)	0	2(3.0)	1(1.6)	0	3(2.0)	0
関節痛	n (%)	0	0	1(1.6)	0	1(0.7)	0
関節炎	n (%)	0	1(1.5)	0	0	1(0.7)	0
筋力低下	n (%)	0	1(1.5)	0	0	1(0.7)	0
筋肉痛	n (%)	0	0	0	1(5.6)	1(0.7)	0
関節腫脹	n (%)	0	0	0	0	0	1(1.0)
四肢痛	n (%)	0	0	0	0	0	1(1.0)
神経系障害	n (%)	0	10(15.2)	8(13.1)	2(11.1)	20(13.4)	4(3.9)
傾眠	n (%)	0	6(9.1)	2(3.3)	1(5.6)	9(6.0)	3(2.9)
頭痛	n (%)	0	1(1.5)	3(4.9)	1(5.6)	5(3.4)	0
アカシジア	n (%)	0	1(1.5)	2(3.3)	0	3(2.0)	0
浮動性めまい	n (%)	0	2(3.0)	0	0	2(1.3)	1(1.0)
注意力障害	n (%)	0	1(1.5)	0	0	1(0.7)	0
感覚鈍麻	n (%)	0	0	1(1.6)	0	1(0.7)	0
ミオクローヌス	n (%)	0	1(1.5)	0	0	1(0.7)	0
咬舌	n (%)	0	1(1.5)	0	0	1(0.7)	0
振戦	n (%)	0	0	1(1.6)	0	1(0.7)	0
精神障害	n (%)	2(50.0)	9(13.6)	4(6.6)	0	15(10.1)	5(4.9)
不眠症	n (%)	0	2(3.0)	1(1.6)	0	3(2.0)	0
自殺念慮	n (%)	0	3(4.5)	0	0	3(2.0)	0
不安	n (%)	0	0	1(1.6)	0	1(0.7)	0
双極１型障害	n (%)	0	1(1.5)	0	0	1(0.7)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a]				All NBI-98854	Placebo
		<40 mg (N=4)	40 mg (N=66)	80 mg (N=61)	100 mg (N=18)	(N=149)	(N=102)
抑うつ気分	n (%)	1(25.0)	0	0	0	1(0.7)	0
抑うつ症状	n (%)	0	1(1.5)	0	0	1(0.7)	0
ディスフェミア	n (%)	0	1(1.5)	0	0	1(0.7)	0
敵意	n (%)	0	1(1.5)	0	0	1(0.7)	0
軽躁	n (%)	0	1(1.5)	0	0	1(0.7)	0
精神状態変化	n (%)	0	1(1.5)	0	0	1(0.7)	1(1.0)
パニック発作	n (%)	1(25.0)	0	0	0	1(0.7)	0
精神病性障害	n (%)	0	0	1(1.6)	0	1(0.7)	2(2.0)
統合失調症	n (%)	0	1(1.5)	0	0	1(0.7)	0
自殺企図	n (%)	0	0	1(1.6)	0	1(0.7)	0
うつ病	n (%)	0	0	0	0	0	1(1.0)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(1.0)
腎および尿路障害	n (%)	0	0	0	0	0	3(2.9)
糖尿	n (%)	0	0	0	0	0	1(1.0)
血尿	n (%)	0	0	0	0	0	1(1.0)
尿閉	n (%)	0	0	0	0	0	1(1.0)
呼吸器、胸郭および縦隔障害	n (%)	0	1(1.5)	1(1.6)	1(5.6)	3(2.0)	2(2.0)
慢性閉塞性肺疾患	n (%)	0	1(1.5)	0	1(5.6)	2(1.3)	1(1.0)
鼻閉	n (%)	0	0	1(1.6)	0	1(0.7)	0
咳嗽	n (%)	0	0	0	0	0	1(1.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=66)	 80 mg (N=61)	 100 mg (N=18)	All NBI-98854 (N=149)	 Placebo (N=102)
皮膚および皮下組織障害	n (%)	0	1(1.5)	2(3.3)	0	3(2.0)	3(2.9)
そう痒症	n (%)	0	1(1.5)	0	0	1(0.7)	1(1.0)
発疹	n (%)	0	0	1(1.6)	0	1(0.7)	1(1.0)
斑状丘疹状皮疹	n (%)	0	0	1(1.6)	0	1(0.7)	0
多汗症	n (%)	0	0	0	0	0	1(1.0)
血管障害	n (%)	0	1(1.5)	1(1.6)	0	2(1.3)	1(1.0)
血腫	n (%)	0	0	1(1.6)	0	1(0.7)	0
高血圧	n (%)	0	1(1.5)	0	0	1(0.7)	1(1.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=44)	 80 mg (N=51)	 100 mg (N=9)	All NBI-98854 (N=105)	 Placebo (N=76)
Any Adverse Event	n (%)	0	23(52.3)	29(56.9)	2(22.2)	54(51.4)	36(47.4)
血液およびリンパ系障害	n (%)	0	0	1(2.0)	0	1(1.0)	0
白血球減少症	n (%)	0	0	1(2.0)	0	1(1.0)	0
心臓障害	n (%)	0	1(2.3)	0	0	1(1.0)	1(1.3)
徐脈	n (%)	0	1(2.3)	0	0	1(1.0)	0
心筋梗塞	n (%)	0	0	0	0	0	1(1.3)
耳および迷路障害	n (%)	0	0	0	0	0	1(1.3)
耳痛	n (%)	0	0	0	0	0	1(1.3)
胃腸障害	n (%)	0	5(11.4)	5(9.8)	0	10(9.5)	12(15.8)
嘔吐	n (%)	0	1(2.3)	3(5.9)	0	4(3.8)	1(1.3)
口内乾燥	n (%)	0	3(6.8)	0	0	3(2.9)	1(1.3)
悪心	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	2(2.6)
腹部圧痛	n (%)	0	1(2.3)	0	0	1(1.0)	0
便秘	n (%)	0	1(2.3)	0	0	1(1.0)	4(5.3)
びらん性胃炎	n (%)	0	0	1(2.0)	0	1(1.0)	0
流涎過多	n (%)	0	0	1(2.0)	0	1(1.0)	0
上腹部痛	n (%)	0	0	0	0	0	1(1.3)
下痢	n (%)	0	0	0	0	0	1(1.3)
消化不良	n (%)	0	0	0	0	0	1(1.3)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(1.3)
歯肉炎	n (%)	0	0	0	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=44)	 80 mg (N=51)	 100 mg (N=9)	All NBI-98854 (N=105)	 Placebo (N=76)
全身障害および投与局所様態	n (%)	0	5(11.4)	2(3.9)	0	7(6.7)	3(3.9)
疲労	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	0
歩行障害	n (%)	0	2(4.5)	0	0	2(1.9)	0
胸痛	n (%)	0	1(2.3)	0	0	1(1.0)	0
易刺激性	n (%)	0	1(2.3)	0	0	1(1.0)	1(1.3)
末梢性浮腫	n (%)	0	1(2.3)	0	0	1(1.0)	1(1.3)
疼痛	n (%)	0	1(2.3)	0	0	1(1.0)	0
発熱	n (%)	0	0	1(2.0)	0	1(1.0)	1(1.3)
感染症および寄生虫症	n (%)	0	7(15.9)	2(3.9)	1(11.1)	10(9.5)	8(10.5)
尿路感染	n (%)	0	4(9.1)	1(2.0)	1(11.1)	6(5.7)	4(5.3)
ダニ皮膚炎	n (%)	0	1(2.3)	0	0	1(1.0)	0
体部白癬	n (%)	0	1(2.3)	0	0	1(1.0)	0
せつ	n (%)	0	1(2.3)	0	0	1(1.0)	0
鼻咽頭炎	n (%)	0	1(2.3)	0	0	1(1.0)	0
副鼻腔炎	n (%)	0	1(2.3)	0	0	1(1.0)	0
上気道感染	n (%)	0	0	1(2.0)	0	1(1.0)	0
外陰膣真菌感染	n (%)	0	1(2.3)	0	0	1(1.0)	0
気管支炎	n (%)	0	0	0	0	0	1(1.3)
耳感染	n (%)	0	0	0	0	0	1(1.3)
口腔ヘルペス	n (%)	0	0	0	0	0	1(1.3)
ウイルス感染	n (%)	0	0	0	0	0	1(1.3)
傷害、中毒および処置合併症	n (%)	0	3(6.8)	2(3.9)	0	5(4.8)	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=44)	 80 mg (N=51)	 100 mg (N=9)	All NBI-98854 (N=105)	 Placebo (N=76)
動物咬傷	n (%)	0	0	1(2.0)	0	1(1.0)	0
第２度熱傷	n (%)	0	0	1(2.0)	0	1(1.0)	0
関節損傷	n (%)	0	1(2.3)	0	0	1(1.0)	0
筋挫傷	n (%)	0	1(2.3)	0	0	1(1.0)	0
交通事故	n (%)	0	1(2.3)	0	0	1(1.0)	0
むち打ち損傷	n (%)	0	1(2.3)	0	0	1(1.0)	0
処置による疼痛	n (%)	0	0	0	0	0	1(1.3)
臨床検査	n (%)	0	3(6.8)	6(11.8)	1(11.1)	10(9.5)	3(3.9)
血中ブドウ糖増加	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	0
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	2(3.9)	0	2(1.9)	1(1.3)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(2.3)	0	0	1(1.0)	0
血中クレアチニン増加	n (%)	0	1(2.3)	0	0	1(1.0)	0
血圧上昇	n (%)	0	0	1(2.0)	0	1(1.0)	0
血中トリグリセリド増加	n (%)	0	0	0	1(11.1)	1(1.0)	0
血中尿素増加	n (%)	0	1(2.3)	0	0	1(1.0)	0
尿中結晶陽性	n (%)	0	0	1(2.0)	0	1(1.0)	0
便潜血陽性	n (%)	0	0	1(2.0)	0	1(1.0)	0
赤血球数増加	n (%)	0	0	1(2.0)	0	1(1.0)	0
体重増加	n (%)	0	0	1(2.0)	0	1(1.0)	0
血中ビリルビン増加	n (%)	0	0	0	0	0	1(1.3)
肝酵素上昇	n (%)	0	0	0	0	0	1(1.3)
好中球数増加	n (%)	0	0	0	0	0	1(1.3)
白血球数増加	n (%)	0	0	0	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144 性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a]				All NBI-98854	Placebo
		<40 mg (N=1)	40 mg (N=44)	80 mg (N=51)	100 mg (N=9)	(N=105)	(N=76)
代謝および栄養障害	n (%)	0	2(4.5)	2(3.9)	0	4(3.8)	2(2.6)
食欲減退	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	1(1.3)
食欲亢進	n (%)	0	0	1(2.0)	0	1(1.0)	0
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(1.3)
筋骨格系および結合組織障害	n (%)	0	5(11.4)	4(7.8)	0	9(8.6)	3(3.9)
関節痛	n (%)	0	3(6.8)	2(3.9)	0	5(4.8)	1(1.3)
四肢不快感	n (%)	0	1(2.3)	0	0	1(1.0)	0
筋痙縮	n (%)	0	0	1(2.0)	0	1(1.0)	0
筋力低下	n (%)	0	1(2.3)	0	0	1(1.0)	0
筋肉痛	n (%)	0	0	1(2.0)	0	1(1.0)	0
顎関節症候群	n (%)	0	1(2.3)	0	0	1(1.0)	0
滑液包炎	n (%)	0	0	0	0	0	1(1.3)
筋骨格硬直	n (%)	0	0	0	0	0	1(1.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(1.3)
口腔乳頭腫	n (%)	0	0	0	0	0	1(1.3)
神経系障害	n (%)	0	7(15.9)	11(21.6)	1(11.1)	19(18.1)	12(15.8)
頭痛	n (%)	0	3(6.8)	2(3.9)	0	5(4.8)	4(5.3)
傾眠	n (%)	0	3(6.8)	2(3.9)	0	5(4.8)	1(1.3)
アカシジア	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	1(1.3)
ジスキネジー	n (%)	0	0	3(5.9)	0	3(2.9)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=44)	 80 mg (N=51)	 100 mg (N=9)	All NBI-98854 (N=105)	 Placebo (N=76)
鎮静	n (%)	0	1(2.3)	2(3.9)	0	3(2.9)	1(1.3)
よだれ	n (%)	0	0	2(3.9)	0	2(1.9)	0
平衡障害	n (%)	0	0	1(2.0)	0	1(1.0)	0
ジストニー	n (%)	0	0	1(2.0)	0	1(1.0)	0
睡眠の質低下	n (%)	0	1(2.3)	0	0	1(1.0)	0
失神	n (%)	0	0	0	1(11.1)	1(1.0)	0
振戦	n (%)	0	0	1(2.0)	0	1(1.0)	0
痙攣	n (%)	0	0	0	0	0	1(1.3)
浮動性めまい	n (%)	0	0	0	0	0	3(3.9)
感覚鈍麻	n (%)	0	0	0	0	0	1(1.3)
片頭痛	n (%)	0	0	0	0	0	1(1.3)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(1.3)
精神障害	n (%)	0	5(11.4)	8(15.7)	0	13(12.4)	9(11.8)
不安	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	0
うつ病	n (%)	0	0	2(3.9)	0	2(1.9)	1(1.3)
自殺念慮	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	4(5.3)
歯ぎしり	n (%)	0	1(2.3)	0	0	1(1.0)	0
不眠症	n (%)	0	0	1(2.0)	0	1(1.0)	1(1.3)
神経過敏	n (%)	0	0	1(2.0)	0	1(1.0)	0
パニック発作	n (%)	0	0	1(2.0)	0	1(1.0)	0
妄想症	n (%)	0	1(2.3)	0	0	1(1.0)	0
精神運動制止遅滞	n (%)	0	1(2.3)	0	0	1(1.0)	0
落ち着きのなさ	n (%)	0	1(2.3)	0	0	1(1.0)	0
統合失調感情障害	n (%)	0	0	1(2.0)	0	1(1.0)	1(1.3)
激越	n (%)	0	0	0	0	0	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a]					
		<40 mg (N=1)	40 mg (N=44)	80 mg (N=51)	100 mg (N=9)	All NBI-98854 (N=105)	Placebo (N=76)
抑うつ症状	n (%)	0	0	0	0	0	1(1.3)
躁病	n (%)	0	0	0	0	0	1(1.3)
統合失調症	n (%)	0	0	0	0	0	1(1.3)
睡眠障害	n (%)	0	0	0	0	0	1(1.3)
生殖系および乳房障害	n (%)	0	0	1(2.0)	0	1(1.0)	2(2.6)
月経過多	n (%)	0	0	1(2.0)	0	1(1.0)	0
腟出血	n (%)	0	0	0	0	0	2(2.6)
呼吸器、胸郭および縦隔障害	n (%)	0	0	1(2.0)	0	1(1.0)	0
鼻閉	n (%)	0	0	1(2.0)	0	1(1.0)	0
皮膚および皮下組織障害	n (%)	0	1(2.3)	0	0	1(1.0)	2(2.6)
網状皮斑	n (%)	0	1(2.3)	0	0	1(1.0)	0
ケラトアカントーマ	n (%)	0	0	0	0	0	1(1.3)
そう痒症	n (%)	0	0	0	0	0	1(1.3)
乾癬	n (%)	0	0	0	0	0	1(1.3)
外科および内科処置	n (%)	0	0	1(2.0)	0	1(1.0)	1(1.3)
抜歯	n (%)	0	0	1(2.0)	0	1(1.0)	0
鼓膜切開	n (%)	0	0	0	0	0	1(1.3)
血管障害	n (%)	0	0	2(3.9)	0	2(1.9)	1(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－144　性別ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=44)	 80 mg (N=51)	 100 mg (N=9)	All NBI-98854 (N=105)	 Placebo (N=76)
ほてり	n (%)	0	0	1(2.0)	0	1(1.0)	1(1.3)
低血圧	n (%)	0	0	1(2.0)	0	1(1.0)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.1より引用（一部改変）

表2.7.4.7－145　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Gender: Male

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=66)	80 mg (N=61)	100 mg (N=18)	All NBI-98854 (N=149)	Placebo (N=102)
Any Adverse Event of Special Interest	n (%)	1(25.0)	18(27.3)	12(19.7)	2(11.1)	33(22.1)	11(10.8)
アカシジア関連有害事象	n (%)	0	1(1.5)	2(3.3)	0	3(2.0)	0
アカシジア	n (%)	0	1(1.5)	2(3.3)	0	3(2.0)	0
不安	n (%)	0	0	1(1.6)	0	1(0.7)	0
不安	n (%)	0	0	1(1.6)	0	1(0.7)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	1(1.6)	0	1(0.7)	0
突然死	n (%)	0	0	1(1.6)	0	1(0.7)	0
うつ病及び自殺関連有害事象	n (%)	1(25.0)	4(6.1)	1(1.6)	0	6(4.0)	1(1.0)
自殺念慮	n (%)	0	3(4.5)	0	0	3(2.0)	0
抑うつ気分	n (%)	1(25.0)	0	0	0	1(0.7)	0
抑うつ症状	n (%)	0	1(1.5)	0	0	1(0.7)	0
自殺企図	n (%)	0	0	1(1.6)	0	1(0.7)	0
うつ病	n (%)	0	0	0	0	0	1(1.0)
嚥下障害関連有害事象	n (%)	0	2(3.0)	0	0	2(1.3)	0
嚥下障害	n (%)	0	2(3.0)	0	0	2(1.3)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	3(4.5)	2(3.3)	2(11.1)	7(4.7)	3(2.9)
疲労	n (%)	0	3(4.5)	2(3.3)	2(11.1)	7(4.7)	3(2.9)
肝障害関連有害事象	n (%)	0	0	1(1.6)	0	1(0.7)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－145　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=66)	80 mg (N=61)	100 mg (N=18)	All NBI-98854 (N=149)	Placebo (N=102)
急性肝炎	n (%)	0	0	1(1.6)	0	1(0.7)	0
低血圧関連有害事象	n (%)	0	4(6.1)	1(1.6)	0	5(3.4)	1(1.0)
転倒・転落	n (%)	0	2(3.0)	1(1.6)	0	3(2.0)	0
浮動性めまい	n (%)	0	2(3.0)	0	0	2(1.3)	1(1.0)
パーキンソニズム関連有害事象	n (%)	0	0	1(1.6)	0	1(0.7)	0
振戦	n (%)	0	0	1(1.6)	0	1(0.7)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	6(9.1)	2(3.3)	1(5.6)	9(6.0)	3(2.9)
傾眠	n (%)	0	6(9.1)	2(3.3)	1(5.6)	9(6.0)	3(2.9)
基礎疾患の悪化に関連する有害事象	n (%)	1(25.0)	7(10.6)	2(3.3)	0	10(6.7)	5(4.9)
自殺念慮	n (%)	0	3(4.5)	0	0	3(2.0)	0
双極１型障害	n (%)	0	1(1.5)	0	0	1(0.7)	0
抑うつ気分	n (%)	1(25.0)	0	0	0	1(0.7)	0
抑うつ症状	n (%)	0	1(1.5)	0	0	1(0.7)	0
敵意	n (%)	0	1(1.5)	0	0	1(0.7)	0
軽躁	n (%)	0	1(1.5)	0	0	1(0.7)	0
精神病性障害	n (%)	0	0	1(1.6)	0	1(0.7)	2(2.0)
統合失調症	n (%)	0	1(1.5)	0	0	1(0.7)	0
自殺企図	n (%)	0	0	1(1.6)	0	1(0.7)	0
うつ病	n (%)	0	0	0	0	0	1(1.0)
易刺激性	n (%)	0	0	0	0	0	1(1.0)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－145　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Male

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=66)	80 mg (N=61)	100 mg (N=18)	All NBI-98854 (N=149)	Placebo (N=102)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(1.0)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－145　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	40 mg (N=44)	80 mg (N=51)	100 mg (N=9)	All NBI-98854 (N=105)	Placebo (N=76)
Any Adverse Event of Special Interest	n (%)	0	10(22.7)	11(21.6)	1(11.1)	22(21.0)	13(17.1)
アカシジア関連有害事象	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	1(1.3)
アカシジア	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	1(1.3)
不安	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	0
不安	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(2.3)	0	1(11.1)	2(1.9)	1(1.3)
胸痛	n (%)	0	1(2.3)	0	0	1(1.0)	0
失神	n (%)	0	0	0	1(11.1)	1(1.0)	0
心筋梗塞	n (%)	0	0	0	0	0	1(1.3)
うつ病及び自殺関連有害事象	n (%)	0	1(2.3)	3(5.9)	0	4(3.8)	5(6.6)
うつ病	n (%)	0	0	2(3.9)	0	2(1.9)	1(1.3)
自殺念慮	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	4(5.3)
抑うつ症状	n (%)	0	0	0	0	0	1(1.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	0
疲労	n (%)	0	2(4.5)	1(2.0)	0	3(2.9)	0
低血圧関連有害事象	n (%)	0	0	1(2.0)	1(11.1)	2(1.9)	3(3.9)
低血圧	n (%)	0	0	1(2.0)	0	1(1.0)	0
失神	n (%)	0	0	0	1(11.1)	1(1.0)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－145　性別ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Gender: Female

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	40 mg (N=44)	80 mg (N=51)	100 mg (N=9)	All NBI-98854 (N=105)	Placebo (N=76)
浮動性めまい	n (%)	0	0	0	0	0	3(3.9)
パーキンソニズム関連有害事象	n (%)	0	0	1(2.0)	0	1(1.0)	0
振戦	n (%)	0	0	1(2.0)	0	1(1.0)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	4(9.1)	4(7.8)	0	8(7.6)	2(2.6)
傾眠	n (%)	0	3(6.8)	2(3.9)	0	5(4.8)	1(1.3)
鎮静	n (%)	0	1(2.3)	2(3.9)	0	3(2.9)	1(1.3)
基礎疾患の悪化に関連する有害事象	n (%)	0	3(6.8)	4(7.8)	0	7(6.7)	8(10.5)
うつ病	n (%)	0	0	2(3.9)	0	2(1.9)	1(1.3)
自殺念慮	n (%)	0	1(2.3)	1(2.0)	0	2(1.9)	4(5.3)
易刺激性	n (%)	0	1(2.3)	0	0	1(1.0)	1(1.3)
妄想症	n (%)	0	1(2.3)	0	0	1(1.0)	0
統合失調感情障害	n (%)	0	0	1(2.0)	0	1(1.0)	1(1.3)
抑うつ症状	n (%)	0	0	0	0	0	1(1.3)
躁病	n (%)	0	0	0	0	0	1(1.3)
統合失調症	n (%)	0	0	0	0	0	1(1.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.1より引用（一部改変）

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
Any Adverse Event	n (%)	66(56.4)	70(58.3)	60(54.5)	136(57.4)
血液およびリンパ系障害	n (%)	2(1.7)	2(1.7)	2(1.8)	4(1.7)
貧血	n (%)	1(0.9)	2(1.7)	2(1.8)	3(1.3)
好中球減少症	n (%)	1(0.9)	0	0	1(0.4)
心臓障害	n (%)	2(1.7)	3(2.5)	3(2.7)	5(2.1)
上室性不整脈	n (%)	1(0.9)	0	0	1(0.4)
心房細動	n (%)	0	1(0.8)	1(0.9)	1(0.4)
左脚ブロック	n (%)	0	1(0.8)	1(0.9)	1(0.4)
心不全	n (%)	0	1(0.8)	1(0.9)	1(0.4)
冠動脈疾患	n (%)	1(0.9)	0	0	1(0.4)
耳および迷路障害	n (%)	3(2.6)	1(0.8)	1(0.9)	4(1.7)
耳鳴	n (%)	2(1.7)	0	0	2(0.8)
耳介軟骨膜炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
聴覚障害	n (%)	1(0.9)	0	0	1(0.4)
内分泌障害	n (%)	1(0.9)	0	0	1(0.4)
甲状腺機能低下症	n (%)	1(0.9)	0	0	1(0.4)
胃腸障害	n (%)	17(14.5)	20(16.7)	15(13.6)	37(15.6)
下痢	n (%)	3(2.6)	5(4.2)	5(4.5)	8(3.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
流涎過多	n (%)	2(1.7)	5(4.2)	2(1.8)	7(3.0)
嘔吐	n (%)	4(3.4)	3(2.5)	3(2.7)	7(3.0)
口内乾燥	n (%)	5(4.3)	1(0.8)	1(0.9)	6(2.5)
便秘	n (%)	3(2.6)	2(1.7)	0	5(2.1)
悪心	n (%)	2(1.7)	3(2.5)	3(2.7)	5(2.1)
上腹部痛	n (%)	1(0.9)	3(2.5)	2(1.8)	4(1.7)
腹痛	n (%)	1(0.9)	2(1.7)	1(0.9)	3(1.3)
嚥下障害	n (%)	3(2.6)	0	0	3(1.3)
結腸ポリープ	n (%)	2(1.7)	0	0	2(0.8)
消化不良	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
痔核	n (%)	2(1.7)	0	0	2(0.8)
歯痛	n (%)	1(0.9)	1(0.8)	0	2(0.8)
憩室	n (%)	1(0.9)	0	0	1(0.4)
胃腸出血	n (%)	1(0.9)	0	0	1(0.4)
メレナ	n (%)	1(0.9)	0	0	1(0.4)
食道食物嵌入	n (%)	1(0.9)	0	0	1(0.4)
食道狭窄	n (%)	1(0.9)	0	0	1(0.4)
食道炎	n (%)	1(0.9)	0	0	1(0.4)
歯の脱落	n (%)	1(0.9)	0	0	1(0.4)
臍ヘルニア	n (%)	1(0.9)	0	0	1(0.4)
全身障害および投与局所様態	n (%)	6(5.1)	16(13.3)	12(10.9)	22(9.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
疲労	n (%)	4(3.4)	5(4.2)	5(4.5)	9(3.8)
歩行障害	n (%)	2(1.7)	1(0.8)	0	3(1.3)
無力症	n (%)	0	2(1.7)	0	2(0.8)
胸痛	n (%)	0	2(1.7)	2(1.8)	2(0.8)
非心臓性胸痛	n (%)	0	2(1.7)	1(0.9)	2(0.8)
末梢性浮腫	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
空腹	n (%)	1(0.9)	0	0	1(0.4)
易刺激性	n (%)	0	1(0.8)	1(0.9)	1(0.4)
倦怠感	n (%)	0	1(0.8)	1(0.9)	1(0.4)
突然死	n (%)	0	1(0.8)	1(0.9)	1(0.4)
口渇	n (%)	1(0.9)	0	0	1(0.4)
肝胆道系障害	n (%)	0	2(1.7)	2(1.8)	2(0.8)
肝不全	n (%)	0	1(0.8)	1(0.9)	1(0.4)
急性肝炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
黄疸	n (%)	0	1(0.8)	1(0.9)	1(0.4)
免疫系障害	n (%)	0	1(0.8)	1(0.9)	1(0.4)
過敏症	n (%)	0	1(0.8)	1(0.9)	1(0.4)
感染症および寄生虫症	n (%)	15(12.8)	17(14.2)	15(13.6)	32(13.5)
鼻咽頭炎	n (%)	4(3.4)	4(3.3)	4(3.6)	8(3.4)
尿路感染	n (%)	2(1.7)	6(5.0)	6(5.5)	8(3.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146　性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
気管支炎	n (%)	1(0.9)	2(1.7)	2(1.8)	3(1.3)
蜂巣炎	n (%)	0	3(2.5)	2(1.8)	3(1.3)
上気道感染	n (%)	3(2.6)	0	0	3(1.3)
ウイルス性胃腸炎	n (%)	2(1.7)	0	0	2(0.8)
四肢膿瘍	n (%)	0	1(0.8)	0	1(0.4)
急性扁桃炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
ブドウ球菌性蜂巣炎	n (%)	1(0.9)	0	0	1(0.4)
眼感染	n (%)	1(0.9)	0	0	1(0.4)
胃腸炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
咬傷感染	n (%)	0	1(0.8)	1(0.9)	1(0.4)
インフルエンザ	n (%)	1(0.9)	0	0	1(0.4)
肺炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
急性腎盂腎炎	n (%)	1(0.9)	0	0	1(0.4)
副鼻腔炎	n (%)	0	1(0.8)	0	1(0.4)
皮下組織膿瘍	n (%)	0	1(0.8)	1(0.9)	1(0.4)
股部白癬	n (%)	1(0.9)	0	0	1(0.4)
傷害、中毒および処置合併症	n (%)	10(8.5)	10(8.3)	7(6.4)	20(8.4)
転倒・転落	n (%)	4(3.4)	2(1.7)	1(0.9)	6(2.5)
挫傷	n (%)	2(1.7)	0	0	2(0.8)
関節脱臼	n (%)	0	2(1.7)	1(0.9)	2(0.8)
交通事故	n (%)	0	2(1.7)	2(1.8)	2(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
節足動物咬傷	n (%)	0	1(0.8)	0	1(0.4)
第２度熱傷	n (%)	1(0.9)	0	0	1(0.4)
頚椎骨折	n (%)	0	1(0.8)	1(0.9)	1(0.4)
擦過傷	n (%)	1(0.9)	0	0	1(0.4)
足骨折	n (%)	0	1(0.8)	1(0.9)	1(0.4)
頭部損傷	n (%)	1(0.9)	0	0	1(0.4)
四肢損傷	n (%)	0	1(0.8)	0	1(0.4)
四肢外傷性切断	n (%)	1(0.9)	0	0	1(0.4)
口腔内損傷	n (%)	0	1(0.8)	1(0.9)	1(0.4)
橈骨骨折	n (%)	0	1(0.8)	1(0.9)	1(0.4)
肋骨骨折	n (%)	0	1(0.8)	0	1(0.4)
引っかき傷	n (%)	1(0.9)	0	0	1(0.4)
皮膚裂傷	n (%)	0	1(0.8)	1(0.9)	1(0.4)
皮下血腫	n (%)	0	1(0.8)	1(0.9)	1(0.4)
臨床検査	n (%)	9(7.7)	16(13.3)	13(11.8)	25(10.5)
体重増加	n (%)	1(0.9)	4(3.3)	4(3.6)	5(2.1)
血中クレアチンホスホキナーゼ増加	n (%)	1(0.9)	2(1.7)	2(1.8)	3(1.3)
体重減少	n (%)	2(1.7)	1(0.8)	1(0.9)	3(1.3)
血中クレアチニン増加	n (%)	0	2(1.7)	1(0.9)	2(0.8)
血中ブドウ糖増加	n (%)	0	2(1.7)	2(1.8)	2(0.8)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
尿中ブドウ糖陽性	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
グリコヘモグロビン増加	n (%)	0	2(1.7)	1(0.9)	2(0.8)
ヘマトクリット減少	n (%)	0	2(1.7)	2(1.8)	2(0.8)
ヘモグロビン減少	n (%)	0	2(1.7)	2(1.8)	2(0.8)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.9)	0	0	1(0.4)
抗精神病薬濃度治療量以上	n (%)	0	1(0.8)	0	1(0.4)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.9)	0	0	1(0.4)
血中ブドウ糖減少	n (%)	0	1(0.8)	0	1(0.4)
血圧上昇	n (%)	0	1(0.8)	1(0.9)	1(0.4)
血中尿素増加	n (%)	0	1(0.8)	1(0.9)	1(0.4)
握力低下	n (%)	1(0.9)	0	0	1(0.4)
肝酵素上昇	n (%)	1(0.9)	0	0	1(0.4)
総蛋白減少	n (%)	0	1(0.8)	1(0.9)	1(0.4)
赤血球数減少	n (%)	0	1(0.8)	1(0.9)	1(0.4)
代謝および栄養障害	n (%)	4(3.4)	8(6.7)	6(5.5)	12(5.1)
食欲減退	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
糖尿病	n (%)	0	2(1.7)	2(1.8)	2(0.8)
食欲不振	n (%)	1(0.9)	0	0	1(0.4)
耐糖能障害	n (%)	1(0.9)	0	0	1(0.4)
高血糖	n (%)	0	1(0.8)	1(0.9)	1(0.4)
高カリウム血症	n (%)	0	1(0.8)	1(0.9)	1(0.4)
高トリグリセリド血症	n (%)	1(0.9)	0	0	1(0.4)
低アルブミン血症	n (%)	0	1(0.8)	1(0.9)	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146　性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
低ナトリウム血症	n (%)	0	1(0.8)	0	1(0.4)
低ナトリウム血症候群	n (%)	0	1(0.8)	1(0.9)	1(0.4)
食欲亢進	n (%)	0	1(0.8)	0	1(0.4)
代謝性アシドーシス	n (%)	0	1(0.8)	1(0.9)	1(0.4)
筋骨格系および結合組織障害	n (%)	9(7.7)	8(6.7)	4(3.6)	17(7.2)
背部痛	n (%)	4(3.4)	0	0	4(1.7)
四肢痛	n (%)	0	3(2.5)	1(0.9)	3(1.3)
関節痛	n (%)	0	2(1.7)	1(0.9)	2(0.8)
関節炎	n (%)	1(0.9)	1(0.8)	0	2(0.8)
関節腫脹	n (%)	0	1(0.8)	1(0.9)	1(0.4)
筋力低下	n (%)	1(0.9)	0	0	1(0.4)
筋骨格系胸痛	n (%)	1(0.9)	0	0	1(0.4)
筋骨格痛	n (%)	0	1(0.8)	1(0.9)	1(0.4)
筋肉痛	n (%)	1(0.9)	0	0	1(0.4)
頚部痛	n (%)	0	1(0.8)	0	1(0.4)
骨関節炎	n (%)	1(0.9)	0	0	1(0.4)
顎痛	n (%)	1(0.9)	0	0	1(0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
肺新生物	n (%)	1(0.9)	0	0	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
甲状腺新生物	n (%)	0	1(0.8)	1(0.9)	1(0.4)
神経系障害	n (%)	23(19.7)	26(21.7)	18(16.4)	49(20.7)
頭痛	n (%)	5(4.3)	9(7.5)	6(5.5)	14(5.9)
傾眠	n (%)	9(7.7)	4(3.3)	2(1.8)	13(5.5)
浮動性めまい	n (%)	4(3.4)	7(5.8)	7(6.4)	11(4.6)
振戦	n (%)	1(0.9)	3(2.5)	1(0.9)	4(1.7)
失神	n (%)	2(1.7)	1(0.8)	0	3(1.3)
アカシジア	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
錐体外路障害	n (%)	0	2(1.7)	2(1.8)	2(0.8)
鎮静	n (%)	2(1.7)	0	0	2(0.8)
遅発性ジスキネジー	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
一過性脳虚血発作	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
平衡障害	n (%)	0	1(0.8)	0	1(0.4)
歯車様固縮	n (%)	0	1(0.8)	1(0.9)	1(0.4)
認知症	n (%)	1(0.9)	0	0	1(0.4)
構語障害	n (%)	0	1(0.8)	0	1(0.4)
顔面神経麻痺	n (%)	0	1(0.8)	1(0.9)	1(0.4)
感覚鈍麻	n (%)	1(0.9)	0	0	1(0.4)
企図振戦	n (%)	1(0.9)	0	0	1(0.4)
片頭痛	n (%)	1(0.9)	0	0	1(0.4)
ミオクローヌス	n (%)	1(0.9)	0	0	1(0.4)
パーキンソニズム	n (%)	0	1(0.8)	1(0.9)	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
咬舌	n (%)	1(0.9)	0	0	1(0.4)
精神障害	n (%)	23(19.7)	16(13.3)	12(10.9)	39(16.5)
自殺念慮	n (%)	5(4.3)	5(4.2)	5(4.5)	10(4.2)
統合失調症	n (%)	4(3.4)	3(2.5)	3(2.7)	7(3.0)
不安	n (%)	2(1.7)	3(2.5)	1(0.9)	5(2.1)
うつ病	n (%)	3(2.6)	2(1.7)	2(1.8)	5(2.1)
不眠症	n (%)	1(0.9)	3(2.5)	2(1.8)	4(1.7)
精神状態変化	n (%)	2(1.7)	0	0	2(0.8)
精神病性障害	n (%)	1(0.9)	1(0.8)	0	2(0.8)
落ち着きのなさ	n (%)	0	2(1.7)	0	2(0.8)
自殺企図	n (%)	0	2(1.7)	2(1.8)	2(0.8)
アルコール症	n (%)	0	1(0.8)	1(0.9)	1(0.4)
死別反応	n (%)	1(0.9)	0	0	1(0.4)
双極１型障害	n (%)	1(0.9)	0	0	1(0.4)
錯乱状態	n (%)	0	1(0.8)	1(0.9)	1(0.4)
抑うつ気分	n (%)	0	1(0.8)	1(0.9)	1(0.4)
抑うつ症状	n (%)	1(0.9)	0	0	1(0.4)
ディスフェミア	n (%)	1(0.9)	0	0	1(0.4)
敵意	n (%)	1(0.9)	0	0	1(0.4)
軽躁	n (%)	1(0.9)	0	0	1(0.4)
リビドー減退	n (%)	1(0.9)	0	0	1(0.4)
外傷後ストレス障害	n (%)	1(0.9)	0	0	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146　性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
統合失調感情障害	n (%)	1(0.9)	0	0	1(0.4)
トランス	n (%)	1(0.9)	0	0	1(0.4)
腎および尿路障害	n (%)	3(2.6)	2(1.7)	2(1.8)	5(2.1)
血尿	n (%)	2(1.7)	0	0	2(0.8)
糖尿	n (%)	0	1(0.8)	1(0.9)	1(0.4)
腎結石症	n (%)	0	1(0.8)	1(0.9)	1(0.4)
尿失禁	n (%)	1(0.9)	0	0	1(0.4)
生殖系および乳房障害	n (%)	2(1.7)	2(1.7)	2(1.8)	4(1.7)
良性前立腺肥大症	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
前立腺炎	n (%)	1(0.9)	0	0	1(0.4)
精巣捻転	n (%)	0	1(0.8)	1(0.9)	1(0.4)
呼吸器、胸郭および縦隔障害	n (%)	7(6.0)	14(11.7)	11(10.0)	21(8.9)
咳嗽	n (%)	2(1.7)	5(4.2)	4(3.6)	7(3.0)
慢性閉塞性肺疾患	n (%)	2(1.7)	2(1.7)	2(1.8)	4(1.7)
呼吸困難	n (%)	1(0.9)	2(1.7)	2(1.8)	3(1.3)
鼻閉	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
副鼻腔うっ血	n (%)	1(0.9)	1(0.8)	0	2(0.8)
アレルギー性副鼻腔炎	n (%)	1(0.9)	0	0	1(0.4)
喘息	n (%)	0	1(0.8)	1(0.9)	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
鼻出血	n (%)	1(0.9)	0	0	1(0.4)
口腔咽頭痛	n (%)	0	1(0.8)	0	1(0.4)
胸水	n (%)	0	1(0.8)	1(0.9)	1(0.4)
アレルギー性鼻炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
鼻漏	n (%)	1(0.9)	0	0	1(0.4)
くしゃみ	n (%)	0	1(0.8)	1(0.9)	1(0.4)
皮膚および皮下組織障害	n (%)	6(5.1)	5(4.2)	4(3.6)	11(4.6)
発疹	n (%)	0	2(1.7)	1(0.9)	2(0.8)
斑状丘疹状皮疹	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
水疱	n (%)	1(0.9)	0	0	1(0.4)
過角化	n (%)	1(0.9)	0	0	1(0.4)
そう痒症	n (%)	1(0.9)	0	0	1(0.4)
全身性皮疹	n (%)	1(0.9)	0	0	1(0.4)
皮膚剥脱	n (%)	0	1(0.8)	1(0.9)	1(0.4)
皮膚病変	n (%)	0	1(0.8)	1(0.9)	1(0.4)
蕁麻疹	n (%)	1(0.9)	0	0	1(0.4)
社会環境	n (%)	1(0.9)	0	0	1(0.4)
社会的入院	n (%)	1(0.9)	0	0	1(0.4)
Unknown	n (%)	1(0.9)	0	0	1(0.4)
皮膚嚢腫	n (%)	1(0.9)	0	0	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146　性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Male

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
血管障害	n (%)	4(3.4)	8(6.7)	7(6.4)	12(5.1)
高血圧	n (%)	1(0.9)	5(4.2)	4(3.6)	6(2.5)
深部静脈血栓症	n (%)	0	2(1.7)	2(1.8)	2(0.8)
本態性高血圧症	n (%)	1(0.9)	0	0	1(0.4)
血腫	n (%)	0	1(0.8)	1(0.9)	1(0.4)
起立性低血圧	n (%)	1(0.9)	0	0	1(0.4)
末梢動脈閉塞性疾患	n (%)	1(0.9)	0	0	1(0.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
Any Adverse Event	n (%)	51(63.8)	72(65.5)	66(63.5)	123(64.7)
血液およびリンパ系障害	n (%)	2(2.5)	3(2.7)	3(2.9)	5(2.6)
好中球減少症	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
貧血	n (%)	0	1(0.9)	1(1.0)	1(0.5)
白血球増加症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
白血球減少症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血小板血症	n (%)	1(1.3)	0	0	1(0.5)
心臓障害	n (%)	3(3.8)	2(1.8)	2(1.9)	5(2.6)
心房細動	n (%)	1(1.3)	0	0	1(0.5)
僧帽弁閉鎖不全症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
洞性頻脈	n (%)	1(1.3)	0	0	1(0.5)
頻脈	n (%)	1(1.3)	0	0	1(0.5)
三尖弁閉鎖不全症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
心室性期外収縮	n (%)	0	1(0.9)	1(1.0)	1(0.5)
先天性、家族性および遺伝性障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
弯足	n (%)	0	1(0.9)	1(1.0)	1(0.5)
耳および迷路障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
耳痛	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
眼障害	n (%)	0	3(2.7)	3(2.9)	3(1.6)
核性白内障	n (%)	0	1(0.9)	1(1.0)	1(0.5)
複視	n (%)	0	1(0.9)	1(1.0)	1(0.5)
兎眼	n (%)	0	1(0.9)	1(1.0)	1(0.5)
黄斑浮腫	n (%)	0	1(0.9)	1(1.0)	1(0.5)
網膜静脈閉塞	n (%)	0	1(0.9)	1(1.0)	1(0.5)
胃腸障害	n (%)	13(16.3)	22(20.0)	18(17.3)	35(18.4)
下痢	n (%)	3(3.8)	6(5.5)	5(4.8)	9(4.7)
便秘	n (%)	3(3.8)	5(4.5)	4(3.8)	8(4.2)
嘔吐	n (%)	3(3.8)	4(3.6)	2(1.9)	7(3.7)
悪心	n (%)	2(2.5)	4(3.6)	4(3.8)	6(3.2)
口内乾燥	n (%)	3(3.8)	2(1.8)	2(1.9)	5(2.6)
腹痛	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
胃食道逆流性疾患	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
歯痛	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
胃炎	n (%)	0	2(1.8)	1(1.0)	2(1.1)
腹部膨満	n (%)	0	1(0.9)	1(1.0)	1(0.5)
上腹部痛	n (%)	1(1.3)	0	0	1(0.5)
腹部圧痛	n (%)	1(1.3)	0	0	1(0.5)
細菌叢異常症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
嚥下障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
変色便	n (%)	1(1.3)	0	0	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
食中毒	n (%)	0	1(0.9)	1(1.0)	1(0.5)
びらん性胃炎	n (%)	0	1(0.9)	0	1(0.5)
裂孔ヘルニア	n (%)	0	1(0.9)	1(1.0)	1(0.5)
流涎過多	n (%)	0	1(0.9)	1(1.0)	1(0.5)
全身障害および投与局所様態	n (%)	12(15.0)	11(10.0)	8(7.7)	23(12.1)
疲労	n (%)	9(11.3)	3(2.7)	3(2.9)	12(6.3)
胸痛	n (%)	3(3.8)	1(0.9)	1(1.0)	4(2.1)
無力症	n (%)	1(1.3)	2(1.8)	0	3(1.6)
易刺激性	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
末梢性浮腫	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
発熱	n (%)	0	2(1.8)	1(1.0)	2(1.1)
歩行障害	n (%)	1(1.3)	0	0	1(0.5)
治癒不良	n (%)	1(1.3)	0	0	1(0.5)
非心臓性胸痛	n (%)	1(1.3)	0	0	1(0.5)
疼痛	n (%)	0	1(0.9)	1(1.0)	1(0.5)
肝胆道系障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
胆石症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
免疫系障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
季節性アレルギー	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
感染症および寄生虫症	n (%)	17(21.3)	27(24.5)	24(23.1)	44(23.2)
尿路感染	n (%)	9(11.3)	8(7.3)	7(6.7)	17(8.9)
鼻咽頭炎	n (%)	2(2.5)	5(4.5)	4(3.8)	7(3.7)
気管支炎	n (%)	1(1.3)	4(3.6)	3(2.9)	5(2.6)
上気道感染	n (%)	1(1.3)	4(3.6)	4(3.8)	5(2.6)
胃腸炎	n (%)	0	3(2.7)	3(2.9)	3(1.6)
ダニ皮膚炎	n (%)	2(2.5)	0	0	2(1.1)
急性副鼻腔炎	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
耳感染	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
外陰腟真菌感染	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
軟部組織膿瘍	n (%)	0	1(0.9)	1(1.0)	1(0.5)
体部白癬	n (%)	1(1.3)	0	0	1(0.5)
蜂巣炎	n (%)	0	1(0.9)	1(1.0)	1(0.5)
憩室炎	n (%)	0	1(0.9)	1(1.0)	1(0.5)
せつ	n (%)	1(1.3)	0	0	1(0.5)
ウイルス性胃腸炎	n (%)	1(1.3)	0	0	1(0.5)
インフルエンザ	n (%)	1(1.3)	0	0	1(0.5)
爪真菌症	n (%)	1(1.3)	0	0	1(0.5)
咽頭炎	n (%)	1(1.3)	0	0	1(0.5)
副鼻腔炎	n (%)	0	1(0.9)	1(1.0)	1(0.5)
皮下組織膿瘍	n (%)	1(1.3)	0	0	1(0.5)
歯膿瘍	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
傷害、中毒および処置合併症	n (%)	6(7.5)	11(10.0)	10(9.6)	17(8.9)
転倒・転落	n (%)	1(1.3)	3(2.7)	3(2.9)	4(2.1)
擦過傷	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
足骨折	n (%)	0	2(1.8)	1(1.0)	2(1.1)
筋挫傷	n (%)	0	2(1.8)	2(1.9)	2(1.1)
動物咬傷	n (%)	0	1(0.9)	1(1.0)	1(0.5)
皮膚化学熱傷	n (%)	0	1(0.9)	1(1.0)	1(0.5)
挫傷	n (%)	0	1(0.9)	1(1.0)	1(0.5)
異物による損傷	n (%)	0	1(0.9)	1(1.0)	1(0.5)
関節損傷	n (%)	1(1.3)	0	0	1(0.5)
関節捻挫	n (%)	1(1.3)	0	0	1(0.5)
膝蓋骨骨折	n (%)	0	1(0.9)	1(1.0)	1(0.5)
腎損傷	n (%)	1(1.3)	0	0	1(0.5)
皮膚裂傷	n (%)	0	1(0.9)	1(1.0)	1(0.5)
熱傷	n (%)	1(1.3)	0	0	1(0.5)
臨床検査	n (%)	10(12.5)	18(16.4)	16(15.4)	28(14.7)
体重減少	n (%)	2(2.5)	2(1.8)	1(1.0)	4(2.1)
体重増加	n (%)	1(1.3)	3(2.7)	3(2.9)	4(2.1)
血中プロラクチン増加	n (%)	2(2.5)	1(0.9)	0	3(1.6)
血中トリグリセリド増加	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
ヘモグロビン減少	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
血中コレステロール増加	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血中クレアチンホスホキナーゼ増加	n (%)	1(1.3)	0	0	1(0.5)
血中クレアチニン増加	n (%)	1(1.3)	0	0	1(0.5)
血中ブドウ糖増加	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血圧上昇	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血中尿素増加	n (%)	1(1.3)	0	0	1(0.5)
尿中結晶陽性	n (%)	0	1(0.9)	1(1.0)	1(0.5)
心電図ＱＴ延長	n (%)	0	1(0.9)	1(1.0)	1(0.5)
尿中ブドウ糖陽性	n (%)	0	1(0.9)	1(1.0)	1(0.5)
グリコヘモグロビン増加	n (%)	1(1.3)	0	0	1(0.5)
心拍数減少	n (%)	0	1(0.9)	1(1.0)	1(0.5)
便潜血陽性	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血小板数減少	n (%)	0	1(0.9)	1(1.0)	1(0.5)
赤血球数増加	n (%)	0	1(0.9)	1(1.0)	1(0.5)
代謝および栄養障害	n (%)	5(6.3)	8(7.3)	7(6.7)	13(6.8)
食欲減退	n (%)	3(3.8)	2(1.8)	1(1.0)	5(2.6)
低ナトリウム血症	n (%)	0	2(1.8)	2(1.9)	2(1.1)
食欲亢進	n (%)	0	2(1.8)	2(1.9)	2(1.1)
食欲不振	n (%)	1(1.3)	0	0	1(0.5)
食欲障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
脱水	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
低カリウム血症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
多飲症	n (%)	1(1.3)	0	0	1(0.5)
筋骨格系および結合組織障害	n (%)	9(11.3)	13(11.8)	12(11.5)	22(11.6)
関節痛	n (%)	2(2.5)	4(3.6)	4(3.8)	6(3.2)
背部痛	n (%)	2(2.5)	4(3.6)	4(3.8)	6(3.2)
骨関節炎	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
筋肉痛	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
四肢痛	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
滑液包炎	n (%)	1(1.3)	0	0	1(0.5)
尾骨痛	n (%)	0	1(0.9)	1(1.0)	1(0.5)
椎間板変性症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
筋固縮	n (%)	0	1(0.9)	0	1(0.5)
筋痙縮	n (%)	0	1(0.9)	1(1.0)	1(0.5)
頚部痛	n (%)	1(1.3)	0	0	1(0.5)
骨減少症	n (%)	1(1.3)	0	0	1(0.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
副腎腺腫	n (%)	0	1(0.9)	1(1.0)	1(0.5)
乳癌	n (%)	0	1(0.9)	1(1.0)	1(0.5)
脂肪腫	n (%)	1(1.3)	0	0	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
神経系障害	n (%)	23(28.8)	23(20.9)	19(18.3)	46(24.2)
頭痛	n (%)	5(6.3)	7(6.4)	6(5.8)	12(6.3)
傾眠	n (%)	6(7.5)	5(4.5)	4(3.8)	11(5.8)
アカシジア	n (%)	6(7.5)	0	0	6(3.2)
浮動性めまい	n (%)	2(2.5)	3(2.7)	3(2.9)	5(2.6)
ジスキネジー	n (%)	1(1.3)	4(3.6)	3(2.9)	5(2.6)
鎮静	n (%)	0	4(3.6)	3(2.9)	4(2.1)
よだれ	n (%)	0	3(2.7)	3(2.9)	3(1.6)
失神	n (%)	2(2.5)	1(0.9)	1(1.0)	3(1.6)
振戦	n (%)	3(3.8)	0	0	3(1.6)
平衡障害	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
ジストニー	n (%)	2(2.5)	0	0	2(1.1)
健忘	n (%)	0	1(0.9)	1(1.0)	1(0.5)
注意力障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
脳症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
嗜眠	n (%)	0	1(0.9)	0	1(0.5)
神経痛	n (%)	1(1.3)	0	0	1(0.5)
末梢性ニューロパチー	n (%)	0	1(0.9)	1(1.0)	1(0.5)
パーキンソニズム	n (%)	1(1.3)	0	0	1(0.5)
妊娠、産褥および周産期の状態	n (%)	0	1(0.9)	1(1.0)	1(0.5)
自然流産	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146　性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
精神障害	n (%)	18(22.5)	19(17.3)	16(15.4)	37(19.5)
うつ病	n (%)	6(7.5)	3(2.7)	2(1.9)	9(4.7)
自殺念慮	n (%)	4(5.0)	5(4.5)	5(4.8)	9(4.7)
不安	n (%)	4(5.0)	4(3.6)	2(1.9)	8(4.2)
不眠症	n (%)	3(3.8)	2(1.8)	2(1.9)	5(2.6)
激越	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
躁病	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
妄想症	n (%)	2(2.5)	0	0	2(1.1)
精神運動制止遅滞	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
抑うつ気分	n (%)	1(1.3)	0	0	1(0.5)
抑うつ症状	n (%)	0	1(0.9)	1(1.0)	1(0.5)
気分動揺	n (%)	0	1(0.9)	0	1(0.5)
神経過敏	n (%)	0	1(0.9)	1(1.0)	1(0.5)
パニック発作	n (%)	1(1.3)	0	0	1(0.5)
落ち着きのなさ	n (%)	1(1.3)	0	0	1(0.5)
統合失調感情障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
統合失調症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
自殺行為	n (%)	0	1(0.9)	1(1.0)	1(0.5)
腎および尿路障害	n (%)	3(3.8)	4(3.6)	4(3.8)	7(3.7)
頻尿	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
排尿困難	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血尿	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146 性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
腎嚢胞	n (%)	1(1.3)	0	0	1(0.5)
急性腎不全	n (%)	1(1.3)	0	0	1(0.5)
尿失禁	n (%)	0	1(0.9)	1(1.0)	1(0.5)
尿臭異常	n (%)	1(1.3)	0	0	1(0.5)
生殖系および乳房障害	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
乳房圧痛	n (%)	1(1.3)	0	0	1(0.5)
乳汁漏出症	n (%)	1(1.3)	0	0	1(0.5)
月経過多	n (%)	0	1(0.9)	1(1.0)	1(0.5)
腟分泌物	n (%)	1(1.3)	0	0	1(0.5)
呼吸器、胸郭および縦隔障害	n (%)	1(1.3)	13(11.8)	12(11.5)	14(7.4)
鼻閉	n (%)	0	4(3.6)	4(3.8)	4(2.1)
喘息	n (%)	1(1.3)	2(1.8)	1(1.0)	3(1.6)
慢性閉塞性肺疾患	n (%)	0	3(2.7)	3(2.9)	3(1.6)
咳嗽	n (%)	1(1.3)	2(1.8)	1(1.0)	3(1.6)
慢性気管支炎	n (%)	0	1(0.9)	1(1.0)	1(0.5)
嚢胞性肺疾患	n (%)	0	1(0.9)	1(1.0)	1(0.5)
呼吸困難	n (%)	0	1(0.9)	0	1(0.5)
口腔咽頭痛	n (%)	0	1(0.9)	1(1.0)	1(0.5)
胸膜線維症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
気道うっ血	n (%)	0	1(0.9)	0	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－146　性別ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Gender: Female

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	 80 mg (N=110)	 80 mg Only[b] (N=104)	All NBI-98854 (N=190)
アレルギー性鼻炎	n (%)	0	1(0.9)	1(1.0)	1(0.5)
皮膚および皮下組織障害	n (%)	5(6.3)	2(1.8)	2(1.9)	7(3.7)
発疹	n (%)	2(2.5)	1(0.9)	1(1.0)	3(1.6)
そう痒症	n (%)	2(2.5)	0	0	2(1.1)
アレルギー性皮膚炎	n (%)	1(1.3)	0	0	1(0.5)
過角化	n (%)	0	1(0.9)	1(1.0)	1(0.5)
丘疹	n (%)	0	1(0.9)	1(1.0)	1(0.5)
外科および内科処置	n (%)	2(2.5)	3(2.7)	3(2.9)	5(2.6)
抜歯	n (%)	2(2.5)	1(0.9)	1(1.0)	3(1.6)
四肢再接合手術	n (%)	0	1(0.9)	1(1.0)	1(0.5)
鼓膜切開	n (%)	0	1(0.9)	1(1.0)	1(0.5)
血管障害	n (%)	2(2.5)	6(5.5)	6(5.8)	8(4.2)
ほてり	n (%)	1(1.3)	2(1.8)	2(1.9)	3(1.6)
高血圧	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
血腫	n (%)	0	1(0.9)	1(1.0)	1(0.5)
低血圧	n (%)	0	1(0.9)	1(1.0)	1(0.5)
レイノー現象	n (%)	0	1(0.9)	1(1.0)	1(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.1より引用（一部改変）

表2.7.4.7－147　性別ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Gender: Male

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	 80 mg (N=120)	 80 mg Only[b] (N=110)	All NBI-98854 (N=237)
Any Adverse Event of Special Interest	n (%)	36(30.8)	36(30.0)	27(24.5)	72(30.4)
アカシジア関連有害事象	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
アカシジア	n (%)	1(0.9)	1(0.8)	1(0.9)	2(0.8)
不安	n (%)	2(1.7)	3(2.5)	1(0.9)	5(2.1)
不安	n (%)	2(1.7)	3(2.5)	1(0.9)	5(2.1)
心血管系及びQT間隔延長関連有害事象	n (%)	2(1.7)	5(4.2)	4(3.6)	7(3.0)
失神	n (%)	2(1.7)	1(0.8)	0	3(1.3)
胸痛	n (%)	0	2(1.7)	2(1.8)	2(0.8)
心不全	n (%)	0	1(0.8)	1(0.9)	1(0.4)
突然死	n (%)	0	1(0.8)	1(0.9)	1(0.4)
うつ病及び自殺関連有害事象	n (%)	9(7.7)	9(7.5)	9(8.2)	18(7.6)
自殺念慮	n (%)	5(4.3)	5(4.2)	5(4.5)	10(4.2)
うつ病	n (%)	3(2.6)	2(1.7)	2(1.8)	5(2.1)
自殺企図	n (%)	0	2(1.7)	2(1.8)	2(0.8)
抑うつ気分	n (%)	0	1(0.8)	1(0.9)	1(0.4)
抑うつ症状	n (%)	1(0.9)	0	0	1(0.4)
嚥下障害関連有害事象	n (%)	3(2.6)	0	0	3(1.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－147　性別ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Gender: Male

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	80 mg (N=120)	80 mg Only[b] (N=110)	All NBI-98854 (N=237)
嚥下障害	n (%)	3(2.6)	0	0	3(1.3)
食道食物嵌入	n (%)	1(0.9)	0	0	1(0.4)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	4(3.4)	8(6.7)	6(5.5)	12(5.1)
疲労	n (%)	4(3.4)	5(4.2)	5(4.5)	9(3.8)
無力症	n (%)	0	2(1.7)	0	2(0.8)
倦怠感	n (%)	0	1(0.8)	1(0.9)	1(0.4)
肝障害関連有害事象	n (%)	0	2(1.7)	2(1.8)	2(0.8)
肝不全	n (%)	0	1(0.8)	1(0.9)	1(0.4)
急性肝炎	n (%)	0	1(0.8)	1(0.9)	1(0.4)
低血圧関連有害事象	n (%)	9(7.7)	8(6.7)	7(6.4)	17(7.2)
浮動性めまい	n (%)	4(3.4)	7(5.8)	7(6.4)	11(4.6)
転倒・転落	n (%)	4(3.4)	2(1.7)	1(0.9)	6(2.5)
失神	n (%)	2(1.7)	1(0.8)	0	3(1.3)
起立性低血圧	n (%)	1(0.9)	0	0	1(0.4)
パーキンソニズム関連有害事象	n (%)	1(0.9)	4(3.3)	2(1.8)	5(2.1)
振戦	n (%)	1(0.9)	3(2.5)	1(0.9)	4(1.7)
歯車様固縮	n (%)	0	1(0.8)	1(0.9)	1(0.4)
パーキンソニズム	n (%)	0	1(0.8)	1(0.9)	1(0.4)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－147　性別ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Gender: Male

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=117)	80 mg (N=120)	80 mg Only[b] (N=110)	All NBI-98854 (N=237)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	11(9.4)	4(3.3)	2(1.8)	15(6.3)
傾眠	n (%)	9(7.7)	4(3.3)	2(1.8)	13(5.5)
鎮静	n (%)	2(1.7)	0	0	2(0.8)
基礎疾患の悪化に関連する有害事象	n (%)	15(12.8)	12(10.0)	11(10.0)	27(11.4)
自殺念慮	n (%)	5(4.3)	5(4.2)	5(4.5)	10(4.2)
統合失調症	n (%)	4(3.4)	3(2.5)	3(2.7)	7(3.0)
うつ病	n (%)	3(2.6)	2(1.7)	2(1.8)	5(2.1)
精神病性障害	n (%)	1(0.9)	1(0.8)	0	2(0.8)
自殺企図	n (%)	0	2(1.7)	2(1.8)	2(0.8)
双極１型障害	n (%)	1(0.9)	0	0	1(0.4)
抑うつ気分	n (%)	0	1(0.8)	1(0.9)	1(0.4)
抑うつ症状	n (%)	1(0.9)	0	0	1(0.4)
敵意	n (%)	1(0.9)	0	0	1(0.4)
軽躁	n (%)	1(0.9)	0	0	1(0.4)
易刺激性	n (%)	0	1(0.8)	1(0.9)	1(0.4)
外傷後ストレス障害	n (%)	1(0.9)	0	0	1(0.4)
統合失調感情障害	n (%)	1(0.9)	0	0	1(0.4)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－147　性別ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Gender: Female

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	80 mg (N=110)	80 mg Only[b] (N=104)	All NBI-98854 (N=190)
Any Adverse Event of Special Interest	n (%)	34(42.5)	35(31.8)	29(27.9)	69(36.3)
アカシジア関連有害事象	n (%)	6(7.5)	0	0	6(3.2)
アカシジア	n (%)	6(7.5)	0	0	6(3.2)
不安	n (%)	4(5.0)	4(3.6)	2(1.9)	8(4.2)
不安	n (%)	4(5.0)	4(3.6)	2(1.9)	8(4.2)
心血管系及びQT間隔延長関連有害事象	n (%)	4(5.0)	3(2.7)	3(2.9)	7(3.7)
胸痛	n (%)	3(3.8)	1(0.9)	1(1.0)	4(2.1)
失神	n (%)	2(2.5)	1(0.9)	1(1.0)	3(1.6)
心電図QT延長	n (%)	0	1(0.9)	1(1.0)	1(0.5)
うつ病及び自殺関連有害事象	n (%)	10(12.5)	9(8.2)	8(7.7)	19(10.0)
うつ病	n (%)	6(7.5)	3(2.7)	2(1.9)	9(4.7)
自殺念慮	n (%)	4(5.0)	5(4.5)	5(4.8)	9(4.7)
抑うつ気分	n (%)	1(1.3)	0	0	1(0.5)
抑うつ症状	n (%)	0	1(0.9)	1(1.0)	1(0.5)
自殺行為	n (%)	0	1(0.9)	1(1.0)	1(0.5)
嚥下障害関連有害事象	n (%)	0	1(0.9)	1(1.0)	1(0.5)
嚥下障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－147　性別ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Gender: Female

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	80 mg (N=110)	80 mg Only[b] (N=104)	All NBI-98854 (N=190)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	9(11.3)	6(5.5)	3(2.9)	15(7.9)
疲労	n (%)	9(11.3)	3(2.7)	3(2.9)	12(6.3)
無力症	n (%)	1(1.3)	2(1.8)	0	3(1.6)
嗜眠	n (%)	0	1(0.9)	0	1(0.5)
高プロラクチン血症関連有害事象	n (%)	3(3.8)	1(0.9)	0	4(2.1)
血中プロラクチン増加	n (%)	2(2.5)	1(0.9)	0	3(1.6)
乳汁漏出症	n (%)	1(1.3)	0	0	1(0.5)
低血圧関連有害事象	n (%)	5(6.3)	8(7.3)	8(7.7)	13(6.8)
浮動性めまい	n (%)	2(2.5)	3(2.7)	3(2.9)	5(2.6)
転倒・転落	n (%)	1(1.3)	3(2.7)	3(2.9)	4(2.1)
失神	n (%)	2(2.5)	1(0.9)	1(1.0)	3(1.6)
低血圧	n (%)	0	1(0.9)	1(1.0)	1(0.5)
パーキンソニズム関連有害事象	n (%)	4(5.0)	1(0.9)	0	5(2.6)
振戦	n (%)	3(3.8)	0	0	3(1.6)
筋固縮	n (%)	0	1(0.9)	0	1(0.5)
パーキンソニズム	n (%)	1(1.3)	0	0	1(0.5)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	6(7.5)	9(8.2)	7(6.7)	15(7.9)
傾眠	n (%)	6(7.5)	5(4.5)	4(3.8)	11(5.8)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－147　性別ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Gender: Female

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=80)	80 mg (N=110)	80 mg Only[b] (N=104)	All NBI-98854 (N=190)
鎮静	n (%)	0	4(3.6)	3(2.9)	4(2.1)
基礎疾患の悪化に関連する有害事象	n (%)	12(15.0)	13(11.8)	12(11.5)	25(13.2)
うつ病	n (%)	6(7.5)	3(2.7)	2(1.9)	9(4.7)
自殺念慮	n (%)	4(5.0)	5(4.5)	5(4.8)	9(4.7)
易刺激性	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
躁病	n (%)	1(1.3)	1(0.9)	1(1.0)	2(1.1)
妄想症	n (%)	2(2.5)	0	0	2(1.1)
抑うつ気分	n (%)	1(1.3)	0	0	1(0.5)
抑うつ症状	n (%)	0	1(0.9)	1(1.0)	1(0.5)
気分動揺	n (%)	0	1(0.9)	0	1(0.5)
統合失調感情障害	n (%)	0	1(0.9)	1(1.0)	1(0.5)
統合失調症	n (%)	0	1(0.9)	1(1.0)	1(0.5)
自殺行為	n (%)	0	1(0.9)	1(1.0)	1(0.5)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.1より引用（一部改変）

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Any System Organ Class		5 (50.0)	7 (100.0)	12 (70.6)	2 (40.0)	31 (64.6)	35 (79.5)	66 (71.7)	21 (44.7)	13 (61.9)	21 (80.8)	34 (72.3)	11 (40.7)	5 (83.3)	4 (57.1)	9 (69.2)	3 (60.0)
Infections and infestations	感染症および寄生虫症	1 (10.0)	3 (42.9)	4 (23.5)	2 (40.0)	5 (10.4)	4 (9.1)	9 (9.8)	4 (8.5)	4 (19.0)	2 (7.7)	6 (12.8)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasopharyngitis	上咽頭炎	0 (0.0)	2 (28.6)	2 (11.8)	2 (40.0)	5 (10.4)	1 (2.3)	6 (6.5)	3 (6.4)	1 (4.8)	1 (3.8)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia	肺炎	1 (10.0)	1 (14.3)	2 (11.8)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Influenza	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Periodontitis	歯周炎	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	上気道感染	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Eczema impetiginous	膿痂疹性湿疹	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	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 (3.7)	0 (0.0)	1 (14.3)	1 (7.7)	0 (0.0)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	1 (7.7)	0 (0.0)
Blepharal papilloma	眼瞼乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	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 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	代謝および栄養障害	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	5 (10.4)	3 (6.8)	8 (8.7)	2 (4.3)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased appetite	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dehydration	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	2 (2.2)	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)
Diabetes mellitus	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hyperuricaemia	高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Polydipsia	多飲症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Psychiatric disorders	精神障害	3 (30.0)	0 (0.0)	3 (17.6)	0 (0.0)	8 (16.7)	9 (20.5)	17 (18.5)	2 (4.3)	4 (19.0)	5 (19.2)	9 (19.1)	2 (7.4)	2 (33.3)	2 (28.6)	4 (30.8)	1 (20.0)
Insomnia	不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	3 (6.8)	4 (4.3)	1 (2.1)	1 (4.8)	1 (3.8)	2 (4.3)	0 (0.0)	0 (0.0)	1 (14.3)	1 (7.7)	0 (0.0)
Schizophrenia	統合失調症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	2 (4.2)	0 (0.0)	2 (2.2)	1 (2.1)	2 (9.5)	0 (0.0)	2 (4.3)	0 (0.0)	2 (33.3)	0 (0.0)	2 (15.4)	0 (0.0)
Anxiety	不安	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	3 (6.8)	4 (4.3)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	0 (0.0)	0 (0.0)	2 (7.7)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disinhibition	脱抑制	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)	0 (0.0)	2 (2.2)	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)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Delusion	妄想	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	1 (7.7)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Sleep disorder	睡眠障害	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Somatic symptom disorder	身体症状症	0 (0.0)	0 (0.0)	0 (0.0)	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 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Nervous system disorders	神経系障害	2 (20.0)	2 (28.6)	4 (23.5)	0 (0.0)	12 (25.0)	20 (45.5)	32 (34.8)	2 (4.3)	3 (14.3)	14 (53.8)	17 (36.2)	4 (14.8)	3 (50.0)	2 (28.6)	5 (38.5)	0 (0.0)
Somnolence	傾眠	1 (10.0)	1 (14.3)	2 (11.8)	0 (0.0)	6 (12.5)	14 (31.8)	20 (21.7)	0 (0.0)	2 (9.5)	6 (23.1)	8 (17.0)	2 (7.4)	1 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Akathisia	アカシジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)	2 (4.5)	4 (4.3)	1 (2.1)	1 (4.8)	1 (3.8)	2 (4.3)	0 (0.0)	1 (16.7)	2 (28.6)	3 (23.1)	0 (0.0)
Headache	頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	2 (4.5)	3 (3.3)	1 (2.1)	0 (0.0)	2 (7.7)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tremor	振戦	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	2 (2.2)	0 (0.0)	0 (0.0)	3 (11.5)	3 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Drooling	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Dysarthria	構語障害	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hypersomnia	過眠症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148 BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Hypoaesthesia	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Sciatica	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Seizure	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Reduced facial expression	表情減少	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye disorders	眼障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	1 (2.1)	1 (4.8)	1 (3.8)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blepharitis	眼瞼炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)	0 (0.0)	2 (2.2)	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)
Deafness neurosensory	感音性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)

MedDRA Version 23.0.

表 2.7.4.7－148 BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Cardiac disorders	心臓障害	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	動悸	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0 (0.0)	2 (28.6)	2 (11.8)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	1 (2.1)	0 (0.0)	2 (7.7)	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthma	喘息	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Throat clearing	咳払い	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148 BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Gastrointestinal disorders	胃腸障害	0 (0.0)	2 (28.6)	2 (11.8)	0 (0.0)	4 (8.3)	11 (25.0)	15 (16.3)	2 (4.3)	3 (14.3)	6 (23.1)	9 (19.1)	3 (11.1)	1 (16.7)	1 (14.3)	2 (15.4)	2 (40.0)
Salivary hypersecretion	流涎過多	0 (0.0)	2 (28.6)	2 (11.8)	0 (0.0)	1 (2.1)	5 (11.4)	6 (6.5)	0 (0.0)	2 (9.5)	2 (7.7)	4 (8.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Constipation	便秘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Nausea	悪心	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	1 (2.1)	0 (0.0)	2 (7.7)	2 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	下痢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Dry mouth	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Abdominal pain upper	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Chronic gastritis	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Gastritis	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	1 (7.7)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	歯痛	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 (4.8)	0 (0.0)	1 (2.1)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Vomiting	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	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 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Hepatic steatosis	脂肪肝	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	4 (8.3)	2 (4.5)	6 (6.5)	3 (6.4)	1 (4.8)	1 (3.8)	2 (4.3)	1 (3.7)	1 (16.7)	2 (28.6)	3 (23.1)	1 (20.0)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	2 (28.6)	2 (15.4)	0 (0.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Alopecia areata	円形脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Blister	水疱	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Dry skin	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Rash	発疹	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Xeroderma	乾皮症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.3)	3 (6.8)	6 (6.5)	4 (8.5)	1 (4.8)	2 (7.7)	3 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Back pain	背部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.3)	1 (2.3)	4 (4.3)	2 (4.3)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neck pain	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Osteoarthritis	変形性関節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Posture abnormal	姿勢異常	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (20.0)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	1 (2.1)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Polyuria	多尿	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－148　BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	1 (10.0)	1 (14.3)	2 (11.8)	0 (0.0)	6 (12.5)	6 (13.6)	12 (13.0)	2 (4.3)	3 (14.3)	4 (15.4)	7 (14.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Malaise	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.3)	2 (4.5)	5 (5.4)	0 (0.0)	2 (9.5)	2 (7.7)	4 (8.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	疲労	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	1 (2.1)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pyrexia	発熱	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)

MedDRA Version 23.0.

表 2.7.4.7－148 BMI 区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Investigations	臨床検査	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (8.3)	2 (4.5)	6 (6.5)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Weight increased	体重増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Blood creatinine increased	血中クレアチニン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	3 (6.4)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	1 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Head injury	頭部損傷	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contusion	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.4.1.1 より引用

表 2.7.4.7－149　BMI 区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
		40 mg (N=10) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=17) n(%)	Placebo (N=5) n(%)	40 mg (N=48) n(%)	80 mg (N=44) n(%)	All MT-5199 (N=92) n(%)	Placebo (N=47) n(%)	40 mg (N=21) n(%)	80 mg (N=26) n(%)	All MT-5199 (N=47) n(%)	Placebo (N=27) n(%)	40 mg (N=6) n(%)	80 mg (N=7) n(%)	All MT-5199 (N=13) n(%)	Placebo (N=5) n(%)
Any AESI		3 (30.0)	5 (71.4)	8 (47.1)	0 (0.0)	19 (39.6)	27 (61.4)	46 (50.0)	6 (12.8)	9 (42.9)	17 (65.4)	26 (55.3)	6 (22.2)	5 (83.3)	4 (57.1)	9 (69.2)	3 (60.0)
Somnolence	傾眠関連有害事象	2 (20.0)	1 (14.3)	3 (17.6)	0 (0.0)	8 (16.7)	16 (36.4)	24 (26.1)	0 (0.0)	4 (19.0)	7 (26.9)	11 (23.4)	2 (7.4)	2 (33.3)	0 (0.0)	2 (15.4)	0 (0.0)
Somnolence	傾眠	1 (10.0)	1 (14.3)	2 (11.8)	0 (0.0)	6 (12.5)	14 (31.8)	20 (21.7)	0 (0.0)	2 (9.5)	6 (23.1)	8 (17.0)	2 (7.4)	1 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Malaise	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (6.3)	2 (4.5)	5 (5.4)	0 (0.0)	2 (9.5)	2 (7.7)	4 (8.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	疲労	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－149　BMI 区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=10) n(%)	<18.5 MT-5199 80 mg (N=7) n(%)	<18.5 MT-5199 All (N=17) n(%)	<18.5 Placebo (N=5) n(%)	18.5 to <25 MT-5199 40 mg (N=48) n(%)	18.5 to <25 MT-5199 80 mg (N=44) n(%)	18.5 to <25 MT-5199 All (N=92) n(%)	18.5 to <25 Placebo (N=47) n(%)	25 to <30 MT-5199 40 mg (N=21) n(%)	25 to <30 MT-5199 80 mg (N=26) n(%)	25 to <30 MT-5199 All (N=47) n(%)	25 to <30 Placebo (N=27) n(%)	>=30 MT-5199 40 mg (N=6) n(%)	>=30 MT-5199 80 mg (N=7) n(%)	>=30 MT-5199 All (N=13) n(%)	>=30 Placebo (N=5) n(%)
Hypersensitivity	過敏症関連有害事象	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	3 (6.3)	3 (6.8)	6 (6.5)	3 (6.4)	1 (4.8)	1 (3.8)	2 (4.3)	2 (7.4)	1 (16.7)	2 (28.6)	3 (23.1)	1 (20.0)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	2 (28.6)	2 (15.4)	0 (0.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Blister	水疱	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (16.7)	0 (0.0)	1 (7.7)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Rash	発疹	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	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 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－149 BMI 区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=10) n(%)	<18.5 MT-5199 80 mg (N=7) n(%)	<18.5 MT-5199 All (N=17) n(%)	<18.5 Placebo (N=5) n(%)	18.5 to <25 MT-5199 40 mg (N=48) n(%)	18.5 to <25 MT-5199 80 mg (N=44) n(%)	18.5 to <25 MT-5199 All (N=92) n(%)	18.5 to <25 Placebo (N=47) n(%)	25 to <30 MT-5199 40 mg (N=21) n(%)	25 to <30 MT-5199 80 mg (N=26) n(%)	25 to <30 MT-5199 All (N=47) n(%)	25 to <30 Placebo (N=27) n(%)	>=30 MT-5199 40 mg (N=6) n(%)	>=30 MT-5199 80 mg (N=7) n(%)	>=30 MT-5199 All (N=13) n(%)	>=30 Placebo (N=5) n(%)
Parkinsonism	パーキンソニズム関連有害事象	0 (0.0)	2 (28.6)	2 (11.8)	0 (0.0)	3 (6.3)	10 (22.7)	13 (14.1)	0 (0.0)	2 (9.5)	6 (23.1)	8 (17.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Salivary hypersecretion	流涎過多	0 (0.0)	2 (28.6)	2 (11.8)	0 (0.0)	1 (2.1)	5 (11.4)	6 (6.5)	0 (0.0)	2 (9.5)	2 (7.7)	4 (8.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Tremor	振戦	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	2 (2.2)	0 (0.0)	0 (0.0)	3 (11.5)	3 (6.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Drooling	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Reduced facial expression	表情減少	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－149 BMI 区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=10) n(%)	<18.5 MT-5199 80 mg (N=7) n(%)	<18.5 All MT-5199 (N=17) n(%)	<18.5 Placebo (N=5) n(%)	18.5 to <25 MT-5199 40 mg (N=48) n(%)	18.5 to <25 MT-5199 80 mg (N=44) n(%)	18.5 to <25 All MT-5199 (N=92) n(%)	18.5 to <25 Placebo (N=47) n(%)	25 to <30 MT-5199 40 mg (N=21) n(%)	25 to <30 MT-5199 80 mg (N=26) n(%)	25 to <30 All MT-5199 (N=47) n(%)	25 to <30 Placebo (N=27) n(%)	>=30 MT-5199 40 mg (N=6) n(%)	>=30 MT-5199 80 mg (N=7) n(%)	>=30 All MT-5199 (N=13) n(%)	>=30 Placebo (N=5) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	2 (20.0)	0 (0.0)	2 (11.8)	0 (0.0)	4 (8.3)	1 (2.3)	5 (5.4)	0 (0.0)	0 (0.0)	2 (7.7)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	0 (0.0)	0 (0.0)	2 (7.7)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hypersomnia	過眠症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Akathisia	アカシジア関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)	3 (6.8)	5 (5.4)	1 (2.1)	1 (4.8)	3 (11.5)	4 (8.5)	0 (0.0)	1 (16.7)	2 (28.6)	3 (23.1)	0 (0.0)
Akathisia	アカシジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.2)	2 (4.5)	4 (4.3)	1 (2.1)	1 (4.8)	1 (3.8)	2 (4.3)	0 (0.0)	1 (16.7)	2 (28.6)	3 (23.1)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	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 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－149　BMI 区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=10) n(%)	<18.5 MT-5199 80 mg (N=7) n(%)	<18.5 MT-5199 All (N=17) n(%)	<18.5 Placebo (N=5) n(%)	18.5 to <25 MT-5199 40 mg (N=48) n(%)	18.5 to <25 MT-5199 80 mg (N=44) n(%)	18.5 to <25 MT-5199 All (N=92) n(%)	18.5 to <25 Placebo (N=47) n(%)	25 to <30 MT-5199 40 mg (N=21) n(%)	25 to <30 MT-5199 80 mg (N=26) n(%)	25 to <30 MT-5199 All (N=47) n(%)	25 to <30 Placebo (N=27) n(%)	>=30 MT-5199 40 mg (N=6) n(%)	>=30 MT-5199 80 mg (N=7) n(%)	>=30 MT-5199 All (N=13) n(%)	>=30 Placebo (N=5) n(%)
Anxiety	不安	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	3 (6.8)	4 (4.3)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	3 (6.8)	4 (4.3)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	2 (20.0)	0 (0.0)	2 (11.8)	0 (0.0)	5 (10.4)	2 (4.5)	7 (7.6)	1 (2.1)	2 (9.5)	3 (11.5)	5 (10.6)	1 (3.7)	2 (33.3)	1 (14.3)	3 (23.1)	1 (20.0)
Schizophrenia	統合失調症	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	2 (4.2)	0 (0.0)	2 (2.2)	1 (2.1)	2 (9.5)	0 (0.0)	2 (4.3)	0 (0.0)	2 (33.3)	0 (0.0)	2 (15.4)	0 (0.0)
Depression	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	0 (0.0)	0 (0.0)	2 (7.7)	2 (4.3)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	1 (7.7)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (10.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－149　BMI 区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=10) n(%)	<18.5 MT-5199 80 mg (N=7) n(%)	<18.5 MT-5199 All (N=17) n(%)	<18.5 Placebo (N=5) n(%)	18.5 to <25 MT-5199 40 mg (N=48) n(%)	18.5 to <25 MT-5199 80 mg (N=44) n(%)	18.5 to <25 MT-5199 All (N=92) n(%)	18.5 to <25 Placebo (N=47) n(%)	25 to <30 MT-5199 40 mg (N=21) n(%)	25 to <30 MT-5199 80 mg (N=26) n(%)	25 to <30 MT-5199 All (N=47) n(%)	25 to <30 Placebo (N=27) n(%)	>=30 MT-5199 40 mg (N=6) n(%)	>=30 MT-5199 80 mg (N=7) n(%)	>=30 MT-5199 All (N=13) n(%)	>=30 Placebo (N=5) n(%)
Dysphagia	嚥下障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	0 (0.0)	1 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	1 (1.1)	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)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	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)
Hepatic steatosis	脂肪肝	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 (4.8)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	1 (2.1)	2 (4.5)	3 (3.3)	1 (2.1)	0 (0.0)	1 (3.8)	1 (2.1)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	1 (14.3)	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.3)	1 (1.1)	0 (0.0)	0 (0.0)	1 (3.8)	1 (2.1)	1 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (2.3)	2 (2.2)	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)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.4.1.2 より引用

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Any System Organ Class		9 (81.8)	11 (100.0)	9 (100.0)	20 (90.9)	64 (88.9)	65 (98.5)	39 (97.5)	129 (93.5)	33 (91.7)	33 (89.2)	23 (85.2)	66 (90.4)	7 (100.0)	7 (77.8)	6 (75.0)	14 (87.5)
Infections and infestations	感染症および寄生虫症	4 (36.4)	7 (63.6)	6 (66.7)	11 (50.0)	25 (34.7)	23 (34.8)	15 (37.5)	48 (34.8)	12 (33.3)	9 (24.3)	7 (25.9)	21 (28.8)	5 (71.4)	1 (11.1)	1 (12.5)	6 (37.5)
Nasopharyngitis	上咽頭炎	0 (0.0)	3 (27.3)	2 (22.2)	3 (13.6)	19 (26.4)	13 (19.7)	7 (17.5)	32 (23.2)	8 (22.2)	6 (16.2)	5 (18.5)	14 (19.2)	3 (42.9)	1 (11.1)	1 (12.5)	4 (25.0)
Cystitis	膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	2 (3.0)	2 (5.0)	3 (2.2)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia	肺炎	1 (9.1)	1 (9.1)	1 (11.1)	2 (9.1)	1 (1.4)	2 (3.0)	2 (5.0)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bronchitis	気管支炎	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Influenza	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cellulitis	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (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)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Folliculitis	毛包炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Gastroenteritis	胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (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)
Otitis externa	外耳炎	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periodontitis	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pharyngitis	咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Tinea pedis	足部白癬	0 (0.0)	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 (5.4)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	帯状疱疹	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mastitis	乳腺炎	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal vestibulitis	鼻前庭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis media	中耳炎	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Subcutaneous abscess	皮下組織膿瘍	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tonsillitis	扁桃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary tract infection	尿路感染	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal infection	膣感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Varicella	水痘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部膣カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin candida	皮膚カンジダ	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nail infection	爪感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Acarodermatitis	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Cystitis bacterial	細菌性膀胱炎	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infected dermal cyst	感染性皮膚嚢腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial vulvovaginitis	細菌性外陰腟炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (11.1)	1 (12.5)	1 (6.3)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (11.1)	1 (12.5)	1 (6.3)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	11 (15.3)	9 (13.6)	6 (15.0)	20 (14.5)	3 (8.3)	3 (8.1)	2 (7.4)	6 (8.2)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Decreased appetite	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.9)	3 (4.5)	1 (2.5)	8 (5.8)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dehydration	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	3 (4.5)	3 (7.5)	4 (2.9)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperuricaemia	高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (1.5)	0 (0.0)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Increased appetite	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Dyslipidaemia	脂質異常症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Electrolyte imbalance	電解質失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypokalaemia	低カリウム血症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypouricaemia	低尿酸血症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marasmus	マラスムス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Polydipsia	多飲症	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Psychiatric disorders	精神障害	6 (54.5)	6 (54.5)	5 (55.6)	12 (54.5)	28 (38.9)	29 (43.9)	18 (45.0)	57 (41.3)	13 (36.1)	19 (51.4)	14 (51.9)	32 (43.8)	5 (71.4)	3 (33.3)	3 (37.5)	8 (50.0)
Schizophrenia	統合失調症	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	9 (12.5)	8 (12.1)	2 (5.0)	17 (12.3)	6 (16.7)	5 (13.5)	3 (11.1)	11 (15.1)	4 (57.1)	0 (0.0)	0 (0.0)	4 (25.0)
Insomnia	不眠症	2 (18.2)	1 (9.1)	1 (11.1)	3 (13.6)	3 (4.2)	9 (13.6)	5 (12.5)	12 (8.7)	5 (13.9)	5 (13.5)	5 (18.5)	10 (13.7)	0 (0.0)	1 (11.1)	1 (12.5)	1 (6.3)
Depression	うつ病	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	3 (4.2)	3 (4.5)	3 (7.5)	6 (4.3)	2 (5.6)	5 (13.5)	4 (14.8)	7 (9.6)	1 (14.3)	1 (11.1)	1 (12.5)	2 (12.5)
Anxiety	不安	1 (9.1)	2 (18.2)	1 (11.1)	3 (13.6)	3 (4.2)	5 (7.6)	4 (10.0)	8 (5.8)	0 (0.0)	2 (5.4)	2 (7.4)	2 (2.7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Suicidal ideation	自殺念慮	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	1 (1.4)	2 (3.0)	1 (2.5)	3 (2.2)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	3 (42.9)	0 (0.0)	0 (0.0)	3 (18.8)
Restlessness	落ち着きのなさ	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (1.5)	1 (2.5)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Bipolar disorder	双極性障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Middle insomnia	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Bruxism	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (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)
Delirium	譫妄	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Disinhibition	脱抑制	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Flat affect	感情の平板化	0 (0.0)	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 (5.4)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination, auditory	幻聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Sleep disorder	睡眠障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Agitation	激越	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delusion	妄想	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (11.1)	1 (12.5)	1 (6.3)
Intentional self-injury	故意の自傷行為	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurosis	神経症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Abulia	無為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major depression	大うつ病	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal behaviour	異常行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somatic hallucination	体感幻覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term (MedDRA)	Preferred Term (MedDRA) in Japanese	40 mg (N=11) n(%)	80 mg (N=11) n(%)	80 mg (no dose reduction) (N=9) n(%)	All MT-5199 (N=22) n(%)	40 mg (N=72) n(%)	80 mg (N=66) n(%)	80 mg (no dose reduction) (N=40) n(%)	All MT-5199 (N=138) n(%)	40 mg (N=36) n(%)	80 mg (N=37) n(%)	80 mg (no dose reduction) (N=27) n(%)	All MT-5199 (N=73) n(%)	40 mg (N=7) n(%)	80 mg (N=9) n(%)	80 mg (no dose reduction) (N=8) n(%)	All MT-5199 (N=16) n(%)
Nervous system disorders	神経系障害	3 (27.3)	4 (36.4)	3 (33.3)	7 (31.8)	34 (47.2)	38 (57.6)	23 (57.5)	72 (52.2)	10 (27.8)	23 (62.2)	15 (55.6)	33 (45.2)	4 (57.1)	4 (44.4)	3 (37.5)	8 (50.0)
Somnolence	傾眠	2 (18.2)	1 (9.1)	1 (11.1)	3 (13.6)	13 (18.1)	19 (28.8)	11 (27.5)	32 (23.2)	3 (8.3)	8 (21.6)	6 (22.2)	11 (15.1)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Tremor	振戦	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	9 (13.6)	5 (12.5)	10 (7.2)	3 (8.3)	5 (13.5)	3 (11.1)	8 (11.0)	0 (0.0)	2 (22.2)	1 (12.5)	2 (12.5)
Akathisia	アカシジア	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	3 (4.2)	7 (10.6)	3 (7.5)	10 (7.2)	4 (11.1)	2 (5.4)	2 (7.4)	6 (8.2)	1 (14.3)	2 (22.2)	2 (25.0)	3 (18.8)
Headache	頭痛	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	2 (2.8)	4 (6.1)	3 (7.5)	6 (4.3)	0 (0.0)	4 (10.8)	2 (7.4)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	浮動性めまい	1 (9.1)	1 (9.1)	1 (11.1)	2 (9.1)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	0 (0.0)	3 (8.1)	3 (11.1)	3 (4.1)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (5.6)	3 (4.5)	2 (5.0)	7 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	3 (4.5)	1 (2.5)	4 (2.9)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Drooling	よだれ	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	2 (3.0)	1 (2.5)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tardive dyskinesia	遅発性ジスキネジア	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	2 (2.8)	2 (3.0)	2 (5.0)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Bradykinesia	運動緩慢	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Dyskinesia	ジスキネジア	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dystonia	ジストニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Seizure	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (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)
Coordination abnormal	協調運動異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Movement disorder	運動障害	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Radial nerve palsy	橈骨神経麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stupor	昏迷	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intercostal neuralgia	肋間神経痛	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vagus nerve disorder	迷走神経障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Eye disorders	眼障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (6.1)	2 (5.0)	4 (2.9)	3 (8.3)	1 (2.7)	0 (0.0)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blepharitis	眼瞼炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cataract	白内障	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye discharge	眼脂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg (N=11) n(%)	80 mg (N=11) n(%)	80 mg (no dose reduction) (N=9) n(%)	All MT-5199 (N=22) n(%)	40 mg (N=72) n(%)	80 mg (N=66) n(%)	80 mg (no dose reduction) (N=40) n(%)	All MT-5199 (N=138) n(%)	40 mg (N=36) n(%)	80 mg (N=37) n(%)	80 mg (no dose reduction) (N=27) n(%)	All MT-5199 (N=73) n(%)	40 mg (N=7) n(%)	80 mg (N=9) n(%)	80 mg (no dose reduction) (N=8) n(%)	All MT-5199 (N=16) n(%)
Ear and labyrinth disorders	耳および迷路障害	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deafness neurosensory	感音性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo	回転性めまい	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Cardiac disorders	心臓障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	3 (4.5)	2 (5.0)	4 (2.9)	2 (5.6)	2 (5.4)	2 (7.4)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	動悸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradycardia	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sinus bradycardia	洞性徐脈	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tachycardia	頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	3 (4.5)	2 (5.0)	4 (2.9)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	高血圧	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	1 (1.5)	0 (0.0)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	2 (5.0)	2 (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)
Deep vein thrombosis	深部静脈血栓症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0 (0.0)	3 (27.3)	2 (22.2)	3 (13.6)	6 (8.3)	5 (7.6)	1 (2.5)	11 (8.0)	2 (5.6)	4 (10.8)	1 (3.7)	6 (8.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthma	喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	0 (0.0)	2 (5.4)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	1 (1.5)	0 (0.0)	2 (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)
Dyspnoea	呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleural effusion	胸水	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Interstitial lung disease	間質性肺疾患	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleurisy	胸膜炎	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	湿性咳嗽	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg (N=11) n(%)	80 mg (N=11) n(%)	80 mg (no dose reduction) (N=9) n(%)	All MT-5199 (N=22) n(%)	40 mg (N=72) n(%)	80 mg (N=66) n(%)	80 mg (no dose reduction) (N=40) n(%)	All MT-5199 (N=138) n(%)	40 mg (N=36) n(%)	80 mg (N=37) n(%)	80 mg (no dose reduction) (N=27) n(%)	All MT-5199 (N=73) n(%)	40 mg (N=7) n(%)	80 mg (N=9) n(%)	80 mg (no dose reduction) (N=8) n(%)	All MT-5199 (N=16) n(%)
Pulmonary embolism	肺塞栓症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory failure	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough variant asthma	咳喘息	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Gastrointestinal disorders	胃腸障害	3 (27.3)	4 (36.4)	3 (33.3)	7 (31.8)	26 (36.1)	30 (45.5)	14 (35.0)	56 (40.6)	9 (25.0)	16 (43.2)	10 (37.0)	25 (34.2)	1 (14.3)	1 (11.1)	1 (12.5)	2 (12.5)
Salivary hypersecretion	流涎過多	0 (0.0)	3 (27.3)	3 (33.3)	3 (13.6)	5 (6.9)	11 (16.7)	3 (7.5)	16 (11.6)	4 (11.1)	7 (18.9)	4 (14.8)	11 (15.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	便秘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.9)	5 (7.6)	3 (7.5)	10 (7.2)	3 (8.3)	4 (10.8)	2 (7.4)	7 (9.6)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Dysphagia	嚥下障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	2 (5.6)	2 (5.4)	1 (3.7)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	下痢	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	3 (4.2)	3 (4.5)	2 (5.0)	6 (4.3)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea	悪心	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	2 (3.0)	2 (5.0)	3 (2.2)	1 (2.8)	3 (8.1)	2 (7.4)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	3 (4.5)	3 (7.5)	5 (3.6)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	4 (6.1)	0 (0.0)	6 (4.3)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (5.6)	0 (0.0)	0 (0.0)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dental caries	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	2 (3.0)	0 (0.0)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain	腹痛	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Dry mouth	口内乾燥	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Gastritis	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	1 (11.1)	1 (12.5)	1 (6.3)
Toothache	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal distension	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aphthous ulcer	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eructation	おくび	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorder	胃腸障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingival bleeding	歯肉出血	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Preferred Term	Preferred Term																
Hypoaesthesia oral	口の感覚鈍麻	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal pruritus	肛門そう痒症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	2 (5.0)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	2 (5.0)	2 (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)
Hepatic steatosis	脂肪肝	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg (N=11) n(%)	80 mg (N=11) n(%)	80 mg (no dose reduction) (N=9) n(%)	All MT-5199 (N=22) n(%)	40 mg (N=72) n(%)	80 mg (N=66) n(%)	80 mg (no dose reduction) (N=40) n(%)	All MT-5199 (N=138) n(%)	40 mg (N=36) n(%)	80 mg (N=37) n(%)	80 mg (no dose reduction) (N=27) n(%)	All MT-5199 (N=73) n(%)	40 mg (N=7) n(%)	80 mg (N=9) n(%)	80 mg (no dose reduction) (N=8) n(%)	All MT-5199 (N=16) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	3 (27.3)	1 (9.1)	1 (11.1)	4 (18.2)	10 (13.9)	15 (22.7)	8 (20.0)	25 (18.1)	9 (25.0)	4 (10.8)	3 (11.1)	13 (17.8)	1 (14.3)	3 (33.3)	2 (25.0)	4 (25.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urticaria	蕁麻疹	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	2 (22.2)	1 (12.5)	2 (12.5)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (6.1)	3 (7.5)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	接触皮膚炎	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	2 (3.0)	1 (2.5)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry skin	皮膚乾燥	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	2 (3.0)	0 (0.0)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	2 (5.6)	1 (2.7)	1 (3.7)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (12.5)	1 (6.3)
Alopecia areata	円形脱毛症	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	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 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Hyperhidrosis	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Blister	水疱	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhage subcutaneous	皮下出血	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ingrowing nail	嵌入爪	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin fissures	皮膚亀裂	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin ulcer	皮膚潰瘍	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Hand dermatitis	手皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	3 (27.3)	2 (18.2)	2 (22.2)	5 (22.7)	14 (19.4)	13 (19.7)	8 (20.0)	27 (19.6)	7 (19.4)	8 (21.6)	6 (22.2)	15 (20.5)	3 (42.9)	0 (0.0)	0 (0.0)	3 (18.8)
Back pain	背部痛	1 (9.1)	1 (9.1)	1 (11.1)	2 (9.1)	5 (6.9)	4 (6.1)	2 (5.0)	9 (6.5)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Arthralgia	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	3 (4.5)	2 (5.0)	4 (2.9)	0 (0.0)	2 (5.4)	2 (7.4)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	1 (2.5)	2 (1.4)	2 (5.6)	2 (5.4)	1 (3.7)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscular weakness	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	2 (3.0)	1 (2.5)	3 (2.2)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Pain in extremity	四肢痛	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Myalgia	筋肉痛	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neck pain	頚部痛	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Posture abnormal	姿勢異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	1 (2.5)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc protrusion	椎間板突出	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoporosis	骨粗鬆症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Periarthritis	関節周囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Tenosynovitis	腱鞘炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Mastication disorder	咀嚼障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Muscle rigidity	筋固縮	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Temporomandibular joint syndrome	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Trigger finger	弾発指	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extremity contracture	四肢拘縮	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot deformity	足変形	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class (MedDRA)	System Organ Class (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	0 (0.0)	2 (18.2)	2 (22.2)	2 (9.1)	2 (2.8)	1 (1.5)	1 (2.5)	3 (2.2)	2 (5.6)	1 (2.7)	0 (0.0)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysuria	排尿困難	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurogenic bladder	神経因性膀胱	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	夜間頻尿	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal glycosuria	腎性糖尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	尿失禁	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention	尿閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bladder prolapse	膀胱脱	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.4)	2 (5.6)	1 (2.7)	1 (3.7)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal discharge	膣分泌物	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Prostatomegaly	前立腺腫大	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	2 (18.2)	3 (27.3)	2 (22.2)	5 (22.7)	16 (22.2)	11 (16.7)	6 (15.0)	27 (19.6)	7 (19.4)	11 (29.7)	7 (25.9)	18 (24.7)	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Malaise	倦怠感	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	7 (9.7)	3 (4.5)	2 (5.0)	10 (7.2)	3 (8.3)	6 (16.2)	3 (11.1)	9 (12.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	口渇	1 (9.1)	1 (9.1)	0 (0.0)	2 (9.1)	4 (5.6)	0 (0.0)	0 (0.0)	4 (2.9)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Fatigue	疲労	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	2 (3.0)	1 (2.5)	4 (2.9)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pyrexia	発熱	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	2 (3.0)	1 (2.5)	3 (2.2)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	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 (5.4)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	死亡	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Calcinosis	石灰沈着症	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chest discomfort	胸部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Feeling hot	熱感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Investigations	臨床検査	2 (18.2)	1 (9.1)	1 (11.1)	3 (13.6)	15 (20.8)	10 (15.2)	5 (12.5)	25 (18.1)	3 (8.3)	4 (10.8)	4 (14.8)	7 (9.6)	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Weight decreased	体重減少	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	3 (4.2)	4 (6.1)	2 (5.0)	7 (5.1)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Weight increased	体重増加	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	5 (6.9)	2 (3.0)	1 (2.5)	7 (5.1)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	4 (6.1)	3 (7.5)	5 (3.6)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	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 (8.1)	3 (11.1)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Blood pressure increased	血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (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)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (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)
Liver function test increased	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood triglycerides increased	血中トリグリセリド増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Blood uric acid increased	血中尿酸増加	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	2 (18.2)	3 (27.3)	3 (33.3)	5 (22.7)	12 (16.7)	13 (19.7)	8 (20.0)	25 (18.1)	5 (13.9)	5 (13.5)	4 (14.8)	10 (13.7)	2 (28.6)	1 (11.1)	0 (0.0)	3 (18.8)
Contusion	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	7 (10.6)	4 (10.0)	9 (6.5)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Fall	転倒	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	5 (7.6)	4 (10.0)	6 (4.3)	0 (0.0)	2 (5.4)	2 (7.4)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin abrasion	皮膚擦過傷	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	1 (1.5)	1 (2.5)	3 (2.2)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (1.5)	0 (0.0)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Thermal burn	熱傷	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	1 (1.5)	0 (0.0)	2 (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)
Heat illness	熱中症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	1 (2.7)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Animal bite	動物咬傷	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ankle fracture	足関節部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (11.1)	0 (0.0)	1 (6.3)
Concussion	脳振盪	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femoral neck fracture	大腿骨頚部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femur fracture	大腿骨骨折	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150 BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Foot fracture	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fractured sacrum	仙骨骨折	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand fracture	手骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint dislocation	関節脱臼	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ligament sprain	靱帯捻挫	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Road traffic accident	交通事故	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Face injury	顔面損傷	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－150　BMI 区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class	System Organ Class	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Tooth fracture	歯牙破折	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid injury	眼瞼損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin wound	皮膚創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.4.2.1 より引用

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Any AESI		9 (81.8)	11 (100.0)	9 (100.0)	20 (90.9)	51 (70.8)	59 (89.4)	34 (85.0)	110 (79.7)	23 (63.9)	31 (83.8)	21 (77.8)	54 (74.0)	5 (71.4)	7 (77.8)	6 (75.0)	12 (75.0)
Somnolence	傾眠関連有害事象	3 (27.3)	2 (18.2)	1 (11.1)	5 (22.7)	21 (29.2)	25 (37.9)	13 (32.5)	46 (33.3)	6 (16.7)	13 (35.1)	8 (29.6)	19 (26.0)	2 (28.6)	0 (0.0)	0 (0.0)	2 (12.5)
Somnolence	傾眠	2 (18.2)	1 (9.1)	1 (11.1)	3 (13.6)	13 (18.1)	19 (28.8)	11 (27.5)	32 (23.2)	3 (8.3)	8 (21.6)	6 (22.2)	11 (15.1)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Malaise	倦怠感	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	7 (9.7)	3 (4.5)	2 (5.0)	10 (7.2)	3 (8.3)	6 (16.2)	3 (11.1)	9 (12.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	疲労	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	2 (3.0)	1 (2.5)	4 (2.9)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (1.5)	0 (0.0)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Asthenia	無力症	0 (0.0)	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 (5.4)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Hypersensitivity	過敏症関連有害事象	2 (18.2)	1 (9.1)	1 (11.1)	3 (13.6)	11 (15.3)	11 (16.7)	9 (22.5)	22 (15.9)	9 (25.0)	3 (8.1)	2 (7.4)	12 (16.4)	1 (14.3)	3 (33.3)	2 (25.0)	4 (25.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	3 (4.5)	3 (7.5)	5 (3.6)	2 (5.6)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urticaria	蕁麻疹	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	2 (22.2)	1 (12.5)	2 (12.5)
Dermatitis contact	接触皮膚炎	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	2 (3.0)	1 (2.5)	2 (1.4)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	2 (5.6)	1 (2.7)	1 (3.7)	3 (4.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (12.5)	1 (6.3)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Blister	水疱	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Erythema	紅斑	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Parkinsonism	パーキンソニズム関連有害事象	1 (9.1)	5 (45.5)	4 (44.4)	6 (27.3)	13 (18.1)	28 (42.4)	12 (30.0)	41 (29.7)	9 (25.0)	15 (40.5)	8 (29.6)	24 (32.9)	1 (14.3)	2 (22.2)	1 (12.5)	3 (18.8)
Salivary hypersecretion	流涎過多	0 (0.0)	3 (27.3)	3 (33.3)	3 (13.6)	5 (6.9)	11 (16.7)	3 (7.5)	16 (11.6)	4 (11.1)	7 (18.9)	4 (14.8)	11 (15.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tremor	振戦	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	9 (13.6)	5 (12.5)	10 (7.2)	3 (8.3)	5 (13.5)	3 (11.1)	8 (11.0)	0 (0.0)	2 (22.2)	1 (12.5)	2 (12.5)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (5.6)	3 (4.5)	2 (5.0)	7 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	3 (4.5)	1 (2.5)	4 (2.9)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Drooling	よだれ	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	2 (3.0)	1 (2.5)	4 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradykinesia	運動緩慢	0 (0.0)	1 (9.1)	0 (0.0)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151 BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	4 (36.4)	1 (9.1)	1 (11.1)	5 (22.7)	9 (12.5)	9 (13.6)	7 (17.5)	18 (13.0)	2 (5.6)	8 (21.6)	6 (22.2)	10 (13.7)	4 (57.1)	1 (11.1)	1 (12.5)	5 (31.3)
Depression	うつ病	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	3 (4.2)	3 (4.5)	3 (7.5)	6 (4.3)	2 (5.6)	5 (13.5)	4 (14.8)	7 (9.6)	1 (14.3)	1 (11.1)	1 (12.5)	2 (12.5)
Suicidal ideation	自殺念慮	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	1 (1.4)	2 (3.0)	1 (2.5)	3 (2.2)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	3 (42.9)	0 (0.0)	0 (0.0)	3 (18.8)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (1.5)	1 (2.5)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Middle insomnia	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major depression	大うつ病	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (2.5)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac events	心血管系及びQT間隔延長関連有害事象	1 (9.1)	1 (9.1)	1 (11.1)	2 (9.1)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Death	死亡	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Myocardial ischaemia	心筋虚血	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperprolactinemia	高プロラクチン血症関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Akathisia	アカシジア関連有害事象	0 (0.0)	2 (18.2)	2 (22.2)	2 (9.1)	6 (8.3)	10 (15.2)	4 (10.0)	16 (11.6)	5 (13.9)	5 (13.5)	3 (11.1)	10 (13.7)	1 (14.3)	2 (22.2)	2 (25.0)	3 (18.8)
Akathisia	アカシジア	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	3 (4.2)	7 (10.6)	3 (7.5)	10 (7.2)	4 (11.1)	2 (5.4)	2 (7.4)	6 (8.2)	1 (14.3)	2 (22.2)	2 (25.0)	3 (18.8)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	3 (4.5)	1 (2.5)	4 (2.9)	1 (2.8)	1 (2.7)	1 (3.7)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	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 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	1 (9.1)	2 (18.2)	1 (11.1)	3 (13.6)	3 (4.2)	5 (7.6)	4 (10.0)	8 (5.8)	0 (0.0)	2 (5.4)	2 (7.4)	2 (2.7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Anxiety	不安	1 (9.1)	2 (18.2)	1 (11.1)	3 (13.6)	3 (4.2)	5 (7.6)	4 (10.0)	8 (5.8)	0 (0.0)	2 (5.4)	2 (7.4)	2 (2.7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	6 (54.5)	1 (9.1)	1 (11.1)	7 (31.8)	16 (22.2)	13 (19.7)	6 (15.0)	29 (21.0)	8 (22.2)	13 (35.1)	10 (37.0)	21 (28.8)	5 (71.4)	2 (22.2)	2 (25.0)	7 (43.8)
Schizophrenia	統合失調症	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	9 (12.5)	8 (12.1)	2 (5.0)	17 (12.3)	6 (16.7)	5 (13.5)	3 (11.1)	11 (15.1)	4 (57.1)	0 (0.0)	0 (0.0)	4 (25.0)
Depression	うつ病	0 (0.0)	1 (9.1)	1 (11.1)	1 (4.5)	3 (4.2)	3 (4.5)	3 (7.5)	6 (4.3)	2 (5.6)	5 (13.5)	4 (14.8)	7 (9.6)	1 (14.3)	1 (11.1)	1 (12.5)	2 (12.5)
Suicidal ideation	自殺念慮	2 (18.2)	0 (0.0)	0 (0.0)	2 (9.1)	1 (1.4)	2 (3.0)	1 (2.5)	3 (2.2)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	3 (42.9)	0 (0.0)	0 (0.0)	3 (18.8)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (1.5)	1 (2.5)	3 (2.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Bipolar disorder	双極性障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	1 (1.5)	1 (2.5)	2 (1.4)	0 (0.0)	1 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (11.1)	1 (12.5)	1 (6.3)
Intentional self-injury	故意の自傷行為	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Major depression	大うつ病	0 (0.0)	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 (2.7)	1 (3.7)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	2 (5.6)	2 (5.4)	1 (3.7)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	2 (5.6)	2 (5.4)	1 (3.7)	4 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151 BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	<18.5 MT-5199 40 mg (N=11) n(%)	<18.5 MT-5199 80 mg (N=11) n(%)	<18.5 MT-5199 80 mg (no dose reduction) (N=9) n(%)	<18.5 All MT-5199 (N=22) n(%)	18.5 to <25 MT-5199 40 mg (N=72) n(%)	18.5 to <25 MT-5199 80 mg (N=66) n(%)	18.5 to <25 MT-5199 80 mg (no dose reduction) (N=40) n(%)	18.5 to <25 All MT-5199 (N=138) n(%)	25 to <30 MT-5199 40 mg (N=36) n(%)	25 to <30 MT-5199 80 mg (N=37) n(%)	25 to <30 MT-5199 80 mg (no dose reduction) (N=27) n(%)	25 to <30 All MT-5199 (N=73) n(%)	>=30 MT-5199 40 mg (N=7) n(%)	>=30 MT-5199 80 mg (N=9) n(%)	>=30 MT-5199 80 mg (no dose reduction) (N=8) n(%)	>=30 All MT-5199 (N=16) n(%)
Hepatotoxicity	肝障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (5.6)	3 (4.5)	2 (5.0)	7 (5.1)	1 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	0 (0.0)	2 (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)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	2 (5.0)	2 (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)
Liver function test increased	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (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)
Hepatic steatosis	脂肪肝	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 (2.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	2 (18.2)	1 (9.1)	1 (11.1)	3 (13.6)	4 (5.6)	9 (13.6)	7 (17.5)	13 (9.4)	0 (0.0)	3 (8.1)	3 (11.1)	3 (4.1)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Dizziness	浮動性めまい	1 (9.1)	1 (9.1)	1 (11.1)	2 (9.1)	2 (2.8)	3 (4.5)	2 (5.0)	5 (3.6)	0 (0.0)	3 (8.1)	3 (11.1)	3 (4.1)	1 (14.3)	0 (0.0)	0 (0.0)	1 (6.3)
Fall	転倒	1 (9.1)	0 (0.0)	0 (0.0)	1 (4.5)	1 (1.4)	5 (7.6)	4 (10.0)	6 (4.3)	0 (0.0)	2 (5.4)	2 (7.4)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	2 (5.0)	2 (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)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－151　BMI 区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI	AESI	<18.5				18.5 to <25				25 to <30				>=30			
		MT-5199				MT-5199				MT-5199				MT-5199			
Preferred Term	Preferred Term	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199	40 mg	80 mg	80 mg (no dose reduction)	All MT-5199
(MedDRA)	(MedDRA) in Japanese	(N=11) n(%)	(N=11) n(%)	(N=9) n(%)	(N=22) n(%)	(N=72) n(%)	(N=66) n(%)	(N=40) n(%)	(N=138) n(%)	(N=36) n(%)	(N=37) n(%)	(N=27) n(%)	(N=73) n(%)	(N=7) n(%)	(N=9) n(%)	(N=8) n(%)	(N=16) n(%)
Cognitive disorder	認知機能低下関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.4.2.2 より引用

表 2.7.4.7－152　BMI 区分ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies								Long-term Exposure			
	NBI-98854				Placebo				NBI-98854			
	<18.5 kg/m^2 (N=7) n (%)	18.5 to <25 kg/m^2 (N=70) n (%)	25 to <30 kg/m^2 (N=82) n (%)	≥30 kg/m^2 (N=95) n (%)	<18.5 kg/m^2 (N=2) n (%)	18.5 to <25 kg/m^2 (N=47) n (%)	25 to <30 kg/m^2 (N=61) n (%)	≥30 kg/m^2 (N=68) n (%)	<18.5 kg/m^2 (N=8) n (%)	18.5 to <25 kg/m^2 (N=116) n (%)	25 to <30 kg/m^2 (N=148) n (%)	≥30 kg/m^2 (N=154) n (%)
At Least 1 AE	1 (14.3)	24 (34.3)	36 (43.9)	50 (52.6)	1 (50.0)	18 (38.3)	23 (37.7)	29 (42.6)	5 (62.5)	67 (57.8)	86 (58.1)	101 (65.6)
At Least 1 SAE	0	1 (1.4)	5 (6.1)	6 (6.3)	0	1 (2.1)	3 (4.9)	2 (2.9)	2 (25.0)	17 (14.7)	13 (8.8)	22 (14.3)
At Least 1 AE Leading to Study Discontinuation	0	0	4 (4.9)	6 (6.3)	0	2 (4.3)	4 (6.6)	2 (2.9)	1 (12.5)	12 (10.3)	15 (10.1)	30 (19.5)
At Least 1 AE Leading to Dose Reduction	0	2 (2.9)	2 (2.4)	3 (3.2)	0	2 (4.3)	1 (1.6)	1 (1.5)	0	8 (6.9)	8 (5.4)	10 (6.5)

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is counted once.

5.3.5.3－2 Table 101 より引用（一部改変）

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

BMI Category: <18.5 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	 40 mg (N=0)	 80 mg (N=5)	 100 mg (N=2)	All NBI-98854 (N=7)	Placebo (N=2)
Any Adverse Event	n (%)	0	0	0	1(50.0)	1(14.3)	1(50.0)
全身障害および投与局所様態	n (%)	0	0	0	1(50.0)	1(14.3)	0
疲労	n (%)	0	0	0	1(50.0)	1(14.3)	0
感染症および寄生虫症	n (%)	0	0	0	1(50.0)	1(14.3)	0
上気道感染	n (%)	0	0	0	1(50.0)	1(14.3)	0
傷害、中毒および処置合併症	n (%)	0	0	0	1(50.0)	1(14.3)	0
節足動物咬傷	n (%)	0	0	0	1(50.0)	1(14.3)	0
神経系障害	n (%)	0	0	0	1(50.0)	1(14.3)	0
傾眠	n (%)	0	0	0	1(50.0)	1(14.3)	0
呼吸器、胸郭および縦隔障害	n (%)	0	0	0	0	0	1(50.0)
咳嗽	n (%)	0	0	0	0	0	1(50.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=29)	 80 mg (N=32)	 100 mg (N=8)	All NBI-98854 (N=70)	Placebo (N=47)
Any Adverse Event	n (%)	0	7(24.1)	13(40.6)	4(50.0)	24(34.3)	18(38.3)
血液およびリンパ系障害	n (%)	0	0	1(3.1)	0	1(1.4)	0
白血球減少症	n (%)	0	0	1(3.1)	0	1(1.4)	0
心臓障害	n (%)	0	0	0	0	0	1(2.1)
心筋梗塞	n (%)	0	0	0	0	0	1(2.1)
耳および迷路障害	n (%)	0	1(3.4)	0	0	1(1.4)	0
耳鳴	n (%)	0	1(3.4)	0	0	1(1.4)	0
眼障害	n (%)	0	0	0	1(12.5)	1(1.4)	0
霧視	n (%)	0	0	0	1(12.5)	1(1.4)	0
胃腸障害	n (%)	0	4(13.8)	2(6.3)	0	6(8.6)	5(10.6)
口内乾燥	n (%)	0	2(6.9)	0	0	2(2.9)	0
嘔吐	n (%)	0	1(3.4)	1(3.1)	0	2(2.9)	0
下痢	n (%)	0	1(3.4)	0	0	1(1.4)	2(4.3)
嚥下障害	n (%)	0	1(3.4)	0	0	1(1.4)	0
メレナ	n (%)	0	1(3.4)	0	0	1(1.4)	0
悪心	n (%)	0	0	1(3.1)	0	1(1.4)	1(2.1)
流涎過多	n (%)	0	0	1(3.1)	0	1(1.4)	0
上腹部痛	n (%)	0	0	0	0	0	1(2.1)
舌痛	n (%)	0	0	0	0	0	1(2.1)
歯痛	n (%)	0	0	0	0	0	1(2.1)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=29)	 80 mg (N=32)	 100 mg (N=8)	All NBI-98854 (N=70)	Placebo (N=47)
全身障害および投与局所様態	n (%)	0	1(3.4)	1(3.1)	0	2(2.9)	3(6.4)
疲労	n (%)	0	1(3.4)	1(3.1)	0	2(2.9)	2(4.3)
口渇	n (%)	0	1(3.4)	0	0	1(1.4)	0
易刺激性	n (%)	0	0	0	0	0	1(2.1)
感染症および寄生虫症	n (%)	0	1(3.4)	0	1(12.5)	2(2.9)	3(6.4)
ウイルス性胃腸炎	n (%)	0	1(3.4)	0	0	1(1.4)	0
鼻咽頭炎	n (%)	0	0	0	1(12.5)	1(1.4)	1(2.1)
尿路感染	n (%)	0	0	0	0	0	2(4.3)
傷害、中毒および処置合併症	n (%)	0	0	2(6.3)	0	2(2.9)	1(2.1)
転倒・転落	n (%)	0	0	1(3.1)	0	1(1.4)	0
四肢損傷	n (%)	0	0	1(3.1)	0	1(1.4)	0
足骨折	n (%)	0	0	0	0	0	1(2.1)
臨床検査	n (%)	0	1(3.4)	4(12.5)	0	5(7.1)	1(2.1)
血中クレアチニン増加	n (%)	0	0	1(3.1)	0	1(1.4)	0
血中ブドウ糖増加	n (%)	0	0	1(3.1)	0	1(1.4)	0
血圧上昇	n (%)	0	0	1(3.1)	0	1(1.4)	0
尿中ブドウ糖陽性	n (%)	0	0	1(3.1)	0	1(1.4)	0
グリコヘモグロビン増加	n (%)	0	0	1(3.1)	0	1(1.4)	1(2.1)
握力低下	n (%)	0	1(3.4)	0	0	1(1.4)	0
体重増加	n (%)	0	0	1(3.1)	0	1(1.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153 BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=29)	 80 mg (N=32)	 100 mg (N=8)	All NBI-98854 (N=70)	Placebo (N=47)
代謝および栄養障害	n (%)	0	0	2(6.3)	0	2(2.9)	2(4.3)
食欲減退	n (%)	0	0	1(3.1)	0	1(1.4)	2(4.3)
低ナトリウム血症	n (%)	0	0	1(3.1)	0	1(1.4)	0
筋骨格系および結合組織障害	n (%)	0	0	3(9.4)	1(12.5)	4(5.7)	1(2.1)
筋肉痛	n (%)	0	0	1(3.1)	1(12.5)	2(2.9)	0
関節痛	n (%)	0	0	1(3.1)	0	1(1.4)	0
背部痛	n (%)	0	0	1(3.1)	0	1(1.4)	0
滑液包炎	n (%)	0	0	0	0	0	1(2.1)
神経系障害	n (%)	0	5(17.2)	6(18.8)	1(12.5)	12(17.1)	5(10.6)
傾眠	n (%)	0	2(6.9)	3(9.4)	0	5(7.1)	1(2.1)
頭痛	n (%)	0	1(3.4)	1(3.1)	1(12.5)	3(4.3)	1(2.1)
浮動性めまい	n (%)	0	2(6.9)	0	0	2(2.9)	1(2.1)
アカシジア	n (%)	0	1(3.4)	0	0	1(1.4)	0
平衡障害	n (%)	0	0	1(3.1)	0	1(1.4)	0
よだれ	n (%)	0	0	1(3.1)	0	1(1.4)	0
ジスキネジー	n (%)	0	0	1(3.1)	0	1(1.4)	0
ミオクローヌス	n (%)	0	1(3.4)	0	0	1(1.4)	0
振戦	n (%)	0	0	1(3.1)	0	1(1.4)	0
痙攣	n (%)	0	0	0	0	0	1(2.1)
鎮静	n (%)	0	0	0	0	0	1(2.1)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(2.1)
精神障害	n (%)	0	4(13.8)	1(3.1)	0	5(7.1)	3(6.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=29)	 80 mg (N=32)	 100 mg (N=8)	All NBI-98854 (N=70)	Placebo (N=47)
自殺念慮	n (%)	0	2(6.9)	0	0	2(2.9)	2(4.3)
抑うつ症状	n (%)	0	1(3.4)	0	0	1(1.4)	0
ディスフェミア	n (%)	0	1(3.4)	0	0	1(1.4)	0
不眠症	n (%)	0	0	1(3.1)	0	1(1.4)	0
統合失調症	n (%)	0	1(3.4)	0	0	1(1.4)	0
うつ病	n (%)	0	0	0	0	0	1(2.1)
躁病	n (%)	0	0	0	0	0	1(2.1)
精神病性障害	n (%)	0	0	0	0	0	1(2.1)
腎および尿路障害	n (%)	0	0	0	0	0	1(2.1)
血尿	n (%)	0	0	0	0	0	1(2.1)
呼吸器、胸郭および縦隔障害	n (%)	0	0	1(3.1)	1(12.5)	2(2.9)	0
慢性閉塞性肺疾患	n (%)	0	0	0	1(12.5)	1(1.4)	0
鼻閉	n (%)	0	0	1(3.1)	0	1(1.4)	0
皮膚および皮下組織障害	n (%)	0	1(3.4)	0	0	1(1.4)	0
そう痒症	n (%)	0	1(3.4)	0	0	1(1.4)	0
外科および内科処置	n (%)	0	0	0	0	0	1(2.1)
鼓膜切開	n (%)	0	0	0	0	0	1(2.1)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=38)	 80 mg (N=32)	 100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
Any Adverse Event	n (%)	1(50.0)	15(39.5)	18(56.3)	2(20.0)	36(43.9)	23(37.7)
心臓障害	n (%)	0	1(2.6)	0	0	1(1.2)	0
徐脈	n (%)	0	1(2.6)	0	0	1(1.2)	0
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(1.6)
トゥレット病	n (%)	0	0	0	0	0	1(1.6)
耳および迷路障害	n (%)	0	0	0	0	0	1(1.6)
耳痛	n (%)	0	0	0	0	0	1(1.6)
眼障害	n (%)	0	0	0	0	0	1(1.6)
結膜出血	n (%)	0	0	0	0	0	1(1.6)
胃腸障害	n (%)	0	2(5.3)	2(6.3)	1(10.0)	5(6.1)	8(13.1)
口内乾燥	n (%)	0	1(2.6)	0	1(10.0)	2(2.4)	1(1.6)
びらん性胃炎	n (%)	0	0	1(3.1)	0	1(1.2)	0
口腔知覚不全	n (%)	0	1(2.6)	0	0	1(1.2)	0
流涎過多	n (%)	0	0	0	1(10.0)	1(1.2)	0
嘔吐	n (%)	0	0	1(3.1)	0	1(1.2)	0
便秘	n (%)	0	0	0	0	0	2(3.3)
下痢	n (%)	0	0	0	0	0	1(1.6)
消化不良	n (%)	0	0	0	0	0	1(1.6)
排便回数増加	n (%)	0	0	0	0	0	1(1.6)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(1.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=38)	 80 mg (N=32)	 100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
悪心	n (%)	0	0	0	0	0	3(4.9)
全身障害および投与局所様態	n (%)	0	4(10.5)	1(3.1)	1(10.0)	6(7.3)	2(3.3)
疲労	n (%)	0	2(5.3)	1(3.1)	1(10.0)	4(4.9)	1(1.6)
歩行障害	n (%)	0	1(2.6)	0	1(10.0)	2(2.4)	0
胸痛	n (%)	0	1(2.6)	0	0	1(1.2)	0
空腹	n (%)	0	1(2.6)	0	0	1(1.2)	0
末梢性浮腫	n (%)	0	1(2.6)	0	0	1(1.2)	0
発熱	n (%)	0	0	0	0	0	1(1.6)
感染症および寄生虫症	n (%)	0	2(5.3)	1(3.1)	0	3(3.7)	5(8.2)
鼻咽頭炎	n (%)	0	0	1(3.1)	0	1(1.2)	0
副鼻腔炎	n (%)	0	1(2.6)	0	0	1(1.2)	0
尿路感染	n (%)	0	1(2.6)	0	0	1(1.2)	2(3.3)
外陰膣真菌感染	n (%)	0	1(2.6)	0	0	1(1.2)	0
耳感染	n (%)	0	0	0	0	0	1(1.6)
口腔ヘルペス	n (%)	0	0	0	0	0	1(1.6)
上気道感染	n (%)	0	0	0	0	0	1(1.6)
傷害、中毒および処置合併症	n (%)	0	1(2.6)	2(6.3)	0	3(3.7)	0
動物咬傷	n (%)	0	0	1(3.1)	0	1(1.2)	0
第２度熱傷	n (%)	0	0	1(3.1)	0	1(1.2)	0
筋挫傷	n (%)	0	1(2.6)	0	0	1(1.2)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153 BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=38)	 80 mg (N=32)	 100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
臨床検査	n (%)	0	2(5.3)	3(9.4)	1(10.0)	6(7.3)	3(4.9)
体重増加	n (%)	0	1(2.6)	1(3.1)	0	2(2.4)	1(1.6)
血中ブドウ糖増加	n (%)	0	1(2.6)	0	0	1(1.2)	0
血中トリグリセリド増加	n (%)	0	0	0	1(10.0)	1(1.2)	0
尿中結晶陽性	n (%)	0	0	1(3.1)	0	1(1.2)	0
ヘマトクリット減少	n (%)	0	0	1(3.1)	0	1(1.2)	0
ヘモグロビン減少	n (%)	0	0	1(3.1)	0	1(1.2)	0
便潜血陽性	n (%)	0	0	1(3.1)	0	1(1.2)	0
赤血球数減少	n (%)	0	0	1(3.1)	0	1(1.2)	0
赤血球数増加	n (%)	0	0	1(3.1)	0	1(1.2)	0
血中カリウム増加	n (%)	0	0	0	0	0	1(1.6)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	0	0	0	1(1.6)
代謝および栄養障害	n (%)	0	1(2.6)	0	0	1(1.2)	1(1.6)
食欲亢進	n (%)	0	1(2.6)	0	0	1(1.2)	1(1.6)
異常体重減少	n (%)	0	0	0	0	0	1(1.6)
筋骨格系および結合組織障害	n (%)	0	4(10.5)	2(6.3)	0	6(7.3)	1(1.6)
関節痛	n (%)	0	2(5.3)	2(6.3)	0	4(4.9)	0
関節炎	n (%)	0	1(2.6)	0	0	1(1.2)	0
顎関節症候群	n (%)	0	1(2.6)	0	0	1(1.2)	0
四肢痛	n (%)	0	0	0	0	0	1(1.6)
神経系障害	n (%)	0	7(18.4)	5(15.6)	0	12(14.6)	4(6.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153 BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=38)	 80 mg (N=32)	 100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
頭痛	n (%)	0	3(7.9)	2(6.3)	0	5(6.1)	1(1.6)
アカシジア	n (%)	0	2(5.3)	1(3.1)	0	3(3.7)	0
鎮静	n (%)	0	1(2.6)	1(3.1)	0	2(2.4)	0
傾眠	n (%)	0	2(5.3)	0	0	2(2.4)	2(3.3)
注意力障害	n (%)	0	1(2.6)	0	0	1(1.2)	0
よだれ	n (%)	0	0	1(3.1)	0	1(1.2)	0
浮動性めまい	n (%)	0	0	0	0	0	1(1.6)
片頭痛	n (%)	0	0	0	0	0	1(1.6)
精神障害	n (%)	1(50.0)	5(13.2)	6(18.8)	0	12(14.6)	5(8.2)
不安	n (%)	0	1(2.6)	2(6.3)	0	3(3.7)	0
歯ぎしり	n (%)	0	1(2.6)	0	0	1(1.2)	0
うつ病	n (%)	0	0	1(3.1)	0	1(1.2)	1(1.6)
敵意	n (%)	0	1(2.6)	0	0	1(1.2)	0
精神状態変化	n (%)	0	1(2.6)	0	0	1(1.2)	0
神経過敏	n (%)	0	0	1(3.1)	0	1(1.2)	0
パニック発作	n (%)	1(50.0)	0	0	0	1(1.2)	0
妄想症	n (%)	0	1(2.6)	0	0	1(1.2)	0
精神運動制止遅滞	n (%)	0	1(2.6)	0	0	1(1.2)	0
落ち着きのなさ	n (%)	0	1(2.6)	0	0	1(1.2)	0
統合失調感情障害	n (%)	0	0	1(3.1)	0	1(1.2)	1(1.6)
自殺企図	n (%)	0	0	1(3.1)	0	1(1.2)	0
激越	n (%)	0	0	0	0	0	1(1.6)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(1.6)
睡眠障害	n (%)	0	0	0	0	0	1(1.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=38)	 80 mg (N=32)	 100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
腎および尿路障害	n (%)	0	0	0	0	0	1(1.6)
尿閉	n (%)	0	0	0	0	0	1(1.6)
呼吸器、胸郭および縦隔障害	n (%)	0	0	1(3.1)	0	1(1.2)	0
鼻閉	n (%)	0	0	1(3.1)	0	1(1.2)	0
皮膚および皮下組織障害	n (%)	0	0	0	0	0	2(3.3)
多汗症	n (%)	0	0	0	0	0	1(1.6)
発疹	n (%)	0	0	0	0	0	1(1.6)
血管障害	n (%)	0	1(2.6)	2(6.3)	0	3(3.7)	1(1.6)
血腫	n (%)	0	0	1(3.1)	0	1(1.2)	0
高血圧	n (%)	0	1(2.6)	0	0	1(1.2)	1(1.6)
低血圧	n (%)	0	0	1(3.1)	0	1(1.2)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=43)	 80 mg (N=43)	 100 mg (N=7)	All NBI-98854 (N=95)	Placebo (N=68)
Any Adverse Event	n (%)	1(50.0)	26(60.5)	22(51.2)	1(14.3)	50(52.6)	29(42.6)
胃腸障害	n (%)	0	8(18.6)	3(7.0)	0	11(11.6)	8(11.8)
口内乾燥	n (%)	0	4(9.3)	0	0	4(4.2)	2(2.9)
悪心	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	0
嘔吐	n (%)	0	1(2.3)	2(4.7)	0	3(3.2)	1(1.5)
便秘	n (%)	0	2(4.7)	0	0	2(2.1)	3(4.4)
腹部圧痛	n (%)	0	1(2.3)	0	0	1(1.1)	0
消化不良	n (%)	0	1(2.3)	0	0	1(1.1)	0
嚥下障害	n (%)	0	1(2.3)	0	0	1(1.1)	0
流涎過多	n (%)	0	0	1(2.3)	0	1(1.1)	0
臍ヘルニア	n (%)	0	1(2.3)	0	0	1(1.1)	0
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(1.5)
歯肉炎	n (%)	0	0	0	0	0	1(1.5)
全身障害および投与局所様態	n (%)	0	5(11.6)	3(7.0)	0	8(8.4)	2(2.9)
疲労	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	0
末梢性浮腫	n (%)	0	2(4.7)	0	0	2(2.1)	1(1.5)
歩行障害	n (%)	0	1(2.3)	0	0	1(1.1)	0
易刺激性	n (%)	0	1(2.3)	0	0	1(1.1)	1(1.5)
疼痛	n (%)	0	1(2.3)	0	0	1(1.1)	0
発熱	n (%)	0	0	1(2.3)	0	1(1.1)	0
突然死	n (%)	0	0	1(2.3)	0	1(1.1)	0
肝胆道系障害	n (%)	0	0	1(2.3)	0	1(1.1)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153 BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=43)	 80 mg (N=43)	 100 mg (N=7)	All NBI-98854 (N=95)	Placebo (N=68)
急性肝炎	n (%)	0	0	1(2.3)	0	1(1.1)	0
黄疸	n (%)	0	0	1(2.3)	0	1(1.1)	0
感染症および寄生虫症	n (%)	0	7(16.3)	2(4.7)	1(14.3)	10(10.5)	6(8.8)
尿路感染	n (%)	0	3(7.0)	1(2.3)	1(14.3)	5(5.3)	4(5.9)
ダニ皮膚炎	n (%)	0	1(2.3)	0	0	1(1.1)	0
体部白癬	n (%)	0	1(2.3)	0	0	1(1.1)	0
せつ	n (%)	0	1(2.3)	0	0	1(1.1)	0
インフルエンザ	n (%)	0	1(2.3)	0	0	1(1.1)	0
鼻咽頭炎	n (%)	0	1(2.3)	0	0	1(1.1)	0
急性腎盂腎炎	n (%)	0	1(2.3)	0	0	1(1.1)	0
上気道感染	n (%)	0	0	1(2.3)	0	1(1.1)	0
気管支炎	n (%)	0	0	0	0	0	1(1.5)
ウイルス感染	n (%)	0	0	0	0	0	1(1.5)
傷害、中毒および処置合併症	n (%)	0	4(9.3)	0	0	4(4.2)	2(2.9)
転倒・転落	n (%)	0	2(4.7)	0	0	2(2.1)	0
関節損傷	n (%)	0	1(2.3)	0	0	1(1.1)	0
交通事故	n (%)	0	1(2.3)	0	0	1(1.1)	0
むち打ち損傷	n (%)	0	1(2.3)	0	0	1(1.1)	0
節足動物咬傷	n (%)	0	0	0	0	0	1(1.5)
処置による疼痛	n (%)	0	0	0	0	0	1(1.5)
臨床検査	n (%)	1(50.0)	2(4.7)	3(7.0)	0	6(6.3)	2(2.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=43)	 80 mg (N=43)	 100 mg (N=7)	All NBI-98854 (N=95)	 Placebo (N=68)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	2(4.7)	0	2(2.1)	0
血中クレアチンホスホキナーゼ増加	n (%)	0	1(2.3)	0	0	1(1.1)	0
血中クレアチニン増加	n (%)	0	1(2.3)	0	0	1(1.1)	0
血中ブドウ糖増加	n (%)	0	0	1(2.3)	0	1(1.1)	0
血中尿素増加	n (%)	0	1(2.3)	0	0	1(1.1)	0
肝酵素上昇	n (%)	1(50.0)	0	0	0	1(1.1)	1(1.5)
血中ビリルビン増加	n (%)	0	0	0	0	0	1(1.5)
好中球数増加	n (%)	0	0	0	0	0	1(1.5)
白血球数増加	n (%)	0	0	0	0	0	1(1.5)
代謝および栄養障害	n (%)	0	2(4.7)	3(7.0)	0	5(5.3)	2(2.9)
食欲減退	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	0
食欲亢進	n (%)	0	0	2(4.7)	0	2(2.1)	0
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(1.5)
低血糖症	n (%)	0	0	0	0	0	1(1.5)
筋骨格系および結合組織障害	n (%)	0	5(11.6)	1(2.3)	0	6(6.3)	3(4.4)
背部痛	n (%)	0	2(4.7)	0	0	2(2.1)	0
筋力低下	n (%)	0	2(4.7)	0	0	2(2.1)	0
関節痛	n (%)	0	1(2.3)	0	0	1(1.1)	1(1.5)
四肢不快感	n (%)	0	1(2.3)	0	0	1(1.1)	0
筋痙縮	n (%)	0	0	1(2.3)	0	1(1.1)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=43)	 80 mg (N=43)	 100 mg (N=7)	All NBI-98854 (N=95)	Placebo (N=68)
関節腫脹	n (%)	0	0	0	0	0	1(1.5)
筋骨格硬直	n (%)	0	0	0	0	0	1(1.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(1.5)
口腔乳頭腫	n (%)	0	0	0	0	0	1(1.5)
神経系障害	n (%)	0	5(11.6)	8(18.6)	1(14.3)	14(14.7)	7(10.3)
傾眠	n (%)	0	5(11.6)	1(2.3)	0	6(6.3)	1(1.5)
アカシジア	n (%)	0	0	2(4.7)	0	2(2.1)	1(1.5)
ジスキネジー	n (%)	0	0	2(4.7)	0	2(2.1)	0
頭痛	n (%)	0	0	2(4.7)	0	2(2.1)	2(2.9)
ジストニー	n (%)	0	0	1(2.3)	0	1(1.1)	0
感覚鈍麻	n (%)	0	0	1(2.3)	0	1(1.1)	1(1.5)
睡眠の質低下	n (%)	0	1(2.3)	0	0	1(1.1)	0
鎮静	n (%)	0	0	1(2.3)	0	1(1.1)	0
失神	n (%)	0	0	0	1(14.3)	1(1.1)	0
咬舌	n (%)	0	1(2.3)	0	0	1(1.1)	0
振戦	n (%)	0	0	1(2.3)	0	1(1.1)	0
浮動性めまい	n (%)	0	0	0	0	0	2(2.9)
精神障害	n (%)	1(50.0)	5(11.6)	5(11.6)	0	11(11.6)	6(8.8)
不眠症	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	1(1.5)
自殺念慮	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	2(2.9)
双極１型障害	n (%)	0	1(2.3)	0	0	1(1.1)	0
抑うつ気分	n (%)	1(50.0)	0	0	0	1(1.1)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	 40 mg (N=43)	 80 mg (N=43)	 100 mg (N=7)	All NBI-98854 (N=95)	Placebo (N=68)
うつ病	n (%)	0	0	1(2.3)	0	1(1.1)	0
軽躁	n (%)	0	1(2.3)	0	0	1(1.1)	0
パニック発作	n (%)	0	0	1(2.3)	0	1(1.1)	0
精神病性障害	n (%)	0	0	1(2.3)	0	1(1.1)	1(1.5)
抑うつ症状	n (%)	0	0	0	0	0	1(1.5)
精神状態変化	n (%)	0	0	0	0	0	1(1.5)
統合失調症	n (%)	0	0	0	0	0	1(1.5)
腎および尿路障害	n (%)	0	0	0	0	0	1(1.5)
糖尿	n (%)	0	0	0	0	0	1(1.5)
生殖系および乳房障害	n (%)	0	0	1(2.3)	0	1(1.1)	2(2.9)
月経過多	n (%)	0	0	1(2.3)	0	1(1.1)	0
腟出血	n (%)	0	0	0	0	0	2(2.9)
呼吸器、胸郭および縦隔障害	n (%)	0	1(2.3)	0	0	1(1.1)	1(1.5)
慢性閉塞性肺疾患	n (%)	0	1(2.3)	0	0	1(1.1)	1(1.5)
皮膚および皮下組織障害	n (%)	0	1(2.3)	2(4.7)	0	3(3.2)	3(4.4)
網状皮斑	n (%)	0	1(2.3)	0	0	1(1.1)	0
発疹	n (%)	0	0	1(2.3)	0	1(1.1)	0
斑状丘疹状皮疹	n (%)	0	0	1(2.3)	0	1(1.1)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－153　BMI区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a]				All NBI-98854	Placebo
		<40 mg (N=2)	40 mg (N=43)	80 mg (N=43)	100 mg (N=7)	(N=95)	(N=68)
ケラトアカントーマ	n (%)	0	0	0	0	0	1(1.5)
そう痒症	n (%)	0	0	0	0	0	2(2.9)
乾癬	n (%)	0	0	0	0	0	1(1.5)
外科および内科処置	n (%)	0	0	1(2.3)	0	1(1.1)	0
抜歯	n (%)	0	0	1(2.3)	0	1(1.1)	0
血管障害	n (%)	0	0	1(2.3)	0	1(1.1)	1(1.5)
ほてり	n (%)	0	0	1(2.3)	0	1(1.1)	1(1.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.5より引用（一部改変）

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）

BMI Category: <18.5 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	40 mg (N=0)	80 mg (N=5)	100 mg (N=2)	All NBI-98854 (N=7)	Placebo (N=2)
Any Adverse Event of Special Interest	n (%)	0	0	0	1(50.0)	1(14.3)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	0	0	1(50.0)	1(14.3)	0
疲労	n (%)	0	0	0	1(50.0)	1(14.3)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	0	0	1(50.0)	1(14.3)	0
傾眠	n (%)	0	0	0	1(50.0)	1(14.3)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	40 mg (N=29)	80 mg (N=32)	100 mg (N=8)	All NBI-98854 (N=70)	Placebo (N=47)
Any Adverse Event of Special Interest	n (%)	0	7(24.1)	6(18.8)	0	13(18.6)	9(19.1)
アカシジア関連有害事象	n (%)	0	1(3.4)	0	0	1(1.4)	0
アカシジア	n (%)	0	1(3.4)	0	0	1(1.4)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	0	0	0	1(2.1)
心筋梗塞	n (%)	0	0	0	0	0	1(2.1)
うつ病及び自殺関連有害事象	n (%)	0	3(10.3)	0	0	3(4.3)	2(4.3)
自殺念慮	n (%)	0	2(6.9)	0	0	2(2.9)	2(4.3)
抑うつ症状	n (%)	0	1(3.4)	0	0	1(1.4)	0
うつ病	n (%)	0	0	0	0	0	1(2.1)
嚥下障害関連有害事象	n (%)	0	1(3.4)	0	0	1(1.4)	0
嚥下障害	n (%)	0	1(3.4)	0	0	1(1.4)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(3.4)	1(3.1)	0	2(2.9)	2(4.3)
疲労	n (%)	0	1(3.4)	1(3.1)	0	2(2.9)	2(4.3)
低血圧関連有害事象	n (%)	0	2(6.9)	1(3.1)	0	3(4.3)	1(2.1)
浮動性めまい	n (%)	0	2(6.9)	0	0	2(2.9)	1(2.1)
転倒・転落	n (%)	0	0	1(3.1)	0	1(1.4)	0
パーキンソニズム関連有害事象	n (%)	0	0	1(3.1)	0	1(1.4)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	40 mg (N=29)	80 mg (N=32)	100 mg (N=8)	All NBI-98854 (N=70)	Placebo (N=47)
振戦	n (%)	0	0	1(3.1)	0	1(1.4)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	2(6.9)	3(9.4)	0	5(7.1)	2(4.3)
傾眠	n (%)	0	2(6.9)	3(9.4)	0	5(7.1)	1(2.1)
鎮静	n (%)	0	0	0	0	0	1(2.1)
基礎疾患の悪化に関連する有害事象	n (%)	0	3(10.3)	0	0	3(4.3)	4(8.5)
自殺念慮	n (%)	0	2(6.9)	0	0	2(2.9)	2(4.3)
抑うつ症状	n (%)	0	1(3.4)	0	0	1(1.4)	0
統合失調症	n (%)	0	1(3.4)	0	0	1(1.4)	0
うつ病	n (%)	0	0	0	0	0	1(2.1)
易刺激性	n (%)	0	0	0	0	0	1(2.1)
躁病	n (%)	0	0	0	0	0	1(2.1)
精神病性障害	n (%)	0	0	0	0	0	1(2.1)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

BMI Category: 25 - <30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	40 mg (N=38)	80 mg (N=32)	100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
Any Adverse Event of Special Interest	n (%)	0	9(23.7)	7(21.9)	1(10.0)	17(20.7)	6(9.8)
アカシジア関連有害事象	n (%)	0	2(5.3)	1(3.1)	0	3(3.7)	0
アカシジア	n (%)	0	2(5.3)	1(3.1)	0	3(3.7)	0
不安	n (%)	0	1(2.6)	2(6.3)	0	3(3.7)	0
不安	n (%)	0	1(2.6)	2(6.3)	0	3(3.7)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(2.6)	0	0	1(1.2)	0
胸痛	n (%)	0	1(2.6)	0	0	1(1.2)	0
うつ病及び自殺関連有害事象	n (%)	0	0	2(6.3)	0	2(2.4)	1(1.6)
うつ病	n (%)	0	0	1(3.1)	0	1(1.2)	1(1.6)
自殺企図	n (%)	0	0	1(3.1)	0	1(1.2)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	2(5.3)	1(3.1)	1(10.0)	4(4.9)	1(1.6)
疲労	n (%)	0	2(5.3)	1(3.1)	1(10.0)	4(4.9)	1(1.6)
低血圧関連有害事象	n (%)	0	0	1(3.1)	0	1(1.2)	1(1.6)
低血圧	n (%)	0	0	1(3.1)	0	1(1.2)	0
浮動性めまい	n (%)	0	0	0	0	0	1(1.6)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	3(7.9)	1(3.1)	0	4(4.9)	2(3.3)
鎮静	n (%)	0	1(2.6)	1(3.1)	0	2(2.4)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

BMI Category: 25 - <30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	40 mg (N=38)	80 mg (N=32)	100 mg (N=10)	All NBI-98854 (N=82)	Placebo (N=61)
傾眠	n (%)	0	2(5.3)	0	0	2(2.4)	2(3.3)
基礎疾患の悪化に関連する有害事象	n (%)	0	2(5.3)	3(9.4)	0	5(6.1)	3(4.9)
うつ病	n (%)	0	0	1(3.1)	0	1(1.2)	1(1.6)
敵意	n (%)	0	1(2.6)	0	0	1(1.2)	0
妄想症	n (%)	0	1(2.6)	0	0	1(1.2)	0
統合失調感情障害	n (%)	0	0	1(3.1)	0	1(1.2)	1(1.6)
自殺企図	n (%)	0	0	1(3.1)	0	1(1.2)	0
統合失調症、妄想型	n (%)	0	0	0	0	0	1(1.6)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

BMI Category: >=30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	40 mg (N=43)	80 mg (N=43)	100 mg (N=7)	All NBI-98854 (N=95)	Placebo (N=68)
Any Adverse Event of Special Interest	n (%)	1(50.0)	12(27.9)	10(23.3)	1(14.3)	24(25.3)	9(13.2)
アカシジア関連有害事象	n (%)	0	0	2(4.7)	0	2(2.1)	1(1.5)
アカシジア	n (%)	0	0	2(4.7)	0	2(2.1)	1(1.5)
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	1(2.3)	1(14.3)	2(2.1)	0
突然死	n (%)	0	0	1(2.3)	0	1(1.1)	0
失神	n (%)	0	0	0	1(14.3)	1(1.1)	0
うつ病及び自殺関連有害事象	n (%)	1(50.0)	2(4.7)	2(4.7)	0	5(5.3)	3(4.4)
自殺念慮	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	2(2.9)
抑うつ気分	n (%)	1(50.0)	0	0	0	1(1.1)	0
うつ病	n (%)	0	0	1(2.3)	0	1(1.1)	0
抑うつ症状	n (%)	0	0	0	0	0	1(1.5)
嚥下障害関連有害事象	n (%)	0	1(2.3)	0	0	1(1.1)	0
嚥下障害	n (%)	0	1(2.3)	0	0	1(1.1)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	0
疲労	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	0
肝障害関連有害事象	n (%)	0	0	1(2.3)	0	1(1.1)	0
急性肝炎	n (%)	0	0	1(2.3)	0	1(1.1)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－154　BMI区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

BMI Category: >=30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=2)	40 mg (N=43)	80 mg (N=43)	100 mg (N=7)	All NBI-98854 (N=95)	Placebo (N=68)
低血圧関連有害事象	n (%)	0	2(4.7)	0	1(14.3)	3(3.2)	2(2.9)
転倒・転落	n (%)	0	2(4.7)	0	0	2(2.1)	0
失神	n (%)	0	0	0	1(14.3)	1(1.1)	0
浮動性めまい	n (%)	0	0	0	0	0	2(2.9)
パーキンソニズム関連有害事象	n (%)	0	0	1(2.3)	0	1(1.1)	0
振戦	n (%)	0	0	1(2.3)	0	1(1.1)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	5(11.6)	2(4.7)	0	7(7.4)	1(1.5)
傾眠	n (%)	0	5(11.6)	1(2.3)	0	6(6.3)	1(1.5)
鎮静	n (%)	0	0	1(2.3)	0	1(1.1)	0
基礎疾患の悪化に関連する有害事象	n (%)	1(50.0)	5(11.6)	3(7.0)	0	9(9.5)	6(8.8)
自殺念慮	n (%)	0	2(4.7)	1(2.3)	0	3(3.2)	2(2.9)
双極１型障害	n (%)	0	1(2.3)	0	0	1(1.1)	0
抑うつ気分	n (%)	1(50.0)	0	0	0	1(1.1)	0
うつ病	n (%)	0	0	1(2.3)	0	1(1.1)	0
軽躁	n (%)	0	1(2.3)	0	0	1(1.1)	0
易刺激性	n (%)	0	1(2.3)	0	0	1(1.1)	1(1.5)
精神病性障害	n (%)	0	0	1(2.3)	0	1(1.1)	1(1.5)
抑うつ症状	n (%)	0	0	0	0	0	1(1.5)
統合失調症	n (%)	0	0	0	0	0	1(1.5)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.5より引用（一部改変）

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

BMI Category: <18.5 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=4)	 80 mg (N=4)	 80 mg Only[b] (N=4)	 All NBI-98854 (N=8)
Any Adverse Event	n (%)	1(25.0)	4(100.0)	4(100.0)	5(62.5)
血液およびリンパ系障害	n (%)	0	1(25.0)	1(25.0)	1(12.5)
貧血	n (%)	0	1(25.0)	1(25.0)	1(12.5)
胃腸障害	n (%)	0	2(50.0)	2(50.0)	2(25.0)
下痢	n (%)	0	1(25.0)	1(25.0)	1(12.5)
胃炎	n (%)	0	1(25.0)	1(25.0)	1(12.5)
裂孔ヘルニア	n (%)	0	1(25.0)	1(25.0)	1(12.5)
全身障害および投与局所様態	n (%)	0	1(25.0)	1(25.0)	1(12.5)
末梢性浮腫	n (%)	0	1(25.0)	1(25.0)	1(12.5)
感染症および寄生虫症	n (%)	0	1(25.0)	1(25.0)	1(12.5)
胃腸炎	n (%)	0	1(25.0)	1(25.0)	1(12.5)
臨床検査	n (%)	0	1(25.0)	1(25.0)	1(12.5)
総蛋白減少	n (%)	0	1(25.0)	1(25.0)	1(12.5)
代謝および栄養障害	n (%)	0	1(25.0)	1(25.0)	1(12.5)
低アルブミン血症	n (%)	0	1(25.0)	1(25.0)	1(12.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: <18.5 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=4)	 80 mg (N=4)	 80 mg Only[b] (N=4)	All NBI-98854 (N=8)
筋骨格系および結合組織障害	n (%)	0	1(25.0)	1(25.0)	1(12.5)
骨関節炎	n (%)	0	1(25.0)	1(25.0)	1(12.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	1(25.0)	1(25.0)	1(12.5)
副腎腺腫	n (%)	0	1(25.0)	1(25.0)	1(12.5)
神経系障害	n (%)	1(25.0)	1(25.0)	1(25.0)	2(25.0)
歯車様固縮	n (%)	0	1(25.0)	1(25.0)	1(12.5)
ジストニー	n (%)	1(25.0)	0	0	1(12.5)
振戦	n (%)	0	1(25.0)	1(25.0)	1(12.5)
精神障害	n (%)	1(25.0)	0	0	1(12.5)
躁病	n (%)	1(25.0)	0	0	1(12.5)
腎および尿路障害	n (%)	0	1(25.0)	1(25.0)	1(12.5)
尿失禁	n (%)	0	1(25.0)	1(25.0)	1(12.5)
生殖系および乳房障害	n (%)	1(25.0)	0	0	1(12.5)
乳房圧痛	n (%)	1(25.0)	0	0	1(12.5)
乳汁漏出症	n (%)	1(25.0)	0	0	1(12.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: <18.5 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=4)	 80 mg (N=4)	 80 mg Only[b] (N=4)	 All NBI-98854 (N=8)
腟分泌物	n (%)	1(25.0)	0	0	1(12.5)
呼吸器、胸郭および縦隔障害	n (%)	0	3(75.0)	3(75.0)	3(37.5)
嚢胞性肺疾患	n (%)	0	1(25.0)	1(25.0)	1(12.5)
慢性閉塞性肺疾患	n (%)	0	1(25.0)	1(25.0)	1(12.5)
胸膜線維症	n (%)	0	1(25.0)	1(25.0)	1(12.5)
血管障害	n (%)	1(25.0)	1(25.0)	1(25.0)	2(25.0)
深部静脈血栓症	n (%)	0	1(25.0)	1(25.0)	1(12.5)
ほてり	n (%)	1(25.0)	0	0	1(12.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
Any Adverse Event	n (%)	27(49.1)	40(65.6)	34(61.8)	67(57.8)
血液およびリンパ系障害	n (%)	0	1(1.6)	1(1.8)	1(0.9)
白血球減少症	n (%)	0	1(1.6)	1(1.8)	1(0.9)
心臓障害	n (%)	1(1.8)	3(4.9)	3(5.5)	4(3.4)
左脚ブロック	n (%)	0	1(1.6)	1(1.8)	1(0.9)
心不全	n (%)	0	1(1.6)	1(1.8)	1(0.9)
僧帽弁閉鎖不全症	n (%)	0	1(1.6)	1(1.8)	1(0.9)
頻脈	n (%)	1(1.8)	0	0	1(0.9)
三尖弁閉鎖不全症	n (%)	0	1(1.6)	1(1.8)	1(0.9)
先天性、家族性および遺伝性障害	n (%)	0	1(1.6)	1(1.8)	1(0.9)
弯足	n (%)	0	1(1.6)	1(1.8)	1(0.9)
耳および迷路障害	n (%)	1(1.8)	1(1.6)	1(1.8)	2(1.7)
耳痛	n (%)	0	1(1.6)	1(1.8)	1(0.9)
耳鳴	n (%)	1(1.8)	0	0	1(0.9)
眼障害	n (%)	0	1(1.6)	1(1.8)	1(0.9)
複視	n (%)	0	1(1.6)	1(1.8)	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
胃腸障害	n (%)	9(16.4)	13(21.3)	10(18.2)	22(19.0)
口内乾燥	n (%)	4(7.3)	1(1.6)	1(1.8)	5(4.3)
嘔吐	n (%)	2(3.6)	3(4.9)	3(5.5)	5(4.3)
便秘	n (%)	0	4(6.6)	3(5.5)	4(3.4)
下痢	n (%)	1(1.8)	3(4.9)	3(5.5)	4(3.4)
悪心	n (%)	1(1.8)	2(3.3)	2(3.6)	3(2.6)
腹痛	n (%)	0	2(3.3)	1(1.8)	2(1.7)
嚥下障害	n (%)	2(3.6)	0	0	2(1.7)
流涎過多	n (%)	0	2(3.3)	1(1.8)	2(1.7)
上腹部痛	n (%)	0	1(1.6)	0	1(0.9)
胃腸出血	n (%)	1(1.8)	0	0	1(0.9)
メレナ	n (%)	1(1.8)	0	0	1(0.9)
食道食物嵌入	n (%)	1(1.8)	0	0	1(0.9)
食道狭窄	n (%)	1(1.8)	0	0	1(0.9)
食道炎	n (%)	1(1.8)	0	0	1(0.9)
歯の脱落	n (%)	1(1.8)	0	0	1(0.9)
歯痛	n (%)	1(1.8)	0	0	1(0.9)
全身障害および投与局所様態	n (%)	5(9.1)	9(14.8)	7(12.7)	14(12.1)
疲労	n (%)	3(5.5)	4(6.6)	4(7.3)	7(6.0)
無力症	n (%)	0	2(3.3)	0	2(1.7)
胸痛	n (%)	1(1.8)	0	0	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155 BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
歩行障害	n (%)	1(1.8)	0	0	1(0.9)
倦怠感	n (%)	0	1(1.6)	1(1.8)	1(0.9)
疼痛	n (%)	0	1(1.6)	1(1.8)	1(0.9)
発熱	n (%)	0	1(1.6)	1(1.8)	1(0.9)
口渇	n (%)	1(1.8)	0	0	1(0.9)
肝胆道系障害	n (%)	0	1(1.6)	1(1.8)	1(0.9)
肝不全	n (%)	0	1(1.6)	1(1.8)	1(0.9)
感染症および寄生虫症	n (%)	7(12.7)	11(18.0)	10(18.2)	18(15.5)
鼻咽頭炎	n (%)	3(5.5)	3(4.9)	3(5.5)	6(5.2)
尿路感染	n (%)	1(1.8)	4(6.6)	4(7.3)	5(4.3)
上気道感染	n (%)	2(3.6)	1(1.6)	1(1.8)	3(2.6)
急性副鼻腔炎	n (%)	1(1.8)	1(1.6)	1(1.8)	2(1.7)
蜂巣炎	n (%)	0	2(3.3)	1(1.8)	2(1.7)
ウイルス性胃腸炎	n (%)	2(3.6)	0	0	2(1.7)
四肢膿瘍	n (%)	0	1(1.6)	0	1(0.9)
憩室炎	n (%)	0	1(1.6)	1(1.8)	1(0.9)
耳感染	n (%)	0	1(1.6)	1(1.8)	1(0.9)
咬傷感染	n (%)	0	1(1.6)	1(1.8)	1(0.9)
爪真菌症	n (%)	1(1.8)	0	0	1(0.9)
咽頭炎	n (%)	1(1.8)	0	0	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
傷害、中毒および処置合併症	n (%)	5(9.1)	8(13.1)	6(10.9)	13(11.2)
転倒・転落	n (%)	2(3.6)	2(3.3)	2(3.6)	4(3.4)
挫傷	n (%)	2(3.6)	1(1.6)	1(1.8)	3(2.6)
節足動物咬傷	n (%)	0	1(1.6)	0	1(0.9)
擦過傷	n (%)	0	1(1.6)	1(1.8)	1(0.9)
頭部損傷	n (%)	1(1.8)	0	0	1(0.9)
関節脱臼	n (%)	0	1(1.6)	1(1.8)	1(0.9)
四肢損傷	n (%)	0	1(1.6)	0	1(0.9)
四肢外傷性切断	n (%)	1(1.8)	0	0	1(0.9)
橈骨骨折	n (%)	0	1(1.6)	1(1.8)	1(0.9)
交通事故	n (%)	0	1(1.6)	1(1.8)	1(0.9)
皮下血腫	n (%)	0	1(1.6)	1(1.8)	1(0.9)
臨床検査	n (%)	3(5.5)	9(14.8)	8(14.5)	12(10.3)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	2(3.3)	2(3.6)	2(1.7)
尿中ブドウ糖陽性	n (%)	0	2(3.3)	2(3.6)	2(1.7)
体重減少	n (%)	1(1.8)	1(1.6)	1(1.8)	2(1.7)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(1.8)	0	0	1(0.9)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(1.8)	0	0	1(0.9)
血中クレアチニン増加	n (%)	0	1(1.6)	0	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
血中ブドウ糖増加	n (%)	0	1(1.6)	1(1.8)	1(0.9)
血圧上昇	n (%)	0	1(1.6)	1(1.8)	1(0.9)
グリコヘモグロビン増加	n (%)	0	1(1.6)	1(1.8)	1(0.9)
握力低下	n (%)	1(1.8)	0	0	1(0.9)
ヘマトクリット減少	n (%)	0	1(1.6)	1(1.8)	1(0.9)
ヘモグロビン減少	n (%)	0	1(1.6)	1(1.8)	1(0.9)
体重増加	n (%)	0	1(1.6)	1(1.8)	1(0.9)
代謝および栄養障害	n (%)	1(1.8)	5(8.2)	3(5.5)	6(5.2)
食欲減退	n (%)	0	1(1.6)	1(1.8)	1(0.9)
糖尿病	n (%)	0	1(1.6)	1(1.8)	1(0.9)
耐糖能障害	n (%)	1(1.8)	0	0	1(0.9)
高カリウム血症	n (%)	0	1(1.6)	1(1.8)	1(0.9)
低ナトリウム血症	n (%)	0	1(1.6)	0	1(0.9)
低ナトリウム血症候群	n (%)	0	1(1.6)	1(1.8)	1(0.9)
食欲亢進	n (%)	0	1(1.6)	0	1(0.9)
代謝性アシドーシス	n (%)	0	1(1.6)	1(1.8)	1(0.9)
筋骨格系および結合組織障害	n (%)	4(7.3)	7(11.5)	5(9.1)	11(9.5)
筋肉痛	n (%)	1(1.8)	1(1.6)	1(1.8)	2(1.7)
四肢痛	n (%)	0	2(3.3)	1(1.8)	2(1.7)
関節痛	n (%)	0	1(1.6)	1(1.8)	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
関節炎	n (%)	0	1(1.6)	0	1(0.9)
背部痛	n (%)	1(1.8)	0	0	1(0.9)
滑液包炎	n (%)	1(1.8)	0	0	1(0.9)
尾骨痛	n (%)	0	1(1.6)	1(1.8)	1(0.9)
椎間板変性症	n (%)	0	1(1.6)	1(1.8)	1(0.9)
関節腫脹	n (%)	0	1(1.6)	1(1.8)	1(0.9)
筋骨格系胸痛	n (%)	1(1.8)	0	0	1(0.9)
頚部痛	n (%)	0	1(1.6)	0	1(0.9)
顎痛	n (%)	1(1.8)	0	0	1(0.9)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	1(1.8)	0	0	1(0.9)
肺新生物	n (%)	1(1.8)	0	0	1(0.9)
神経系障害	n (%)	12(21.8)	15(24.6)	10(18.2)	27(23.3)
傾眠	n (%)	5(9.1)	5(8.2)	2(3.6)	10(8.6)
頭痛	n (%)	2(3.6)	5(8.2)	4(7.3)	7(6.0)
浮動性めまい	n (%)	3(5.5)	3(4.9)	3(5.5)	6(5.2)
失神	n (%)	2(3.6)	1(1.6)	1(1.8)	3(2.6)
アカシジア	n (%)	1(1.8)	0	0	1(0.9)
平衡障害	n (%)	0	1(1.6)	1(1.8)	1(0.9)
注意力障害	n (%)	0	1(1.6)	1(1.8)	1(0.9)
よだれ	n (%)	0	1(1.6)	1(1.8)	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
ジスキネジー	n (%)	0	1(1.6)	1(1.8)	1(0.9)
顔面神経麻痺	n (%)	0	1(1.6)	1(1.8)	1(0.9)
企図振戦	n (%)	1(1.8)	0	0	1(0.9)
片頭痛	n (%)	1(1.8)	0	0	1(0.9)
ミオクローヌス	n (%)	1(1.8)	0	0	1(0.9)
鎮静	n (%)	1(1.8)	0	0	1(0.9)
遅発性ジスキネジー	n (%)	1(1.8)	0	0	1(0.9)
振戦	n (%)	0	1(1.6)	0	1(0.9)
妊娠、産褥および周産期の状態	n (%)	0	1(1.6)	1(1.8)	1(0.9)
自然流産	n (%)	0	1(1.6)	1(1.8)	1(0.9)
精神障害	n (%)	12(21.8)	9(14.8)	7(12.7)	21(18.1)
自殺念慮	n (%)	4(7.3)	2(3.3)	2(3.6)	6(5.2)
統合失調症	n (%)	3(5.5)	1(1.6)	1(1.8)	4(3.4)
不安	n (%)	1(1.8)	2(3.3)	1(1.8)	3(2.6)
うつ病	n (%)	3(5.5)	0	0	3(2.6)
不眠症	n (%)	0	3(4.9)	3(5.5)	3(2.6)
精神病性障害	n (%)	1(1.8)	1(1.6)	0	2(1.7)
錯乱状態	n (%)	0	1(1.6)	1(1.8)	1(0.9)
抑うつ症状	n (%)	1(1.8)	0	0	1(0.9)
ディスフェミア	n (%)	1(1.8)	0	0	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
精神状態変化	n (%)	1(1.8)	0	0	1(0.9)
外傷後ストレス障害	n (%)	1(1.8)	0	0	1(0.9)
落ち着きのなさ	n (%)	0	1(1.6)	0	1(0.9)
自殺企図	n (%)	0	1(1.6)	1(1.8)	1(0.9)
腎および尿路障害	n (%)	0	3(4.9)	3(5.5)	3(2.6)
血尿	n (%)	0	1(1.6)	1(1.8)	1(0.9)
腎結石症	n (%)	0	1(1.6)	1(1.8)	1(0.9)
頻尿	n (%)	0	1(1.6)	1(1.8)	1(0.9)
生殖系および乳房障害	n (%)	2(3.6)	3(4.9)	3(5.5)	5(4.3)
良性前立腺肥大症	n (%)	1(1.8)	1(1.6)	1(1.8)	2(1.7)
月経過多	n (%)	0	1(1.6)	1(1.8)	1(0.9)
前立腺炎	n (%)	1(1.8)	0	0	1(0.9)
精巣捻転	n (%)	0	1(1.6)	1(1.8)	1(0.9)
呼吸器、胸郭および縦隔障害	n (%)	3(5.5)	5(8.2)	5(9.1)	8(6.9)
咳嗽	n (%)	0	3(4.9)	3(5.5)	3(2.6)
呼吸困難	n (%)	1(1.8)	1(1.6)	1(1.8)	2(1.7)
鼻閉	n (%)	0	2(3.3)	2(3.6)	2(1.7)
アレルギー性副鼻腔炎	n (%)	1(1.8)	0	0	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	 80 mg (N=61)	 80 mg Only[b] (N=55)	All NBI-98854 (N=116)
慢性閉塞性肺疾患	n (%)	1(1.8)	0	0	1(0.9)
鼻出血	n (%)	1(1.8)	0	0	1(0.9)
口腔咽頭痛	n (%)	0	1(1.6)	1(1.8)	1(0.9)
胸水	n (%)	0	1(1.6)	1(1.8)	1(0.9)
皮膚および皮下組織障害	n (%)	1(1.8)	2(3.3)	2(3.6)	3(2.6)
過角化	n (%)	0	1(1.6)	1(1.8)	1(0.9)
そう痒症	n (%)	1(1.8)	0	0	1(0.9)
発疹	n (%)	0	1(1.6)	1(1.8)	1(0.9)
皮膚剥脱	n (%)	0	1(1.6)	1(1.8)	1(0.9)
外科および内科処置	n (%)	0	1(1.6)	1(1.8)	1(0.9)
鼓膜切開	n (%)	0	1(1.6)	1(1.8)	1(0.9)
Unknown	n (%)	1(1.8)	0	0	1(0.9)
皮膚嚢腫	n (%)	1(1.8)	0	0	1(0.9)
血管障害	n (%)	1(1.8)	2(3.3)	2(3.6)	3(2.6)
本態性高血圧症	n (%)	1(1.8)	0	0	1(0.9)
血腫	n (%)	0	1(1.6)	1(1.8)	1(0.9)
ほてり	n (%)	0	1(1.6)	1(1.8)	1(0.9)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	All NBI-98854 (N=148)
Any Adverse Event	n (%)	35(53.0)	51(62.2)	44(58.7)	86(58.1)
血液およびリンパ系障害	n (%)	2(3.0)	1(1.2)	1(1.3)	3(2.0)
好中球減少症	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
貧血	n (%)	1(1.5)	0	0	1(0.7)
心臓障害	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
上室性不整脈	n (%)	1(1.5)	0	0	1(0.7)
心房細動	n (%)	0	1(1.2)	1(1.3)	1(0.7)
耳および迷路障害	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
耳介軟骨膜炎	n (%)	0	1(1.2)	1(1.3)	1(0.7)
耳鳴	n (%)	1(1.5)	0	0	1(0.7)
内分泌障害	n (%)	1(1.5)	0	0	1(0.7)
甲状腺機能低下症	n (%)	1(1.5)	0	0	1(0.7)
眼障害	n (%)	0	1(1.2)	1(1.3)	1(0.7)
核性白内障	n (%)	0	1(1.2)	1(1.3)	1(0.7)
黄斑浮腫	n (%)	0	1(1.2)	1(1.3)	1(0.7)
網膜静脈閉塞	n (%)	0	1(1.2)	1(1.3)	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	 All NBI-98854 (N=148)
胃腸障害	n (%)	9(13.6)	11(13.4)	7(9.3)	20(13.5)
嘔吐	n (%)	3(4.5)	2(2.4)	0	5(3.4)
便秘	n (%)	3(4.5)	1(1.2)	0	4(2.7)
上腹部痛	n (%)	2(3.0)	1(1.2)	1(1.3)	3(2.0)
流涎過多	n (%)	2(3.0)	1(1.2)	0	3(2.0)
歯痛	n (%)	1(1.5)	2(2.4)	1(1.3)	3(2.0)
結腸ポリープ	n (%)	2(3.0)	0	0	2(1.4)
下痢	n (%)	0	2(2.4)	2(2.7)	2(1.4)
口内乾燥	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
消化不良	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
痔核	n (%)	2(3.0)	0	0	2(1.4)
腹痛	n (%)	1(1.5)	0	0	1(0.7)
憩室	n (%)	1(1.5)	0	0	1(0.7)
嚥下障害	n (%)	1(1.5)	0	0	1(0.7)
胃炎	n (%)	0	1(1.2)	0	1(0.7)
びらん性胃炎	n (%)	0	1(1.2)	0	1(0.7)
胃食道逆流性疾患	n (%)	0	1(1.2)	1(1.3)	1(0.7)
悪心	n (%)	0	1(1.2)	1(1.3)	1(0.7)
全身障害および投与局所様態	n (%)	6(9.1)	9(11.0)	5(6.7)	15(10.1)
疲労	n (%)	4(6.1)	3(3.7)	3(4.0)	7(4.7)
胸痛	n (%)	1(1.5)	2(2.4)	2(2.7)	3(2.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	All NBI-98854 (N=148)
歩行障害	n (%)	1(1.5)	1(1.2)	0	2(1.4)
無力症	n (%)	0	1(1.2)	0	1(0.7)
空腹	n (%)	1(1.5)	0	0	1(0.7)
非心臓性胸痛	n (%)	0	1(1.2)	0	1(0.7)
末梢性浮腫	n (%)	1(1.5)	0	0	1(0.7)
発熱	n (%)	0	1(1.2)	0	1(0.7)
免疫系障害	n (%)	0	1(1.2)	1(1.3)	1(0.7)
過敏症	n (%)	0	1(1.2)	1(1.3)	1(0.7)
感染症および寄生虫症	n (%)	3(4.5)	20(24.4)	17(22.7)	23(15.5)
尿路感染	n (%)	1(1.5)	7(8.5)	6(8.0)	8(5.4)
鼻咽頭炎	n (%)	1(1.5)	4(4.9)	4(5.3)	5(3.4)
気管支炎	n (%)	0	4(4.9)	3(4.0)	4(2.7)
上気道感染	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
急性扁桃炎	n (%)	0	1(1.2)	1(1.3)	1(0.7)
蜂巣炎	n (%)	0	1(1.2)	1(1.3)	1(0.7)
胃腸炎	n (%)	0	1(1.2)	1(1.3)	1(0.7)
副鼻腔炎	n (%)	0	1(1.2)	0	1(0.7)
皮下組織膿瘍	n (%)	0	1(1.2)	1(1.3)	1(0.7)
外陰腟真菌感染	n (%)	0	1(1.2)	1(1.3)	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	All NBI-98854 (N=148)
傷害、中毒および処置合併症	n (%)	3(4.5)	6(7.3)	5(6.7)	9(6.1)
足骨折	n (%)	0	3(3.7)	2(2.7)	3(2.0)
動物咬傷	n (%)	0	1(1.2)	1(1.3)	1(0.7)
転倒・転落	n (%)	0	1(1.2)	1(1.3)	1(0.7)
関節捻挫	n (%)	1(1.5)	0	0	1(0.7)
筋挫傷	n (%)	0	1(1.2)	1(1.3)	1(0.7)
膝蓋骨骨折	n (%)	0	1(1.2)	1(1.3)	1(0.7)
引っかき傷	n (%)	1(1.5)	0	0	1(0.7)
熱傷	n (%)	1(1.5)	0	0	1(0.7)
臨床検査	n (%)	8(12.1)	12(14.6)	8(10.7)	20(13.5)
体重減少	n (%)	2(3.0)	2(2.4)	1(1.3)	4(2.7)
血中プロラクチン増加	n (%)	2(3.0)	1(1.2)	0	3(2.0)
体重増加	n (%)	1(1.5)	2(2.4)	2(2.7)	3(2.0)
血中トリグリセリド増加	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
ヘモグロビン減少	n (%)	0	2(2.4)	2(2.7)	2(1.4)
抗精神病薬濃度治療量以上	n (%)	0	1(1.2)	0	1(0.7)
血中ブドウ糖減少	n (%)	0	1(1.2)	0	1(0.7)
尿中結晶陽性	n (%)	0	1(1.2)	1(1.3)	1(0.7)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(1.5)	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	 All NBI-98854 (N=148)
グリコヘモグロビン増加	n (%)	0	1(1.2)	0	1(0.7)
ヘマトクリット減少	n (%)	0	1(1.2)	1(1.3)	1(0.7)
肝酵素上昇	n (%)	1(1.5)	0	0	1(0.7)
便潜血陽性	n (%)	0	1(1.2)	1(1.3)	1(0.7)
血小板数減少	n (%)	0	1(1.2)	1(1.3)	1(0.7)
赤血球数減少	n (%)	0	1(1.2)	1(1.3)	1(0.7)
赤血球数増加	n (%)	0	1(1.2)	1(1.3)	1(0.7)
代謝および栄養障害	n (%)	3(4.5)	4(4.9)	3(4.0)	7(4.7)
食欲減退	n (%)	1(1.5)	2(2.4)	1(1.3)	3(2.0)
低ナトリウム血症	n (%)	0	2(2.4)	2(2.7)	2(1.4)
高トリグリセリド血症	n (%)	1(1.5)	0	0	1(0.7)
低カリウム血症	n (%)	0	1(1.2)	1(1.3)	1(0.7)
多飲症	n (%)	1(1.5)	0	0	1(0.7)
筋骨格系および結合組織障害	n (%)	5(7.6)	7(8.5)	4(5.3)	12(8.1)
関節痛	n (%)	1(1.5)	4(4.9)	3(4.0)	5(3.4)
背部痛	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
関節炎	n (%)	1(1.5)	0	0	1(0.7)
筋固縮	n (%)	0	1(1.2)	0	1(0.7)
頚部痛	n (%)	1(1.5)	0	0	1(0.7)
骨減少症	n (%)	1(1.5)	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155 BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	All NBI-98854 (N=148)
四肢痛	n (%)	0	1(1.2)	0	1(0.7)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	1(1.5)	0	0	1(0.7)
脂肪腫	n (%)	1(1.5)	0	0	1(0.7)
神経系障害	n (%)	14(21.2)	19(23.2)	14(18.7)	33(22.3)
頭痛	n (%)	4(6.1)	7(8.5)	4(5.3)	11(7.4)
浮動性めまい	n (%)	1(1.5)	5(6.1)	5(6.7)	6(4.1)
アカシジア	n (%)	4(6.1)	1(1.2)	1(1.3)	5(3.4)
傾眠	n (%)	2(3.0)	2(2.4)	2(2.7)	4(2.7)
錐体外路障害	n (%)	0	2(2.4)	2(2.7)	2(1.4)
パーキンソニズム	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
鎮静	n (%)	0	2(2.4)	1(1.3)	2(1.4)
一過性脳虚血発作	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
振戦	n (%)	1(1.5)	1(1.2)	0	2(1.4)
平衡障害	n (%)	0	1(1.2)	0	1(0.7)
認知症	n (%)	1(1.5)	0	0	1(0.7)
よだれ	n (%)	0	1(1.2)	1(1.3)	1(0.7)
構語障害	n (%)	0	1(1.2)	0	1(0.7)
ジスキネジー	n (%)	0	1(1.2)	0	1(0.7)
遅発性ジスキネジー	n (%)	0	1(1.2)	1(1.3)	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155 BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	 All NBI-98854 (N=148)
精神障害	n (%)	11(16.7)	16(19.5)	12(16.0)	27(18.2)
うつ病	n (%)	3(4.5)	3(3.7)	2(2.7)	6(4.1)
自殺念慮	n (%)	2(3.0)	3(3.7)	3(4.0)	5(3.4)
不安	n (%)	1(1.5)	3(3.7)	1(1.3)	4(2.7)
激越	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
不眠症	n (%)	1(1.5)	1(1.2)	0	2(1.4)
妄想症	n (%)	2(3.0)	0	0	2(1.4)
落ち着きのなさ	n (%)	1(1.5)	1(1.2)	0	2(1.4)
統合失調症	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
抑うつ気分	n (%)	0	1(1.2)	1(1.3)	1(0.7)
抑うつ症状	n (%)	0	1(1.2)	1(1.3)	1(0.7)
敵意	n (%)	1(1.5)	0	0	1(0.7)
リビドー減退	n (%)	1(1.5)	0	0	1(0.7)
躁病	n (%)	0	1(1.2)	1(1.3)	1(0.7)
精神状態変化	n (%)	1(1.5)	0	0	1(0.7)
気分動揺	n (%)	0	1(1.2)	0	1(0.7)
神経過敏	n (%)	0	1(1.2)	1(1.3)	1(0.7)
精神運動制止遅滞	n (%)	1(1.5)	0	0	1(0.7)
統合失調感情障害	n (%)	0	1(1.2)	1(1.3)	1(0.7)
自殺企図	n (%)	0	1(1.2)	1(1.3)	1(0.7)
腎および尿路障害	n (%)	2(3.0)	1(1.2)	1(1.3)	3(2.0)
排尿困難	n (%)	0	1(1.2)	1(1.3)	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	All NBI-98854 (N=148)
血尿	n (%)	1(1.5)	0	0	1(0.7)
急性腎不全	n (%)	1(1.5)	0	0	1(0.7)
呼吸器、胸郭および縦隔障害	n (%)	1(1.5)	13(15.9)	9(12.0)	14(9.5)
咳嗽	n (%)	0	3(3.7)	1(1.3)	3(2.0)
鼻閉	n (%)	1(1.5)	2(2.4)	2(2.7)	3(2.0)
喘息	n (%)	0	2(2.4)	1(1.3)	2(1.4)
慢性閉塞性肺疾患	n (%)	0	2(2.4)	2(2.7)	2(1.4)
呼吸困難	n (%)	0	2(2.4)	1(1.3)	2(1.4)
慢性気管支炎	n (%)	0	1(1.2)	1(1.3)	1(0.7)
口腔咽頭痛	n (%)	0	1(1.2)	0	1(0.7)
気道うっ血	n (%)	0	1(1.2)	0	1(0.7)
アレルギー性鼻炎	n (%)	0	1(1.2)	1(1.3)	1(0.7)
副鼻腔うっ血	n (%)	0	1(1.2)	0	1(0.7)
皮膚および皮下組織障害	n (%)	2(3.0)	2(2.4)	1(1.3)	4(2.7)
発疹	n (%)	1(1.5)	1(1.2)	0	2(1.4)
過角化	n (%)	1(1.5)	0	0	1(0.7)
皮膚病変	n (%)	0	1(1.2)	1(1.3)	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	 80 mg (N=82)	 80 mg Only[b] (N=75)	 All NBI-98854 (N=148)
外科および内科処置	n (%)	1(1.5)	0	0	1(0.7)
抜歯	n (%)	1(1.5)	0	0	1(0.7)
血管障害	n (%)	2(3.0)	7(8.5)	6(8.0)	9(6.1)
高血圧	n (%)	1(1.5)	4(4.9)	3(4.0)	5(3.4)
血腫	n (%)	0	1(1.2)	1(1.3)	1(0.7)
ほてり	n (%)	0	1(1.2)	1(1.3)	1(0.7)
低血圧	n (%)	0	1(1.2)	1(1.3)	1(0.7)
起立性低血圧	n (%)	1(1.5)	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
Any Adverse Event	n (%)	54(75.0)	47(57.3)	44(55.7)	101(65.6)
血液およびリンパ系障害	n (%)	2(2.8)	2(2.4)	2(2.5)	4(2.6)
貧血	n (%)	0	2(2.4)	2(2.5)	2(1.3)
白血球増加症	n (%)	0	1(1.2)	1(1.3)	1(0.6)
好中球減少症	n (%)	1(1.4)	0	0	1(0.6)
血小板血症	n (%)	1(1.4)	0	0	1(0.6)
心臓障害	n (%)	3(4.2)	1(1.2)	1(1.3)	4(2.6)
心房細動	n (%)	1(1.4)	0	0	1(0.6)
冠動脈疾患	n (%)	1(1.4)	0	0	1(0.6)
洞性頻脈	n (%)	1(1.4)	0	0	1(0.6)
心室性期外収縮	n (%)	0	1(1.2)	1(1.3)	1(0.6)
耳および迷路障害	n (%)	1(1.4)	0	0	1(0.6)
聴覚障害	n (%)	1(1.4)	0	0	1(0.6)
眼障害	n (%)	0	1(1.2)	1(1.3)	1(0.6)
兎眼	n (%)	0	1(1.2)	1(1.3)	1(0.6)
胃腸障害	n (%)	12(16.7)	16(19.5)	14(17.7)	28(18.2)
下痢	n (%)	5(6.9)	5(6.1)	4(5.1)	10(6.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
悪心	n (%)	3(4.2)	4(4.9)	4(5.1)	7(4.5)
便秘	n (%)	3(4.2)	2(2.4)	1(1.3)	5(3.2)
口内乾燥	n (%)	3(4.2)	1(1.2)	1(1.3)	4(2.6)
嘔吐	n (%)	2(2.8)	2(2.4)	2(2.5)	4(2.6)
腹痛	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
流涎過多	n (%)	0	3(3.7)	2(2.5)	3(1.9)
胃食道逆流性疾患	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
腹部膨満	n (%)	0	1(1.2)	1(1.3)	1(0.6)
上腹部痛	n (%)	0	1(1.2)	1(1.3)	1(0.6)
腹部圧痛	n (%)	1(1.4)	0	0	1(0.6)
細菌叢異常症	n (%)	0	1(1.2)	1(1.3)	1(0.6)
嚥下障害	n (%)	0	1(1.2)	1(1.3)	1(0.6)
変色便	n (%)	1(1.4)	0	0	1(0.6)
食中毒	n (%)	0	1(1.2)	1(1.3)	1(0.6)
歯痛	n (%)	0	1(1.2)	1(1.3)	1(0.6)
臍ヘルニア	n (%)	1(1.4)	0	0	1(0.6)
全身障害および投与局所様態	n (%)	7(9.7)	8(9.8)	7(8.9)	15(9.7)
疲労	n (%)	6(8.3)	1(1.2)	1(1.3)	7(4.5)
易刺激性	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
無力症	n (%)	1(1.4)	1(1.2)	0	2(1.3)
胸痛	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
非心臓性胸痛	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
末梢性浮腫	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
歩行障害	n (%)	1(1.4)	0	0	1(0.6)
治癒不良	n (%)	1(1.4)	0	0	1(0.6)
突然死	n (%)	0	1(1.2)	1(1.3)	1(0.6)
肝胆道系障害	n (%)	0	2(2.4)	2(2.5)	2(1.3)
胆石症	n (%)	0	1(1.2)	1(1.3)	1(0.6)
急性肝炎	n (%)	0	1(1.2)	1(1.3)	1(0.6)
黄疸	n (%)	0	1(1.2)	1(1.3)	1(0.6)
免疫系障害	n (%)	0	1(1.2)	1(1.3)	1(0.6)
季節性アレルギー	n (%)	0	1(1.2)	1(1.3)	1(0.6)
感染症および寄生虫症	n (%)	22(30.6)	12(14.6)	11(13.9)	34(22.1)
尿路感染	n (%)	9(12.5)	3(3.7)	3(3.8)	12(7.8)
気管支炎	n (%)	2(2.8)	2(2.4)	2(2.5)	4(2.6)
鼻咽頭炎	n (%)	2(2.8)	2(2.4)	1(1.3)	4(2.6)
上気道感染	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
ダニ皮膚炎	n (%)	2(2.8)	0	0	2(1.3)
胃腸炎	n (%)	0	2(2.4)	2(2.5)	2(1.3)
インフルエンザ	n (%)	2(2.8)	0	0	2(1.3)
軟部組織膿瘍	n (%)	0	1(1.2)	1(1.3)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
体部白癬	n (%)	1(1.4)	0	0	1(0.6)
蜂巣炎	n (%)	0	1(1.2)	1(1.3)	1(0.6)
ブドウ球菌性蜂巣炎	n (%)	1(1.4)	0	0	1(0.6)
耳感染	n (%)	1(1.4)	0	0	1(0.6)
眼感染	n (%)	1(1.4)	0	0	1(0.6)
せつ	n (%)	1(1.4)	0	0	1(0.6)
ウイルス性胃腸炎	n (%)	1(1.4)	0	0	1(0.6)
肺炎	n (%)	0	1(1.2)	1(1.3)	1(0.6)
急性腎盂腎炎	n (%)	1(1.4)	0	0	1(0.6)
副鼻腔炎	n (%)	0	1(1.2)	1(1.3)	1(0.6)
皮下組織膿瘍	n (%)	1(1.4)	0	0	1(0.6)
股部白癬	n (%)	1(1.4)	0	0	1(0.6)
歯膿瘍	n (%)	0	1(1.2)	1(1.3)	1(0.6)
外陰腟真菌感染	n (%)	1(1.4)	0	0	1(0.6)
傷害、中毒および処置合併症	n (%)	8(11.1)	7(8.5)	6(7.6)	15(9.7)
転倒・転落	n (%)	3(4.2)	2(2.4)	1(1.3)	5(3.2)
擦過傷	n (%)	2(2.8)	1(1.2)	1(1.3)	3(1.9)
皮膚裂傷	n (%)	0	2(2.4)	2(2.5)	2(1.3)
第２度熱傷	n (%)	1(1.4)	0	0	1(0.6)
頚椎骨折	n (%)	0	1(1.2)	1(1.3)	1(0.6)
皮膚化学熱傷	n (%)	0	1(1.2)	1(1.3)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
異物による損傷	n (%)	0	1(1.2)	1(1.3)	1(0.6)
関節脱臼	n (%)	0	1(1.2)	0	1(0.6)
関節損傷	n (%)	1(1.4)	0	0	1(0.6)
口腔内損傷	n (%)	0	1(1.2)	1(1.3)	1(0.6)
筋挫傷	n (%)	0	1(1.2)	1(1.3)	1(0.6)
腎損傷	n (%)	1(1.4)	0	0	1(0.6)
肋骨骨折	n (%)	0	1(1.2)	0	1(0.6)
交通事故	n (%)	0	1(1.2)	1(1.3)	1(0.6)
臨床検査	n (%)	8(11.1)	12(14.6)	12(15.2)	20(13.0)
体重増加	n (%)	1(1.4)	4(4.9)	4(5.1)	5(3.2)
血中クレアチンホスホキナーゼ増加	n (%)	2(2.8)	2(2.4)	2(2.5)	4(2.6)
血中クレアチニン増加	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
血中ブドウ糖増加	n (%)	0	2(2.4)	2(2.5)	2(1.3)
血中尿素増加	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
血中コレステロール増加	n (%)	0	1(1.2)	1(1.3)	1(0.6)
血圧上昇	n (%)	0	1(1.2)	1(1.3)	1(0.6)
血中トリグリセリド増加	n (%)	0	1(1.2)	1(1.3)	1(0.6)
心電図ＱＴ延長	n (%)	0	1(1.2)	1(1.3)	1(0.6)
尿中ブドウ糖陽性	n (%)	1(1.4)	0	0	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
グリコヘモグロビン増加	n (%)	1(1.4)	0	0	1(0.6)
ヘモグロビン減少	n (%)	1(1.4)	0	0	1(0.6)
心拍数減少	n (%)	0	1(1.2)	1(1.3)	1(0.6)
体重減少	n (%)	1(1.4)	0	0	1(0.6)
代謝および栄養障害	n (%)	5(6.9)	6(7.3)	6(7.6)	11(7.1)
食欲減退	n (%)	3(4.2)	0	0	3(1.9)
食欲不振	n (%)	2(2.8)	0	0	2(1.3)
食欲亢進	n (%)	0	2(2.4)	2(2.5)	2(1.3)
食欲障害	n (%)	0	1(1.2)	1(1.3)	1(0.6)
脱水	n (%)	0	1(1.2)	1(1.3)	1(0.6)
糖尿病	n (%)	0	1(1.2)	1(1.3)	1(0.6)
高血糖	n (%)	0	1(1.2)	1(1.3)	1(0.6)
筋骨格系および結合組織障害	n (%)	9(12.5)	6(7.3)	6(7.6)	15(9.7)
背部痛	n (%)	4(5.6)	3(3.7)	3(3.8)	7(4.5)
骨関節炎	n (%)	2(2.8)	1(1.2)	1(1.3)	3(1.9)
関節痛	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
四肢痛	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
筋痙縮	n (%)	0	1(1.2)	1(1.3)	1(0.6)
筋力低下	n (%)	1(1.4)	0	0	1(0.6)
筋骨格痛	n (%)	0	1(1.2)	1(1.3)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	 All NBI-98854 (N=154)
筋肉痛	n (%)	1(1.4)	0	0	1(0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	2(2.4)	2(2.5)	2(1.3)
乳癌	n (%)	0	1(1.2)	1(1.3)	1(0.6)
甲状腺新生物	n (%)	0	1(1.2)	1(1.3)	1(0.6)
神経系障害	n (%)	19(26.4)	14(17.1)	12(15.2)	33(21.4)
傾眠	n (%)	8(11.1)	2(2.4)	2(2.5)	10(6.5)
頭痛	n (%)	4(5.6)	4(4.9)	4(5.1)	8(5.2)
浮動性めまい	n (%)	2(2.8)	2(2.4)	2(2.5)	4(2.6)
ジスキネジー	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
鎮静	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
失神	n (%)	2(2.8)	1(1.2)	0	3(1.9)
振戦	n (%)	3(4.2)	0	0	3(1.9)
アカシジア	n (%)	2(2.8)	0	0	2(1.3)
健忘	n (%)	0	1(1.2)	1(1.3)	1(0.6)
平衡障害	n (%)	1(1.4)	0	0	1(0.6)
よだれ	n (%)	0	1(1.2)	1(1.3)	1(0.6)
ジストニー	n (%)	1(1.4)	0	0	1(0.6)
脳症	n (%)	0	1(1.2)	1(1.3)	1(0.6)
感覚鈍麻	n (%)	1(1.4)	0	0	1(0.6)
嗜眠	n (%)	0	1(1.2)	0	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
神経痛	n (%)	1(1.4)	0	0	1(0.6)
末梢性ニューロパチー	n (%)	0	1(1.2)	1(1.3)	1(0.6)
咬舌	n (%)	1(1.4)	0	0	1(0.6)
精神障害	n (%)	17(23.6)	10(12.2)	9(11.4)	27(17.5)
自殺念慮	n (%)	3(4.2)	5(6.1)	5(6.3)	8(5.2)
不安	n (%)	4(5.6)	2(2.4)	1(1.3)	6(3.9)
うつ病	n (%)	3(4.2)	2(2.4)	2(2.5)	5(3.2)
不眠症	n (%)	3(4.2)	1(1.2)	1(1.3)	4(2.6)
統合失調症	n (%)	0	2(2.4)	2(2.5)	2(1.3)
激越	n (%)	0	1(1.2)	1(1.3)	1(0.6)
アルコール症	n (%)	0	1(1.2)	1(1.3)	1(0.6)
死別反応	n (%)	1(1.4)	0	0	1(0.6)
双極１型障害	n (%)	1(1.4)	0	0	1(0.6)
抑うつ気分	n (%)	1(1.4)	0	0	1(0.6)
軽躁	n (%)	1(1.4)	0	0	1(0.6)
パニック発作	n (%)	1(1.4)	0	0	1(0.6)
精神運動制止遅滞	n (%)	0	1(1.2)	1(1.3)	1(0.6)
統合失調感情障害	n (%)	1(1.4)	0	0	1(0.6)
自殺行為	n (%)	0	1(1.2)	1(1.3)	1(0.6)
トランス	n (%)	1(1.4)	0	0	1(0.6)
腎および尿路障害	n (%)	4(5.6)	1(1.2)	1(1.3)	5(3.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	 All NBI-98854 (N=154)
糖尿	n (%)	0	1(1.2)	1(1.3)	1(0.6)
血尿	n (%)	1(1.4)	0	0	1(0.6)
頻尿	n (%)	1(1.4)	0	0	1(0.6)
腎嚢胞	n (%)	1(1.4)	0	0	1(0.6)
尿失禁	n (%)	1(1.4)	0	0	1(0.6)
尿臭異常	n (%)	1(1.4)	0	0	1(0.6)
呼吸器、胸郭および縦隔障害	n (%)	4(5.6)	6(7.3)	6(7.6)	10(6.5)
咳嗽	n (%)	3(4.2)	1(1.2)	1(1.3)	4(2.6)
慢性閉塞性肺疾患	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
喘息	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
鼻閉	n (%)	0	1(1.2)	1(1.3)	1(0.6)
アレルギー性鼻炎	n (%)	0	1(1.2)	1(1.3)	1(0.6)
鼻漏	n (%)	1(1.4)	0	0	1(0.6)
副鼻腔うっ血	n (%)	1(1.4)	0	0	1(0.6)
くしゃみ	n (%)	0	1(1.2)	1(1.3)	1(0.6)
皮膚および皮下組織障害	n (%)	8(11.1)	3(3.7)	3(3.8)	11(7.1)
そう痒症	n (%)	2(2.8)	0	0	2(1.3)
発疹	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－155　BMI区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	 80 mg (N=82)	 80 mg Only[b] (N=79)	All NBI-98854 (N=154)
斑状丘疹状皮疹	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
水疱	n (%)	1(1.4)	0	0	1(0.6)
アレルギー性皮膚炎	n (%)	1(1.4)	0	0	1(0.6)
全身性皮疹	n (%)	1(1.4)	0	0	1(0.6)
丘疹	n (%)	0	1(1.2)	1(1.3)	1(0.6)
蕁麻疹	n (%)	1(1.4)	0	0	1(0.6)
社会環境	n (%)	1(1.4)	0	0	1(0.6)
社会的入院	n (%)	1(1.4)	0	0	1(0.6)
外科および内科処置	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
抜歯	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
四肢再接合手術	n (%)	0	1(1.2)	1(1.3)	1(0.6)
血管障害	n (%)	2(2.8)	4(4.9)	4(5.1)	6(3.9)
高血圧	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
深部静脈血栓症	n (%)	0	1(1.2)	1(1.3)	1(0.6)
末梢動脈閉塞性疾患	n (%)	1(1.4)	0	0	1(0.6)
レイノー現象	n (%)	0	1(1.2)	1(1.3)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.5より引用（一部改変）

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

BMI Category: <18.5 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=4)	80 mg (N=4)	80 mg Only[b] (N=4)	All NBI-98854 (N=8)
Any Adverse Event of Special Interest	n (%)	1(25.0)	1(25.0)	1(25.0)	2(25.0)
高プロラクチン血症関連有害事象	n (%)	1(25.0)	0	0	1(12.5)
乳汁漏出症	n (%)	1(25.0)	0	0	1(12.5)
パーキンソニズム関連有害事象	n (%)	0	1(25.0)	1(25.0)	1(12.5)
歯車様固縮	n (%)	0	1(25.0)	1(25.0)	1(12.5)
振戦	n (%)	0	1(25.0)	1(25.0)	1(12.5)
基礎疾患の悪化に関連する有害事象	n (%)	1(25.0)	0	0	1(12.5)
躁病	n (%)	1(25.0)	0	0	1(12.5)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	80 mg (N=61)	80 mg Only[b] (N=55)	All NBI-98854 (N=116)
Any Adverse Event of Special Interest	n (%)	21(38.2)	21(34.4)	15(27.3)	42(36.2)
アカシジア関連有害事象	n (%)	1(1.8)	0	0	1(0.9)
アカシジア	n (%)	1(1.8)	0	0	1(0.9)
不安	n (%)	1(1.8)	2(3.3)	1(1.8)	3(2.6)
不安	n (%)	1(1.8)	2(3.3)	1(1.8)	3(2.6)
心血管系及びQT間隔延長関連有害事象	n (%)	3(5.5)	2(3.3)	2(3.6)	5(4.3)
失神	n (%)	2(3.6)	1(1.6)	1(1.8)	3(2.6)
心不全	n (%)	0	1(1.6)	1(1.8)	1(0.9)
胸痛	n (%)	1(1.8)	0	0	1(0.9)
うつ病及び自殺関連有害事象	n (%)	8(14.5)	3(4.9)	3(5.5)	11(9.5)
自殺念慮	n (%)	4(7.3)	2(3.3)	2(3.6)	6(5.2)
うつ病	n (%)	3(5.5)	0	0	3(2.6)
抑うつ症状	n (%)	1(1.8)	0	0	1(0.9)
自殺企図	n (%)	0	1(1.6)	1(1.8)	1(0.9)
嚥下障害関連有害事象	n (%)	2(3.6)	0	0	2(1.7)
嚥下障害	n (%)	2(3.6)	0	0	2(1.7)
食道食物嵌入	n (%)	1(1.8)	0	0	1(0.9)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	80 mg (N=61)	80 mg Only[b] (N=55)	All NBI-98854 (N=116)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	3(5.5)	7(11.5)	5(9.1)	10(8.6)
疲労	n (%)	3(5.5)	4(6.6)	4(7.3)	7(6.0)
無力症	n (%)	0	2(3.3)	0	2(1.7)
倦怠感	n (%)	0	1(1.6)	1(1.8)	1(0.9)
肝障害関連有害事象	n (%)	0	1(1.6)	1(1.8)	1(0.9)
肝不全	n (%)	0	1(1.6)	1(1.8)	1(0.9)
低血圧関連有害事象	n (%)	5(9.1)	5(8.2)	5(9.1)	10(8.6)
浮動性めまい	n (%)	3(5.5)	3(4.9)	3(5.5)	6(5.2)
転倒・転落	n (%)	2(3.6)	2(3.3)	2(3.6)	4(3.4)
失神	n (%)	2(3.6)	1(1.6)	1(1.8)	3(2.6)
パーキンソニズム関連有害事象	n (%)	0	1(1.6)	0	1(0.9)
振戦	n (%)	0	1(1.6)	0	1(0.9)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	6(10.9)	5(8.2)	2(3.6)	11(9.5)
傾眠	n (%)	5(9.1)	5(8.2)	2(3.6)	10(8.6)
鎮静	n (%)	1(1.8)	0	0	1(0.9)
基礎疾患の悪化に関連する有害事象	n (%)	10(18.2)	5(8.2)	4(7.3)	15(12.9)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 18.5 - <25 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=55)	80 mg (N=61)	80 mg Only[b] (N=55)	All NBI-98854 (N=116)
自殺念慮	n (%)	4(7.3)	2(3.3)	2(3.6)	6(5.2)
統合失調症	n (%)	3(5.5)	1(1.6)	1(1.8)	4(3.4)
うつ病	n (%)	3(5.5)	0	0	3(2.6)
精神病性障害	n (%)	1(1.8)	1(1.6)	0	2(1.7)
抑うつ症状	n (%)	1(1.8)	0	0	1(0.9)
外傷後ストレス障害	n (%)	1(1.8)	0	0	1(0.9)
自殺企図	n (%)	0	1(1.6)	1(1.8)	1(0.9)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	80 mg (N=82)	80 mg Only[b] (N=75)	All NBI-98854 (N=148)
Any Adverse Event of Special Interest	n (%)	21(31.8)	26(31.7)	20(26.7)	47(31.8)
アカシジア関連有害事象	n (%)	4(6.1)	1(1.2)	1(1.3)	5(3.4)
アカシジア	n (%)	4(6.1)	1(1.2)	1(1.3)	5(3.4)
不安	n (%)	1(1.5)	3(3.7)	1(1.3)	4(2.7)
不安	n (%)	1(1.5)	3(3.7)	1(1.3)	4(2.7)
心血管系及びQT間隔延長関連有害事象	n (%)	1(1.5)	2(2.4)	2(2.7)	3(2.0)
胸痛	n (%)	1(1.5)	2(2.4)	2(2.7)	3(2.0)
うつ病及び自殺関連有害事象	n (%)	5(7.6)	8(9.8)	7(9.3)	13(8.8)
うつ病	n (%)	3(4.5)	3(3.7)	2(2.7)	6(4.1)
自殺念慮	n (%)	2(3.0)	3(3.7)	3(4.0)	5(3.4)
抑うつ気分	n (%)	0	1(1.2)	1(1.3)	1(0.7)
抑うつ症状	n (%)	0	1(1.2)	1(1.3)	1(0.7)
自殺企図	n (%)	0	1(1.2)	1(1.3)	1(0.7)
嚥下障害関連有害事象	n (%)	1(1.5)	0	0	1(0.7)
嚥下障害	n (%)	1(1.5)	0	0	1(0.7)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	4(6.1)	4(4.9)	3(4.0)	8(5.4)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	80 mg (N=82)	80 mg Only[b] (N=75)	All NBI-98854 (N=148)
疲労	n (%)	4(6.1)	3(3.7)	3(4.0)	7(4.7)
無力症	n (%)	0	1(1.2)	0	1(0.7)
高プロラクチン血症関連有害事象	n (%)	2(3.0)	1(1.2)	0	3(2.0)
血中プロラクチン増加	n (%)	2(3.0)	1(1.2)	0	3(2.0)
低血圧関連有害事象	n (%)	2(3.0)	7(8.5)	7(9.3)	9(6.1)
浮動性めまい	n (%)	1(1.5)	5(6.1)	5(6.7)	6(4.1)
転倒・転落	n (%)	0	1(1.2)	1(1.3)	1(0.7)
低血圧	n (%)	0	1(1.2)	1(1.3)	1(0.7)
起立性低血圧	n (%)	1(1.5)	0	0	1(0.7)
パーキンソニズム関連有害事象	n (%)	2(3.0)	3(3.7)	1(1.3)	5(3.4)
パーキンソニズム	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
振戦	n (%)	1(1.5)	1(1.2)	0	2(1.4)
筋固縮	n (%)	0	1(1.2)	0	1(0.7)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	2(3.0)	4(4.9)	3(4.0)	6(4.1)
傾眠	n (%)	2(3.0)	2(2.4)	2(2.7)	4(2.7)
鎮静	n (%)	0	2(2.4)	1(1.3)	2(1.4)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: 25 - <30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=66)	80 mg (N=82)	80 mg Only[b] (N=75)	All NBI-98854 (N=148)
基礎疾患の悪化に関連する有害事象	n (%)	7(10.6)	11(13.4)	10(13.3)	18(12.2)
うつ病	n (%)	3(4.5)	3(3.7)	2(2.7)	6(4.1)
自殺念慮	n (%)	2(3.0)	3(3.7)	3(4.0)	5(3.4)
妄想症	n (%)	2(3.0)	0	0	2(1.4)
統合失調症	n (%)	1(1.5)	1(1.2)	1(1.3)	2(1.4)
抑うつ気分	n (%)	0	1(1.2)	1(1.3)	1(0.7)
抑うつ症状	n (%)	0	1(1.2)	1(1.3)	1(0.7)
敵意	n (%)	1(1.5)	0	0	1(0.7)
躁病	n (%)	0	1(1.2)	1(1.3)	1(0.7)
気分動揺	n (%)	0	1(1.2)	0	1(0.7)
統合失調感情障害	n (%)	0	1(1.2)	1(1.3)	1(0.7)
自殺企図	n (%)	0	1(1.2)	1(1.3)	1(0.7)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	80 mg (N=82)	80 mg Only[b] (N=79)	All NBI-98854 (N=154)
Any Adverse Event of Special Interest	n (%)	27(37.5)	23(28.0)	20(25.3)	50(32.5)
アカシジア関連有害事象	n (%)	2(2.8)	0	0	2(1.3)
アカシジア	n (%)	2(2.8)	0	0	2(1.3)
不安	n (%)	4(5.6)	2(2.4)	1(1.3)	6(3.9)
不安	n (%)	4(5.6)	2(2.4)	1(1.3)	6(3.9)
心血管系及びQT間隔延長関連有害事象	n (%)	2(2.8)	4(4.9)	3(3.8)	6(3.9)
失神	n (%)	2(2.8)	1(1.2)	0	3(1.9)
胸痛	n (%)	1(1.4)	1(1.2)	1(1.3)	2(1.3)
心電図QT延長	n (%)	0	1(1.2)	1(1.3)	1(0.6)
突然死	n (%)	0	1(1.2)	1(1.3)	1(0.6)
うつ病及び自殺関連有害事象	n (%)	6(8.3)	7(8.5)	7(8.9)	13(8.4)
自殺念慮	n (%)	3(4.2)	5(6.1)	5(6.3)	8(5.2)
うつ病	n (%)	3(4.2)	2(2.4)	2(2.5)	5(3.2)
抑うつ気分	n (%)	1(1.4)	0	0	1(0.6)
自殺行為	n (%)	0	1(1.2)	1(1.3)	1(0.6)
嚥下障害関連有害事象	n (%)	0	1(1.2)	1(1.3)	1(0.6)
嚥下障害	n (%)	0	1(1.2)	1(1.3)	1(0.6)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	80 mg (N=82)	80 mg Only[b] (N=79)	All NBI-98854 (N=154)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	6(8.3)	3(3.7)	1(1.3)	9(5.8)
疲労	n (%)	6(8.3)	1(1.2)	1(1.3)	7(4.5)
無力症	n (%)	1(1.4)	1(1.2)	0	2(1.3)
嗜眠	n (%)	0	1(1.2)	0	1(0.6)
肝障害関連有害事象	n (%)	0	1(1.2)	1(1.3)	1(0.6)
急性肝炎	n (%)	0	1(1.2)	1(1.3)	1(0.6)
低血圧関連有害事象	n (%)	7(9.7)	4(4.9)	3(3.8)	11(7.1)
転倒・転落	n (%)	3(4.2)	2(2.4)	1(1.3)	5(3.2)
浮動性めまい	n (%)	2(2.8)	2(2.4)	2(2.5)	4(2.6)
失神	n (%)	2(2.8)	1(1.2)	0	3(1.9)
パーキンソニズム関連有害事象	n (%)	3(4.2)	0	0	3(1.9)
振戦	n (%)	3(4.2)	0	0	3(1.9)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	9(12.5)	4(4.9)	4(5.1)	13(8.4)
傾眠	n (%)	8(11.1)	2(2.4)	2(2.5)	10(6.5)
鎮静	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
基礎疾患の悪化に関連する有害事象	n (%)	9(12.5)	9(11.0)	9(11.4)	18(11.7)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－156　BMI区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

BMI Category: >=30 kg/m²

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=72)	80 mg (N=82)	80 mg Only[b] (N=79)	All NBI-98854 (N=154)
自殺念慮	n (%)	3(4.2)	5(6.1)	5(6.3)	8(5.2)
うつ病	n (%)	3(4.2)	2(2.4)	2(2.5)	5(3.2)
易刺激性	n (%)	1(1.4)	2(2.4)	2(2.5)	3(1.9)
統合失調症	n (%)	0	2(2.4)	2(2.5)	2(1.3)
双極１型障害	n (%)	1(1.4)	0	0	1(0.6)
抑うつ気分	n (%)	1(1.4)	0	0	1(0.6)
軽躁	n (%)	1(1.4)	0	0	1(0.6)
統合失調感情障害	n (%)	1(1.4)	0	0	1(0.6)
自殺行為	n (%)	0	1(1.2)	1(1.3)	1(0.6)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.5より引用（一部改変）

表 2.7.4.7－157　CYP2D6 フェノタイプごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies						Long-term Exposure		
	NBI-98854			Placebo			NBI-98854		
	Poor Metabolizer (N=13) n (%)	Not Poor Metabolizer (N=239) n (%)	Status Not Reported (N=2) n (%)	Poor Metabolizer (N=7) n (%)	Not Poor Metabolizer (N=171) n (%)	Status Not Reported (N=0) n (%)	Poor Metabolizer (N=23) n (%)	Not Poor Metabolizer (N=403) n (%)	Status Not Reported (N=1) n (%)
At Least 1 AE	6 (46.2)	103 (43.1)	2 (100)	0	71 (41.5)	0	16 (69.6)	242 (60.0)	1 (100)
At Least 1 SAE	1 (7.7)	11 (4.6)	0	0	6 (3.5)	0	5 (21.7)	49 (12.2)	0
At Least 1 AE Leading to Study Discontinuation	2 (15.4)	8 (3.3)	0	0	8 (4.7)	0	4 (17.4)	54 (13.4)	0
At Least 1 AE Leading to Dose Reduction	2 (15.4)	5 (2.1)	0	0	4 (2.3)	0	3 (13.0)	23 (5.7)	0

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is only counted once for that category.

5.3.5.3－2 Table 100 より引用（一部改変）

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

CYP2D6 Genotype: Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=8)	 80 mg (N=4)	 100 mg (N=0)	All NBI-98854 (N=13)	Placebo (N=7)
Any Adverse Event	n (%)	1(100.0)	4(50.0)	1(25.0)	0	6(46.2)	0
心臓障害	n (%)	0	1(12.5)	0	0	1(7.7)	0
徐脈	n (%)	0	1(12.5)	0	0	1(7.7)	0
全身障害および投与局所様態	n (%)	0	2(25.0)	0	0	2(15.4)	0
歩行障害	n (%)	0	2(25.0)	0	0	2(15.4)	0
疲労	n (%)	0	1(12.5)	0	0	1(7.7)	0
末梢性浮腫	n (%)	0	1(12.5)	0	0	1(7.7)	0
感染症および寄生虫症	n (%)	0	1(12.5)	0	0	1(7.7)	0
体部白癬	n (%)	0	1(12.5)	0	0	1(7.7)	0
尿路感染	n (%)	0	1(12.5)	0	0	1(7.7)	0
臨床検査	n (%)	1(100.0)	0	0	0	1(7.7)	0
肝酵素上昇	n (%)	1(100.0)	0	0	0	1(7.7)	0
筋骨格系および結合組織障害	n (%)	0	2(25.0)	0	0	2(15.4)	0
背部痛	n (%)	0	1(12.5)	0	0	1(7.7)	0
顎関節症候群	n (%)	0	1(12.5)	0	0	1(7.7)	0
神経系障害	n (%)	0	1(12.5)	1(25.0)	0	2(15.4)	0
傾眠	n (%)	0	1(12.5)	1(25.0)	0	2(15.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=8)	 80 mg (N=4)	 100 mg (N=0)	All NBI-98854 (N=13)	Placebo (N=7)
精神障害	n (%)	1(100.0)	2(25.0)	0	0	3(23.1)	0
双極１型障害	n (%)	0	1(12.5)	0	0	1(7.7)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(7.7)	0
精神運動制止遅滞	n (%)	0	1(12.5)	0	0	1(7.7)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
Any Adverse Event	n (%)	1(25.0)	43(42.6)	51(47.7)	8(29.6)	103(43.1)	71(41.5)
血液およびリンパ系障害	n (%)	0	0	1(0.9)	0	1(0.4)	0
白血球減少症	n (%)	0	0	1(0.9)	0	1(0.4)	0
心臓障害	n (%)	0	0	0	0	0	1(0.6)
心筋梗塞	n (%)	0	0	0	0	0	1(0.6)
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(0.6)
トゥレット病	n (%)	0	0	0	0	0	1(0.6)
耳および迷路障害	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
耳鳴	n (%)	0	1(1.0)	0	0	1(0.4)	0
耳痛	n (%)	0	0	0	0	0	1(0.6)
眼障害	n (%)	0	0	0	1(3.7)	1(0.4)	1(0.6)
霧視	n (%)	0	0	0	1(3.7)	1(0.4)	0
結膜出血	n (%)	0	0	0	0	0	1(0.6)
胃腸障害	n (%)	0	14(13.9)	7(6.5)	1(3.7)	22(9.2)	21(12.3)
口内乾燥	n (%)	0	7(6.9)	0	1(3.7)	8(3.3)	3(1.8)
嘔吐	n (%)	0	2(2.0)	4(3.7)	0	6(2.5)	1(0.6)
悪心	n (%)	0	2(2.0)	2(1.9)	0	4(1.7)	4(2.3)
流涎過多	n (%)	0	0	2(1.9)	1(3.7)	3(1.3)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
便秘	n (%)	0	2(2.0)	0	0	2(0.8)	5(2.9)
嚥下障害	n (%)	0	2(2.0)	0	0	2(0.8)	0
腹部圧痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
下痢	n (%)	0	1(1.0)	0	0	1(0.4)	3(1.8)
消化不良	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
びらん性胃炎	n (%)	0	0	1(0.9)	0	1(0.4)	0
メレナ	n (%)	0	1(1.0)	0	0	1(0.4)	0
口腔知覚不全	n (%)	0	1(1.0)	0	0	1(0.4)	0
臍ヘルニア	n (%)	0	1(1.0)	0	0	1(0.4)	0
上腹部痛	n (%)	0	0	0	0	0	1(0.6)
排便回数増加	n (%)	0	0	0	0	0	1(0.6)
胃食道逆流性疾患	n (%)	0	0	0	0	0	2(1.2)
歯肉炎	n (%)	0	0	0	0	0	1(0.6)
舌痛	n (%)	0	0	0	0	0	1(0.6)
歯痛	n (%)	0	0	0	0	0	1(0.6)
全身障害および投与局所様態	n (%)	0	8(7.9)	5(4.7)	2(7.4)	15(6.3)	7(4.1)
疲労	n (%)	0	4(4.0)	3(2.8)	2(7.4)	9(3.8)	3(1.8)
末梢性浮腫	n (%)	0	2(2.0)	0	0	2(0.8)	1(0.6)
胸痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
歩行障害	n (%)	0	0	0	1(3.7)	1(0.4)	0
空腹	n (%)	0	1(1.0)	0	0	1(0.4)	0
易刺激性	n (%)	0	1(1.0)	0	0	1(0.4)	2(1.2)
疼痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
発熱	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
突然死	n (%)	0	0	1(0.9)	0	1(0.4)	0
口渇	n (%)	0	1(1.0)	0	0	1(0.4)	0
肝胆道系障害	n (%)	0	0	1(0.9)	0	1(0.4)	0
急性肝炎	n (%)	0	0	1(0.9)	0	1(0.4)	0
黄疸	n (%)	0	0	1(0.9)	0	1(0.4)	0
感染症および寄生虫症	n (%)	0	9(8.9)	3(2.8)	3(11.1)	15(6.3)	14(8.2)
尿路感染	n (%)	0	3(3.0)	1(0.9)	1(3.7)	5(2.1)	8(4.7)
鼻咽頭炎	n (%)	0	1(1.0)	1(0.9)	1(3.7)	3(1.3)	1(0.6)
上気道感染	n (%)	0	0	1(0.9)	1(3.7)	2(0.8)	1(0.6)
ダニ皮膚炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
せつ	n (%)	0	1(1.0)	0	0	1(0.4)	0
ウイルス性胃腸炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
インフルエンザ	n (%)	0	1(1.0)	0	0	1(0.4)	0
急性腎盂腎炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
副鼻腔炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
外陰腟真菌感染	n (%)	0	1(1.0)	0	0	1(0.4)	0
気管支炎	n (%)	0	0	0	0	0	1(0.6)
耳感染	n (%)	0	0	0	0	0	1(0.6)
口腔ヘルペス	n (%)	0	0	0	0	0	1(0.6)
ウイルス感染	n (%)	0	0	0	0	0	1(0.6)
傷害、中毒および処置合併症	n (%)	0	5(5.0)	4(3.7)	1(3.7)	10(4.2)	3(1.8)
転倒・転落	n (%)	0	2(2.0)	1(0.9)	0	3(1.3)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
動物咬傷	n (%)	0	0	1(0.9)	0	1(0.4)	0
節足動物咬傷	n (%)	0	0	0	1(3.7)	1(0.4)	1(0.6)
第２度熱傷	n (%)	0	0	1(0.9)	0	1(0.4)	0
関節損傷	n (%)	0	1(1.0)	0	0	1(0.4)	0
四肢損傷	n (%)	0	0	1(0.9)	0	1(0.4)	0
筋挫傷	n (%)	0	1(1.0)	0	0	1(0.4)	0
交通事故	n (%)	0	1(1.0)	0	0	1(0.4)	0
むち打ち損傷	n (%)	0	1(1.0)	0	0	1(0.4)	0
足骨折	n (%)	0	0	0	0	0	1(0.6)
処置による疼痛	n (%)	0	0	0	0	0	1(0.6)
臨床検査	n (%)	0	4(4.0)	10(9.3)	1(3.7)	15(6.3)	6(3.5)
体重増加	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	1(0.6)
血中クレアチニン増加	n (%)	0	1(1.0)	1(0.9)	0	2(0.8)	0
血中ブドウ糖増加	n (%)	0	0	2(1.9)	0	2(0.8)	0
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	2(1.9)	0	2(0.8)	1(0.6)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(1.0)	0	0	1(0.4)	0
血圧上昇	n (%)	0	0	1(0.9)	0	1(0.4)	0
血中トリグリセリド増加	n (%)	0	0	0	1(3.7)	1(0.4)	0
血中尿素増加	n (%)	0	1(1.0)	0	0	1(0.4)	0
尿中結晶陽性	n (%)	0	0	1(0.9)	0	1(0.4)	0
尿中ブドウ糖陽性	n (%)	0	0	1(0.9)	0	1(0.4)	0
グリコヘモグロビン増加	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
握力低下	n (%)	0	1(1.0)	0	0	1(0.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
ヘマトクリット減少	n (%)	0	0	1(0.9)	0	1(0.4)	0
ヘモグロビン減少	n (%)	0	0	1(0.9)	0	1(0.4)	0
便潜血陽性	n (%)	0	0	1(0.9)	0	1(0.4)	0
赤血球数減少	n (%)	0	0	1(0.9)	0	1(0.4)	0
赤血球数増加	n (%)	0	0	1(0.9)	0	1(0.4)	0
血中ビリルビン増加	n (%)	0	0	0	0	0	1(0.6)
血中カリウム増加	n (%)	0	0	0	0	0	1(0.6)
肝酵素上昇	n (%)	0	0	0	0	0	1(0.6)
好中球数増加	n (%)	0	0	0	0	0	1(0.6)
白血球数増加	n (%)	0	0	0	0	0	1(0.6)
代謝および栄養障害	n (%)	0	3(3.0)	5(4.7)	0	8(3.3)	5(2.9)
食欲減退	n (%)	0	2(2.0)	2(1.9)	0	4(1.7)	2(1.2)
食欲亢進	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	1(0.6)
低ナトリウム血症	n (%)	0	0	1(0.9)	0	1(0.4)	0
異常体重減少	n (%)	0	0	0	0	0	1(0.6)
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(0.6)
低血糖症	n (%)	0	0	0	0	0	1(0.6)
筋骨格系および結合組織障害	n (%)	0	7(6.9)	6(5.6)	1(3.7)	14(5.9)	5(2.9)
関節痛	n (%)	0	3(3.0)	3(2.8)	0	6(2.5)	1(0.6)
背部痛	n (%)	0	1(1.0)	1(0.9)	0	2(0.8)	0
筋力低下	n (%)	0	2(2.0)	0	0	2(0.8)	0
筋肉痛	n (%)	0	0	1(0.9)	1(3.7)	2(0.8)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
関節炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
四肢不快感	n (%)	0	1(1.0)	0	0	1(0.4)	0
筋痙縮	n (%)	0	0	1(0.9)	0	1(0.4)	0
滑液包炎	n (%)	0	0	0	0	0	1(0.6)
関節腫脹	n (%)	0	0	0	0	0	1(0.6)
筋骨格硬直	n (%)	0	0	0	0	0	1(0.6)
四肢痛	n (%)	0	0	0	0	0	1(0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(0.6)
口腔乳頭腫	n (%)	0	0	0	0	0	1(0.6)
神経系障害	n (%)	0	15(14.9)	18(16.8)	3(11.1)	36(15.1)	16(9.4)
傾眠	n (%)	0	8(7.9)	3(2.8)	1(3.7)	12(5.0)	4(2.3)
頭痛	n (%)	0	3(3.0)	5(4.7)	1(3.7)	9(3.8)	4(2.3)
アカシジア	n (%)	0	3(3.0)	3(2.8)	0	6(2.5)	1(0.6)
ジスキネジー	n (%)	0	0	3(2.8)	0	3(1.3)	0
鎮静	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	1(0.6)
浮動性めまい	n (%)	0	2(2.0)	0	0	2(0.8)	4(2.3)
よだれ	n (%)	0	0	2(1.9)	0	2(0.8)	0
振戦	n (%)	0	0	2(1.9)	0	2(0.8)	0
平衡障害	n (%)	0	0	1(0.9)	0	1(0.4)	0
注意力障害	n (%)	0	1(1.0)	0	0	1(0.4)	0
ジストニー	n (%)	0	0	1(0.9)	0	1(0.4)	0
感覚鈍麻	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
ミオクローヌス	n (%)	0	1(1.0)	0	0	1(0.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	 Placebo (N=171)
睡眠の質低下	n (%)	0	1(1.0)	0	0	1(0.4)	0
失神	n (%)	0	0	0	1(3.7)	1(0.4)	0
咬舌	n (%)	0	1(1.0)	0	0	1(0.4)	0
痙攣	n (%)	0	0	0	0	0	1(0.6)
片頭痛	n (%)	0	0	0	0	0	1(0.6)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(0.6)
精神障害	n (%)	1(25.0)	12(11.9)	12(11.2)	0	25(10.5)	14(8.2)
自殺念慮	n (%)	0	4(4.0)	1(0.9)	0	5(2.1)	4(2.3)
不眠症	n (%)	0	2(2.0)	2(1.9)	0	4(1.7)	1(0.6)
不安	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	0
うつ病	n (%)	0	0	2(1.9)	0	2(0.8)	2(1.2)
パニック発作	n (%)	1(25.0)	0	1(0.9)	0	2(0.8)	0
歯ぎしり	n (%)	0	1(1.0)	0	0	1(0.4)	0
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
ディスフェミア	n (%)	0	1(1.0)	0	0	1(0.4)	0
敵意	n (%)	0	1(1.0)	0	0	1(0.4)	0
軽躁	n (%)	0	1(1.0)	0	0	1(0.4)	0
精神状態変化	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
神経過敏	n (%)	0	0	1(0.9)	0	1(0.4)	0
妄想症	n (%)	0	1(1.0)	0	0	1(0.4)	0
精神病性障害	n (%)	0	0	1(0.9)	0	1(0.4)	2(1.2)
落ち着きのなさ	n (%)	0	1(1.0)	0	0	1(0.4)	0
統合失調感情障害	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
自殺企図	n (%)	0	0	1(0.9)	0	1(0.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	Placebo (N=171)
激越	n (%)	0	0	0	0	0	1(0.6)
躁病	n (%)	0	0	0	0	0	1(0.6)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.6)
睡眠障害	n (%)	0	0	0	0	0	1(0.6)
腎および尿路障害	n (%)	0	0	0	0	0	3(1.8)
糖尿	n (%)	0	0	0	0	0	1(0.6)
血尿	n (%)	0	0	0	0	0	1(0.6)
尿閉	n (%)	0	0	0	0	0	1(0.6)
生殖系および乳房障害	n (%)	0	0	1(0.9)	0	1(0.4)	2(1.2)
月経過多	n (%)	0	0	1(0.9)	0	1(0.4)	0
腟出血	n (%)	0	0	0	0	0	2(1.2)
呼吸器、胸郭および縦隔障害	n (%)	0	1(1.0)	2(1.9)	1(3.7)	4(1.7)	2(1.2)
慢性閉塞性肺疾患	n (%)	0	1(1.0)	0	1(3.7)	2(0.8)	1(0.6)
鼻閉	n (%)	0	0	2(1.9)	0	2(0.8)	0
咳嗽	n (%)	0	0	0	0	0	1(0.6)
皮膚および皮下組織障害	n (%)	0	2(2.0)	1(0.9)	0	3(1.3)	5(2.9)
網状皮斑	n (%)	0	1(1.0)	0	0	1(0.4)	0
そう痒症	n (%)	0	1(1.0)	0	0	1(0.4)	2(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=101)	 80 mg (N=107)	 100 mg (N=27)	All NBI-98854 (N=239)	Placebo (N=171)
斑状丘疹状皮疹	n (%)	0	0	1(0.9)	0	1(0.4)	0
多汗症	n (%)	0	0	0	0	0	1(0.6)
ケラトアカントーマ	n (%)	0	0	0	0	0	1(0.6)
乾癬	n (%)	0	0	0	0	0	1(0.6)
発疹	n (%)	0	0	0	0	0	1(0.6)
外科および内科処置	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
抜歯	n (%)	0	0	1(0.9)	0	1(0.4)	0
鼓膜切開	n (%)	0	0	0	0	0	1(0.6)
血管障害	n (%)	0	1(1.0)	3(2.8)	0	4(1.7)	2(1.2)
血腫	n (%)	0	0	1(0.9)	0	1(0.4)	0
ほてり	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
高血圧	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
低血圧	n (%)	0	0	1(0.9)	0	1(0.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－158　CYP2D6フェノタイプごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Reported

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	 40 mg (N=1)	 80 mg (N=1)	 100 mg (N=0)	All NBI-98854 (N=2)	Placebo (N=0)
Any Adverse Event	n (%)	0	1(100.0)	1(100.0)	0	2(100.0)	0
臨床検査	n (%)	0	1(100.0)	0	0	1(50.0)	0
血中ブドウ糖増加	n (%)	0	1(100.0)	0	0	1(50.0)	0
神経系障害	n (%)	0	1(100.0)	0	0	1(50.0)	0
頭痛	n (%)	0	1(100.0)	0	0	1(50.0)	0
皮膚および皮下組織障害	n (%)	0	0	1(100.0)	0	1(50.0)	0
発疹	n (%)	0	0	1(100.0)	0	1(50.0)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.4より引用（一部改変）

表 2.7.4.7－159　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）

CYP2D6 Genotype: Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=8)	 80 mg (N=4)	 100 mg (N=0)	All NBI-98854 (N=13)	Placebo (N=7)
Any Adverse Event of Special Interest	n (%)	1(100.0)	2(25.0)	1(25.0)	0	4(30.8)	0
うつ病及び自殺関連有害事象	n (%)	1(100.0)	0	0	0	1(7.7)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(7.7)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(12.5)	0	0	1(7.7)	0
疲労	n (%)	0	1(12.5)	0	0	1(7.7)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	1(12.5)	1(25.0)	0	2(15.4)	0
傾眠	n (%)	0	1(12.5)	1(25.0)	0	2(15.4)	0
基礎疾患の悪化に関連する有害事象	n (%)	1(100.0)	1(12.5)	0	0	2(15.4)	0
双極１型障害	n (%)	0	1(12.5)	0	0	1(7.7)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(7.7)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－159 CYP2D6フェノタイプごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=101)	80 mg (N=107)	100 mg (N=27)	All NBI-98854 (N=239)	Placebo (N=171)
Any Adverse Event of Special Interest	n (%)	0	26(25.7)	22(20.6)	3(11.1)	51(21.3)	24(14.0)
アカシジア関連有害事象	n (%)	0	3(3.0)	3(2.8)	0	6(2.5)	1(0.6)
アカシジア	n (%)	0	3(3.0)	3(2.8)	0	6(2.5)	1(0.6)
不安	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	0
不安	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(1.0)	1(0.9)	1(3.7)	3(1.3)	1(0.6)
胸痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
突然死	n (%)	0	0	1(0.9)	0	1(0.4)	0
失神	n (%)	0	0	0	1(3.7)	1(0.4)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.6)
うつ病及び自殺関連有害事象	n (%)	0	5(5.0)	4(3.7)	0	9(3.8)	6(3.5)
自殺念慮	n (%)	0	4(4.0)	1(0.9)	0	5(2.1)	4(2.3)
うつ病	n (%)	0	0	2(1.9)	0	2(0.8)	2(1.2)
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
自殺企図	n (%)	0	0	1(0.9)	0	1(0.4)	0
嚥下障害関連有害事象	n (%)	0	2(2.0)	0	0	2(0.8)	0
嚥下障害	n (%)	0	2(2.0)	0	0	2(0.8)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	4(4.0)	3(2.8)	2(7.4)	9(3.8)	3(1.8)
疲労	n (%)	0	4(4.0)	3(2.8)	2(7.4)	9(3.8)	3(1.8)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－159　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=101)	80 mg (N=107)	100 mg (N=27)	All NBI-98854 (N=239)	Placebo (N=171)
肝障害関連有害事象	n (%)	0	0	1(0.9)	0	1(0.4)	0
急性肝炎	n (%)	0	0	1(0.9)	0	1(0.4)	0
低血圧関連有害事象	n (%)	0	4(4.0)	2(1.9)	1(3.7)	7(2.9)	4(2.3)
転倒・転落	n (%)	0	2(2.0)	1(0.9)	0	3(1.3)	0
浮動性めまい	n (%)	0	2(2.0)	0	0	2(0.8)	4(2.3)
低血圧	n (%)	0	0	1(0.9)	0	1(0.4)	0
失神	n (%)	0	0	0	1(3.7)	1(0.4)	0
パーキンソニズム関連有害事象	n (%)	0	0	2(1.9)	0	2(0.8)	0
振戦	n (%)	0	0	2(1.9)	0	2(0.8)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	9(8.9)	5(4.7)	1(3.7)	15(6.3)	5(2.9)
傾眠	n (%)	0	8(7.9)	3(2.8)	1(3.7)	12(5.0)	4(2.3)
鎮静	n (%)	0	1(1.0)	2(1.9)	0	3(1.3)	1(0.6)
基礎疾患の悪化に関連する有害事象	n (%)	0	9(8.9)	6(5.6)	0	15(6.3)	13(7.6)
自殺念慮	n (%)	0	4(4.0)	1(0.9)	0	5(2.1)	4(2.3)
うつ病	n (%)	0	0	2(1.9)	0	2(0.8)	2(1.2)
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
敵意	n (%)	0	1(1.0)	0	0	1(0.4)	0
軽躁	n (%)	0	1(1.0)	0	0	1(0.4)	0
易刺激性	n (%)	0	1(1.0)	0	0	1(0.4)	2(1.2)
妄想症	n (%)	0	1(1.0)	0	0	1(0.4)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－159　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=101)	80 mg (N=107)	100 mg (N=27)	All NBI-98854 (N=239)	Placebo (N=171)
精神病性障害	n (%)	0	0	1(0.9)	0	1(0.4)	2(1.2)
統合失調感情障害	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
自殺企図	n (%)	0	0	1(0.9)	0	1(0.4)	0
躁病	n (%)	0	0	0	0	0	1(0.6)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.6)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表 2.7.4.7－159 CYP2D6フェノタイプごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験 ISS）（続き）

CYP2D6 Genotype: Not Reported

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=0)	40 mg (N=1)	80 mg (N=1)	100 mg (N=0)	All NBI-98854 (N=2)	Placebo (N=0)
No subjects met these criteria							

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.4より引用（一部改変）

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

CYP2D6 Genotype: Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=12)	 80 mg (N=11)	 80 mg Only[b] (N=9)	 All NBI-98854 (N=23)
Any Adverse Event	n (%)	8(66.7)	8(72.7)	6(66.7)	16(69.6)
胃腸障害	n (%)	1(8.3)	4(36.4)	3(33.3)	5(21.7)
便秘	n (%)	1(8.3)	2(18.2)	1(11.1)	3(13.0)
腹痛	n (%)	0	1(9.1)	1(11.1)	1(4.3)
上腹部痛	n (%)	0	1(9.1)	1(11.1)	1(4.3)
流涎過多	n (%)	0	1(9.1)	0	1(4.3)
全身障害および投与局所様態	n (%)	1(8.3)	2(18.2)	0	3(13.0)
歩行障害	n (%)	1(8.3)	1(9.1)	0	2(8.7)
無力症	n (%)	0	1(9.1)	0	1(4.3)
疲労	n (%)	1(8.3)	0	0	1(4.3)
末梢性浮腫	n (%)	1(8.3)	0	0	1(4.3)
感染症および寄生虫症	n (%)	3(25.0)	3(27.3)	2(22.2)	6(26.1)
尿路感染	n (%)	1(8.3)	1(9.1)	1(11.1)	2(8.7)
急性扁桃炎	n (%)	0	1(9.1)	1(11.1)	1(4.3)
体部白癬	n (%)	1(8.3)	0	0	1(4.3)
気管支炎	n (%)	0	1(9.1)	1(11.1)	1(4.3)
ブドウ球菌性蜂巣炎	n (%)	1(8.3)	0	0	1(4.3)
ウイルス性胃腸炎	n (%)	1(8.3)	0	0	1(4.3)
副鼻腔炎	n (%)	0	1(9.1)	0	1(4.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=12)	 80 mg (N=11)	 80 mg Only[b] (N=9)	All NBI-98854 (N=23)
股部白癬	n (%)	1(8.3)	0	0	1(4.3)
傷害、中毒および処置合併症	n (%)	1(8.3)	0	0	1(4.3)
頭部損傷	n (%)	1(8.3)	0	0	1(4.3)
四肢外傷性切断	n (%)	1(8.3)	0	0	1(4.3)
臨床検査	n (%)	1(8.3)	3(27.3)	1(11.1)	4(17.4)
抗精神病薬濃度治療量以上	n (%)	0	1(9.1)	0	1(4.3)
血中ブドウ糖減少	n (%)	0	1(9.1)	0	1(4.3)
グリコヘモグロビン増加	n (%)	0	1(9.1)	0	1(4.3)
ヘモグロビン減少	n (%)	0	1(9.1)	1(11.1)	1(4.3)
体重減少	n (%)	1(8.3)	0	0	1(4.3)
筋骨格系および結合組織障害	n (%)	2(16.7)	2(18.2)	0	4(17.4)
関節痛	n (%)	0	1(9.1)	0	1(4.3)
背部痛	n (%)	1(8.3)	0	0	1(4.3)
頚部痛	n (%)	1(8.3)	0	0	1(4.3)
四肢痛	n (%)	0	1(9.1)	0	1(4.3)
神経系障害	n (%)	4(33.3)	2(18.2)	0	6(26.1)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=12)	 80 mg (N=11)	 80 mg Only[b] (N=9)	All NBI-98854 (N=23)
平衡障害	n (%)	1(8.3)	1(9.1)	0	2(8.7)
頭痛	n (%)	0	2(18.2)	0	2(8.7)
傾眠	n (%)	2(16.7)	0	0	2(8.7)
構語障害	n (%)	0	1(9.1)	0	1(4.3)
パーキンソニズム	n (%)	1(8.3)	0	0	1(4.3)
精神障害	n (%)	2(16.7)	3(27.3)	1(11.1)	5(21.7)
不安	n (%)	0	1(9.1)	0	1(4.3)
双極１型障害	n (%)	1(8.3)	0	0	1(4.3)
うつ病	n (%)	1(8.3)	0	0	1(4.3)
不眠症	n (%)	0	1(9.1)	0	1(4.3)
落ち着きのなさ	n (%)	0	1(9.1)	0	1(4.3)
自殺念慮	n (%)	0	1(9.1)	1(11.1)	1(4.3)
呼吸器、胸郭および縦隔障害	n (%)	0	4(36.4)	2(22.2)	4(17.4)
喘息	n (%)	0	1(9.1)	1(11.1)	1(4.3)
咳嗽	n (%)	0	1(9.1)	1(11.1)	1(4.3)
口腔咽頭痛	n (%)	0	1(9.1)	0	1(4.3)
副鼻腔うっ血	n (%)	0	1(9.1)	0	1(4.3)
皮膚および皮下組織障害	n (%)	0	1(9.1)	0	1(4.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=12)	 80 mg (N=11)	 80 mg Only[b] (N=9)	All NBI-98854 (N=23)
発疹	n (%)	0	1(9.1)	0	1(4.3)
外科および内科処置	n (%)	1(8.3)	0	0	1(4.3)
抜歯	n (%)	1(8.3)	0	0	1(4.3)
血管障害	n (%)	1(8.3)	1(9.1)	1(11.1)	2(8.7)
本態性高血圧症	n (%)	1(8.3)	0	0	1(4.3)
高血圧	n (%)	0	1(9.1)	1(11.1)	1(4.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
Any Adverse Event	n (%)	109(58.9)	133(61.0)	119(58.3)	242(60.0)
血液およびリンパ系障害	n (%)	4(2.2)	5(2.3)	5(2.5)	9(2.2)
貧血	n (%)	1(0.5)	3(1.4)	3(1.5)	4(1.0)
好中球減少症	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.7)
白血球増加症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
白血球減少症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
血小板血症	n (%)	1(0.5)	0	0	1(0.2)
心臓障害	n (%)	5(2.7)	5(2.3)	5(2.5)	10(2.5)
心房細動	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
上室性不整脈	n (%)	1(0.5)	0	0	1(0.2)
左脚ブロック	n (%)	0	1(0.5)	1(0.5)	1(0.2)
心不全	n (%)	0	1(0.5)	1(0.5)	1(0.2)
冠動脈疾患	n (%)	1(0.5)	0	0	1(0.2)
僧帽弁閉鎖不全症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
洞性頻脈	n (%)	1(0.5)	0	0	1(0.2)
頻脈	n (%)	1(0.5)	0	0	1(0.2)
三尖弁閉鎖不全症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
心室性期外収縮	n (%)	0	1(0.5)	1(0.5)	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
先天性、家族性および遺伝性障害	n (%)	0	1(0.5)	1(0.5)	1(0.2)
弯足	n (%)	0	1(0.5)	1(0.5)	1(0.2)
耳および迷路障害	n (%)	3(1.6)	2(0.9)	2(1.0)	5(1.2)
耳鳴	n (%)	2(1.1)	0	0	2(0.5)
耳介軟骨膜炎	n (%)	0	1(0.5)	1(0.5)	1(0.2)
耳痛	n (%)	0	1(0.5)	1(0.5)	1(0.2)
聴覚障害	n (%)	1(0.5)	0	0	1(0.2)
内分泌障害	n (%)	1(0.5)	0	0	1(0.2)
甲状腺機能低下症	n (%)	1(0.5)	0	0	1(0.2)
眼障害	n (%)	0	3(1.4)	3(1.5)	3(0.7)
核性白内障	n (%)	0	1(0.5)	1(0.5)	1(0.2)
複視	n (%)	0	1(0.5)	1(0.5)	1(0.2)
兎眼	n (%)	0	1(0.5)	1(0.5)	1(0.2)
黄斑浮腫	n (%)	0	1(0.5)	1(0.5)	1(0.2)
網膜静脈閉塞	n (%)	0	1(0.5)	1(0.5)	1(0.2)
胃腸障害	n (%)	29(15.7)	38(17.4)	30(14.7)	67(16.6)
下痢	n (%)	6(3.2)	11(5.0)	10(4.9)	17(4.2)
嘔吐	n (%)	7(3.8)	7(3.2)	5(2.5)	14(3.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
口内乾燥	n (%)	8(4.3)	3(1.4)	3(1.5)	11(2.7)
悪心	n (%)	4(2.2)	7(3.2)	7(3.4)	11(2.7)
便秘	n (%)	5(2.7)	5(2.3)	3(1.5)	10(2.5)
流涎過多	n (%)	2(1.1)	5(2.3)	3(1.5)	7(1.7)
腹痛	n (%)	2(1.1)	3(1.4)	2(1.0)	5(1.2)
歯痛	n (%)	2(1.1)	3(1.4)	2(1.0)	5(1.2)
上腹部痛	n (%)	2(1.1)	2(0.9)	1(0.5)	4(1.0)
嚥下障害	n (%)	3(1.6)	1(0.5)	1(0.5)	4(1.0)
胃食道逆流性疾患	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
結腸ポリープ	n (%)	2(1.1)	0	0	2(0.5)
消化不良	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
胃炎	n (%)	0	2(0.9)	1(0.5)	2(0.5)
痔核	n (%)	2(1.1)	0	0	2(0.5)
腹部膨満	n (%)	0	1(0.5)	1(0.5)	1(0.2)
腹部圧痛	n (%)	1(0.5)	0	0	1(0.2)
細菌叢異常症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
憩室	n (%)	1(0.5)	0	0	1(0.2)
変色便	n (%)	1(0.5)	0	0	1(0.2)
食中毒	n (%)	0	1(0.5)	1(0.5)	1(0.2)
びらん性胃炎	n (%)	0	1(0.5)	0	1(0.2)
胃腸出血	n (%)	1(0.5)	0	0	1(0.2)
裂孔ヘルニア	n (%)	0	1(0.5)	1(0.5)	1(0.2)
メレナ	n (%)	1(0.5)	0	0	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
食道食物嵌入	n (%)	1(0.5)	0	0	1(0.2)
食道狭窄	n (%)	1(0.5)	0	0	1(0.2)
食道炎	n (%)	1(0.5)	0	0	1(0.2)
歯の脱落	n (%)	1(0.5)	0	0	1(0.2)
臍ヘルニア	n (%)	1(0.5)	0	0	1(0.2)
全身障害および投与局所様態	n (%)	17(9.2)	25(11.5)	20(9.8)	42(10.4)
疲労	n (%)	12(6.5)	8(3.7)	8(3.9)	20(5.0)
胸痛	n (%)	3(1.6)	3(1.4)	3(1.5)	6(1.5)
無力症	n (%)	1(0.5)	3(1.4)	0	4(1.0)
易刺激性	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
非心臓性胸痛	n (%)	1(0.5)	2(0.9)	1(0.5)	3(0.7)
末梢性浮腫	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
歩行障害	n (%)	2(1.1)	0	0	2(0.5)
発熱	n (%)	0	2(0.9)	1(0.5)	2(0.5)
空腹	n (%)	1(0.5)	0	0	1(0.2)
治癒不良	n (%)	1(0.5)	0	0	1(0.2)
倦怠感	n (%)	0	1(0.5)	1(0.5)	1(0.2)
疼痛	n (%)	0	1(0.5)	1(0.5)	1(0.2)
突然死	n (%)	0	1(0.5)	1(0.5)	1(0.2)
口渇	n (%)	1(0.5)	0	0	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
肝胆道系障害	n (%)	0	3(1.4)	3(1.5)	3(0.7)
胆石症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
肝不全	n (%)	0	1(0.5)	1(0.5)	1(0.2)
急性肝炎	n (%)	0	1(0.5)	1(0.5)	1(0.2)
黄疸	n (%)	0	1(0.5)	1(0.5)	1(0.2)
免疫系障害	n (%)	0	2(0.9)	2(1.0)	2(0.5)
過敏症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
季節性アレルギー	n (%)	0	1(0.5)	1(0.5)	1(0.2)
感染症および寄生虫症	n (%)	29(15.7)	40(18.3)	36(17.6)	69(17.1)
尿路感染	n (%)	10(5.4)	13(6.0)	12(5.9)	23(5.7)
鼻咽頭炎	n (%)	6(3.2)	9(4.1)	8(3.9)	15(3.7)
上気道感染	n (%)	4(2.2)	4(1.8)	4(2.0)	8(2.0)
気管支炎	n (%)	2(1.1)	5(2.3)	4(2.0)	7(1.7)
蜂巣炎	n (%)	0	4(1.8)	3(1.5)	4(1.0)
胃腸炎	n (%)	0	4(1.8)	4(2.0)	4(1.0)
ダニ皮膚炎	n (%)	2(1.1)	0	0	2(0.5)
急性副鼻腔炎	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
耳感染	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
ウイルス性胃腸炎	n (%)	2(1.1)	0	0	2(0.5)
インフルエンザ	n (%)	2(1.1)	0	0	2(0.5)
皮下組織膿瘍	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
外陰腟真菌感染	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
四肢膿瘍	n (%)	0	1(0.5)	0	1(0.2)
軟部組織膿瘍	n (%)	0	1(0.5)	1(0.5)	1(0.2)
憩室炎	n (%)	0	1(0.5)	1(0.5)	1(0.2)
眼感染	n (%)	1(0.5)	0	0	1(0.2)
せつ	n (%)	1(0.5)	0	0	1(0.2)
咬傷感染	n (%)	0	1(0.5)	1(0.5)	1(0.2)
爪真菌症	n (%)	1(0.5)	0	0	1(0.2)
咽頭炎	n (%)	1(0.5)	0	0	1(0.2)
急性腎盂腎炎	n (%)	1(0.5)	0	0	1(0.2)
副鼻腔炎	n (%)	0	1(0.5)	1(0.5)	1(0.2)
歯膿瘍	n (%)	0	1(0.5)	1(0.5)	1(0.2)
傷害、中毒および処置合併症	n (%)	15(8.1)	21(9.6)	17(8.3)	36(8.9)
転倒・転落	n (%)	5(2.7)	5(2.3)	4(2.0)	10(2.5)
擦過傷	n (%)	2(1.1)	2(0.9)	2(1.0)	4(1.0)
挫傷	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.7)
足骨折	n (%)	0	3(1.4)	2(1.0)	3(0.7)
関節脱臼	n (%)	0	2(0.9)	1(0.5)	2(0.5)
筋挫傷	n (%)	0	2(0.9)	2(1.0)	2(0.5)
交通事故	n (%)	0	2(0.9)	2(1.0)	2(0.5)
皮膚裂傷	n (%)	0	2(0.9)	2(1.0)	2(0.5)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
動物咬傷	n (%)	0	1(0.5)	1(0.5)	1(0.2)
節足動物咬傷	n (%)	0	1(0.5)	0	1(0.2)
第２度熱傷	n (%)	1(0.5)	0	0	1(0.2)
頚椎骨折	n (%)	0	1(0.5)	1(0.5)	1(0.2)
皮膚化学熱傷	n (%)	0	1(0.5)	1(0.5)	1(0.2)
異物による損傷	n (%)	0	1(0.5)	1(0.5)	1(0.2)
関節損傷	n (%)	1(0.5)	0	0	1(0.2)
関節捻挫	n (%)	1(0.5)	0	0	1(0.2)
四肢損傷	n (%)	0	1(0.5)	0	1(0.2)
口腔内損傷	n (%)	0	1(0.5)	1(0.5)	1(0.2)
膝蓋骨骨折	n (%)	0	1(0.5)	1(0.5)	1(0.2)
橈骨骨折	n (%)	0	1(0.5)	1(0.5)	1(0.2)
腎損傷	n (%)	1(0.5)	0	0	1(0.2)
肋骨骨折	n (%)	0	1(0.5)	0	1(0.2)
引っかき傷	n (%)	1(0.5)	0	0	1(0.2)
皮下血腫	n (%)	0	1(0.5)	1(0.5)	1(0.2)
熱傷	n (%)	1(0.5)	0	0	1(0.2)
臨床検査	n (%)	18(9.7)	31(14.2)	28(13.7)	49(12.2)
体重増加	n (%)	2(1.1)	7(3.2)	7(3.4)	9(2.2)
体重減少	n (%)	3(1.6)	3(1.4)	2(1.0)	6(1.5)
γ－グルタミルトランスフェラーゼ増加	n (%)	2(1.1)	3(1.4)	3(1.5)	5(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
血中クレアチンホスホキナーゼ増加	n (%)	2(1.1)	2(0.9)	2(1.0)	4(1.0)
血中クレアチニン増加	n (%)	1(0.5)	2(0.9)	1(0.5)	3(0.7)
血中ブドウ糖増加	n (%)	0	3(1.4)	3(1.5)	3(0.7)
血中プロラクチン増加	n (%)	2(1.1)	1(0.5)	0	3(0.7)
血中トリグリセリド増加	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
尿中ブドウ糖陽性	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
ヘモグロビン減少	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
血圧上昇	n (%)	0	2(0.9)	2(1.0)	2(0.5)
血中尿素増加	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
グリコヘモグロビン増加	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
ヘマトクリット減少	n (%)	0	2(0.9)	2(1.0)	2(0.5)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.5)	0	0	1(0.2)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.5)	0	0	1(0.2)
血中コレステロール増加	n (%)	0	1(0.5)	1(0.5)	1(0.2)
尿中結晶陽性	n (%)	0	1(0.5)	1(0.5)	1(0.2)
心電図ＱＴ延長	n (%)	0	1(0.5)	1(0.5)	1(0.2)
握力低下	n (%)	1(0.5)	0	0	1(0.2)
心拍数減少	n (%)	0	1(0.5)	1(0.5)	1(0.2)
肝酵素上昇	n (%)	1(0.5)	0	0	1(0.2)
便潜血陽性	n (%)	0	1(0.5)	1(0.5)	1(0.2)
血小板数減少	n (%)	0	1(0.5)	1(0.5)	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
総蛋白減少	n (%)	0	1(0.5)	1(0.5)	1(0.2)
赤血球数減少	n (%)	0	1(0.5)	1(0.5)	1(0.2)
赤血球数増加	n (%)	0	1(0.5)	1(0.5)	1(0.2)
代謝および栄養障害	n (%)	9(4.9)	16(7.3)	13(6.4)	25(6.2)
食欲減退	n (%)	4(2.2)	3(1.4)	2(1.0)	7(1.7)
低ナトリウム血症	n (%)	0	3(1.4)	2(1.0)	3(0.7)
食欲亢進	n (%)	0	3(1.4)	2(1.0)	3(0.7)
食欲不振	n (%)	2(1.1)	0	0	2(0.5)
糖尿病	n (%)	0	2(0.9)	2(1.0)	2(0.5)
食欲障害	n (%)	0	1(0.5)	1(0.5)	1(0.2)
脱水	n (%)	0	1(0.5)	1(0.5)	1(0.2)
耐糖能障害	n (%)	1(0.5)	0	0	1(0.2)
高血糖	n (%)	0	1(0.5)	1(0.5)	1(0.2)
高カリウム血症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
高トリグリセリド血症	n (%)	1(0.5)	0	0	1(0.2)
低アルブミン血症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
低カリウム血症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
低ナトリウム血症候群	n (%)	0	1(0.5)	1(0.5)	1(0.2)
代謝性アシドーシス	n (%)	0	1(0.5)	1(0.5)	1(0.2)
多飲症	n (%)	1(0.5)	0	0	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
筋骨格系および結合組織障害	n (%)	16(8.6)	19(8.7)	16(7.8)	35(8.7)
背部痛	n (%)	5(2.7)	4(1.8)	4(2.0)	9(2.2)
関節痛	n (%)	2(1.1)	5(2.3)	5(2.5)	7(1.7)
骨関節炎	n (%)	2(1.1)	2(0.9)	2(1.0)	4(1.0)
四肢痛	n (%)	1(0.5)	3(1.4)	2(1.0)	4(1.0)
筋肉痛	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.7)
関節炎	n (%)	1(0.5)	1(0.5)	0	2(0.5)
滑液包炎	n (%)	1(0.5)	0	0	1(0.2)
尾骨痛	n (%)	0	1(0.5)	1(0.5)	1(0.2)
椎間板変性症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
関節腫脹	n (%)	0	1(0.5)	1(0.5)	1(0.2)
筋固縮	n (%)	0	1(0.5)	0	1(0.2)
筋痙縮	n (%)	0	1(0.5)	1(0.5)	1(0.2)
筋力低下	n (%)	1(0.5)	0	0	1(0.2)
筋骨格系胸痛	n (%)	1(0.5)	0	0	1(0.2)
筋骨格痛	n (%)	0	1(0.5)	1(0.5)	1(0.2)
頚部痛	n (%)	0	1(0.5)	0	1(0.2)
骨減少症	n (%)	1(0.5)	0	0	1(0.2)
顎痛	n (%)	1(0.5)	0	0	1(0.2)
良性、悪性および詳細不明の新生物 （嚢胞およびポリープを含む）	n (%)	2(1.1)	3(1.4)	3(1.5)	5(1.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
副腎腺腫	n (%)	0	1(0.5)	1(0.5)	1(0.2)
乳癌	n (%)	0	1(0.5)	1(0.5)	1(0.2)
脂肪腫	n (%)	1(0.5)	0	0	1(0.2)
肺新生物	n (%)	1(0.5)	0	0	1(0.2)
甲状腺新生物	n (%)	0	1(0.5)	1(0.5)	1(0.2)
神経系障害	n (%)	42(22.7)	47(21.6)	37(18.1)	89(22.1)
頭痛	n (%)	10(5.4)	14(6.4)	12(5.9)	24(6.0)
傾眠	n (%)	13(7.0)	9(4.1)	6(2.9)	22(5.5)
浮動性めまい	n (%)	6(3.2)	10(4.6)	10(4.9)	16(4.0)
アカシジア	n (%)	7(3.8)	1(0.5)	1(0.5)	8(2.0)
振戦	n (%)	4(2.2)	3(1.4)	1(0.5)	7(1.7)
鎮静	n (%)	2(1.1)	4(1.8)	3(1.5)	6(1.5)
失神	n (%)	4(2.2)	2(0.9)	1(0.5)	6(1.5)
ジスキネジー	n (%)	1(0.5)	4(1.8)	3(1.5)	5(1.2)
よだれ	n (%)	0	3(1.4)	3(1.5)	3(0.7)
ジストニー	n (%)	2(1.1)	0	0	2(0.5)
錐体外路障害	n (%)	0	2(0.9)	2(1.0)	2(0.5)
遅発性ジスキネジー	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
一過性脳虚血発作	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
健忘	n (%)	0	1(0.5)	1(0.5)	1(0.2)
平衡障害	n (%)	0	1(0.5)	1(0.5)	1(0.2)
歯車様固縮	n (%)	0	1(0.5)	1(0.5)	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
認知症	n (%)	1(0.5)	0	0	1(0.2)
注意力障害	n (%)	0	1(0.5)	1(0.5)	1(0.2)
脳症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
顔面神経麻痺	n (%)	0	1(0.5)	1(0.5)	1(0.2)
感覚鈍麻	n (%)	1(0.5)	0	0	1(0.2)
企図振戦	n (%)	1(0.5)	0	0	1(0.2)
嗜眠	n (%)	0	1(0.5)	0	1(0.2)
片頭痛	n (%)	1(0.5)	0	0	1(0.2)
ミオクローヌス	n (%)	1(0.5)	0	0	1(0.2)
神経痛	n (%)	1(0.5)	0	0	1(0.2)
末梢性ニューロパチー	n (%)	0	1(0.5)	1(0.5)	1(0.2)
パーキンソニズム	n (%)	0	1(0.5)	1(0.5)	1(0.2)
咬舌	n (%)	1(0.5)	0	0	1(0.2)
妊娠、産褥および周産期の状態	n (%)	0	1(0.5)	1(0.5)	1(0.2)
自然流産	n (%)	0	1(0.5)	1(0.5)	1(0.2)
精神障害	n (%)	39(21.1)	31(14.2)	26(12.7)	70(17.4)
自殺念慮	n (%)	9(4.9)	9(4.1)	9(4.4)	18(4.5)
不安	n (%)	6(3.2)	6(2.8)	3(1.5)	12(3.0)
うつ病	n (%)	8(4.3)	4(1.8)	3(1.5)	12(3.0)
不眠症	n (%)	4(2.2)	4(1.8)	4(2.0)	8(2.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
統合失調症	n (%)	4(2.2)	4(1.8)	4(2.0)	8(2.0)
激越	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
抑うつ気分	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
抑うつ症状	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
躁病	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
精神状態変化	n (%)	2(1.1)	0	0	2(0.5)
妄想症	n (%)	2(1.1)	0	0	2(0.5)
精神運動制止遅滞	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
精神病性障害	n (%)	1(0.5)	1(0.5)	0	2(0.5)
落ち着きのなさ	n (%)	1(0.5)	1(0.5)	0	2(0.5)
統合失調感情障害	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(0.9)	2(1.0)	2(0.5)
死別反応	n (%)	1(0.5)	0	0	1(0.2)
錯乱状態	n (%)	0	1(0.5)	1(0.5)	1(0.2)
ディスフェミア	n (%)	1(0.5)	0	0	1(0.2)
敵意	n (%)	1(0.5)	0	0	1(0.2)
軽躁	n (%)	1(0.5)	0	0	1(0.2)
リビドー減退	n (%)	1(0.5)	0	0	1(0.2)
気分動揺	n (%)	0	1(0.5)	0	1(0.2)
神経過敏	n (%)	0	1(0.5)	1(0.5)	1(0.2)
パニック発作	n (%)	1(0.5)	0	0	1(0.2)
外傷後ストレス障害	n (%)	1(0.5)	0	0	1(0.2)
自殺行為	n (%)	0	1(0.5)	1(0.5)	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
トランス	n (%)	1(0.5)	0	0	1(0.2)
腎および尿路障害	n (%)	6(3.2)	6(2.8)	6(2.9)	12(3.0)
血尿	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.7)
頻尿	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
尿失禁	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
排尿困難	n (%)	0	1(0.5)	1(0.5)	1(0.2)
糖尿	n (%)	0	1(0.5)	1(0.5)	1(0.2)
腎結石症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
腎嚢胞	n (%)	1(0.5)	0	0	1(0.2)
急性腎不全	n (%)	1(0.5)	0	0	1(0.2)
尿臭異常	n (%)	1(0.5)	0	0	1(0.2)
生殖系および乳房障害	n (%)	3(1.6)	3(1.4)	3(1.5)	6(1.5)
良性前立腺肥大症	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
乳房圧痛	n (%)	1(0.5)	0	0	1(0.2)
乳汁漏出症	n (%)	1(0.5)	0	0	1(0.2)
月経過多	n (%)	0	1(0.5)	1(0.5)	1(0.2)
前立腺炎	n (%)	1(0.5)	0	0	1(0.2)
精巣捻転	n (%)	0	1(0.5)	1(0.5)	1(0.2)
腟分泌物	n (%)	1(0.5)	0	0	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	 All NBI-98854 (N=403)
呼吸器、胸郭および縦隔障害	n (%)	8(4.3)	23(10.6)	21(10.3)	31(7.7)
咳嗽	n (%)	3(1.6)	6(2.8)	4(2.0)	9(2.2)
慢性閉塞性肺疾患	n (%)	2(1.1)	5(2.3)	5(2.5)	7(1.7)
鼻閉	n (%)	1(0.5)	5(2.3)	5(2.5)	6(1.5)
呼吸困難	n (%)	1(0.5)	3(1.4)	2(1.0)	4(1.0)
喘息	n (%)	1(0.5)	2(0.9)	1(0.5)	3(0.7)
アレルギー性鼻炎	n (%)	0	2(0.9)	2(1.0)	2(0.5)
アレルギー性副鼻腔炎	n (%)	1(0.5)	0	0	1(0.2)
慢性気管支炎	n (%)	0	1(0.5)	1(0.5)	1(0.2)
嚢胞性肺疾患	n (%)	0	1(0.5)	1(0.5)	1(0.2)
鼻出血	n (%)	1(0.5)	0	0	1(0.2)
口腔咽頭痛	n (%)	0	1(0.5)	1(0.5)	1(0.2)
胸水	n (%)	0	1(0.5)	1(0.5)	1(0.2)
胸膜線維症	n (%)	0	1(0.5)	1(0.5)	1(0.2)
気道うっ血	n (%)	0	1(0.5)	0	1(0.2)
鼻漏	n (%)	1(0.5)	0	0	1(0.2)
副鼻腔うっ血	n (%)	1(0.5)	0	0	1(0.2)
くしゃみ	n (%)	0	1(0.5)	1(0.5)	1(0.2)
皮膚および皮下組織障害	n (%)	11(5.9)	5(2.3)	5(2.5)	16(4.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
そう痒症	n (%)	3(1.6)	0	0	3(0.7)
発疹	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.7)
過角化	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
斑状丘疹状皮疹	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
水疱	n (%)	1(0.5)	0	0	1(0.2)
アレルギー性皮膚炎	n (%)	1(0.5)	0	0	1(0.2)
全身性皮疹	n (%)	1(0.5)	0	0	1(0.2)
丘疹	n (%)	0	1(0.5)	1(0.5)	1(0.2)
皮膚剥脱	n (%)	0	1(0.5)	1(0.5)	1(0.2)
皮膚病変	n (%)	0	1(0.5)	1(0.5)	1(0.2)
蕁麻疹	n (%)	1(0.5)	0	0	1(0.2)
社会環境	n (%)	1(0.5)	0	0	1(0.2)
社会的入院	n (%)	1(0.5)	0	0	1(0.2)
外科および内科処置	n (%)	1(0.5)	3(1.4)	3(1.5)	4(1.0)
抜歯	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
四肢再接合手術	n (%)	0	1(0.5)	1(0.5)	1(0.2)
鼓膜切開	n (%)	0	1(0.5)	1(0.5)	1(0.2)
Unknown	n (%)	1(0.5)	0	0	1(0.2)
皮膚嚢腫	n (%)	1(0.5)	0	0	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	 80 mg (N=218)	 80 mg Only[b] (N=204)	All NBI-98854 (N=403)
血管障害	n (%)	5(2.7)	13(6.0)	12(5.9)	18(4.5)
高血圧	n (%)	2(1.1)	5(2.3)	4(2.0)	7(1.7)
ほてり	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
深部静脈血栓症	n (%)	0	2(0.9)	2(1.0)	2(0.5)
血腫	n (%)	0	2(0.9)	2(1.0)	2(0.5)
低血圧	n (%)	0	1(0.5)	1(0.5)	1(0.2)
起立性低血圧	n (%)	1(0.5)	0	0	1(0.2)
末梢動脈閉塞性疾患	n (%)	1(0.5)	0	0	1(0.2)
レイノー現象	n (%)	0	1(0.5)	1(0.5)	1(0.2)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－160　CYP2D6フェノタイプごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Reported

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=0)	 80 mg (N=1)	 80 mg Only[b] (N=1)	All NBI-98854 (N=1)
Any Adverse Event	n (%)	0	1(100.0)	1(100.0)	1(100.0)
感染症および寄生虫症	n (%)	0	1(100.0)	1(100.0)	1(100.0)
肺炎	n (%)	0	1(100.0)	1(100.0)	1(100.0)
精神障害	n (%)	0	1(100.0)	1(100.0)	1(100.0)
アルコール症	n (%)	0	1(100.0)	1(100.0)	1(100.0)
うつ病	n (%)	0	1(100.0)	1(100.0)	1(100.0)
皮膚および皮下組織障害	n (%)	0	1(100.0)	1(100.0)	1(100.0)
発疹	n (%)	0	1(100.0)	1(100.0)	1(100.0)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.4より引用（一部改変）

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

CYP2D6 Genotype: Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=12)	80 mg (N=11)	80 mg Only[b] (N=9)	All NBI-98854 (N=23)
Any Adverse Event of Special Interest	n (%)	5(41.7)	3(27.3)	1(11.1)	8(34.8)
不安	n (%)	0	1(9.1)	0	1(4.3)
不安	n (%)	0	1(9.1)	0	1(4.3)
うつ病及び自殺関連有害事象	n (%)	1(8.3)	1(9.1)	1(11.1)	2(8.7)
うつ病	n (%)	1(8.3)	0	0	1(4.3)
自殺念慮	n (%)	0	1(9.1)	1(11.1)	1(4.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	1(8.3)	1(9.1)	0	2(8.7)
無力症	n (%)	0	1(9.1)	0	1(4.3)
疲労	n (%)	1(8.3)	0	0	1(4.3)
パーキンソニズム関連有害事象	n (%)	1(8.3)	0	0	1(4.3)
パーキンソニズム	n (%)	1(8.3)	0	0	1(4.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	2(16.7)	0	0	2(8.7)
傾眠	n (%)	2(16.7)	0	0	2(8.7)
基礎疾患の悪化に関連する有害事象	n (%)	2(16.7)	1(9.1)	1(11.1)	3(13.0)
双極１型障害	n (%)	1(8.3)	0	0	1(4.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=12)	80 mg (N=11)	80 mg Only[b] (N=9)	All NBI-98854 (N=23)
うつ病	n (%)	1(8.3)	0	0	1(4.3)
自殺念慮	n (%)	0	1(9.1)	1(11.1)	1(4.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	80 mg (N=218)	80 mg Only[b] (N=204)	All NBI-98854 (N=403)
Any Adverse Event of Special Interest	n (%)	65(35.1)	67(30.7)	54(26.5)	132(32.8)
アカシジア関連有害事象	n (%)	7(3.8)	1(0.5)	1(0.5)	8(2.0)
アカシジア	n (%)	7(3.8)	1(0.5)	1(0.5)	8(2.0)
不安	n (%)	6(3.2)	6(2.8)	3(1.5)	12(3.0)
不安	n (%)	6(3.2)	6(2.8)	3(1.5)	12(3.0)
心血管系及びQT間隔延長関連有害事象	n (%)	6(3.2)	8(3.7)	7(3.4)	14(3.5)
胸痛	n (%)	3(1.6)	3(1.4)	3(1.5)	6(1.5)
失神	n (%)	4(2.2)	2(0.9)	1(0.5)	6(1.5)
心不全	n (%)	0	1(0.5)	1(0.5)	1(0.2)
心電図QT延長	n (%)	0	1(0.5)	1(0.5)	1(0.2)
突然死	n (%)	0	1(0.5)	1(0.5)	1(0.2)
うつ病及び自殺関連有害事象	n (%)	18(9.7)	16(7.3)	15(7.4)	34(8.4)
自殺念慮	n (%)	9(4.9)	9(4.1)	9(4.4)	18(4.5)
うつ病	n (%)	8(4.3)	4(1.8)	3(1.5)	12(3.0)
抑うつ気分	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
抑うつ症状	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(0.9)	2(1.0)	2(0.5)
自殺行為	n (%)	0	1(0.5)	1(0.5)	1(0.2)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	80 mg (N=218)	80 mg Only[b] (N=204)	All NBI-98854 (N=403)
嚥下障害関連有害事象	n (%)	3(1.6)	1(0.5)	1(0.5)	4(1.0)
嚥下障害	n (%)	3(1.6)	1(0.5)	1(0.5)	4(1.0)
食道食物嵌入	n (%)	1(0.5)	0	0	1(0.2)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	12(6.5)	13(6.0)	9(4.4)	25(6.2)
疲労	n (%)	12(6.5)	8(3.7)	8(3.9)	20(5.0)
無力症	n (%)	1(0.5)	3(1.4)	0	4(1.0)
嗜眠	n (%)	0	1(0.5)	0	1(0.2)
倦怠感	n (%)	0	1(0.5)	1(0.5)	1(0.2)
肝障害関連有害事象	n (%)	0	2(0.9)	2(1.0)	2(0.5)
肝不全	n (%)	0	1(0.5)	1(0.5)	1(0.2)
急性肝炎	n (%)	0	1(0.5)	1(0.5)	1(0.2)
高プロラクチン血症関連有害事象	n (%)	3(1.6)	1(0.5)	0	4(1.0)
血中プロラクチン増加	n (%)	2(1.1)	1(0.5)	0	3(0.7)
乳汁漏出症	n (%)	1(0.5)	0	0	1(0.2)
低血圧関連有害事象	n (%)	14(7.6)	16(7.3)	15(7.4)	30(7.4)
浮動性めまい	n (%)	6(3.2)	10(4.6)	10(4.9)	16(4.0)
転倒・転落	n (%)	5(2.7)	5(2.3)	4(2.0)	10(2.5)
失神	n (%)	4(2.2)	2(0.9)	1(0.5)	6(1.5)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	80 mg (N=218)	80 mg Only[b] (N=204)	All NBI-98854 (N=403)
低血圧	n (%)	0	1(0.5)	1(0.5)	1(0.2)
起立性低血圧	n (%)	1(0.5)	0	0	1(0.2)
パーキンソニズム関連有害事象	n (%)	4(2.2)	5(2.3)	2(1.0)	9(2.2)
振戦	n (%)	4(2.2)	3(1.4)	1(0.5)	7(1.7)
歯車様固縮	n (%)	0	1(0.5)	1(0.5)	1(0.2)
筋固縮	n (%)	0	1(0.5)	0	1(0.2)
パーキンソニズム	n (%)	0	1(0.5)	1(0.5)	1(0.2)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	15(8.1)	13(6.0)	9(4.4)	28(6.9)
傾眠	n (%)	13(7.0)	9(4.1)	6(2.9)	22(5.5)
鎮静	n (%)	2(1.1)	4(1.8)	3(1.5)	6(1.5)
基礎疾患の悪化に関連する有害事象	n (%)	25(13.5)	23(10.6)	21(10.3)	48(11.9)
自殺念慮	n (%)	9(4.9)	9(4.1)	9(4.4)	18(4.5)
うつ病	n (%)	8(4.3)	4(1.8)	3(1.5)	12(3.0)
統合失調症	n (%)	4(2.2)	4(1.8)	4(2.0)	8(2.0)
易刺激性	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
抑うつ気分	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
抑うつ症状	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
躁病	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
妄想症	n (%)	2(1.1)	0	0	2(0.5)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Poor Metabolizer

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=185)	80 mg (N=218)	80 mg Only[b] (N=204)	All NBI-98854 (N=403)
精神病性障害	n (%)	1(0.5)	1(0.5)	0	2(0.5)
統合失調感情障害	n (%)	1(0.5)	1(0.5)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(0.9)	2(1.0)	2(0.5)
敵意	n (%)	1(0.5)	0	0	1(0.2)
軽躁	n (%)	1(0.5)	0	0	1(0.2)
気分動揺	n (%)	0	1(0.5)	0	1(0.2)
外傷後ストレス障害	n (%)	1(0.5)	0	0	1(0.2)
自殺行為	n (%)	0	1(0.5)	1(0.5)	1(0.2)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－161　CYP2D6フェノタイプごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

CYP2D6 Genotype: Not Reported

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=0)	80 mg (N=1)	80 mg Only[b] (N=1)	All NBI-98854 (N=1)
Any Adverse Event of Special Interest	n (%)	0	1(100.0)	1(100.0)	1(100.0)
うつ病及び自殺関連有害事象	n (%)	0	1(100.0)	1(100.0)	1(100.0)
うつ病	n (%)	0	1(100.0)	1(100.0)	1(100.0)
基礎疾患の悪化に関連する有害事象	n (%)	0	1(100.0)	1(100.0)	1(100.0)
うつ病	n (%)	0	1(100.0)	1(100.0)	1(100.0)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.4より引用（一部改変）

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Any System Organ Class		9 (75.0)	11 (68.8)	20 (71.4)	8 (57.1)	45 (61.6)	56 (82.4)	101 (71.6)	29 (41.4)
Infections and infestations	感染症および寄生虫症	4 (33.3)	2 (12.5)	6 (21.4)	0 (0.0)	6 (8.2)	7 (10.3)	13 (9.2)	7 (10.0)
Nasopharyngitis	上咽頭炎	3 (25.0)	1 (6.3)	4 (14.3)	0 (0.0)	3 (4.1)	3 (4.4)	6 (4.3)	6 (8.6)
Pneumonia	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	2 (2.9)	3 (2.1)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Periodontitis	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Upper respiratory tract infection	上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Skin papilloma	皮膚乳頭腫	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blepharal papilloma	眼瞼乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	1 (8.3)	1 (6.3)	2 (7.1)	2 (14.3)	5 (6.8)	3 (4.4)	8 (5.7)	0 (0.0)
Decreased appetite	食欲減退	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Dehydration	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Diabetes mellitus	糖尿病	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperuricaemia	高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Polydipsia	多飲症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hyperlipidaemia	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Psychiatric disorders	精神障害	3 (25.0)	4 (25.0)	7 (25.0)	1 (7.1)	14 (19.2)	12 (17.6)	26 (18.4)	4 (5.7)
Insomnia	不眠症	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	1 (1.4)	5 (7.4)	6 (4.3)	1 (1.4)
Schizophrenia	統合失調症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (9.6)	0 (0.0)	7 (5.0)	1 (1.4)
Anxiety	不安	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	4 (5.9)	4 (2.8)	0 (0.0)
Depression	うつ病	0 (0.0)	1 (6.3)	1 (3.6)	1 (7.1)	1 (1.4)	2 (2.9)	3 (2.1)	0 (0.0)
Disinhibition	脱抑制	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.4)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	1 (1.4)
Delusion	妄想	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Panic attack	パニック発作	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Somatic symptom disorder	身体症状症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Nervous system disorders	神経系障害	4 (33.3)	8 (50.0)	12 (42.9)	1 (7.1)	16 (21.9)	30 (44.1)	46 (32.6)	5 (7.1)
Somnolence	傾眠	2 (16.7)	3 (18.8)	5 (17.9)	1 (7.1)	8 (11.0)	18 (26.5)	26 (18.4)	1 (1.4)
Akathisia	アカシジア	0 (0.0)	3 (18.8)	3 (10.7)	0 (0.0)	4 (5.5)	2 (2.9)	6 (4.3)	1 (1.4)
Headache	頭痛	1 (8.3)	2 (12.5)	3 (10.7)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	2 (2.9)
Tremor	振戦	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	4 (5.9)	4 (2.8)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.4)	3 (2.1)	1 (1.4)
Drooling	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Dyslalia	構音障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypoaesthesia	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Sciatica	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Seizure	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Eye disorders	眼障害	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	2 (2.9)
Blepharitis	眼瞼炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	1 (1.4)
Eyelid ptosis	眼瞼下垂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Keratitis	角膜炎	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Ear and labyrinth disorders	耳および迷路障害	2 (16.7)	0 (0.0)	2 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deafness neurosensory	感音性難聴	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	心臓障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Palpitations	動悸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Vascular disorders	血管障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	1 (1.4)
Hypertension	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0 (0.0)	2 (12.5)	2 (7.1)	0 (0.0)	1 (1.4)	2 (2.9)	3 (2.1)	1 (1.4)
Asthma	喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Gastrointestinal disorders	胃腸障害	0 (0.0)	1 (6.3)	1 (3.6)	1 (7.1)	8 (11.0)	19 (27.9)	27 (19.1)	6 (8.6)
Salivary hypersecretion	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.1)	9 (13.2)	12 (8.5)	1 (1.4)
Constipation	便秘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	1 (1.5)	3 (2.1)	1 (1.4)
Nausea	悪心	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.4)	3 (2.1)	1 (1.4)
Diarrhoea	下痢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	1 (1.4)
Dry mouth	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Gastritis	胃炎	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Toothache	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	1 (1.4)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0 (0.0)	1 (6.3)	1 (3.6)	1 (7.1)	6 (8.2)	5 (7.4)	11 (7.8)	4 (5.7)
Urticaria	蕁麻疹	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	2 (2.7)	1 (1.5)	3 (2.1)	0 (0.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	1 (1.5)	2 (1.4)	2 (2.9)
Alopecia areata	円形脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Blister	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Dry skin	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (8.3)	0 (0.0)	1 (3.6)	1 (7.1)	3 (4.1)	5 (7.4)	8 (5.7)	4 (5.7)
Back pain	背部痛	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	2 (2.7)	2 (2.9)	4 (2.8)	2 (2.9)
Neck pain	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Posture abnormal	姿勢異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Renal and urinary disorders	腎および尿路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.4)	1 (1.4)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Polyuria	多尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	1 (8.3)	2 (12.5)	3 (10.7)	0 (0.0)	9 (12.3)	9 (13.2)	18 (12.8)	2 (2.9)
Malaise	倦怠感	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	5 (6.8)	3 (4.4)	8 (5.7)	0 (0.0)
Fatigue	疲労	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Thirst	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.4)	1 (1.4)
Asthenia	無力症	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Feeling abnormal	異常感	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	1 (1.4)
Pyrexia	発熱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Investigations	臨床検査	1 (8.3)	0 (0.0)	1 (3.6)	1 (7.1)	3 (4.1)	2 (2.9)	5 (3.5)	0 (0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Weight increased	体重増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－162　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.1)	2 (2.9)	5 (3.5)	3 (4.3)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Head injury	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Contusion	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	1 (1.4)
Heat illness	熱中症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.6.1.1 より引用

表 2.7.4.7－163　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Any AESI		4 (33.3)	10 (62.5)	14 (50.0)	3 (21.4)	32 (43.8)	43 (63.2)	75 (53.2)	12 (17.1)
Somnolence	傾眠関連有害事象	2 (16.7)	3 (18.8)	5 (17.9)	1 (7.1)	14 (19.2)	21 (30.9)	35 (24.8)	1 (1.4)
Somnolence	傾眠	2 (16.7)	3 (18.8)	5 (17.9)	1 (7.1)	8 (11.0)	18 (26.5)	26 (18.4)	1 (1.4)
Malaise	倦怠感	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	5 (6.8)	3 (4.4)	8 (5.7)	0 (0.0)
Fatigue	疲労	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	0 (0.0)	2 (12.5)	2 (7.1)	1 (7.1)	5 (6.8)	5 (7.4)	10 (7.1)	5 (7.1)
Urticaria	蕁麻疹	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	2 (2.7)	1 (1.5)	3 (2.1)	0 (0.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	1 (1.5)	2 (1.4)	2 (2.9)
Blister	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－163　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Parkinsonism	パーキンソニズム関連有害事象	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	5 (6.8)	17 (25.0)	22 (15.6)	1 (1.4)
Salivary hypersecretion	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.1)	9 (13.2)	12 (8.5)	1 (1.4)
Tremor	振戦	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	4 (5.9)	4 (2.8)	0 (0.0)
Drooling	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	0 (0.0)	1 (6.3)	1 (3.6)	1 (7.1)	6 (8.2)	2 (2.9)	8 (5.7)	0 (0.0)
Depression	うつ病	0 (0.0)	1 (6.3)	1 (3.6)	1 (7.1)	1 (1.4)	2 (2.9)	3 (2.1)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Akathisia	アカシジア関連有害事象	0 (0.0)	4 (25.0)	4 (14.3)	0 (0.0)	4 (5.5)	4 (5.9)	8 (5.7)	1 (1.4)
Akathisia	アカシジア	0 (0.0)	3 (18.8)	3 (10.7)	0 (0.0)	4 (5.5)	2 (2.9)	6 (4.3)	1 (1.4)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	4 (5.9)	4 (2.8)	0 (0.0)
Anxiety	不安	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	4 (5.9)	4 (2.8)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－163　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=12) n(%)	80 mg (N=16) n(%)	All MT-5199 (N=28) n(%)	Placebo (N=14) n(%)	40 mg (N=73) n(%)	80 mg (N=68) n(%)	All MT-5199 (N=141) n(%)	Placebo (N=70) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	0 (0.0)	2 (12.5)	2 (7.1)	1 (7.1)	11 (15.1)	4 (5.9)	15 (10.6)	2 (2.9)
Schizophrenia	統合失調症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (9.6)	0 (0.0)	7 (5.0)	1 (1.4)
Depression	うつ病	0 (0.0)	1 (6.3)	1 (3.6)	1 (7.1)	1 (1.4)	2 (2.9)	3 (2.1)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.4)	1 (1.4)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (6.3)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (8.3)	0 (0.0)	1 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	1 (0.7)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)	0 (0.0)
Hypotension	低血圧関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	4 (5.9)	5 (3.5)	2 (2.9)
Dizziness	浮動性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.4)	3 (2.1)	1 (1.4)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.5)	2 (1.4)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.6.1.2 より引用

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Any System Organ Class		17 (100.0)	21 (91.3)	15 (88.2)	38 (95.0)	96 (88.1)	95 (95.0)	62 (92.5)	191 (91.4)
Infections and infestations	感染症および寄生虫症	7 (41.2)	6 (26.1)	5 (29.4)	13 (32.5)	39 (35.8)	34 (34.0)	24 (35.8)	73 (34.9)
Nasopharyngitis	上咽頭炎	6 (35.3)	4 (17.4)	3 (17.6)	10 (25.0)	24 (22.0)	19 (19.0)	12 (17.9)	43 (20.6)
Cystitis	膀胱炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	2 (1.8)	2 (2.0)	2 (3.0)	4 (1.9)
Pneumonia	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	3 (3.0)	3 (4.5)	5 (2.4)
Bronchitis	気管支炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Influenza	インフルエンザ	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Upper respiratory tract infection	上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	1 (1.0)	0 (0.0)	3 (1.4)
Cellulitis	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Folliculitis	毛包炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Gastroenteritis	胃腸炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Otitis externa	外耳炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Periodontitis	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Pharyngitis	咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Tinea pedis	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.5)	2 (1.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Herpes zoster	帯状疱疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Mastitis	乳腺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Nasal vestibulitis	鼻前庭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Otitis media	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Subcutaneous abscess	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Tonsillitis	扁桃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Urinary tract infection	尿路感染	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal infection	腟感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Varicella	水痘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Vulvovaginal candidiasis	外陰部腟カンジダ症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Eczema impetiginous	膿痂疹性湿疹	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin candida	皮膚カンジダ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Nail infection	爪感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Acarodermatitis	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Cystitis bacterial	細菌性膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Infected dermal cyst	感染性皮膚嚢腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Bacterial vulvovaginitis	細菌性外陰腟炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin papilloma	皮膚乳頭腫	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolism and nutrition disorders	代謝および栄養障害	2 (11.8)	1 (4.3)	0 (0.0)	3 (7.5)	14 (12.8)	11 (11.0)	8 (11.9)	25 (12.0)
Decreased appetite	食欲減退	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	5 (4.6)	3 (3.0)	1 (1.5)	8 (3.8)
Dehydration	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	4 (4.0)	4 (6.0)	5 (2.4)
Hyperuricaemia	高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	1 (1.0)	0 (0.0)	3 (1.4)
Diabetes mellitus	糖尿病	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Increased appetite	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Dyslipidaemia	脂質異常症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	2 (3.0)	2 (1.0)
Type 2 diabetes mellitus	２型糖尿病	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Electrolyte imbalance	電解質失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hypokalaemia	低カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hypouricaemia	低尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Marasmus	マラスムス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Polydipsia	多飲症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hyperlipidaemia	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Psychiatric disorders	精神障害	11 (64.7)	11 (47.8)	7 (41.2)	22 (55.0)	41 (37.6)	46 (46.0)	33 (49.3)	87 (41.6)
Schizophrenia	統合失調症	2 (11.8)	1 (4.3)	0 (0.0)	3 (7.5)	19 (17.4)	12 (12.0)	5 (7.5)	31 (14.8)
Insomnia	不眠症	4 (23.5)	3 (13.0)	3 (17.6)	7 (17.5)	6 (5.5)	13 (13.0)	9 (13.4)	19 (9.1)
Depression	うつ病	3 (17.6)	3 (13.0)	2 (11.8)	6 (15.0)	3 (2.8)	7 (7.0)	7 (10.4)	10 (4.8)
Anxiety	不安	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	4 (3.7)	9 (9.0)	7 (10.4)	13 (6.2)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (5.5)	3 (3.0)	2 (3.0)	9 (4.3)
Restlessness	落ち着きのなさ	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	2 (1.8)	1 (1.0)	1 (1.5)	3 (1.4)
Suicide attempt	自殺企図	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	2 (1.8)	1 (1.0)	1 (1.5)	3 (1.4)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	2 (3.0)	4 (1.9)
Middle insomnia	中期不眠症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Bruxism	歯ぎしり	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Delirium	譫妄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Disinhibition	脱抑制	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Flat affect	感情の平板化	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hallucination, auditory	幻聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Sleep disorder	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Agitation	激越	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Delusion	妄想	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Hypomania	軽躁	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Neurosis	神経症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Panic attack	パニック発作	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abulia	無為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Abnormal behaviour	異常行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Somatic hallucination	体感幻覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Nervous system disorders	神経系障害	6 (35.3)	14 (60.9)	9 (52.9)	20 (50.0)	45 (41.3)	55 (55.0)	35 (52.2)	100 (47.8)
Somnolence	傾眠	2 (11.8)	3 (13.0)	2 (11.8)	5 (12.5)	17 (15.6)	25 (25.0)	16 (23.9)	42 (20.1)
Tremor	振戦	1 (5.9)	4 (17.4)	3 (17.6)	5 (12.5)	4 (3.7)	12 (12.0)	6 (9.0)	16 (7.7)
Akathisia	アカシジア	1 (5.9)	4 (17.4)	4 (23.5)	5 (12.5)	7 (6.4)	8 (8.0)	4 (6.0)	15 (7.2)
Headache	頭痛	1 (5.9)	2 (8.7)	0 (0.0)	3 (7.5)	3 (2.8)	6 (6.0)	5 (7.5)	9 (4.3)
Dizziness	浮動性めまい	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	3 (2.8)	7 (7.0)	6 (9.0)	10 (4.8)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.6)	3 (3.0)	2 (3.0)	8 (3.8)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	4 (4.0)	2 (3.0)	6 (2.9)
Drooling	よだれ	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	2 (2.0)	1 (1.5)	4 (1.9)
Tardive dyskinesia	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.8)	2 (2.0)	2 (3.0)	5 (2.4)
Hypoaesthesia	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	2 (3.0)	4 (1.9)
Bradykinesia	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	0 (0.0)	3 (1.4)
Dyskinesia	ジスキネジア	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Disturbance in attention	注意力障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Dysarthria	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.0)
Dystonia	ジストニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Seizure	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Restless legs syndrome	下肢静止不能症候群	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Coordination abnormal	協調運動異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Dyslalia	構音障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Movement disorder	運動障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Radial nerve palsy	橈骨神経麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Sciatica	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Stupor	昏迷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Intercostal neuralgia	肋間神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Vagus nerve disorder	迷走神経障害	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Eye disorders	眼障害	2 (11.8)	0 (0.0)	0 (0.0)	2 (5.0)	1 (0.9)	5 (5.0)	2 (3.0)	6 (2.9)
Blepharitis	眼瞼炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Cataract	白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Eye discharge	眼脂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Eye pain	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Eyelid ptosis	眼瞼下垂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Keratitis	角膜炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	2 (11.8)	1 (4.3)	1 (5.9)	3 (7.5)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Deafness neurosensory	感音性難聴	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Vertigo	回転性めまい	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Cardiac disorders	心臓障害	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	3 (2.8)	5 (5.0)	4 (6.0)	8 (3.8)
Palpitations	動悸	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Bradycardia	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Long QT syndrome	ＱＴ延長症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Sinus bradycardia	洞性徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Tachycardia	頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Vascular disorders	血管障害	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	3 (2.8)	3 (3.0)	2 (3.0)	6 (2.9)
Hypertension	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.8)	1 (1.0)	0 (0.0)	4 (1.9)
Hypotension	低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	2 (3.0)	2 (1.0)
Deep vein thrombosis	深部静脈血栓症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3 (17.6)	3 (13.0)	1 (5.9)	6 (15.0)	5 (4.6)	9 (9.0)	3 (4.5)	14 (6.7)
Asthma	喘息	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	1 (0.9)	2 (2.0)	1 (1.5)	3 (1.4)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	1 (1.5)	3 (1.4)
Dyspnoea	呼吸困難	1 (5.9)	1 (4.3)	0 (0.0)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleural effusion	胸水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Upper respiratory tract inflammation	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.0)
Cough	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Interstitial lung disease	間質性肺疾患	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleurisy	胸膜炎	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	湿性咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Pulmonary embolism	肺塞栓症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory failure	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Cough variant asthma	咳喘息	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Gastrointestinal disorders	胃腸障害	7 (41.2)	5 (21.7)	2 (11.8)	12 (30.0)	32 (29.4)	46 (46.0)	26 (38.8)	78 (37.3)
Salivary hypersecretion	流涎過多	1 (5.9)	2 (8.7)	0 (0.0)	3 (7.5)	8 (7.3)	19 (19.0)	10 (14.9)	27 (12.9)
Constipation	便秘	1 (5.9)	3 (13.0)	1 (5.9)	4 (10.0)	8 (7.3)	6 (6.0)	4 (6.0)	14 (6.7)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.6)	5 (5.0)	3 (4.5)	10 (4.8)
Diarrhoea	下痢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (5.5)	3 (3.0)	2 (3.0)	9 (4.3)
Nausea	悪心	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	5 (5.0)	4 (6.0)	6 (2.9)
Stomatitis	口内炎	3 (17.6)	0 (0.0)	0 (0.0)	3 (7.5)	1 (0.9)	3 (3.0)	3 (4.5)	4 (1.9)
Vomiting	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	5 (5.0)	1 (1.5)	7 (3.3)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.7)	0 (0.0)	0 (0.0)	4 (1.9)
Dental caries	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	0 (0.0)	4 (1.9)
Abdominal pain	腹痛	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Dry mouth	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.0)	2 (3.0)	3 (1.4)
Gastritis	胃炎	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Toothache	歯痛	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Abdominal distension	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Abdominal pain upper	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Aphthous ulcer	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Chronic gastritis	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Eructation	おくび	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Gastrointestinal disorder	胃腸障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Gingival bleeding	歯肉出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Haemorrhoids	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hypoaesthesia oral	口の感覚鈍麻	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal pruritus	肛門そう痒症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	2 (3.0)	3 (1.4)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	2 (3.0)	2 (1.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	5 (29.4)	3 (13.0)	2 (11.8)	8 (20.0)	18 (16.5)	20 (20.0)	12 (17.9)	38 (18.2)
Eczema	湿疹	2 (11.8)	0 (0.0)	0 (0.0)	2 (5.0)	2 (1.8)	3 (3.0)	2 (3.0)	5 (2.4)
Urticaria	蕁麻疹	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	3 (2.8)	1 (1.0)	0 (0.0)	4 (1.9)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.0)	3 (4.5)	4 (1.9)
Dermatitis contact	接触皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	1 (1.5)	4 (1.9)
Dry skin	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	0 (0.0)	4 (1.9)
Pruritus	そう痒症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	2 (2.0)	2 (3.0)	3 (1.4)
Hyperkeratosis	過角化	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	2 (3.0)	3 (1.4)
Alopecia areata	円形脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Hyperhidrosis	多汗症	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Blister	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Erythema	紅斑	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhage subcutaneous	皮下出血	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ingrowing nail	嵌入爪	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Skin fissures	皮膚亀裂	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Skin ulcer	皮膚潰瘍	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hand dermatitis	手皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	6 (35.3)	2 (8.7)	1 (5.9)	8 (20.0)	21 (19.3)	21 (21.0)	15 (22.4)	42 (20.1)
Back pain	背部痛	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	6 (5.5)	6 (6.0)	4 (6.0)	12 (5.7)
Arthralgia	関節痛	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	0 (0.0)	4 (4.0)	3 (4.5)	4 (1.9)
Osteoarthritis	変形性関節症	2 (11.8)	1 (4.3)	0 (0.0)	3 (7.5)	0 (0.0)	3 (3.0)	2 (3.0)	3 (1.4)
Muscular weakness	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	3 (3.0)	2 (3.0)	5 (2.4)
Pain in extremity	四肢痛	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	2 (2.0)	2 (3.0)	4 (1.9)
Myalgia	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.7)	0 (0.0)	0 (0.0)	4 (1.9)
Musculoskeletal pain	筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	1 (1.0)	1 (1.5)	3 (1.4)
Neck pain	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.0)	2 (3.0)	3 (1.4)
Posture abnormal	姿勢異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	1 (1.5)	3 (1.4)
Intervertebral disc protrusion	椎間板突出	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Osteoporosis	骨粗鬆症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Periarthritis	関節周囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Tenosynovitis	腱鞘炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Mastication disorder	咀嚼障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Muscle rigidity	筋固縮	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Temporomandibular joint syndrome	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Trigger finger	弾発指	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Extremity contracture	四肢拘縮	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot deformity	足変形	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Renal and urinary disorders	腎および尿路障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	4 (3.7)	3 (3.0)	3 (4.5)	7 (3.3)
Dysuria	排尿困難	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Neurogenic bladder	神経因性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Nocturia	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Polyuria	多尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Renal glycosuria	腎性糖尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Urinary incontinence	尿失禁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Urinary retention	尿閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Bladder prolapse	膀胱脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.7)	1 (1.0)	1 (1.5)	5 (2.4)
Benign prostatic hyperplasia	良性前立腺肥大症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Galactorrhoea	乳汁漏出症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Vaginal discharge	膣分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Prostatomegaly	前立腺腫大	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	3 (17.6)	6 (26.1)	3 (17.6)	9 (22.5)	24 (22.0)	19 (19.0)	12 (17.9)	43 (20.6)
Malaise	倦怠感	1 (5.9)	3 (13.0)	1 (5.9)	4 (10.0)	9 (8.3)	7 (7.0)	4 (6.0)	16 (7.7)
Thirst	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (6.4)	2 (2.0)	1 (1.5)	9 (4.3)
Fatigue	疲労	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	3 (3.0)	2 (3.0)	5 (2.4)
Pyrexia	発熱	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	3 (2.8)	2 (2.0)	1 (1.5)	5 (2.4)
Feeling abnormal	異常感	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	2 (2.0)	1 (1.5)	2 (1.0)
Asthenia	無力症	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Death	死亡	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Calcinosis	石灰沈着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Chest discomfort	胸部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Discomfort	不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Feeling hot	熱感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Oedema	浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Propulsive gait	突進性歩行	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Investigations	臨床検査	3 (17.6)	3 (13.0)	3 (17.6)	6 (15.0)	19 (17.4)	12 (12.0)	7 (10.4)	31 (14.8)
Weight decreased	体重減少	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	5 (4.6)	4 (4.0)	2 (3.0)	9 (4.3)
Weight increased	体重増加	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	6 (5.5)	2 (2.0)	1 (1.5)	8 (3.8)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	5 (5.0)	4 (6.0)	7 (3.3)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	2 (2.0)	2 (3.0)	2 (1.0)
Blood creatinine increased	血中クレアチニン増加	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Blood pressure increased	血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Liver function test increased	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Blood triglycerides increased	血中トリグリセリド増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Blood uric acid increased	血中尿酸増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	3 (17.6)	2 (8.7)	2 (11.8)	5 (12.5)	18 (16.5)	20 (20.0)	13 (19.4)	38 (18.2)
Contusion	挫傷	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	4 (3.7)	7 (7.0)	4 (6.0)	11 (5.3)
Fall	転倒	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	6 (6.0)	5 (7.5)	8 (3.8)
Skin abrasion	皮膚擦過傷	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	2 (1.8)	2 (2.0)	2 (3.0)	4 (1.9)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.8)	1 (1.0)	0 (0.0)	4 (1.9)
Thermal burn	熱傷	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	1 (0.9)	1 (1.0)	0 (0.0)	2 (1.0)
Heat illness	熱中症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	1 (1.0)	0 (0.0)	3 (1.4)
Animal bite	動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Ankle fracture	足関節部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Concussion	脳振盪	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Femoral neck fracture	大腿骨頚部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Femur fracture	大腿骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Foot fracture	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Fractured sacrum	仙骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hand fracture	手骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Head injury	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Joint dislocation	関節脱臼	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Ligament sprain	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Road traffic accident	交通事故	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

MedDRA Version 23.0.

表 2.7.4.7－164　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Face injury	顔面損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Tooth fracture	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Eyelid injury	眼瞼損傷	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin wound	皮膚創傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.6.2.1 より引用

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Any AESI		11 (64.7)	18 (78.3)	12 (70.6)	29 (72.5)	77 (70.6)	90 (90.0)	58 (86.6)	167 (79.9)
Somnolence	傾眠関連有害事象	3 (17.6)	5 (21.7)	2 (11.8)	8 (20.0)	29 (26.6)	35 (35.0)	20 (29.9)	64 (30.6)
Somnolence	傾眠	2 (11.8)	3 (13.0)	2 (11.8)	5 (12.5)	17 (15.6)	25 (25.0)	16 (23.9)	42 (20.1)
Malaise	倦怠感	1 (5.9)	3 (13.0)	1 (5.9)	4 (10.0)	9 (8.3)	7 (7.0)	4 (6.0)	16 (7.7)
Fatigue	疲労	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	3 (3.0)	2 (3.0)	5 (2.4)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.8)	1 (1.0)	0 (0.0)	4 (1.9)
Asthenia	無力症	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Hypersensitivity	過敏症関連有害事象	5 (29.4)	3 (13.0)	2 (11.8)	8 (20.0)	18 (16.5)	15 (15.0)	12 (17.9)	33 (15.8)
Eczema	湿疹	2 (11.8)	0 (0.0)	0 (0.0)	2 (5.0)	2 (1.8)	3 (3.0)	2 (3.0)	5 (2.4)
Stomatitis	口内炎	3 (17.6)	0 (0.0)	0 (0.0)	3 (7.5)	1 (0.9)	3 (3.0)	3 (4.5)	4 (1.9)
Urticaria	蕁麻疹	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	3 (2.8)	1 (1.0)	0 (0.0)	4 (1.9)
Dermatitis contact	接触皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	1 (1.5)	4 (1.9)
Pruritus	そう痒症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	2 (2.0)	2 (3.0)	3 (1.4)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	2 (3.0)	3 (1.4)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Blister	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Dermatitis infected	感染性皮膚炎	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Hand dermatitis	手皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Parkinsonism	パーキンソニズム関連有害事象	3 (17.6)	8 (34.8)	4 (23.5)	11 (27.5)	21 (19.3)	42 (42.0)	21 (31.3)	63 (30.1)
Salivary hypersecretion	流涎過多	1 (5.9)	2 (8.7)	0 (0.0)	3 (7.5)	8 (7.3)	19 (19.0)	10 (14.9)	27 (12.9)
Tremor	振戦	1 (5.9)	4 (17.4)	3 (17.6)	5 (12.5)	4 (3.7)	12 (12.0)	6 (9.0)	16 (7.7)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.6)	3 (3.0)	2 (3.0)	8 (3.8)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	4 (4.0)	2 (3.0)	6 (2.9)
Drooling	よだれ	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	2 (2.0)	1 (1.5)	4 (1.9)
Bradykinesia	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.0)	0 (0.0)	3 (1.4)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Movement disorder	運動障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Propulsive gait	突進性歩行	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	4 (23.5)	4 (17.4)	2 (11.8)	8 (20.0)	15 (13.8)	15 (15.0)	13 (19.4)	30 (14.4)
Depression	うつ病	3 (17.6)	3 (13.0)	2 (11.8)	6 (15.0)	3 (2.8)	7 (7.0)	7 (10.4)	10 (4.8)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (5.5)	3 (3.0)	2 (3.0)	9 (4.3)
Suicide attempt	自殺企図	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	2 (1.8)	1 (1.0)	1 (1.5)	3 (1.4)
Middle insomnia	中期不眠症	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Disturbance in attention	注意力障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Alcohol abuse	アルコール乱用	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Cardiac events	心血管系及びQT間隔延長関連有害事象	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	3 (2.8)	0 (0.0)	0 (0.0)	3 (1.4)
Death	死亡	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hyperprolactinemia	高プロラクチン血症関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.0)	1 (1.5)	2 (1.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=17) n(%)	80 mg (N=23) n(%)	80 mg (no dose reduction) (N=17) n(%)	All MT-5199 (N=40) n(%)	40 mg (N=109) n(%)	80 mg (N=100) n(%)	80 mg (no dose reduction) (N=67) n(%)	All MT-5199 (N=209) n(%)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Akathisia	アカシジア関連有害事象	1 (5.9)	6 (26.1)	4 (23.5)	7 (17.5)	11 (10.1)	13 (13.0)	7 (10.4)	24 (11.5)
Akathisia	アカシジア	1 (5.9)	4 (17.4)	4 (23.5)	5 (12.5)	7 (6.4)	8 (8.0)	4 (6.0)	15 (7.2)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	4 (4.0)	2 (3.0)	6 (2.9)
Restlessness	落ち着きのなさ	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	2 (1.8)	1 (1.0)	1 (1.5)	3 (1.4)
Movement disorder	運動障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	4 (3.7)	9 (9.0)	7 (10.4)	13 (6.2)
Anxiety	不安	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	4 (3.7)	9 (9.0)	7 (10.4)	13 (6.2)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	5 (29.4)	5 (21.7)	3 (17.6)	10 (25.0)	30 (27.5)	24 (24.0)	16 (23.9)	54 (25.8)
Schizophrenia	統合失調症	2 (11.8)	1 (4.3)	0 (0.0)	3 (7.5)	19 (17.4)	12 (12.0)	5 (7.5)	31 (14.8)
Depression	うつ病	3 (17.6)	3 (13.0)	2 (11.8)	6 (15.0)	3 (2.8)	7 (7.0)	7 (10.4)	10 (4.8)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (5.5)	3 (3.0)	2 (3.0)	9 (4.3)
Suicide attempt	自殺企図	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	2 (1.8)	1 (1.0)	1 (1.5)	3 (1.4)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (2.0)	2 (3.0)	4 (1.9)
Depressed mood	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hypomania	軽躁	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.5)	1 (0.5)
Dysphagia	嚥下障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.6)	5 (5.0)	3 (4.5)	10 (4.8)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.6)	5 (5.0)	3 (4.5)	10 (4.8)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－165　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=17) n(%)	Yes MT-5199 80 mg (N=23) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=17) n(%)	Yes All MT-5199 (N=40) n(%)	No MT-5199 40 mg (N=109) n(%)	No MT-5199 80 mg (N=100) n(%)	No MT-5199 80 mg (no dose reduction) (N=67) n(%)	No All MT-5199 (N=209) n(%)
Hepatotoxicity	肝障害関連有害事象	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	4 (3.7)	3 (3.0)	2 (3.0)	7 (3.3)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	2 (3.0)	2 (1.0)
Liver function test increased	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Hypotension	低血圧関連有害事象	1 (5.9)	1 (4.3)	1 (5.9)	2 (5.0)	6 (5.5)	12 (12.0)	10 (14.9)	18 (8.6)
Dizziness	浮動性めまい	1 (5.9)	0 (0.0)	0 (0.0)	1 (2.5)	3 (2.8)	7 (7.0)	6 (9.0)	10 (4.8)
Fall	転倒	0 (0.0)	1 (4.3)	1 (5.9)	1 (2.5)	2 (1.8)	6 (6.0)	5 (7.5)	8 (3.8)
Hypotension	低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	2 (3.0)	2 (1.0)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Cognitive disorder	認知機能低下関連有害事象	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	2 (1.8)	0 (0.0)	0 (0.0)	2 (1.0)
Disturbance in attention	注意力障害	0 (0.0)	1 (4.3)	0 (0.0)	1 (2.5)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.5)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.6.2.2 より引用

表 2.7.4.7－166　ベースライン時の肝機能値異常の有無ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Yes (N=30) n (%)	No (N=224) n (%)	Yes (N=17) n (%)	No (N=161) n (%)	Yes (N=40) n (%)	No (N=387) n (%)
At Least 1 AE	14 (46.7)	97 (43.3)	6 (35.3)	65 (40.4)	26 (65.0)	233 (60.2)
At Least 1 SAE	0	12 (5.4)	2 (11.8)	4 (2.5)	6 (15.0)	48 (12.4)
At Least 1 AE Leading to Study Discontinuation	1 (3.3)	9 (4.0)	1 (5.9)	7 (4.3)	6 (15.0)	52 (13.4)
At Least 1 AE Leading to Dose Reduction	1 (3.3)	6 (2.7)	0	4 (2.5)	3 (7.5)	23 (5.9)

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is counted once for that category.

5.3.5.3－2 Table 106 より引用（一部改変）

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=8)	 80 mg (N=19)	 100 mg (N=2)	All NBI-98854 (N=30)	 Placebo (N=17)
Any Adverse Event	n (%)	1(100.0)	4(50.0)	8(42.1)	1(50.0)	14(46.7)	6(35.3)
心臓障害	n (%)	0	0	0	0	0	1(5.9)
心筋梗塞	n (%)	0	0	0	0	0	1(5.9)
胃腸障害	n (%)	0	1(12.5)	2(10.5)	0	3(10.0)	1(5.9)
嘔吐	n (%)	0	0	2(10.5)	0	2(6.7)	0
口内乾燥	n (%)	0	1(12.5)	0	0	1(3.3)	1(5.9)
悪心	n (%)	0	0	1(5.3)	0	1(3.3)	0
全身障害および投与局所様態	n (%)	0	1(12.5)	1(5.3)	1(50.0)	3(10.0)	0
疲労	n (%)	0	1(12.5)	1(5.3)	1(50.0)	3(10.0)	0
感染症および寄生虫症	n (%)	0	1(12.5)	1(5.3)	1(50.0)	3(10.0)	1(5.9)
上気道感染	n (%)	0	0	1(5.3)	1(50.0)	2(6.7)	0
尿路感染	n (%)	0	1(12.5)	0	0	1(3.3)	1(5.9)
傷害、中毒および処置合併症	n (%)	0	0	0	1(50.0)	1(3.3)	1(5.9)
節足動物咬傷	n (%)	0	0	0	1(50.0)	1(3.3)	0
足骨折	n (%)	0	0	0	0	0	1(5.9)
臨床検査	n (%)	1(100.0)	0	3(15.8)	0	4(13.3)	0
体重増加	n (%)	0	0	2(10.5)	0	2(6.7)	0

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=8)	 80 mg (N=19)	 100 mg (N=2)	All NBI-98854 (N=30)	 Placebo (N=17)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	1(5.3)	0	1(3.3)	0
肝酵素上昇	n (%)	1(100.0)	0	0	0	1(3.3)	0
代謝および栄養障害	n (%)	0	0	1(5.3)	0	1(3.3)	0
食欲減退	n (%)	0	0	1(5.3)	0	1(3.3)	0
筋骨格系および結合組織障害	n (%)	0	0	1(5.3)	0	1(3.3)	0
筋痙縮	n (%)	0	0	1(5.3)	0	1(3.3)	0
神経系障害	n (%)	0	2(25.0)	0	1(50.0)	3(10.0)	2(11.8)
傾眠	n (%)	0	1(12.5)	0	1(50.0)	2(6.7)	0
アカシジア	n (%)	0	1(12.5)	0	0	1(3.3)	1(5.9)
痙攣	n (%)	0	0	0	0	0	1(5.9)
精神障害	n (%)	1(100.0)	2(25.0)	3(15.8)	0	6(20.0)	1(5.9)
不安	n (%)	0	1(12.5)	1(5.3)	0	2(6.7)	0
不眠症	n (%)	0	0	2(10.5)	0	2(6.7)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(3.3)	0
抑うつ症状	n (%)	0	1(12.5)	0	0	1(3.3)	0
統合失調症	n (%)	0	0	0	0	0	1(5.9)
皮膚および皮下組織障害	n (%)	0	1(12.5)	1(5.3)	0	2(6.7)	1(5.9)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=8)	 80 mg (N=19)	 100 mg (N=2)	All NBI-98854 (N=30)	 Placebo (N=17)
そう痒症	n (%)	0	1(12.5)	0	0	1(3.3)	0
斑状丘疹状皮疹	n (%)	0	0	1(5.3)	0	1(3.3)	0
多汗症	n (%)	0	0	0	0	0	1(5.9)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854	Placebo
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	(N=224)	(N=161)
Any Adverse Event	n (%)	1(25.0)	44(43.1)	45(48.4)	7(28.0)	97(43.3)	65(40.4)
血液およびリンパ系障害	n (%)	0	0	1(1.1)	0	1(0.4)	0
白血球減少症	n (%)	0	0	1(1.1)	0	1(0.4)	0
心臓障害	n (%)	0	1(1.0)	0	0	1(0.4)	0
徐脈	n (%)	0	1(1.0)	0	0	1(0.4)	0
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(0.6)
トゥレット病	n (%)	0	0	0	0	0	1(0.6)
耳および迷路障害	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
耳鳴	n (%)	0	1(1.0)	0	0	1(0.4)	0
耳痛	n (%)	0	0	0	0	0	1(0.6)
眼障害	n (%)	0	0	0	1(4.0)	1(0.4)	1(0.6)
霧視	n (%)	0	0	0	1(4.0)	1(0.4)	0
結膜出血	n (%)	0	0	0	0	0	1(0.6)
胃腸障害	n (%)	0	13(12.7)	5(5.4)	1(4.0)	19(8.5)	20(12.4)
口内乾燥	n (%)	0	6(5.9)	0	1(4.0)	7(3.1)	2(1.2)
嘔吐	n (%)	0	2(2.0)	2(2.2)	0	4(1.8)	1(0.6)
悪心	n (%)	0	2(2.0)	1(1.1)	0	3(1.3)	4(2.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854	Placebo
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	(N=224)	(N=161)
流涎過多	n (%)	0	0	2(2.2)	1(4.0)	3(1.3)	0
便秘	n (%)	0	2(2.0)	0	0	2(0.9)	5(3.1)
嚥下障害	n (%)	0	2(2.0)	0	0	2(0.9)	0
腹部圧痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
下痢	n (%)	0	1(1.0)	0	0	1(0.4)	3(1.9)
消化不良	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
びらん性胃炎	n (%)	0	0	1(1.1)	0	1(0.4)	0
メレナ	n (%)	0	1(1.0)	0	0	1(0.4)	0
口腔知覚不全	n (%)	0	1(1.0)	0	0	1(0.4)	0
臍ヘルニア	n (%)	0	1(1.0)	0	0	1(0.4)	0
上腹部痛	n (%)	0	0	0	0	0	1(0.6)
排便回数増加	n (%)	0	0	0	0	0	1(0.6)
胃食道逆流性疾患	n (%)	0	0	0	0	0	2(1.2)
歯肉炎	n (%)	0	0	0	0	0	1(0.6)
舌痛	n (%)	0	0	0	0	0	1(0.6)
歯痛	n (%)	0	0	0	0	0	1(0.6)
全身障害および投与局所様態	n (%)	0	9(8.8)	4(4.3)	1(4.0)	14(6.3)	7(4.3)
疲労	n (%)	0	4(3.9)	2(2.2)	1(4.0)	7(3.1)	3(1.9)
歩行障害	n (%)	0	2(2.0)	0	1(4.0)	3(1.3)	0
末梢性浮腫	n (%)	0	3(2.9)	0	0	3(1.3)	1(0.6)
胸痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
空腹	n (%)	0	1(1.0)	0	0	1(0.4)	0
易刺激性	n (%)	0	1(1.0)	0	0	1(0.4)	2(1.2)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854	Placebo
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	(N=224)	(N=161)
疼痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
発熱	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
突然死	n (%)	0	0	1(1.1)	0	1(0.4)	0
口渇	n (%)	0	1(1.0)	0	0	1(0.4)	0
肝胆道系障害	n (%)	0	0	1(1.1)	0	1(0.4)	0
急性肝炎	n (%)	0	0	1(1.1)	0	1(0.4)	0
黄疸	n (%)	0	0	1(1.1)	0	1(0.4)	0
感染症および寄生虫症	n (%)	0	9(8.8)	2(2.2)	2(8.0)	13(5.8)	13(8.1)
尿路感染	n (%)	0	3(2.9)	1(1.1)	1(4.0)	5(2.2)	7(4.3)
鼻咽頭炎	n (%)	0	1(1.0)	1(1.1)	1(4.0)	3(1.3)	1(0.6)
ダニ皮膚炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
体部白癬	n (%)	0	1(1.0)	0	0	1(0.4)	0
せつ	n (%)	0	1(1.0)	0	0	1(0.4)	0
ウイルス性胃腸炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
インフルエンザ	n (%)	0	1(1.0)	0	0	1(0.4)	0
急性腎盂腎炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
副鼻腔炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
外陰腟真菌感染	n (%)	0	1(1.0)	0	0	1(0.4)	0
気管支炎	n (%)	0	0	0	0	0	1(0.6)
耳感染	n (%)	0	0	0	0	0	1(0.6)
口腔ヘルペス	n (%)	0	0	0	0	0	1(0.6)
上気道感染	n (%)	0	0	0	0	0	1(0.6)
ウイルス感染	n (%)	0	0	0	0	0	1(0.6)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854	Placebo
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	(N=224)	(N=161)
傷害、中毒および処置合併症	n (%)	0	5(4.9)	4(4.3)	0	9(4.0)	2(1.2)
転倒・転落	n (%)	0	2(2.0)	1(1.1)	0	3(1.3)	0
動物咬傷	n (%)	0	0	1(1.1)	0	1(0.4)	0
第２度熱傷	n (%)	0	0	1(1.1)	0	1(0.4)	0
関節損傷	n (%)	0	1(1.0)	0	0	1(0.4)	0
四肢損傷	n (%)	0	0	1(1.1)	0	1(0.4)	0
筋挫傷	n (%)	0	1(1.0)	0	0	1(0.4)	0
交通事故	n (%)	0	1(1.0)	0	0	1(0.4)	0
むち打ち損傷	n (%)	0	1(1.0)	0	0	1(0.4)	0
節足動物咬傷	n (%)	0	0	0	0	0	1(0.6)
処置による疼痛	n (%)	0	0	0	0	0	1(0.6)
臨床検査	n (%)	0	5(4.9)	7(7.5)	1(4.0)	13(5.8)	6(3.7)
血中ブドウ糖増加	n (%)	0	1(1.0)	2(2.2)	0	3(1.3)	0
血中クレアチニン増加	n (%)	0	1(1.0)	1(1.1)	0	2(0.9)	0
血中クレアチンホスホキナーゼ増加	n (%)	0	1(1.0)	0	0	1(0.4)	0
血圧上昇	n (%)	0	0	1(1.1)	0	1(0.4)	0
血中トリグリセリド増加	n (%)	0	0	0	1(4.0)	1(0.4)	0
血中尿素増加	n (%)	0	1(1.0)	0	0	1(0.4)	0
尿中結晶陽性	n (%)	0	0	1(1.1)	0	1(0.4)	0
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
尿中ブドウ糖陽性	n (%)	0	0	1(1.1)	0	1(0.4)	0

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854	Placebo
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	(N=224)	(N=161)
グリコヘモグロビン増加	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
握力低下	n (%)	0	1(1.0)	0	0	1(0.4)	0
ヘマトクリット減少	n (%)	0	0	1(1.1)	0	1(0.4)	0
ヘモグロビン減少	n (%)	0	0	1(1.1)	0	1(0.4)	0
便潜血陽性	n (%)	0	0	1(1.1)	0	1(0.4)	0
赤血球数減少	n (%)	0	0	1(1.1)	0	1(0.4)	0
赤血球数増加	n (%)	0	0	1(1.1)	0	1(0.4)	0
体重増加	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
血中ビリルビン増加	n (%)	0	0	0	0	0	1(0.6)
血中カリウム増加	n (%)	0	0	0	0	0	1(0.6)
肝酵素上昇	n (%)	0	0	0	0	0	1(0.6)
好中球数増加	n (%)	0	0	0	0	0	1(0.6)
白血球数増加	n (%)	0	0	0	0	0	1(0.6)
代謝および栄養障害	n (%)	0	3(2.9)	4(4.3)	0	7(3.1)	5(3.1)
食欲減退	n (%)	0	2(2.0)	1(1.1)	0	3(1.3)	2(1.2)
食欲亢進	n (%)	0	1(1.0)	2(2.2)	0	3(1.3)	1(0.6)
低ナトリウム血症	n (%)	0	0	1(1.1)	0	1(0.4)	0
異常体重減少	n (%)	0	0	0	0	0	1(0.6)
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(0.6)
低血糖症	n (%)	0	0	0	0	0	1(0.6)
筋骨格系および結合組織障害	n (%)	0	9(8.8)	5(5.4)	1(4.0)	15(6.7)	5(3.1)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854 (N=224)	Placebo (N=161)
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)		
関節痛	n (%)	0	3(2.9)	3(3.2)	0	6(2.7)	1(0.6)
背部痛	n (%)	0	2(2.0)	1(1.1)	0	3(1.3)	0
筋力低下	n (%)	0	2(2.0)	0	0	2(0.9)	0
筋肉痛	n (%)	0	0	1(1.1)	1(4.0)	2(0.9)	0
関節炎	n (%)	0	1(1.0)	0	0	1(0.4)	0
四肢不快感	n (%)	0	1(1.0)	0	0	1(0.4)	0
顎関節症候群	n (%)	0	1(1.0)	0	0	1(0.4)	0
滑液包炎	n (%)	0	0	0	0	0	1(0.6)
関節腫脹	n (%)	0	0	0	0	0	1(0.6)
筋骨格硬直	n (%)	0	0	0	0	0	1(0.6)
四肢痛	n (%)	0	0	0	0	0	1(0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(0.6)
口腔乳頭腫	n (%)	0	0	0	0	0	1(0.6)
神経系障害	n (%)	0	15(14.7)	19(20.4)	2(8.0)	36(16.1)	14(8.7)
傾眠	n (%)	0	8(7.8)	4(4.3)	0	12(5.4)	4(2.5)
頭痛	n (%)	0	4(3.9)	5(5.4)	1(4.0)	10(4.5)	4(2.5)
アカシジア	n (%)	0	2(2.0)	3(3.2)	0	5(2.2)	0
ジスキネジー	n (%)	0	0	3(3.2)	0	3(1.3)	0
鎮静	n (%)	0	1(1.0)	2(2.2)	0	3(1.3)	1(0.6)
浮動性めまい	n (%)	0	2(2.0)	0	0	2(0.9)	4(2.5)
よだれ	n (%)	0	0	2(2.2)	0	2(0.9)	0
振戦	n (%)	0	0	2(2.2)	0	2(0.9)	0

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854 (N=224)	Placebo (N=161)
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)		
平衡障害	n (%)	0	0	1(1.1)	0	1(0.4)	0
注意力障害	n (%)	0	1(1.0)	0	0	1(0.4)	0
ジストニー	n (%)	0	0	1(1.1)	0	1(0.4)	0
感覚鈍麻	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
ミオクローヌス	n (%)	0	1(1.0)	0	0	1(0.4)	0
睡眠の質低下	n (%)	0	1(1.0)	0	0	1(0.4)	0
失神	n (%)	0	0	0	1(4.0)	1(0.4)	0
咬舌	n (%)	0	1(1.0)	0	0	1(0.4)	0
片頭痛	n (%)	0	0	0	0	0	1(0.6)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(0.6)
精神障害	n (%)	1(25.0)	12(11.8)	9(9.7)	0	22(9.8)	13(8.1)
自殺念慮	n (%)	0	4(3.9)	1(1.1)	0	5(2.2)	4(2.5)
うつ病	n (%)	0	0	2(2.2)	0	2(0.9)	2(1.2)
不眠症	n (%)	0	2(2.0)	0	0	2(0.9)	1(0.6)
パニック発作	n (%)	1(25.0)	0	1(1.1)	0	2(0.9)	0
不安	n (%)	0	0	1(1.1)	0	1(0.4)	0
双極１型障害	n (%)	0	1(1.0)	0	0	1(0.4)	0
歯ぎしり	n (%)	0	1(1.0)	0	0	1(0.4)	0
ディスフェミア	n (%)	0	1(1.0)	0	0	1(0.4)	0
敵意	n (%)	0	1(1.0)	0	0	1(0.4)	0
軽躁	n (%)	0	1(1.0)	0	0	1(0.4)	0
精神状態変化	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
神経過敏	n (%)	0	0	1(1.1)	0	1(0.4)	0
妄想症	n (%)	0	1(1.0)	0	0	1(0.4)	0

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]				All NBI-98854 (N=224)	Placebo (N=161)
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)		
精神運動制止遅滞	n (%)	0	1(1.0)	0	0	1(0.4)	0
精神病性障害	n (%)	0	0	1(1.1)	0	1(0.4)	2(1.2)
落ち着きのなさ	n (%)	0	1(1.0)	0	0	1(0.4)	0
統合失調感情障害	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.4)	0
自殺企図	n (%)	0	0	1(1.1)	0	1(0.4)	0
激越	n (%)	0	0	0	0	0	1(0.6)
抑うつ症状	n (%)	0	0	0	0	0	1(0.6)
躁病	n (%)	0	0	0	0	0	1(0.6)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.6)
睡眠障害	n (%)	0	0	0	0	0	1(0.6)
腎および尿路障害	n (%)	0	0	0	0	0	3(1.9)
糖尿	n (%)	0	0	0	0	0	1(0.6)
血尿	n (%)	0	0	0	0	0	1(0.6)
尿閉	n (%)	0	0	0	0	0	1(0.6)
生殖系および乳房障害	n (%)	0	0	1(1.1)	0	1(0.4)	2(1.2)
月経過多	n (%)	0	0	1(1.1)	0	1(0.4)	0
腟出血	n (%)	0	0	0	0	0	2(1.2)
呼吸器、胸郭および縦隔障害	n (%)	0	1(1.0)	2(2.2)	1(4.0)	4(1.8)	2(1.2)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－167　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b]					
		<40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	All NBI-98854 (N=224)	Placebo (N=161)
慢性閉塞性肺疾患	n (%)	0	1(1.0)	0	1(4.0)	2(0.9)	1(0.6)
鼻閉	n (%)	0	0	2(2.2)	0	2(0.9)	0
咳嗽	n (%)	0	0	0	0	0	1(0.6)
皮膚および皮下組織障害	n (%)	0	1(1.0)	1(1.1)	0	2(0.9)	4(2.5)
網状皮斑	n (%)	0	1(1.0)	0	0	1(0.4)	0
発疹	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
ケラトアカントーマ	n (%)	0	0	0	0	0	1(0.6)
そう痒症	n (%)	0	0	0	0	0	2(1.2)
乾癬	n (%)	0	0	0	0	0	1(0.6)
外科および内科処置	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
抜歯	n (%)	0	0	1(1.1)	0	1(0.4)	0
鼓膜切開	n (%)	0	0	0	0	0	1(0.6)
血管障害	n (%)	0	1(1.0)	3(3.2)	0	4(1.8)	2(1.2)
血腫	n (%)	0	0	1(1.1)	0	1(0.4)	0
ほてり	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
高血圧	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
低血圧	n (%)	0	0	1(1.1)	0	1(0.4)	0

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.10より引用（一部改変）

表2.7.4.7－168　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Hepatic Abnormality[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	40 mg (N=8)	80 mg (N=19)	100 mg (N=2)	All NBI-98854 (N=30)	Placebo (N=17)
Any Adverse Event of Special Interest	n (%)	1(100.0)	3(37.5)	2(10.5)	1(50.0)	7(23.3)	2(11.8)
アカシジア関連有害事象	n (%)	0	1(12.5)	0	0	1(3.3)	1(5.9)
アカシジア	n (%)	0	1(12.5)	0	0	1(3.3)	1(5.9)
不安	n (%)	0	1(12.5)	1(5.3)	0	2(6.7)	0
不安	n (%)	0	1(12.5)	1(5.3)	0	2(6.7)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	0	0	0	1(5.9)
心筋梗塞	n (%)	0	0	0	0	0	1(5.9)
うつ病及び自殺関連有害事象	n (%)	1(100.0)	1(12.5)	0	0	2(6.7)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(3.3)	0
抑うつ症状	n (%)	0	1(12.5)	0	0	1(3.3)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(12.5)	1(5.3)	1(50.0)	3(10.0)	0
疲労	n (%)	0	1(12.5)	1(5.3)	1(50.0)	3(10.0)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	1(12.5)	0	1(50.0)	2(6.7)	0
傾眠	n (%)	0	1(12.5)	0	1(50.0)	2(6.7)	0
基礎疾患の悪化に関連する有害事象	n (%)	1(100.0)	1(12.5)	0	0	2(6.7)	1(5.9)
抑うつ気分	n (%)	1(100.0)	0	0	0	1(3.3)	0

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－168　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	40 mg (N=8)	80 mg (N=19)	100 mg (N=2)	All NBI-98854 (N=30)	Placebo (N=17)
抑うつ症状	n (%)	0	1(12.5)	0	0	1(3.3)	0
統合失調症	n (%)	0	0	0	0	0	1(5.9)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－168　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	All NBI-98854 (N=224)	Placebo (N=161)
Any Adverse Event of Special Interest	n (%)	0	25(24.5)	21(22.6)	2(8.0)	48(21.4)	22(13.7)
アカシジア関連有害事象	n (%)	0	2(2.0)	3(3.2)	0	5(2.2)	0
アカシジア	n (%)	0	2(2.0)	3(3.2)	0	5(2.2)	0
不安	n (%)	0	0	1(1.1)	0	1(0.4)	0
不安	n (%)	0	0	1(1.1)	0	1(0.4)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(1.0)	1(1.1)	1(4.0)	3(1.3)	0
胸痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
突然死	n (%)	0	0	1(1.1)	0	1(0.4)	0
失神	n (%)	0	0	0	1(4.0)	1(0.4)	0
うつ病及び自殺関連有害事象	n (%)	0	4(3.9)	4(4.3)	0	8(3.6)	6(3.7)
自殺念慮	n (%)	0	4(3.9)	1(1.1)	0	5(2.2)	4(2.5)
うつ病	n (%)	0	0	2(2.2)	0	2(0.9)	2(1.2)
自殺企図	n (%)	0	0	1(1.1)	0	1(0.4)	0
抑うつ症状	n (%)	0	0	0	0	0	1(0.6)
嚥下障害関連有害事象	n (%)	0	2(2.0)	0	0	2(0.9)	0
嚥下障害	n (%)	0	2(2.0)	0	0	2(0.9)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	4(3.9)	2(2.2)	1(4.0)	7(3.1)	3(1.9)
疲労	n (%)	0	4(3.9)	2(2.2)	1(4.0)	7(3.1)	3(1.9)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－168 ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	All NBI-98854 (N=224)	Placebo (N=161)
肝障害関連有害事象	n (%)	0	0	1(1.1)	0	1(0.4)	0
急性肝炎	n (%)	0	0	1(1.1)	0	1(0.4)	0
低血圧関連有害事象	n (%)	0	4(3.9)	2(2.2)	1(4.0)	7(3.1)	4(2.5)
転倒・転落	n (%)	0	2(2.0)	1(1.1)	0	3(1.3)	0
浮動性めまい	n (%)	0	2(2.0)	0	0	2(0.9)	4(2.5)
低血圧	n (%)	0	0	1(1.1)	0	1(0.4)	0
失神	n (%)	0	0	0	1(4.0)	1(0.4)	0
パーキンソニズム関連有害事象	n (%)	0	0	2(2.2)	0	2(0.9)	0
振戦	n (%)	0	0	2(2.2)	0	2(0.9)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	9(8.8)	6(6.5)	0	15(6.7)	5(3.1)
傾眠	n (%)	0	8(7.8)	4(4.3)	0	12(5.4)	4(2.5)
鎮静	n (%)	0	1(1.0)	2(2.2)	0	3(1.3)	1(0.6)
基礎疾患の悪化に関連する有害事象	n (%)	0	9(8.8)	6(6.5)	0	15(6.7)	12(7.5)
自殺念慮	n (%)	0	4(3.9)	1(1.1)	0	5(2.2)	4(2.5)
うつ病	n (%)	0	0	2(2.2)	0	2(0.9)	2(1.2)
双極１型障害	n (%)	0	1(1.0)	0	0	1(0.4)	0
敵意	n (%)	0	1(1.0)	0	0	1(0.4)	0
軽躁	n (%)	0	1(1.0)	0	0	1(0.4)	0
易刺激性	n (%)	0	1(1.0)	0	0	1(0.4)	2(1.2)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－168　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=102)	80 mg (N=93)	100 mg (N=25)	All NBI-98854 (N=224)	Placebo (N=161)
妄想症	n (%)	0	1(1.0)	0	0	1(0.4)	0
精神病性障害	n (%)	0	0	1(1.1)	0	1(0.4)	2(1.2)
統合失調感情障害	n (%)	0	0	1(1.1)	0	1(0.4)	1(0.6)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.4)	0
自殺企図	n (%)	0	0	1(1.1)	0	1(0.4)	0
抑うつ症状	n (%)	0	0	0	0	0	1(0.6)
躁病	n (%)	0	0	0	0	0	1(0.6)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.6)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.10より引用（一部改変）

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	 80 mg (N=24)	 80 mg Only[c] (N=22)	All NBI-98854 (N=40)
Any Adverse Event	n (%)	9(56.3)	17(70.8)	15(68.2)	26(65.0)
血液およびリンパ系障害	n (%)	1(6.3)	0	0	1(2.5)
貧血	n (%)	1(6.3)	0	0	1(2.5)
胃腸障害	n (%)	3(18.8)	7(29.2)	5(22.7)	10(25.0)
下痢	n (%)	1(6.3)	2(8.3)	2(9.1)	3(7.5)
口内乾燥	n (%)	2(12.5)	1(4.2)	1(4.5)	3(7.5)
腹痛	n (%)	1(6.3)	1(4.2)	0	2(5.0)
嘔吐	n (%)	1(6.3)	1(4.2)	0	2(5.0)
上腹部痛	n (%)	0	1(4.2)	0	1(2.5)
便秘	n (%)	1(6.3)	0	0	1(2.5)
細菌叢異常症	n (%)	0	1(4.2)	1(4.5)	1(2.5)
嚥下障害	n (%)	1(6.3)	0	0	1(2.5)
悪心	n (%)	1(6.3)	0	0	1(2.5)
流涎過多	n (%)	0	1(4.2)	1(4.5)	1(2.5)
歯痛	n (%)	0	1(4.2)	1(4.5)	1(2.5)
全身障害および投与局所様態	n (%)	1(6.3)	2(8.3)	2(9.1)	3(7.5)
易刺激性	n (%)	0	2(8.3)	2(9.1)	2(5.0)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	 80 mg (N=24)	 80 mg Only[c] (N=22)	All NBI-98854 (N=40)
非心臓性胸痛	n (%)	1(6.3)	0	0	1(2.5)
感染症および寄生虫症	n (%)	2(12.5)	5(20.8)	3(13.6)	7(17.5)
胃腸炎	n (%)	0	2(8.3)	2(9.1)	2(5.0)
上気道感染	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
尿路感染	n (%)	1(6.3)	1(4.2)	0	2(5.0)
四肢膿瘍	n (%)	0	1(4.2)	0	1(2.5)
気管支炎	n (%)	1(6.3)	0	0	1(2.5)
蜂巣炎	n (%)	0	1(4.2)	0	1(2.5)
耳感染	n (%)	1(6.3)	0	0	1(2.5)
副鼻腔炎	n (%)	0	1(4.2)	1(4.5)	1(2.5)
歯膿瘍	n (%)	0	1(4.2)	1(4.5)	1(2.5)
外陰腟真菌感染	n (%)	0	1(4.2)	1(4.5)	1(2.5)
傷害、中毒および処置合併症	n (%)	1(6.3)	3(12.5)	2(9.1)	4(10.0)
節足動物咬傷	n (%)	0	1(4.2)	0	1(2.5)
擦過傷	n (%)	0	1(4.2)	1(4.5)	1(2.5)
足骨折	n (%)	0	1(4.2)	1(4.5)	1(2.5)
腎損傷	n (%)	1(6.3)	0	0	1(2.5)
皮膚裂傷	n (%)	0	1(4.2)	1(4.5)	1(2.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	 80 mg (N=24)	 80 mg Only[c] (N=22)	All NBI-98854 (N=40)
臨床検査	n (%)	1(6.3)	9(37.5)	8(36.4)	10(25.0)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(6.3)	3(12.5)	3(13.6)	4(10.0)
体重増加	n (%)	0	4(16.7)	4(18.2)	4(10.0)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(4.2)	1(4.5)	1(2.5)
血中プロラクチン増加	n (%)	0	1(4.2)	0	1(2.5)
代謝および栄養障害	n (%)	1(6.3)	0	0	1(2.5)
食欲減退	n (%)	1(6.3)	0	0	1(2.5)
筋骨格系および結合組織障害	n (%)	1(6.3)	2(8.3)	1(4.5)	3(7.5)
背部痛	n (%)	0	1(4.2)	1(4.5)	1(2.5)
筋痙縮	n (%)	0	1(4.2)	1(4.5)	1(2.5)
筋肉痛	n (%)	1(6.3)	0	0	1(2.5)
四肢痛	n (%)	0	1(4.2)	0	1(2.5)
神経系障害	n (%)	4(25.0)	6(25.0)	6(27.3)	10(25.0)
浮動性めまい	n (%)	0	3(12.5)	3(13.6)	3(7.5)
頭痛	n (%)	1(6.3)	2(8.3)	2(9.1)	3(7.5)
アカシジア	n (%)	2(12.5)	0	0	2(5.0)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	 80 mg (N=24)	 80 mg Only[c] (N=22)	 All NBI-98854 (N=40)
よだれ	n (%)	0	1(4.2)	1(4.5)	1(2.5)
ジストニー	n (%)	1(6.3)	0	0	1(2.5)
神経痛	n (%)	1(6.3)	0	0	1(2.5)
一過性脳虚血発作	n (%)	0	1(4.2)	1(4.5)	1(2.5)
振戦	n (%)	1(6.3)	0	0	1(2.5)
精神障害	n (%)	6(37.5)	6(25.0)	4(18.2)	12(30.0)
不安	n (%)	2(12.5)	3(12.5)	1(4.5)	5(12.5)
自殺念慮	n (%)	1(6.3)	3(12.5)	3(13.6)	4(10.0)
抑うつ症状	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
不眠症	n (%)	0	2(8.3)	2(9.1)	2(5.0)
統合失調症	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
激越	n (%)	0	1(4.2)	1(4.5)	1(2.5)
死別反応	n (%)	1(6.3)	0	0	1(2.5)
うつ病	n (%)	0	1(4.2)	1(4.5)	1(2.5)
躁病	n (%)	1(6.3)	0	0	1(2.5)
精神病性障害	n (%)	1(6.3)	0	0	1(2.5)
落ち着きのなさ	n (%)	0	1(4.2)	0	1(2.5)
腎および尿路障害	n (%)	2(12.5)	1(4.2)	1(4.5)	3(7.5)
血尿	n (%)	1(6.3)	0	0	1(2.5)
腎結石症	n (%)	0	1(4.2)	1(4.5)	1(2.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	 80 mg (N=24)	 80 mg Only[c] (N=22)	 All NBI-98854 (N=40)
腎嚢胞	n (%)	1(6.3)	0	0	1(2.5)
生殖系および乳房障害	n (%)	1(6.3)	0	0	1(2.5)
乳房圧痛	n (%)	1(6.3)	0	0	1(2.5)
乳汁漏出症	n (%)	1(6.3)	0	0	1(2.5)
膣分泌物	n (%)	1(6.3)	0	0	1(2.5)
呼吸器、胸郭および縦隔障害	n (%)	2(12.5)	1(4.2)	1(4.5)	3(7.5)
咳嗽	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
アレルギー性副鼻腔炎	n (%)	1(6.3)	0	0	1(2.5)
喘息	n (%)	1(6.3)	0	0	1(2.5)
くしゃみ	n (%)	0	1(4.2)	1(4.5)	1(2.5)
皮膚および皮下組織障害	n (%)	2(12.5)	2(8.3)	2(9.1)	4(10.0)
そう痒症	n (%)	1(6.3)	0	0	1(2.5)
斑状丘疹状皮疹	n (%)	0	1(4.2)	1(4.5)	1(2.5)
皮膚剥脱	n (%)	0	1(4.2)	1(4.5)	1(2.5)
蕁麻疹	n (%)	1(6.3)	0	0	1(2.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	 80 mg (N=24)	 80 mg Only[c] (N=22)	 All NBI-98854 (N=40)
血管障害	n (%)	1(6.3)	3(12.5)	3(13.6)	4(10.0)
ほてり	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
高血圧	n (%)	0	1(4.2)	1(4.5)	1(2.5)
レイノー現象	n (%)	0	1(4.2)	1(4.5)	1(2.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
Any Adverse Event	n (%)	108(59.7)	125(60.7)	111(57.8)	233(60.2)
血液およびリンパ系障害	n (%)	3(1.7)	5(2.4)	5(2.6)	8(2.1)
貧血	n (%)	0	3(1.5)	3(1.6)	3(0.8)
好中球減少症	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
白血球増加症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
白血球減少症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
血小板血症	n (%)	1(0.6)	0	0	1(0.3)
心臓障害	n (%)	5(2.8)	5(2.4)	5(2.6)	10(2.6)
心房細動	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
上室性不整脈	n (%)	1(0.6)	0	0	1(0.3)
左脚ブロック	n (%)	0	1(0.5)	1(0.5)	1(0.3)
心不全	n (%)	0	1(0.5)	1(0.5)	1(0.3)
冠動脈疾患	n (%)	1(0.6)	0	0	1(0.3)
僧帽弁閉鎖不全症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
洞性頻脈	n (%)	1(0.6)	0	0	1(0.3)
頻脈	n (%)	1(0.6)	0	0	1(0.3)
三尖弁閉鎖不全症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
心室性期外収縮	n (%)	0	1(0.5)	1(0.5)	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
先天性、家族性および遺伝性障害	n (%)	0	1(0.5)	1(0.5)	1(0.3)
弯足	n (%)	0	1(0.5)	1(0.5)	1(0.3)
耳および迷路障害	n (%)	3(1.7)	2(1.0)	2(1.0)	5(1.3)
耳鳴	n (%)	2(1.1)	0	0	2(0.5)
耳介軟骨膜炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
耳痛	n (%)	0	1(0.5)	1(0.5)	1(0.3)
聴覚障害	n (%)	1(0.6)	0	0	1(0.3)
内分泌障害	n (%)	1(0.6)	0	0	1(0.3)
甲状腺機能低下症	n (%)	1(0.6)	0	0	1(0.3)
眼障害	n (%)	0	3(1.5)	3(1.6)	3(0.8)
核性白内障	n (%)	0	1(0.5)	1(0.5)	1(0.3)
複視	n (%)	0	1(0.5)	1(0.5)	1(0.3)
兎眼	n (%)	0	1(0.5)	1(0.5)	1(0.3)
黄斑浮腫	n (%)	0	1(0.5)	1(0.5)	1(0.3)
網膜静脈閉塞	n (%)	0	1(0.5)	1(0.5)	1(0.3)
胃腸障害	n (%)	27(14.9)	35(17.0)	28(14.6)	62(16.0)
下痢	n (%)	5(2.8)	9(4.4)	8(4.2)	14(3.6)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
便秘	n (%)	5(2.8)	7(3.4)	4(2.1)	12(3.1)
嘔吐	n (%)	6(3.3)	6(2.9)	5(2.6)	12(3.1)
悪心	n (%)	3(1.7)	7(3.4)	7(3.6)	10(2.6)
口内乾燥	n (%)	6(3.3)	2(1.0)	2(1.0)	8(2.1)
流涎過多	n (%)	2(1.1)	5(2.4)	2(1.0)	7(1.8)
腹痛	n (%)	1(0.6)	3(1.5)	3(1.6)	4(1.0)
上腹部痛	n (%)	2(1.1)	2(1.0)	2(1.0)	4(1.0)
歯痛	n (%)	2(1.1)	2(1.0)	1(0.5)	4(1.0)
嚥下障害	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
胃食道逆流性疾患	n (%)	1(0.6)	2(1.0)	2(1.0)	3(0.8)
結腸ポリープ	n (%)	2(1.1)	0	0	2(0.5)
消化不良	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
胃炎	n (%)	0	2(1.0)	1(0.5)	2(0.5)
痔核	n (%)	2(1.1)	0	0	2(0.5)
腹部膨満	n (%)	0	1(0.5)	1(0.5)	1(0.3)
腹部圧痛	n (%)	1(0.6)	0	0	1(0.3)
憩室	n (%)	1(0.6)	0	0	1(0.3)
変色便	n (%)	1(0.6)	0	0	1(0.3)
食中毒	n (%)	0	1(0.5)	1(0.5)	1(0.3)
びらん性胃炎	n (%)	0	1(0.5)	0	1(0.3)
胃腸出血	n (%)	1(0.6)	0	0	1(0.3)
裂孔ヘルニア	n (%)	0	1(0.5)	1(0.5)	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
メレナ	n (%)	1(0.6)	0	0	1(0.3)
食道食物嵌入	n (%)	1(0.6)	0	0	1(0.3)
食道狭窄	n (%)	1(0.6)	0	0	1(0.3)
食道炎	n (%)	1(0.6)	0	0	1(0.3)
歯の脱落	n (%)	1(0.6)	0	0	1(0.3)
臍ヘルニア	n (%)	1(0.6)	0	0	1(0.3)
全身障害および投与局所様態	n (%)	17(9.4)	25(12.1)	18(9.4)	42(10.9)
疲労	n (%)	13(7.2)	8(3.9)	8(4.2)	21(5.4)
胸痛	n (%)	3(1.7)	3(1.5)	3(1.6)	6(1.6)
無力症	n (%)	1(0.6)	4(1.9)	0	5(1.3)
歩行障害	n (%)	3(1.7)	1(0.5)	0	4(1.0)
末梢性浮腫	n (%)	2(1.1)	2(1.0)	2(1.0)	4(1.0)
非心臓性胸痛	n (%)	0	2(1.0)	1(0.5)	2(0.5)
発熱	n (%)	0	2(1.0)	1(0.5)	2(0.5)
空腹	n (%)	1(0.6)	0	0	1(0.3)
治癒不良	n (%)	1(0.6)	0	0	1(0.3)
易刺激性	n (%)	1(0.6)	0	0	1(0.3)
倦怠感	n (%)	0	1(0.5)	1(0.5)	1(0.3)
疼痛	n (%)	0	1(0.5)	1(0.5)	1(0.3)
突然死	n (%)	0	1(0.5)	1(0.5)	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
口渇	n (%)	1(0.6)	0	0	1(0.3)
肝胆道系障害	n (%)	0	3(1.5)	3(1.6)	3(0.8)
胆石症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
肝不全	n (%)	0	1(0.5)	1(0.5)	1(0.3)
急性肝炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
黄疸	n (%)	0	1(0.5)	1(0.5)	1(0.3)
免疫系障害	n (%)	0	2(1.0)	2(1.0)	2(0.5)
過敏症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
季節性アレルギー	n (%)	0	1(0.5)	1(0.5)	1(0.3)
感染症および寄生虫症	n (%)	30(16.6)	39(18.9)	36(18.8)	69(17.8)
尿路感染	n (%)	10(5.5)	13(6.3)	13(6.8)	23(5.9)
鼻咽頭炎	n (%)	6(3.3)	9(4.4)	8(4.2)	15(3.9)
気管支炎	n (%)	1(0.6)	6(2.9)	5(2.6)	7(1.8)
上気道感染	n (%)	3(1.7)	3(1.5)	3(1.6)	6(1.6)
蜂巣炎	n (%)	0	3(1.5)	3(1.6)	3(0.8)
ウイルス性胃腸炎	n (%)	3(1.7)	0	0	3(0.8)
ダニ皮膚炎	n (%)	2(1.1)	0	0	2(0.5)
急性副鼻腔炎	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
胃腸炎	n (%)	0	2(1.0)	2(1.0)	2(0.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
インフルエンザ	n (%)	2(1.1)	0	0	2(0.5)
皮下組織膿瘍	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
軟部組織膿瘍	n (%)	0	1(0.5)	1(0.5)	1(0.3)
急性扁桃炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
体部白癬	n (%)	1(0.6)	0	0	1(0.3)
ブドウ球菌性蜂巣炎	n (%)	1(0.6)	0	0	1(0.3)
憩室炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
耳感染	n (%)	0	1(0.5)	1(0.5)	1(0.3)
眼感染	n (%)	1(0.6)	0	0	1(0.3)
せつ	n (%)	1(0.6)	0	0	1(0.3)
咬傷感染	n (%)	0	1(0.5)	1(0.5)	1(0.3)
爪真菌症	n (%)	1(0.6)	0	0	1(0.3)
咽頭炎	n (%)	1(0.6)	0	0	1(0.3)
肺炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
急性腎盂腎炎	n (%)	1(0.6)	0	0	1(0.3)
副鼻腔炎	n (%)	0	1(0.5)	0	1(0.3)
股部白癬	n (%)	1(0.6)	0	0	1(0.3)
外陰膣真菌感染	n (%)	1(0.6)	0	0	1(0.3)
傷害、中毒および処置合併症	n (%)	15(8.3)	18(8.7)	15(7.8)	33(8.5)
転倒・転落	n (%)	5(2.8)	5(2.4)	4(2.1)	10(2.6)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
挫傷	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
擦過傷	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
足骨折	n (%)	0	2(1.0)	1(0.5)	2(0.5)
関節脱臼	n (%)	0	2(1.0)	1(0.5)	2(0.5)
筋挫傷	n (%)	0	2(1.0)	2(1.0)	2(0.5)
交通事故	n (%)	0	2(1.0)	2(1.0)	2(0.5)
動物咬傷	n (%)	0	1(0.5)	1(0.5)	1(0.3)
第２度熱傷	n (%)	1(0.6)	0	0	1(0.3)
頚椎骨折	n (%)	0	1(0.5)	1(0.5)	1(0.3)
皮膚化学熱傷	n (%)	0	1(0.5)	1(0.5)	1(0.3)
異物による損傷	n (%)	0	1(0.5)	1(0.5)	1(0.3)
頭部損傷	n (%)	1(0.6)	0	0	1(0.3)
関節損傷	n (%)	1(0.6)	0	0	1(0.3)
関節捻挫	n (%)	1(0.6)	0	0	1(0.3)
四肢損傷	n (%)	0	1(0.5)	0	1(0.3)
四肢外傷性切断	n (%)	1(0.6)	0	0	1(0.3)
口腔内損傷	n (%)	0	1(0.5)	1(0.5)	1(0.3)
膝蓋骨骨折	n (%)	0	1(0.5)	1(0.5)	1(0.3)
橈骨骨折	n (%)	0	1(0.5)	1(0.5)	1(0.3)
肋骨骨折	n (%)	0	1(0.5)	0	1(0.3)
引っかき傷	n (%)	1(0.6)	0	0	1(0.3)
皮膚裂傷	n (%)	0	1(0.5)	1(0.5)	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
皮下血腫	n (%)	0	1(0.5)	1(0.5)	1(0.3)
熱傷	n (%)	1(0.6)	0	0	1(0.3)
臨床検査	n (%)	18(9.9)	25(12.1)	21(10.9)	43(11.1)
体重減少	n (%)	4(2.2)	3(1.5)	2(1.0)	7(1.8)
体重増加	n (%)	2(1.1)	3(1.5)	3(1.6)	5(1.3)
ヘモグロビン減少	n (%)	1(0.6)	3(1.5)	3(1.6)	4(1.0)
血中クレアチンホスホキナーゼ増加	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
血中クレアチニン増加	n (%)	1(0.6)	2(1.0)	1(0.5)	3(0.8)
血中ブドウ糖増加	n (%)	0	3(1.5)	3(1.6)	3(0.8)
血中トリグリセリド増加	n (%)	1(0.6)	2(1.0)	2(1.0)	3(0.8)
尿中ブドウ糖陽性	n (%)	1(0.6)	2(1.0)	2(1.0)	3(0.8)
グリコヘモグロビン増加	n (%)	1(0.6)	2(1.0)	1(0.5)	3(0.8)
血圧上昇	n (%)	0	2(1.0)	2(1.0)	2(0.5)
血中プロラクチン増加	n (%)	2(1.1)	0	0	2(0.5)
血中尿素増加	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
ヘマトクリット減少	n (%)	0	2(1.0)	2(1.0)	2(0.5)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
抗精神病薬濃度治療量以上	n (%)	0	1(0.5)	0	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
血中コレステロール増加	n (%)	0	1(0.5)	1(0.5)	1(0.3)
血中ブドウ糖減少	n (%)	0	1(0.5)	0	1(0.3)
尿中結晶陽性	n (%)	0	1(0.5)	1(0.5)	1(0.3)
心電図ＱＴ延長	n (%)	0	1(0.5)	1(0.5)	1(0.3)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
握力低下	n (%)	1(0.6)	0	0	1(0.3)
心拍数減少	n (%)	0	1(0.5)	1(0.5)	1(0.3)
肝酵素上昇	n (%)	1(0.6)	0	0	1(0.3)
便潜血陽性	n (%)	0	1(0.5)	1(0.5)	1(0.3)
血小板数減少	n (%)	0	1(0.5)	1(0.5)	1(0.3)
総蛋白減少	n (%)	0	1(0.5)	1(0.5)	1(0.3)
赤血球数減少	n (%)	0	1(0.5)	1(0.5)	1(0.3)
赤血球数増加	n (%)	0	1(0.5)	1(0.5)	1(0.3)
代謝および栄養障害	n (%)	8(4.4)	16(7.8)	13(6.8)	24(6.2)
食欲減退	n (%)	3(1.7)	3(1.5)	2(1.0)	6(1.6)
低ナトリウム血症	n (%)	0	3(1.5)	2(1.0)	3(0.8)
食欲亢進	n (%)	0	3(1.5)	2(1.0)	3(0.8)
食欲不振	n (%)	2(1.1)	0	0	2(0.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
糖尿病	n (%)	0	2(1.0)	2(1.0)	2(0.5)
食欲障害	n (%)	0	1(0.5)	1(0.5)	1(0.3)
脱水	n (%)	0	1(0.5)	1(0.5)	1(0.3)
耐糖能障害	n (%)	1(0.6)	0	0	1(0.3)
高血糖	n (%)	0	1(0.5)	1(0.5)	1(0.3)
高カリウム血症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
高トリグリセリド血症	n (%)	1(0.6)	0	0	1(0.3)
低アルブミン血症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
低カリウム血症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
低ナトリウム血症候群	n (%)	0	1(0.5)	1(0.5)	1(0.3)
代謝性アシドーシス	n (%)	0	1(0.5)	1(0.5)	1(0.3)
多飲症	n (%)	1(0.6)	0	0	1(0.3)
筋骨格系および結合組織障害	n (%)	17(9.4)	19(9.2)	15(7.8)	36(9.3)
背部痛	n (%)	6(3.3)	3(1.5)	3(1.6)	9(2.3)
関節痛	n (%)	2(1.1)	6(2.9)	5(2.6)	8(2.1)
骨関節炎	n (%)	2(1.1)	2(1.0)	2(1.0)	4(1.0)
四肢痛	n (%)	1(0.6)	3(1.5)	2(1.0)	4(1.0)
関節炎	n (%)	1(0.6)	1(0.5)	0	2(0.5)
筋肉痛	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
頚部痛	n (%)	1(0.6)	1(0.5)	0	2(0.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
滑液包炎	n (%)	1(0.6)	0	0	1(0.3)
尾骨痛	n (%)	0	1(0.5)	1(0.5)	1(0.3)
椎間板変性症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
関節腫脹	n (%)	0	1(0.5)	1(0.5)	1(0.3)
筋固縮	n (%)	0	1(0.5)	0	1(0.3)
筋力低下	n (%)	1(0.6)	0	0	1(0.3)
筋骨格系胸痛	n (%)	1(0.6)	0	0	1(0.3)
筋骨格痛	n (%)	0	1(0.5)	1(0.5)	1(0.3)
骨減少症	n (%)	1(0.6)	0	0	1(0.3)
顎痛	n (%)	1(0.6)	0	0	1(0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	2(1.1)	3(1.5)	3(1.6)	5(1.3)
副腎腺腫	n (%)	0	1(0.5)	1(0.5)	1(0.3)
乳癌	n (%)	0	1(0.5)	1(0.5)	1(0.3)
脂肪腫	n (%)	1(0.6)	0	0	1(0.3)
肺新生物	n (%)	1(0.6)	0	0	1(0.3)
甲状腺新生物	n (%)	0	1(0.5)	1(0.5)	1(0.3)
神経系障害	n (%)	42(23.2)	43(20.9)	31(16.1)	85(22.0)
傾眠	n (%)	15(8.3)	9(4.4)	6(3.1)	24(6.2)
頭痛	n (%)	9(5.0)	14(6.8)	10(5.2)	23(5.9)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
浮動性めまい	n (%)	6(3.3)	7(3.4)	7(3.6)	13(3.4)
アカシジア	n (%)	5(2.8)	1(0.5)	1(0.5)	6(1.6)
鎮静	n (%)	2(1.1)	4(1.9)	3(1.6)	6(1.6)
失神	n (%)	4(2.2)	2(1.0)	1(0.5)	6(1.6)
振戦	n (%)	3(1.7)	3(1.5)	1(0.5)	6(1.6)
ジスキネジー	n (%)	1(0.6)	4(1.9)	3(1.6)	5(1.3)
平衡障害	n (%)	1(0.6)	2(1.0)	1(0.5)	3(0.8)
よだれ	n (%)	0	2(1.0)	2(1.0)	2(0.5)
錐体外路障害	n (%)	0	2(1.0)	2(1.0)	2(0.5)
パーキンソニズム	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
遅発性ジスキネジー	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
健忘	n (%)	0	1(0.5)	1(0.5)	1(0.3)
歯車様固縮	n (%)	0	1(0.5)	1(0.5)	1(0.3)
認知症	n (%)	1(0.6)	0	0	1(0.3)
注意力障害	n (%)	0	1(0.5)	1(0.5)	1(0.3)
構語障害	n (%)	0	1(0.5)	0	1(0.3)
ジストニー	n (%)	1(0.6)	0	0	1(0.3)
脳症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
顔面神経麻痺	n (%)	0	1(0.5)	1(0.5)	1(0.3)
感覚鈍麻	n (%)	1(0.6)	0	0	1(0.3)
企図振戦	n (%)	1(0.6)	0	0	1(0.3)
嗜眠	n (%)	0	1(0.5)	0	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
片頭痛	n (%)	1(0.6)	0	0	1(0.3)
ミオクローヌス	n (%)	1(0.6)	0	0	1(0.3)
末梢性ニューロパチー	n (%)	0	1(0.5)	1(0.5)	1(0.3)
咬舌	n (%)	1(0.6)	0	0	1(0.3)
一過性脳虚血発作	n (%)	1(0.6)	0	0	1(0.3)
妊娠、産褥および周産期の状態	n (%)	0	1(0.5)	1(0.5)	1(0.3)
自然流産	n (%)	0	1(0.5)	1(0.5)	1(0.3)
精神障害	n (%)	35(19.3)	29(14.1)	24(12.5)	64(16.5)
自殺念慮	n (%)	8(4.4)	7(3.4)	7(3.6)	15(3.9)
うつ病	n (%)	9(5.0)	4(1.9)	3(1.6)	13(3.4)
不安	n (%)	4(2.2)	4(1.9)	2(1.0)	8(2.1)
不眠症	n (%)	4(2.2)	3(1.5)	2(1.0)	7(1.8)
統合失調症	n (%)	3(1.7)	3(1.5)	3(1.6)	6(1.6)
激越	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
抑うつ気分	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
精神状態変化	n (%)	2(1.1)	0	0	2(0.5)
妄想症	n (%)	2(1.1)	0	0	2(0.5)
精神運動制止遅滞	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
落ち着きのなさ	n (%)	1(0.6)	1(0.5)	0	2(0.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
統合失調感情障害	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(1.0)	2(1.0)	2(0.5)
アルコール症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
双極１型障害	n (%)	1(0.6)	0	0	1(0.3)
錯乱状態	n (%)	0	1(0.5)	1(0.5)	1(0.3)
ディスフェミア	n (%)	1(0.6)	0	0	1(0.3)
敵意	n (%)	1(0.6)	0	0	1(0.3)
軽躁	n (%)	1(0.6)	0	0	1(0.3)
リビドー減退	n (%)	1(0.6)	0	0	1(0.3)
躁病	n (%)	0	1(0.5)	1(0.5)	1(0.3)
気分動揺	n (%)	0	1(0.5)	0	1(0.3)
神経過敏	n (%)	0	1(0.5)	1(0.5)	1(0.3)
パニック発作	n (%)	1(0.6)	0	0	1(0.3)
外傷後ストレス障害	n (%)	1(0.6)	0	0	1(0.3)
精神病性障害	n (%)	0	1(0.5)	0	1(0.3)
自殺行為	n (%)	0	1(0.5)	1(0.5)	1(0.3)
トランス	n (%)	1(0.6)	0	0	1(0.3)
腎および尿路障害	n (%)	4(2.2)	5(2.4)	5(2.6)	9(2.3)
血尿	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
頻尿	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
尿失禁	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169　ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
排尿困難	n (%)	0	1(0.5)	1(0.5)	1(0.3)
糖尿	n (%)	0	1(0.5)	1(0.5)	1(0.3)
急性腎不全	n (%)	1(0.6)	0	0	1(0.3)
尿臭異常	n (%)	1(0.6)	0	0	1(0.3)
生殖系および乳房障害	n (%)	2(1.1)	3(1.5)	3(1.6)	5(1.3)
良性前立腺肥大症	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
月経過多	n (%)	0	1(0.5)	1(0.5)	1(0.3)
前立腺炎	n (%)	1(0.6)	0	0	1(0.3)
精巣捻転	n (%)	0	1(0.5)	1(0.5)	1(0.3)
呼吸器、胸郭および縦隔障害	n (%)	6(3.3)	26(12.6)	22(11.5)	32(8.3)
咳嗽	n (%)	2(1.1)	6(2.9)	4(2.1)	8(2.1)
慢性閉塞性肺疾患	n (%)	2(1.1)	5(2.4)	5(2.6)	7(1.8)
鼻閉	n (%)	1(0.6)	5(2.4)	5(2.6)	6(1.6)
呼吸困難	n (%)	1(0.6)	3(1.5)	2(1.0)	4(1.0)
喘息	n (%)	0	3(1.5)	2(1.0)	3(0.8)
口腔咽頭痛	n (%)	0	2(1.0)	1(0.5)	2(0.5)
アレルギー性鼻炎	n (%)	0	2(1.0)	2(1.0)	2(0.5)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
副鼻腔うっ血	n (%)	1(0.6)	1(0.5)	0	2(0.5)
慢性気管支炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
嚢胞性肺疾患	n (%)	0	1(0.5)	1(0.5)	1(0.3)
鼻出血	n (%)	1(0.6)	0	0	1(0.3)
胸水	n (%)	0	1(0.5)	1(0.5)	1(0.3)
胸膜線維症	n (%)	0	1(0.5)	1(0.5)	1(0.3)
気道うっ血	n (%)	0	1(0.5)	0	1(0.3)
鼻漏	n (%)	1(0.6)	0	0	1(0.3)
皮膚および皮下組織障害	n (%)	9(5.0)	5(2.4)	4(2.1)	14(3.6)
発疹	n (%)	2(1.1)	3(1.5)	2(1.0)	5(1.3)
過角化	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
そう痒症	n (%)	2(1.1)	0	0	2(0.5)
水疱	n (%)	1(0.6)	0	0	1(0.3)
アレルギー性皮膚炎	n (%)	1(0.6)	0	0	1(0.3)
全身性皮疹	n (%)	1(0.6)	0	0	1(0.3)
斑状丘疹状皮疹	n (%)	1(0.6)	0	0	1(0.3)
丘疹	n (%)	0	1(0.5)	1(0.5)	1(0.3)
皮膚病変	n (%)	0	1(0.5)	1(0.5)	1(0.3)
社会環境	n (%)	1(0.6)	0	0	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－169 ベースライン時の肝機能値異常の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	 80 mg (N=206)	 80 mg Only[c] (N=192)	All NBI-98854 (N=387)
社会的入院	n (%)	1(0.6)	0	0	1(0.3)
外科および内科処置	n (%)	2(1.1)	3(1.5)	3(1.6)	5(1.3)
抜歯	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
四肢再接合手術	n (%)	0	1(0.5)	1(0.5)	1(0.3)
鼓膜切開	n (%)	0	1(0.5)	1(0.5)	1(0.3)
Unknown	n (%)	1(0.6)	0	0	1(0.3)
皮膚嚢腫	n (%)	1(0.6)	0	0	1(0.3)
血管障害	n (%)	5(2.8)	11(5.3)	10(5.2)	16(4.1)
高血圧	n (%)	2(1.1)	5(2.4)	4(2.1)	7(1.8)
深部静脈血栓症	n (%)	0	2(1.0)	2(1.0)	2(0.5)
血腫	n (%)	0	2(1.0)	2(1.0)	2(0.5)
本態性高血圧症	n (%)	1(0.6)	0	0	1(0.3)
ほてり	n (%)	0	1(0.5)	1(0.5)	1(0.3)
低血圧	n (%)	0	1(0.5)	1(0.5)	1(0.3)
起立性低血圧	n (%)	1(0.6)	0	0	1(0.3)
末梢動脈閉塞性疾患	n (%)	1(0.6)	0	0	1(0.3)

[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.10より引用（一部改変）

表2.7.4.7－170　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Hepatic Abnormality[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	80 mg (N=24)	80 mg Only[c] (N=22)	All NBI-98854 (N=40)
Any Adverse Event of Special Interest	n (%)	5(31.3)	8(33.3)	6(27.3)	13(32.5)
アカシジア関連有害事象	n (%)	2(12.5)	0	0	2(5.0)
アカシジア	n (%)	2(12.5)	0	0	2(5.0)
不安	n (%)	2(12.5)	3(12.5)	1(4.5)	5(12.5)
不安	n (%)	2(12.5)	3(12.5)	1(4.5)	5(12.5)
うつ病及び自殺関連有害事象	n (%)	2(12.5)	3(12.5)	3(13.6)	5(12.5)
自殺念慮	n (%)	1(6.3)	3(12.5)	3(13.6)	4(10.0)
抑うつ症状	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
うつ病	n (%)	0	1(4.2)	1(4.5)	1(2.5)
嚥下障害関連有害事象	n (%)	1(6.3)	0	0	1(2.5)
嚥下障害	n (%)	1(6.3)	0	0	1(2.5)
高プロラクチン血症関連有害事象	n (%)	1(6.3)	1(4.2)	0	2(5.0)
血中プロラクチン増加	n (%)	0	1(4.2)	0	1(2.5)
乳汁漏出症	n (%)	1(6.3)	0	0	1(2.5)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－170　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=16)	80 mg (N=24)	80 mg Only[c] (N=22)	All NBI-98854 (N=40)
低血圧関連有害事象	n (%)	0	3(12.5)	3(13.6)	3(7.5)
浮動性めまい	n (%)	0	3(12.5)	3(13.6)	3(7.5)
パーキンソニズム関連有害事象	n (%)	1(6.3)	0	0	1(2.5)
振戦	n (%)	1(6.3)	0	0	1(2.5)
基礎疾患の悪化に関連する有害事象	n (%)	3(18.8)	4(16.7)	4(18.2)	7(17.5)
自殺念慮	n (%)	1(6.3)	3(12.5)	3(13.6)	4(10.0)
抑うつ症状	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
易刺激性	n (%)	0	2(8.3)	2(9.1)	2(5.0)
統合失調症	n (%)	1(6.3)	1(4.2)	1(4.5)	2(5.0)
うつ病	n (%)	0	1(4.2)	1(4.5)	1(2.5)
躁病	n (%)	1(6.3)	0	0	1(2.5)
精神病性障害	n (%)	1(6.3)	0	0	1(2.5)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－170　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	80 mg (N=206)	80 mg Only[c] (N=192)	All NBI-98854 (N=387)
Any Adverse Event of Special Interest	n (%)	65(35.9)	63(30.6)	50(26.0)	128(33.1)
アカシジア関連有害事象	n (%)	5(2.8)	1(0.5)	1(0.5)	6(1.6)
アカシジア	n (%)	5(2.8)	1(0.5)	1(0.5)	6(1.6)
不安	n (%)	4(2.2)	4(1.9)	2(1.0)	8(2.1)
不安	n (%)	4(2.2)	4(1.9)	2(1.0)	8(2.1)
心血管系及びQT間隔延長関連有害事象	n (%)	6(3.3)	8(3.9)	7(3.6)	14(3.6)
胸痛	n (%)	3(1.7)	3(1.5)	3(1.6)	6(1.6)
失神	n (%)	4(2.2)	2(1.0)	1(0.5)	6(1.6)
心不全	n (%)	0	1(0.5)	1(0.5)	1(0.3)
心電図QT延長	n (%)	0	1(0.5)	1(0.5)	1(0.3)
突然死	n (%)	0	1(0.5)	1(0.5)	1(0.3)
うつ病及び自殺関連有害事象	n (%)	17(9.4)	15(7.3)	14(7.3)	32(8.3)
自殺念慮	n (%)	8(4.4)	7(3.4)	7(3.6)	15(3.9)
うつ病	n (%)	9(5.0)	4(1.9)	3(1.6)	13(3.4)
抑うつ気分	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(1.0)	2(1.0)	2(0.5)
自殺行為	n (%)	0	1(0.5)	1(0.5)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－170　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	80 mg (N=206)	80 mg Only[c] (N=192)	All NBI-98854 (N=387)
嚥下障害関連有害事象	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
嚥下障害	n (%)	2(1.1)	1(0.5)	1(0.5)	3(0.8)
食道食物嵌入	n (%)	1(0.6)	0	0	1(0.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	13(7.2)	14(6.8)	9(4.7)	27(7.0)
疲労	n (%)	13(7.2)	8(3.9)	8(4.2)	21(5.4)
無力症	n (%)	1(0.6)	4(1.9)	0	5(1.3)
嗜眠	n (%)	0	1(0.5)	0	1(0.3)
倦怠感	n (%)	0	1(0.5)	1(0.5)	1(0.3)
肝障害関連有害事象	n (%)	0	2(1.0)	2(1.0)	2(0.5)
肝不全	n (%)	0	1(0.5)	1(0.5)	1(0.3)
急性肝炎	n (%)	0	1(0.5)	1(0.5)	1(0.3)
高プロラクチン血症関連有害事象	n (%)	2(1.1)	0	0	2(0.5)
血中プロラクチン増加	n (%)	2(1.1)	0	0	2(0.5)
低血圧関連有害事象	n (%)	14(7.7)	13(6.3)	12(6.3)	27(7.0)
浮動性めまい	n (%)	6(3.3)	7(3.4)	7(3.6)	13(3.4)
転倒・転落	n (%)	5(2.8)	5(2.4)	4(2.1)	10(2.6)
失神	n (%)	4(2.2)	2(1.0)	1(0.5)	6(1.6)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－170　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	80 mg (N=206)	80 mg Only[c] (N=192)	All NBI-98854 (N=387)
低血圧	n (%)	0	1(0.5)	1(0.5)	1(0.3)
起立性低血圧	n (%)	1(0.6)	0	0	1(0.3)
パーキンソニズム関連有害事象	n (%)	4(2.2)	5(2.4)	2(1.0)	9(2.3)
振戦	n (%)	3(1.7)	3(1.5)	1(0.5)	6(1.6)
パーキンソニズム	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
歯車様固縮	n (%)	0	1(0.5)	1(0.5)	1(0.3)
筋固縮	n (%)	0	1(0.5)	0	1(0.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	17(9.4)	13(6.3)	9(4.7)	30(7.8)
傾眠	n (%)	15(8.3)	9(4.4)	6(3.1)	24(6.2)
鎮静	n (%)	2(1.1)	4(1.9)	3(1.6)	6(1.6)
基礎疾患の悪化に関連する有害事象	n (%)	24(13.3)	21(10.2)	19(9.9)	45(11.6)
自殺念慮	n (%)	8(4.4)	7(3.4)	7(3.6)	15(3.9)
うつ病	n (%)	9(5.0)	4(1.9)	3(1.6)	13(3.4)
統合失調症	n (%)	3(1.7)	3(1.5)	3(1.6)	6(1.6)
抑うつ気分	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
妄想症	n (%)	2(1.1)	0	0	2(0.5)
統合失調感情障害	n (%)	1(0.6)	1(0.5)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(1.0)	2(1.0)	2(0.5)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－170　ベースライン時の肝機能値異常の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Hepatic Abnormality[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=181)	80 mg (N=206)	80 mg Only[c] (N=192)	All NBI-98854 (N=387)
双極１型障害	n (%)	1(0.6)	0	0	1(0.3)
敵意	n (%)	1(0.6)	0	0	1(0.3)
軽躁	n (%)	1(0.6)	0	0	1(0.3)
易刺激性	n (%)	1(0.6)	0	0	1(0.3)
躁病	n (%)	0	1(0.5)	1(0.5)	1(0.3)
気分動揺	n (%)	0	1(0.5)	0	1(0.3)
外傷後ストレス障害	n (%)	1(0.6)	0	0	1(0.3)
精神病性障害	n (%)	0	1(0.5)	0	1(0.3)
自殺行為	n (%)	0	1(0.5)	1(0.5)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.10より引用（一部改変）

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Any System Organ Class		35 (63.6)	45 (83.3)	80 (73.4)	20 (37.7)	19 (63.3)	22 (73.3)	41 (68.3)	17 (54.8)
Infections and infestations	感染症および寄生虫症	6 (10.9)	5 (9.3)	11 (10.1)	3 (5.7)	4 (13.3)	4 (13.3)	8 (13.3)	4 (12.9)
Nasopharyngitis	上咽頭炎	3 (5.5)	2 (3.7)	5 (4.6)	3 (5.7)	3 (10.0)	2 (6.7)	5 (8.3)	3 (9.7)
Pneumonia	肺炎	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Influenza	インフルエンザ	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periodontitis	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	上気道感染	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	1 (3.2)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Blepharal papilloma	眼瞼乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	4 (7.3)	2 (3.7)	6 (5.5)	1 (1.9)	2 (6.7)	2 (6.7)	4 (6.7)	1 (3.2)
Decreased appetite	食欲減退	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Dehydration	脱水	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Diabetes mellitus	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Hyperuricaemia	高尿酸血症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polydipsia	多飲症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Psychiatric disorders	精神障害	12 (21.8)	8 (14.8)	20 (18.3)	1 (1.9)	5 (16.7)	8 (26.7)	13 (21.7)	4 (12.9)
Insomnia	不眠症	2 (3.6)	4 (7.4)	6 (5.5)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	1 (3.2)
Schizophrenia	統合失調症	7 (12.7)	0 (0.0)	7 (6.4)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (3.7)	2 (1.8)	0 (0.0)	1 (3.3)	2 (6.7)	3 (5.0)	0 (0.0)
Depression	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	3 (10.0)	4 (6.7)	1 (3.2)
Disinhibition	脱抑制	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.3)	1 (3.2)
Delusion	妄想	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	1 (3.2)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Somatic symptom disorder	身体症状症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Nervous system disorders	神経系障害	9 (16.4)	26 (48.1)	35 (32.1)	4 (7.5)	11 (36.7)	12 (40.0)	23 (38.3)	2 (6.5)
Somnolence	傾眠	5 (9.1)	16 (29.6)	21 (19.3)	1 (1.9)	5 (16.7)	5 (16.7)	10 (16.7)	1 (3.2)
Akathisia	アカシジア	2 (3.6)	3 (5.6)	5 (4.6)	1 (1.9)	2 (6.7)	2 (6.7)	4 (6.7)	0 (0.0)
Headache	頭痛	0 (0.0)	4 (7.4)	4 (3.7)	1 (1.9)	1 (3.3)	0 (0.0)	1 (1.7)	1 (3.2)
Tremor	振戦	0 (0.0)	4 (7.4)	4 (3.7)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	1 (1.9)	1 (0.9)	1 (1.9)	0 (0.0)	2 (6.7)	2 (3.3)	0 (0.0)
Drooling	よだれ	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Hypoaesthesia	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Sciatica	坐骨神経痛	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Seizure	痙攣発作	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Eye disorders	眼障害	1 (1.8)	2 (3.7)	3 (2.8)	2 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blepharitis	眼瞼炎	0 (0.0)	1 (1.9)	1 (0.9)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	0 (0.0)	2 (3.3)	0 (0.0)
Deafness neurosensory	感音性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Cardiac disorders	心臓障害	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	動悸	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	1 (1.8)	0 (0.0)	1 (0.9)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	高血圧	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1 (1.8)	4 (7.4)	5 (4.6)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthma	喘息	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Gastrointestinal disorders	胃腸障害	5 (9.1)	12 (22.2)	17 (15.6)	2 (3.8)	3 (10.0)	8 (26.7)	11 (18.3)	5 (16.1)
Salivary hypersecretion	流涎過多	3 (5.5)	7 (13.0)	10 (9.2)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.3)	1 (3.2)
Constipation	便秘	1 (1.8)	1 (1.9)	2 (1.8)	1 (1.9)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Nausea	悪心	0 (0.0)	2 (3.7)	2 (1.8)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	1 (3.2)
Diarrhoea	下痢	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	1 (3.2)
Dry mouth	口内乾燥	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Dysphagia	嚥下障害	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Gastritis	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Toothache	歯痛	1 (1.8)	0 (0.0)	1 (0.9)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4 (7.3)	6 (11.1)	10 (9.2)	5 (9.4)	2 (6.7)	0 (0.0)	2 (3.3)	0 (0.0)
Urticaria	蕁麻疹	1 (1.8)	2 (3.7)	3 (2.8)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Eczema	湿疹	0 (0.0)	1 (1.9)	1 (0.9)	3 (5.7)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Alopecia areata	円形脱毛症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry skin	皮膚乾燥	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (1.8)	5 (9.3)	6 (5.5)	2 (3.8)	3 (10.0)	0 (0.0)	3 (5.0)	3 (9.7)
Back pain	背部痛	0 (0.0)	2 (3.7)	2 (1.8)	1 (1.9)	3 (10.0)	0 (0.0)	3 (5.0)	1 (3.2)
Neck pain	頚部痛	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Posture abnormal	姿勢異常	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Muscle spasms	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	1 (3.2)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Polyuria	多尿	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	7 (12.7)	6 (11.1)	13 (11.9)	1 (1.9)	3 (10.0)	5 (16.7)	8 (13.3)	1 (3.2)
Malaise	倦怠感	3 (5.5)	1 (1.9)	4 (3.7)	0 (0.0)	2 (6.7)	3 (10.0)	5 (8.3)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (3.7)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	口渇	2 (3.6)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Asthenia	無力症	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Oedema	浮腫	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	1 (1.8)	0 (0.0)	1 (0.9)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pyrexia	発熱	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Investigations	臨床検査	4 (7.3)	2 (3.7)	6 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)
Weight increased	体重増加	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－171　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	3 (5.5)	1 (1.9)	4 (3.7)	3 (5.7)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Fall	転倒	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contusion	挫傷	0 (0.0)	1 (1.9)	1 (0.9)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Sedation complication	鎮静合併症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.1.1.1 より引用

表 2.7.4.7－172　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Any AESI		23 (41.8)	36 (66.7)	59 (54.1)	10 (18.9)	13 (43.3)	17 (56.7)	30 (50.0)	5 (16.1)
Somnolence	傾眠関連有害事象	9 (16.4)	17 (31.5)	26 (23.9)	1 (1.9)	7 (23.3)	7 (23.3)	14 (23.3)	1 (3.2)
Somnolence	傾眠	5 (9.1)	16 (29.6)	21 (19.3)	1 (1.9)	5 (16.7)	5 (16.7)	10 (16.7)	1 (3.2)
Malaise	倦怠感	3 (5.5)	1 (1.9)	4 (3.7)	0 (0.0)	2 (6.7)	3 (10.0)	5 (8.3)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (3.7)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Sedation complication	鎮静合併症	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	3 (5.5)	6 (11.1)	9 (8.3)	5 (9.4)	2 (6.7)	1 (3.3)	3 (5.0)	1 (3.2)
Urticaria	蕁麻疹	1 (1.8)	2 (3.7)	3 (2.8)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Eczema	湿疹	0 (0.0)	1 (1.9)	1 (0.9)	3 (5.7)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Rash	発疹	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－172　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Parkinsonism	パーキンソニズム関連有害事象	4 (7.3)	14 (25.9)	18 (16.5)	0 (0.0)	1 (3.3)	4 (13.3)	5 (8.3)	1 (3.2)
Salivary hypersecretion	流涎過多	3 (5.5)	7 (13.0)	10 (9.2)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.3)	1 (3.2)
Tremor	振戦	0 (0.0)	4 (7.4)	4 (3.7)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Drooling	よだれ	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	3 (5.5)	0 (0.0)	3 (2.8)	0 (0.0)	3 (10.0)	3 (10.0)	6 (10.0)	1 (3.2)
Depression	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	3 (10.0)	4 (6.7)	1 (3.2)
Depressed mood	抑うつ気分	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	1 (3.2)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Akathisia	アカシジア関連有害事象	2 (3.6)	5 (9.3)	7 (6.4)	1 (1.9)	2 (6.7)	3 (10.0)	5 (8.3)	0 (0.0)
Akathisia	アカシジア	2 (3.6)	3 (5.6)	5 (4.6)	1 (1.9)	2 (6.7)	2 (6.7)	4 (6.7)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (3.7)	2 (1.8)	0 (0.0)	1 (3.3)	2 (6.7)	3 (5.0)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (3.7)	2 (1.8)	0 (0.0)	1 (3.3)	2 (6.7)	3 (5.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－172　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder				Bipolar Disorder/Depressive Disorder			
		MT-5199				MT-5199			
		40 mg (N=55) n(%)	80 mg (N=54) n(%)	All MT-5199 (N=109) n(%)	Placebo (N=53) n(%)	40 mg (N=30) n(%)	80 mg (N=30) n(%)	All MT-5199 (N=60) n(%)	Placebo (N=31) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	9 (16.4)	0 (0.0)	9 (8.3)	1 (1.9)	2 (6.7)	6 (20.0)	8 (13.3)	2 (6.5)
Schizophrenia	統合失調症	7 (12.7)	0 (0.0)	7 (6.4)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	3 (10.0)	4 (6.7)	1 (3.2)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.7)	2 (3.3)	1 (3.2)
Depressed mood	抑うつ気分	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	1 (3.2)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Dysphagia	嚥下障害	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (3.3)	1 (1.7)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.8)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.9)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.3)	0 (0.0)	1 (1.7)	0 (0.0)
Hypotension	低血圧関連有害事象	1 (1.8)	2 (3.7)	3 (2.8)	2 (3.8)	0 (0.0)	2 (6.7)	2 (3.3)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	1 (1.9)	1 (0.9)	1 (1.9)	0 (0.0)	2 (6.7)	2 (3.3)	0 (0.0)
Fall	転倒	1 (1.8)	1 (1.9)	2 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.1.1.2 より引用

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	 80 mg (N=79) n(%)	 80 mg (no dose reduction) (N=50) n(%)	 All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	 80 mg (N=44) n(%)	 80 mg (no dose reduction) (N=34) n(%)	 All MT-5199 (N=88) n(%)
Any System Organ Class		75 (91.5)	75 (94.9)	46 (92.0)	150 (93.2)	38 (86.4)	41 (93.2)	31 (91.2)	79 (89.8)
Infections and infestations	感染症および寄生虫症	31 (37.8)	29 (36.7)	18 (36.0)	60 (37.3)	15 (34.1)	11 (25.0)	11 (32.4)	26 (29.5)
Nasopharyngitis	上咽頭炎	19 (23.2)	17 (21.5)	9 (18.0)	36 (22.4)	11 (25.0)	6 (13.6)	6 (17.6)	17 (19.3)
Cystitis	膀胱炎	1 (1.2)	2 (2.5)	2 (4.0)	3 (1.9)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Pneumonia	肺炎	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	0 (0.0)	2 (4.5)	2 (5.9)	2 (2.3)
Bronchitis	気管支炎	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza	インフルエンザ	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Upper respiratory tract infection	上気道感染	2 (2.4)	1 (1.3)	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cellulitis	蜂巣炎	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Folliculitis	毛包炎	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	胃腸炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Otitis externa	外耳炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Periodontitis	歯周炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Pharyngitis	咽頭炎	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Gingivitis	歯肉炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	帯状疱疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Mastitis	乳腺炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal vestibulitis	鼻前庭炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis media	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subcutaneous abscess	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Tonsillitis	扁桃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Urinary tract infection	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Vaginal infection	腟感染	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Varicella	水痘	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin candida	皮膚カンジダ	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nail infection	爪感染	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Acarodermatitis	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Cystitis bacterial	細菌性膀胱炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infected dermal cyst	感染性皮膚嚢腫	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial vulvovaginitis	細菌性外陰腟炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Metabolism and nutrition disorders	代謝および栄養障害	11 (13.4)	6 (7.6)	2 (4.0)	17 (10.6)	5 (11.4)	6 (13.6)	6 (17.6)	11 (12.5)
Decreased appetite	食欲減退	2 (2.4)	3 (3.8)	0 (0.0)	5 (3.1)	3 (6.8)	1 (2.3)	1 (2.9)	4 (4.5)
Dehydration	脱水	1 (1.2)	2 (2.5)	2 (4.0)	3 (1.9)	0 (0.0)	2 (4.5)	2 (5.9)	2 (2.3)
Hyperuricaemia	高尿酸血症	2 (2.4)	1 (1.3)	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Increased appetite	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Dyslipidaemia	脂質異常症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	2 (5.9)	2 (2.3)
Type 2 diabetes mellitus	２型糖尿病	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Electrolyte imbalance	電解質失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Hypokalaemia	低カリウム血症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypouricaemia	低尿酸血症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marasmus	マラスムス	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polydipsia	多飲症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Psychiatric disorders	精神障害	35 (42.7)	32 (40.5)	19 (38.0)	67 (41.6)	17 (38.6)	25 (56.8)	21 (61.8)	42 (47.7)
Schizophrenia	統合失調症	21 (25.6)	13 (16.5)	5 (10.0)	34 (21.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Insomnia	不眠症	5 (6.1)	10 (12.7)	7 (14.0)	15 (9.3)	5 (11.4)	6 (13.6)	5 (14.7)	11 (12.5)
Depression	うつ病	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	4 (9.1)	9 (20.5)	8 (23.5)	13 (14.8)
Anxiety	不安	3 (3.7)	5 (6.3)	4 (8.0)	8 (5.0)	2 (4.5)	4 (9.1)	3 (8.8)	6 (6.8)
Suicidal ideation	自殺念慮	4 (4.9)	3 (3.8)	2 (4.0)	7 (4.3)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Restlessness	落ち着きのなさ	2 (2.4)	2 (2.5)	1 (2.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	2 (4.5)	2 (5.9)	4 (4.5)
Middle insomnia	中期不眠症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Bruxism	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Delirium	譫妄	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disinhibition	脱抑制	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Flat affect	感情の平板化	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Hallucination, auditory	幻聴	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Agitation	激越	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	 80 mg (N=79) n(%)	 80 mg (no dose reduction) (N=50) n(%)	 All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	 80 mg (N=44) n(%)	 80 mg (no dose reduction) (N=34) n(%)	 All MT-5199 (N=88) n(%)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Intentional self-injury	故意の自傷行為	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurosis	神経症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Abulia	無為	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Abnormal behaviour	異常行動	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somatic hallucination	体感幻覚	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Nervous system disorders	神経系障害	33 (40.2)	46 (58.2)	27 (54.0)	79 (49.1)	18 (40.9)	23 (52.3)	17 (50.0)	41 (46.6)
Somnolence	傾眠	11 (13.4)	20 (25.3)	13 (26.0)	31 (19.3)	8 (18.2)	8 (18.2)	5 (14.7)	16 (18.2)
Tremor	振戦	4 (4.9)	10 (12.7)	6 (12.0)	14 (8.7)	1 (2.3)	6 (13.6)	3 (8.8)	7 (8.0)
Akathisia	アカシジア	6 (7.3)	6 (7.6)	3 (6.0)	12 (7.5)	2 (4.5)	6 (13.6)	5 (14.7)	8 (9.1)
Headache	頭痛	2 (2.4)	8 (10.1)	5 (10.0)	10 (6.2)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Dizziness	浮動性めまい	3 (3.7)	4 (5.1)	3 (6.0)	7 (4.3)	1 (2.3)	3 (6.8)	3 (8.8)	4 (4.5)
Parkinsonism	パーキンソニズム	3 (3.7)	3 (3.8)	2 (4.0)	6 (3.7)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Extrapyramidal disorder	錐体外路障害	2 (2.4)	3 (3.8)	1 (2.0)	5 (3.1)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Drooling	よだれ	2 (2.4)	3 (3.8)	2 (4.0)	5 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tardive dyskinesia	遅発性ジスキネジア	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Hypoaesthesia	感覚鈍麻	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Bradykinesia	運動緩慢	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Dyskinesia	ジスキネジア	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Disturbance in attention	注意力障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Dysarthria	構語障害	0 (0.0)	2 (2.5)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dystonia	ジストニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Seizure	痙攣発作	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Coordination abnormal	協調運動異常	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	 80 mg (N=79) n(%)	 80 mg (no dose reduction) (N=50) n(%)	 All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	 80 mg (N=44) n(%)	 80 mg (no dose reduction) (N=34) n(%)	 All MT-5199 (N=88) n(%)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Loss of consciousness	意識消失	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Neuralgia	神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Radial nerve palsy	橈骨神経麻痺	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stupor	昏迷	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intercostal neuralgia	肋間神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Cognitive disorder	認知障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vagus nerve disorder	迷走神経障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Eye disorders	眼障害	1 (1.2)	4 (5.1)	2 (4.0)	5 (3.1)	2 (4.5)	1 (2.3)	0 (0.0)	3 (3.4)
Blepharitis	眼瞼炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Cataract	白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye discharge	眼脂	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	2 (4.5)	1 (2.3)	1 (2.9)	3 (3.4)
Deafness neurosensory	感音性難聴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Tinnitus	耳鳴	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo	回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Cardiac disorders	心臓障害	2 (2.4)	3 (3.8)	2 (4.0)	5 (3.1)	2 (4.5)	2 (4.5)	2 (5.9)	4 (4.5)
Palpitations	動悸	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Bradycardia	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Long QT syndrome	ＱＴ延長症候群	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Sinus bradycardia	洞性徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Tachycardia	頻脈	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	2 (2.4)	2 (2.5)	1 (2.0)	4 (2.5)	2 (4.5)	1 (2.3)	1 (2.9)	3 (3.4)
Hypertension	高血圧	2 (2.4)	1 (1.3)	0 (0.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Hypotension	低血圧	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Deep vein thrombosis	深部静脈血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	80 mg (N=79) n(%)	80 mg (no dose reduction) (N=50) n(%)	All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	80 mg (N=44) n(%)	80 mg (no dose reduction) (N=34) n(%)	All MT-5199 (N=88) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	4 (4.9)	9 (11.4)	2 (4.0)	13 (8.1)	4 (9.1)	3 (6.8)	2 (5.9)	7 (8.0)
Asthma	喘息	0 (0.0)	2 (2.5)	0 (0.0)	2 (1.2)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Dyspnoea	呼吸困難	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Pleural effusion	胸水	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Upper respiratory tract inflammation	上気道の炎症	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	2 (2.5)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Interstitial lung disease	間質性肺疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Pleurisy	胸膜炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	湿性咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Pulmonary embolism	肺塞栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Respiratory failure	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Rhinitis allergic	アレルギー性鼻炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough variant asthma	咳喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Throat clearing	咳払い	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Gastrointestinal disorders	胃腸障害	22 (26.8)	35 (44.3)	16 (32.0)	57 (35.4)	17 (38.6)	16 (36.4)	12 (35.3)	33 (37.5)
Salivary hypersecretion	流涎過多	8 (9.8)	15 (19.0)	6 (12.0)	23 (14.3)	1 (2.3)	6 (13.6)	4 (11.8)	7 (8.0)
Constipation	便秘	6 (7.3)	7 (8.9)	4 (8.0)	13 (8.1)	3 (6.8)	2 (4.5)	1 (2.9)	5 (5.7)
Dysphagia	嚥下障害	4 (4.9)	4 (5.1)	2 (4.0)	8 (5.0)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Diarrhoea	下痢	4 (4.9)	2 (2.5)	1 (2.0)	6 (3.7)	2 (4.5)	1 (2.3)	1 (2.9)	3 (3.4)
Nausea	悪心	1 (1.2)	3 (3.8)	2 (4.0)	4 (2.5)	1 (2.3)	2 (4.5)	2 (5.9)	3 (3.4)
Stomatitis	口内炎	2 (2.4)	3 (3.8)	3 (6.0)	5 (3.1)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Vomiting	嘔吐	2 (2.4)	5 (6.3)	1 (2.0)	7 (4.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal discomfort	腹部不快感	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Dental caries	齲歯	0 (0.0)	2 (2.5)	0 (0.0)	2 (1.2)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Abdominal pain	腹痛	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Dry mouth	口内乾燥	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Gastritis	胃炎	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Toothache	歯痛	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Abdominal distension	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aphthous ulcer	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Chronic gastritis	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Eructation	おくび	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Gastrointestinal disorder	胃腸障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Gingival bleeding	歯肉出血	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Hypoaesthesia oral	口の感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Anal pruritus	肛門そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Anal eczema	肛門湿疹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	2 (2.5)	2 (4.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Hepatic function abnormal	肝機能異常	0 (0.0)	2 (2.5)	2 (4.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	14 (17.1)	20 (25.3)	12 (24.0)	34 (21.1)	9 (20.5)	3 (6.8)	2 (5.9)	12 (13.6)
Eczema	湿疹	1 (1.2)	3 (3.8)	2 (4.0)	4 (2.5)	3 (6.8)	0 (0.0)	0 (0.0)	3 (3.4)
Urticaria	蕁麻疹	2 (2.4)	2 (2.5)	1 (2.0)	4 (2.5)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	3 (3.8)	2 (4.0)	3 (1.9)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Dermatitis contact	接触皮膚炎	1 (1.2)	2 (2.5)	1 (2.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Dry skin	皮膚乾燥	1 (1.2)	2 (2.5)	0 (0.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Pruritus	そう痒症	2 (2.4)	2 (2.5)	2 (4.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	2 (2.4)	1 (1.3)	0 (0.0)	3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	2 (2.5)	2 (4.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Alopecia areata	円形脱毛症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Dermatitis	皮膚炎	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperhidrosis	多汗症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Blister	水疱	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Haemorrhage subcutaneous	皮下出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Ingrowing nail	嵌入爪	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Skin fissures	皮膚亀裂	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin ulcer	皮膚潰瘍	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	14 (17.1)	15 (19.0)	11 (22.0)	29 (18.0)	13 (29.5)	8 (18.2)	5 (14.7)	21 (23.9)
Back pain	背部痛	2 (2.4)	4 (5.1)	3 (6.0)	6 (3.7)	5 (11.4)	2 (4.5)	1 (2.9)	7 (8.0)
Arthralgia	関節痛	0 (0.0)	3 (3.8)	3 (6.0)	3 (1.9)	1 (2.3)	2 (4.5)	1 (2.9)	3 (3.4)
Osteoarthritis	変形性関節症	1 (1.2)	3 (3.8)	2 (4.0)	4 (2.5)	1 (2.3)	1 (2.3)	0 (0.0)	2 (2.3)
Muscular weakness	筋力低下	2 (2.4)	3 (3.8)	2 (4.0)	5 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain in extremity	四肢痛	2 (2.4)	2 (2.5)	2 (4.0)	4 (2.5)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Myalgia	筋肉痛	4 (4.9)	0 (0.0)	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	筋骨格痛	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Neck pain	頚部痛	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Posture abnormal	姿勢異常	1 (1.2)	2 (2.5)	1 (2.0)	3 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc protrusion	椎間板突出	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Osteoporosis	骨粗鬆症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Periarthritis	関節周囲炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Tenosynovitis	腱鞘炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Mastication disorder	咀嚼障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Temporomandibular joint syndrome	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Trigger finger	弾発指	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Extremity contracture	四肢拘縮	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Foot deformity	足変形	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	2 (2.4)	3 (3.8)	2 (4.0)	5 (3.1)	2 (4.5)	1 (2.3)	1 (2.9)	3 (3.4)
Dysuria	排尿困難	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Neurogenic bladder	神経因性膀胱	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	夜間頻尿	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal glycosuria	腎性糖尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Urinary incontinence	尿失禁	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention	尿閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Bladder prolapse	膀胱脱	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	3 (3.7)	1 (1.3)	1 (2.0)	4 (2.5)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal discharge	膣分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Prostatomegaly	前立腺腫大	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	80 mg (N=79) n(%)	80 mg (no dose reduction) (N=50) n(%)	All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	80 mg (N=44) n(%)	80 mg (no dose reduction) (N=34) n(%)	All MT-5199 (N=88) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	16 (19.5)	17 (21.5)	10 (20.0)	33 (20.5)	11 (25.0)	8 (18.2)	5 (14.7)	19 (21.6)
Malaise	倦怠感	6 (7.3)	6 (7.6)	2 (4.0)	12 (7.5)	4 (9.1)	4 (9.1)	3 (8.8)	8 (9.1)
Thirst	口渇	3 (3.7)	2 (2.5)	1 (2.0)	5 (3.1)	4 (9.1)	0 (0.0)	0 (0.0)	4 (4.5)
Fatigue	疲労	0 (0.0)	3 (3.8)	3 (6.0)	3 (1.9)	2 (4.5)	1 (2.3)	0 (0.0)	3 (3.4)
Pyrexia	発熱	3 (3.7)	2 (2.5)	1 (2.0)	5 (3.1)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Feeling abnormal	異常感	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Asthenia	無力症	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	死亡	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Calcinosis	石灰沈着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Chest discomfort	胸部不快感	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Feeling hot	熱感	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inflammation	炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Investigations	臨床検査	15 (18.3)	12 (15.2)	8 (16.0)	27 (16.8)	7 (15.9)	3 (6.8)	2 (5.9)	10 (11.4)
Weight decreased	体重減少	4 (4.9)	4 (5.1)	2 (4.0)	8 (5.0)	2 (4.5)	1 (2.3)	1 (2.9)	3 (3.4)
Weight increased	体重増加	3 (3.7)	3 (3.8)	2 (4.0)	6 (3.7)	3 (6.8)	0 (0.0)	0 (0.0)	3 (3.4)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2 (2.4)	4 (5.1)	4 (8.0)	6 (3.7)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	2 (2.5)	2 (4.0)	2 (1.2)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Blood creatinine increased	血中クレアチニン増加	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Blood pressure increased	血圧上昇	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Liver function test increased	肝機能検査値上昇	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Blood pressure decreased	血圧低下	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood triglycerides increased	血中トリグリセリド増加	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood uric acid increased	血中尿酸増加	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	14 (17.1)	16 (20.3)	10 (20.0)	30 (18.6)	7 (15.9)	6 (13.6)	5 (14.7)	13 (14.8)
Contusion	挫傷	3 (3.7)	7 (8.9)	4 (8.0)	10 (6.2)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Fall	転倒	2 (2.4)	5 (6.3)	4 (8.0)	7 (4.3)	0 (0.0)	2 (4.5)	2 (5.9)	2 (2.3)
Skin abrasion	皮膚擦過傷	2 (2.4)	2 (2.5)	2 (4.0)	4 (2.5)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Sedation complication	鎮静合併症	3 (3.7)	1 (1.3)	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thermal burn	熱傷	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Heat illness	熱中症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	1 (2.3)	0 (0.0)	2 (2.3)
Animal bite	動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Ankle fracture	足関節部骨折	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Concussion	脳振盪	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femoral neck fracture	大腿骨頚部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Femur fracture	大腿骨骨折	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot fracture	足骨折	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fractured sacrum	仙骨骨折	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand fracture	手骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Head injury	頭部損傷	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint dislocation	関節脱臼	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Ligament sprain	靱帯捻挫	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Road traffic accident	交通事故	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－173　基礎疾患区分ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Face injury	顔面損傷	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Tooth fracture	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Eyelid injury	眼瞼損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Skin wound	皮膚創傷	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.1.2.1 より引用

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Any AESI		58 (70.7)	71 (89.9)	42 (84.0)	129 (80.1)	30 (68.2)	37 (84.1)	28 (82.4)	67 (76.1)
Somnolence	傾眠関連有害事象	20 (24.4)	28 (35.4)	15 (30.0)	48 (29.8)	12 (27.3)	12 (27.3)	7 (20.6)	24 (27.3)
Somnolence	傾眠	11 (13.4)	20 (25.3)	13 (26.0)	31 (19.3)	8 (18.2)	8 (18.2)	5 (14.7)	16 (18.2)
Malaise	倦怠感	6 (7.3)	6 (7.6)	2 (4.0)	12 (7.5)	4 (9.1)	4 (9.1)	3 (8.8)	8 (9.1)
Fatigue	疲労	0 (0.0)	3 (3.8)	3 (6.0)	3 (1.9)	2 (4.5)	1 (2.3)	0 (0.0)	3 (3.4)
Sedation complication	鎮静合併症	3 (3.7)	1 (1.3)	0 (0.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	2 (2.5)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Sedation	鎮静	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Hypersensitivity	過敏症関連有害事象	14 (17.1)	16 (20.3)	13 (26.0)	30 (18.6)	9 (20.5)	2 (4.5)	1 (2.9)	11 (12.5)
Eczema	湿疹	1 (1.2)	3 (3.8)	2 (4.0)	4 (2.5)	3 (6.8)	0 (0.0)	0 (0.0)	3 (3.4)
Stomatitis	口内炎	2 (2.4)	3 (3.8)	3 (6.0)	5 (3.1)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Urticaria	蕁麻疹	2 (2.4)	2 (2.5)	1 (2.0)	4 (2.5)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Dermatitis contact	接触皮膚炎	1 (1.2)	2 (2.5)	1 (2.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Pruritus	そう痒症	2 (2.4)	2 (2.5)	2 (4.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	2 (2.5)	2 (4.0)	2 (1.2)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Conjunctivitis	結膜炎	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Erythema	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Rash erythematous	紅斑性皮疹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Parkinsonism	パーキンソニズム関連有害事象	19 (23.2)	36 (45.6)	17 (34.0)	55 (34.2)	5 (11.4)	14 (31.8)	8 (23.5)	19 (21.6)
Salivary hypersecretion	流涎過多	8 (9.8)	15 (19.0)	6 (12.0)	23 (14.3)	1 (2.3)	6 (13.6)	4 (11.8)	7 (8.0)
Tremor	振戦	4 (4.9)	10 (12.7)	6 (12.0)	14 (8.7)	1 (2.3)	6 (13.6)	3 (8.8)	7 (8.0)
Parkinsonism	パーキンソニズム	3 (3.7)	3 (3.8)	2 (4.0)	6 (3.7)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Extrapyramidal disorder	錐体外路障害	2 (2.4)	3 (3.8)	1 (2.0)	5 (3.1)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Drooling	よだれ	2 (2.4)	3 (3.8)	2 (4.0)	5 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradykinesia	運動緩慢	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Gait disturbance	歩行障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Muscle rigidity	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Musculoskeletal stiffness	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Reduced facial expression	表情減少	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	10 (12.2)	6 (7.6)	4 (8.0)	16 (9.9)	9 (20.5)	13 (29.5)	11 (32.4)	22 (25.0)
Depression	うつ病	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	4 (9.1)	9 (20.5)	8 (23.5)	13 (14.8)
Suicidal ideation	自殺念慮	4 (4.9)	3 (3.8)	2 (4.0)	7 (4.3)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Suicide attempt	自殺企図	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Middle insomnia	中期不眠症	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Disturbance in attention	注意力障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Intentional overdose	企図的過量投与	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Cardiac events	心血管系及びQT間隔延長関連有害事象	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Death	死亡	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Long QT syndrome	ＱＴ延長症候群	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Hyperprolactinemia	高プロラクチン血症関連有害事象	1 (1.2)	1 (1.3)	1 (2.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Menstruation irregular	不規則月経	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Akathisia	アカシジア関連有害事象	10 (12.2)	11 (13.9)	5 (10.0)	21 (13.0)	2 (4.5)	8 (18.2)	6 (17.6)	10 (11.4)
Akathisia	アカシジア	6 (7.3)	6 (7.6)	3 (6.0)	12 (7.5)	2 (4.5)	6 (13.6)	5 (14.7)	8 (9.1)
Extrapyramidal disorder	錐体外路障害	2 (2.4)	3 (3.8)	1 (2.0)	5 (3.1)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Restlessness	落ち着きのなさ	2 (2.4)	2 (2.5)	1 (2.0)	4 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Anxiety	不安	3 (3.7)	5 (6.3)	4 (8.0)	8 (5.0)	2 (4.5)	4 (9.1)	3 (8.8)	6 (6.8)
Anxiety	不安	3 (3.7)	5 (6.3)	4 (8.0)	8 (5.0)	2 (4.5)	4 (9.1)	3 (8.8)	6 (6.8)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	26 (31.7)	16 (20.3)	7 (14.0)	42 (26.1)	9 (20.5)	13 (29.5)	12 (35.3)	22 (25.0)
Schizophrenia	統合失調症	21 (25.6)	13 (16.5)	5 (10.0)	34 (21.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	4 (9.1)	9 (20.5)	8 (23.5)	13 (14.8)
Suicidal ideation	自殺念慮	4 (4.9)	3 (3.8)	2 (4.0)	7 (4.3)	2 (4.5)	0 (0.0)	0 (0.0)	2 (2.3)
Suicide attempt	自殺企図	2 (2.4)	1 (1.3)	1 (2.0)	3 (1.9)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.5)	2 (4.5)	2 (5.9)	4 (4.5)
Depressed mood	抑うつ気分	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Intentional self-injury	故意の自傷行為	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Dysphagia	嚥下障害関連有害事象	4 (4.9)	4 (5.1)	2 (4.0)	8 (5.0)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)
Dysphagia	嚥下障害	4 (4.9)	4 (5.1)	2 (4.0)	8 (5.0)	1 (2.3)	1 (2.3)	1 (2.9)	2 (2.3)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－174　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Schizophrenia/Schizoaffective Disorder MT-5199 40 mg (N=82) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (N=79) n(%)	Schizophrenia/Schizoaffective Disorder MT-5199 80 mg (no dose reduction) (N=50) n(%)	Schizophrenia/Schizoaffective Disorder All MT-5199 (N=161) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 40 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (N=44) n(%)	Bipolar Disorder/Depressive Disorder MT-5199 80 mg (no dose reduction) (N=34) n(%)	Bipolar Disorder/Depressive Disorder All MT-5199 (N=88) n(%)
Hepatotoxicity	肝障害関連有害事象	2 (2.4)	3 (3.8)	2 (4.0)	5 (3.1)	3 (6.8)	0 (0.0)	0 (0.0)	3 (3.4)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.2)	1 (1.3)	0 (0.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	2 (2.5)	2 (4.0)	2 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Liver function test increased	肝機能検査値上昇	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	0 (0.0)	1 (1.1)
Hypotension	低血圧関連有害事象	6 (7.3)	9 (11.4)	7 (14.0)	15 (9.3)	1 (2.3)	4 (9.1)	4 (11.8)	5 (5.7)
Dizziness	浮動性めまい	3 (3.7)	4 (5.1)	3 (6.0)	7 (4.3)	1 (2.3)	3 (6.8)	3 (8.8)	4 (4.5)
Fall	転倒	2 (2.4)	5 (6.3)	4 (8.0)	7 (4.3)	0 (0.0)	2 (4.5)	2 (5.9)	2 (2.3)
Hypotension	低血圧	0 (0.0)	1 (1.3)	1 (2.0)	1 (0.6)	0 (0.0)	1 (2.3)	1 (2.9)	1 (1.1)
Blood pressure decreased	血圧低下	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知機能低下関連有害事象	2 (2.4)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Disturbance in attention	注意力障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.3)	0 (0.0)	1 (1.1)
Cognitive disorder	認知障害	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.1.2.2 より引用

表 2.7.4.7－175　基礎疾患区分ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Schizophrenia or Schizoaffective Disorder (N=183) n (%)	Mood Disorder (N=71) n (%)	Schizophrenia or Schizoaffective Disorder (N=134) n (%)	Mood Disorder (N=44) n (%)	Schizophrenia or Schizoaffective Disorder (N=306) n (%)	Mood Disorder (N=121) n (%)
At Least 1 AE	73 (39.9)	38 (53.5)	54 (40.3)	17 (38.6)	180 (58.8)	79 (65.3)
At Least 1 SAE	11 (6.0)	1 (1.4)	6 (4.5)	0	40 (13.1)	14 (11.6)
At Least 1 AE Leading to Study Discontinuation	8 (4.4)	2 (2.8)	8 (6.0)	0	44 (14.4)	14 (11.6)
At Least 1 AE Leading to Dose Reduction	2 (1.1)	5 (7.0)	1 (0.7)	3 (6.8)	14 (4.6)	12 (9.9)

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is counted once.

5.3.5.3－2 Table 99 より引用（一部改変）

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
Any Adverse Event	n (%)	1(25.0)	34(41.5)	30(42.9)	8(29.6)	73(39.9)	54(40.3)
心臓障害	n (%)	0	0	0	0	0	1(0.7)
心筋梗塞	n (%)	0	0	0	0	0	1(0.7)
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(0.7)
トゥレット病	n (%)	0	0	0	0	0	1(0.7)
眼障害	n (%)	0	0	0	1(3.7)	1(0.5)	1(0.7)
霧視	n (%)	0	0	0	1(3.7)	1(0.5)	0
結膜出血	n (%)	0	0	0	0	0	1(0.7)
胃腸障害	n (%)	0	8(9.8)	1(1.4)	1(3.7)	10(5.5)	14(10.4)
口内乾燥	n (%)	0	4(4.9)	0	1(3.7)	5(2.7)	3(2.2)
流涎過多	n (%)	0	0	1(1.4)	1(3.7)	2(1.1)	0
腹部圧痛	n (%)	0	1(1.2)	0	0	1(0.5)	0
消化不良	n (%)	0	1(1.2)	0	0	1(0.5)	0
嚥下障害	n (%)	0	1(1.2)	0	0	1(0.5)	0
口腔知覚不全	n (%)	0	1(1.2)	0	0	1(0.5)	0
臍ヘルニア	n (%)	0	1(1.2)	0	0	1(0.5)	0
嘔吐	n (%)	0	1(1.2)	0	0	1(0.5)	1(0.7)
便秘	n (%)	0	0	0	0	0	1(0.7)
下痢	n (%)	0	0	0	0	0	1(0.7)
排便回数増加	n (%)	0	0	0	0	0	1(0.7)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
歯肉炎	n (%)	0	0	0	0	0	1(0.7)
舌痛	n (%)	0	0	0	0	0	1(0.7)
悪心	n (%)	0	0	0	0	0	3(2.2)
歯痛	n (%)	0	0	0	0	0	1(0.7)
全身障害および投与局所様態	n (%)	0	6(7.3)	2(2.9)	2(7.4)	10(5.5)	4(3.0)
疲労	n (%)	0	2(2.4)	1(1.4)	2(7.4)	5(2.7)	3(2.2)
末梢性浮腫	n (%)	0	3(3.7)	0	0	3(1.6)	0
歩行障害	n (%)	0	1(1.2)	0	1(3.7)	2(1.1)	0
胸痛	n (%)	0	1(1.2)	0	0	1(0.5)	0
空腹	n (%)	0	1(1.2)	0	0	1(0.5)	0
突然死	n (%)	0	0	1(1.4)	0	1(0.5)	0
易刺激性	n (%)	0	0	0	0	0	1(0.7)
肝胆道系障害	n (%)	0	0	1(1.4)	0	1(0.5)	0
急性肝炎	n (%)	0	0	1(1.4)	0	1(0.5)	0
黄疸	n (%)	0	0	1(1.4)	0	1(0.5)	0
感染症および寄生虫症	n (%)	0	10(12.2)	2(2.9)	3(11.1)	15(8.2)	11(8.2)
尿路感染	n (%)	0	4(4.9)	1(1.4)	1(3.7)	6(3.3)	8(6.0)
鼻咽頭炎	n (%)	0	1(1.2)	1(1.4)	1(3.7)	3(1.6)	1(0.7)
ダニ皮膚炎	n (%)	0	1(1.2)	0	0	1(0.5)	0
体部白癬	n (%)	0	1(1.2)	0	0	1(0.5)	0
せつ	n (%)	0	1(1.2)	0	0	1(0.5)	0
ウイルス性胃腸炎	n (%)	0	1(1.2)	0	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
インフルエンザ	n (%)	0	1(1.2)	0	0	1(0.5)	0
急性腎盂腎炎	n (%)	0	1(1.2)	0	0	1(0.5)	0
副鼻腔炎	n (%)	0	1(1.2)	0	0	1(0.5)	0
上気道感染	n (%)	0	0	0	1(3.7)	1(0.5)	1(0.7)
外陰膣真菌感染	n (%)	0	1(1.2)	0	0	1(0.5)	0
気管支炎	n (%)	0	0	0	0	0	1(0.7)
傷害、中毒および処置合併症	n (%)	0	4(4.9)	4(5.7)	1(3.7)	9(4.9)	2(1.5)
転倒・転落	n (%)	0	2(2.4)	1(1.4)	0	3(1.6)	0
動物咬傷	n (%)	0	0	1(1.4)	0	1(0.5)	0
節足動物咬傷	n (%)	0	0	0	1(3.7)	1(0.5)	1(0.7)
第２度熱傷	n (%)	0	0	1(1.4)	0	1(0.5)	0
関節損傷	n (%)	0	1(1.2)	0	0	1(0.5)	0
四肢損傷	n (%)	0	0	1(1.4)	0	1(0.5)	0
筋挫傷	n (%)	0	1(1.2)	0	0	1(0.5)	0
足骨折	n (%)	0	0	0	0	0	1(0.7)
臨床検査	n (%)	0	4(4.9)	6(8.6)	1(3.7)	11(6.0)	3(2.2)
血中クレアチニン増加	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	0
血中ブドウ糖増加	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	0
体重増加	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(1.2)	0	0	1(0.5)	0
血圧上昇	n (%)	0	0	1(1.4)	0	1(0.5)	0
血中トリグリセリド増加	n (%)	0	0	0	1(3.7)	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
血中尿素増加	n (%)	0	1(1.2)	0	0	1(0.5)	0
尿中結晶陽性	n (%)	0	0	1(1.4)	0	1(0.5)	0
尿中ブドウ糖陽性	n (%)	0	0	1(1.4)	0	1(0.5)	0
グリコヘモグロビン増加	n (%)	0	0	1(1.4)	0	1(0.5)	1(0.7)
ヘマトクリット減少	n (%)	0	0	1(1.4)	0	1(0.5)	0
ヘモグロビン減少	n (%)	0	0	1(1.4)	0	1(0.5)	0
便潜血陽性	n (%)	0	0	1(1.4)	0	1(0.5)	0
赤血球数減少	n (%)	0	0	1(1.4)	0	1(0.5)	0
赤血球数増加	n (%)	0	0	1(1.4)	0	1(0.5)	0
血中ビリルビン増加	n (%)	0	0	0	0	0	1(0.7)
肝酵素上昇	n (%)	0	0	0	0	0	1(0.7)
代謝および栄養障害	n (%)	0	2(2.4)	2(2.9)	0	4(2.2)	3(2.2)
食欲亢進	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
食欲減退	n (%)	0	1(1.2)	0	0	1(0.5)	1(0.7)
低ナトリウム血症	n (%)	0	0	1(1.4)	0	1(0.5)	0
異常体重減少	n (%)	0	0	0	0	0	1(0.7)
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(0.7)
筋骨格系および結合組織障害	n (%)	0	5(6.1)	3(4.3)	1(3.7)	9(4.9)	3(2.2)
関節痛	n (%)	0	2(2.4)	2(2.9)	0	4(2.2)	0
背部痛	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	0
関節炎	n (%)	0	1(1.2)	0	0	1(0.5)	0
筋力低下	n (%)	0	1(1.2)	0	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176 基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
筋肉痛	n (%)	0	0	0	1(3.7)	1(0.5)	0
関節腫脹	n (%)	0	0	0	0	0	1(0.7)
筋骨格硬直	n (%)	0	0	0	0	0	1(0.7)
四肢痛	n (%)	0	0	0	0	0	1(0.7)
神経系障害	n (%)	0	7(8.5)	7(10.0)	3(11.1)	17(9.3)	10(7.5)
傾眠	n (%)	0	2(2.4)	3(4.3)	1(3.7)	6(3.3)	3(2.2)
頭痛	n (%)	0	2(2.4)	1(1.4)	1(3.7)	4(2.2)	2(1.5)
アカシジア	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
鎮静	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
注意力障害	n (%)	0	1(1.2)	0	0	1(0.5)	0
浮動性めまい	n (%)	0	1(1.2)	0	0	1(0.5)	3(2.2)
感覚鈍麻	n (%)	0	0	1(1.4)	0	1(0.5)	0
失神	n (%)	0	0	0	1(3.7)	1(0.5)	0
振戦	n (%)	0	0	1(1.4)	0	1(0.5)	0
痙攣	n (%)	0	0	0	0	0	1(0.7)
精神障害	n (%)	1(25.0)	8(9.8)	8(11.4)	0	17(9.3)	11(8.2)
自殺念慮	n (%)	0	3(3.7)	1(1.4)	0	4(2.2)	2(1.5)
不眠症	n (%)	0	2(2.4)	1(1.4)	0	3(1.6)	1(0.7)
うつ病	n (%)	0	0	2(2.9)	0	2(1.1)	1(0.7)
歯ぎしり	n (%)	0	1(1.2)	0	0	1(0.5)	0
抑うつ症状	n (%)	0	1(1.2)	0	0	1(0.5)	0
敵意	n (%)	0	1(1.2)	0	0	1(0.5)	0
軽躁	n (%)	0	1(1.2)	0	0	1(0.5)	0
精神状態変化	n (%)	0	1(1.2)	0	0	1(0.5)	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
神経過敏	n (%)	0	0	1(1.4)	0	1(0.5)	0
パニック発作	n (%)	1(25.0)	0	0	0	1(0.5)	0
精神病性障害	n (%)	0	0	1(1.4)	0	1(0.5)	2(1.5)
落ち着きのなさ	n (%)	0	1(1.2)	0	0	1(0.5)	0
統合失調感情障害	n (%)	0	0	1(1.4)	0	1(0.5)	1(0.7)
統合失調症	n (%)	0	1(1.2)	0	0	1(0.5)	1(0.7)
自殺企図	n (%)	0	0	1(1.4)	0	1(0.5)	0
激越	n (%)	0	0	0	0	0	1(0.7)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.7)
睡眠障害	n (%)	0	0	0	0	0	1(0.7)
腎および尿路障害	n (%)	0	0	0	0	0	2(1.5)
血尿	n (%)	0	0	0	0	0	1(0.7)
尿閉	n (%)	0	0	0	0	0	1(0.7)
生殖系および乳房障害	n (%)	0	0	0	0	0	2(1.5)
腟出血	n (%)	0	0	0	0	0	2(1.5)
呼吸器、胸郭および縦隔障害	n (%)	0	1(1.2)	0	1(3.7)	2(1.1)	2(1.5)
慢性閉塞性肺疾患	n (%)	0	1(1.2)	0	1(3.7)	2(1.1)	1(0.7)
咳嗽	n (%)	0	0	0	0	0	1(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	 40 mg (N=82)	 80 mg (N=70)	 100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
皮膚および皮下組織障害	n (%)	0	1(1.2)	2(2.9)	0	3(1.6)	4(3.0)
そう痒症	n (%)	0	1(1.2)	0	0	1(0.5)	2(1.5)
発疹	n (%)	0	0	1(1.4)	0	1(0.5)	1(0.7)
斑状丘疹状皮疹	n (%)	0	0	1(1.4)	0	1(0.5)	0
多汗症	n (%)	0	0	0	0	0	1(0.7)
外科および内科処置	n (%)	0	0	1(1.4)	0	1(0.5)	0
抜歯	n (%)	0	0	1(1.4)	0	1(0.5)	0
血管障害	n (%)	0	1(1.2)	2(2.9)	0	3(1.6)	1(0.7)
ほてり	n (%)	0	0	1(1.4)	0	1(0.5)	0
高血圧	n (%)	0	1(1.2)	0	0	1(0.5)	1(0.7)
低血圧	n (%)	0	0	1(1.4)	0	1(0.5)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=28)	 80 mg (N=42)	 100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
Any Adverse Event	n (%)	1(100.0)	14(50.0)	23(54.8)	0	38(53.5)	17(38.6)
血液およびリンパ系障害	n (%)	0	0	1(2.4)	0	1(1.4)	0
白血球減少症	n (%)	0	0	1(2.4)	0	1(1.4)	0
心臓障害	n (%)	0	1(3.6)	0	0	1(1.4)	0
徐脈	n (%)	0	1(3.6)	0	0	1(1.4)	0
耳および迷路障害	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
耳鳴	n (%)	0	1(3.6)	0	0	1(1.4)	0
耳痛	n (%)	0	0	0	0	0	1(2.3)
胃腸障害	n (%)	0	6(21.4)	6(14.3)	0	12(16.9)	7(15.9)
嘔吐	n (%)	0	1(3.6)	4(9.5)	0	5(7.0)	0
悪心	n (%)	0	2(7.1)	2(4.8)	0	4(5.6)	1(2.3)
口内乾燥	n (%)	0	3(10.7)	0	0	3(4.2)	0
便秘	n (%)	0	2(7.1)	0	0	2(2.8)	4(9.1)
下痢	n (%)	0	1(3.6)	0	0	1(1.4)	2(4.5)
嚥下障害	n (%)	0	1(3.6)	0	0	1(1.4)	0
びらん性胃炎	n (%)	0	0	1(2.4)	0	1(1.4)	0
メレナ	n (%)	0	1(3.6)	0	0	1(1.4)	0
流涎過多	n (%)	0	0	1(2.4)	0	1(1.4)	0
上腹部痛	n (%)	0	0	0	0	0	1(2.3)
消化不良	n (%)	0	0	0	0	0	1(2.3)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(2.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=28)	 80 mg (N=42)	 100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
全身障害および投与局所様態	n (%)	0	4(14.3)	3(7.1)	0	7(9.9)	3(6.8)
疲労	n (%)	0	3(10.7)	2(4.8)	0	5(7.0)	0
歩行障害	n (%)	0	1(3.6)	0	0	1(1.4)	0
易刺激性	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
疼痛	n (%)	0	1(3.6)	0	0	1(1.4)	0
発熱	n (%)	0	0	1(2.4)	0	1(1.4)	1(2.3)
口渇	n (%)	0	1(3.6)	0	0	1(1.4)	0
末梢性浮腫	n (%)	0	0	0	0	0	1(2.3)
感染症および寄生虫症	n (%)	0	0	1(2.4)	0	1(1.4)	3(6.8)
上気道感染	n (%)	0	0	1(2.4)	0	1(1.4)	0
耳感染	n (%)	0	0	0	0	0	1(2.3)
口腔ヘルペス	n (%)	0	0	0	0	0	1(2.3)
ウイルス感染	n (%)	0	0	0	0	0	1(2.3)
傷害、中毒および処置合併症	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
交通事故	n (%)	0	1(3.6)	0	0	1(1.4)	0
むち打ち損傷	n (%)	0	1(3.6)	0	0	1(1.4)	0
処置による疼痛	n (%)	0	0	0	0	0	1(2.3)
臨床検査	n (%)	1(100.0)	1(3.6)	4(9.5)	0	6(8.5)	3(6.8)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	2(4.8)	0	2(2.8)	1(2.3)
血中ブドウ糖増加	n (%)	0	0	1(2.4)	0	1(1.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=28)	 80 mg (N=42)	 100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
握力低下	n (%)	0	1(3.6)	0	0	1(1.4)	0
肝酵素上昇	n (%)	1(100.0)	0	0	0	1(1.4)	0
体重増加	n (%)	0	0	1(2.4)	0	1(1.4)	0
血中カリウム増加	n (%)	0	0	0	0	0	1(2.3)
好中球数増加	n (%)	0	0	0	0	0	1(2.3)
白血球数増加	n (%)	0	0	0	0	0	1(2.3)
代謝および栄養障害	n (%)	0	1(3.6)	3(7.1)	0	4(5.6)	2(4.5)
食欲減退	n (%)	0	1(3.6)	2(4.8)	0	3(4.2)	1(2.3)
食欲亢進	n (%)	0	0	1(2.4)	0	1(1.4)	0
低血糖症	n (%)	0	0	0	0	0	1(2.3)
筋骨格系および結合組織障害	n (%)	0	4(14.3)	3(7.1)	0	7(9.9)	2(4.5)
関節痛	n (%)	0	1(3.6)	1(2.4)	0	2(2.8)	1(2.3)
背部痛	n (%)	0	1(3.6)	0	0	1(1.4)	0
四肢不快感	n (%)	0	1(3.6)	0	0	1(1.4)	0
筋痙縮	n (%)	0	0	1(2.4)	0	1(1.4)	0
筋力低下	n (%)	0	1(3.6)	0	0	1(1.4)	0
筋肉痛	n (%)	0	0	1(2.4)	0	1(1.4)	0
顎関節症候群	n (%)	0	1(3.6)	0	0	1(1.4)	0
滑液包炎	n (%)	0	0	0	0	0	1(2.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(2.3)
口腔乳頭腫	n (%)	0	0	0	0	0	1(2.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=28)	 80 mg (N=42)	 100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
神経系障害	n (%)	0	10(35.7)	12(28.6)	0	22(31.0)	6(13.6)
傾眠	n (%)	0	7(25.0)	1(2.4)	0	8(11.3)	1(2.3)
頭痛	n (%)	0	2(7.1)	4(9.5)	0	6(8.5)	2(4.5)
アカシジア	n (%)	0	2(7.1)	2(4.8)	0	4(5.6)	0
ジスキネジー	n (%)	0	0	3(7.1)	0	3(4.2)	0
よだれ	n (%)	0	0	2(4.8)	0	2(2.8)	0
平衡障害	n (%)	0	0	1(2.4)	0	1(1.4)	0
浮動性めまい	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
ジストニー	n (%)	0	0	1(2.4)	0	1(1.4)	0
ミオクローヌス	n (%)	0	1(3.6)	0	0	1(1.4)	0
睡眠の質低下	n (%)	0	1(3.6)	0	0	1(1.4)	0
鎮静	n (%)	0	0	1(2.4)	0	1(1.4)	0
咬舌	n (%)	0	1(3.6)	0	0	1(1.4)	0
振戦	n (%)	0	0	1(2.4)	0	1(1.4)	0
感覚鈍麻	n (%)	0	0	0	0	0	1(2.3)
片頭痛	n (%)	0	0	0	0	0	1(2.3)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(2.3)
精神障害	n (%)	1(100.0)	6(21.4)	4(9.5)	0	11(15.5)	3(6.8)
不安	n (%)	0	1(3.6)	2(4.8)	0	3(4.2)	0
双極１型障害	n (%)	0	1(3.6)	0	0	1(1.4)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(1.4)	0
ディスフェミア	n (%)	0	1(3.6)	0	0	1(1.4)	0
不眠症	n (%)	0	0	1(2.4)	0	1(1.4)	0
パニック発作	n (%)	0	0	1(2.4)	0	1(1.4)	0
妄想症	n (%)	0	1(3.6)	0	0	1(1.4)	0

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=28)	 80 mg (N=42)	 100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
精神運動制止遅滞	n (%)	0	1(3.6)	0	0	1(1.4)	0
自殺念慮	n (%)	0	1(3.6)	0	0	1(1.4)	2(4.5)
うつ病	n (%)	0	0	0	0	0	1(2.3)
抑うつ症状	n (%)	0	0	0	0	0	1(2.3)
躁病	n (%)	0	0	0	0	0	1(2.3)
腎および尿路障害	n (%)	0	0	0	0	0	1(2.3)
糖尿	n (%)	0	0	0	0	0	1(2.3)
生殖系および乳房障害	n (%)	0	0	1(2.4)	0	1(1.4)	0
月経過多	n (%)	0	0	1(2.4)	0	1(1.4)	0
呼吸器、胸郭および縦隔障害	n (%)	0	0	2(4.8)	0	2(2.8)	0
鼻閉	n (%)	0	0	2(4.8)	0	2(2.8)	0
皮膚および皮下組織障害	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
網状皮斑	n (%)	0	1(3.6)	0	0	1(1.4)	0
ケラトアカントーマ	n (%)	0	0	0	0	0	1(2.3)
乾癬	n (%)	0	0	0	0	0	1(2.3)
外科および内科処置	n (%)	0	0	0	0	0	1(2.3)
鼓膜切開	n (%)	0	0	0	0	0	1(2.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－176　基礎疾患区分ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	 40 mg (N=28)	 80 mg (N=42)	 100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
血管障害	n (%)	0	0	1(2.4)	0	1(1.4)	1(2.3)
血腫	n (%)	0	0	1(2.4)	0	1(1.4)	0
ほてり	n (%)	0	0	0	0	0	1(2.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.3より引用（一部改変）

表2.7.4.7－177　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=82)	80 mg (N=70)	100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
Any Adverse Event of Special Interest	n (%)	0	15(18.3)	16(22.9)	3(11.1)	34(18.6)	18(13.4)
アカシジア関連有害事象	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
アカシジア	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(1.2)	1(1.4)	1(3.7)	3(1.6)	1(0.7)
胸痛	n (%)	0	1(1.2)	0	0	1(0.5)	0
突然死	n (%)	0	0	1(1.4)	0	1(0.5)	0
失神	n (%)	0	0	0	1(3.7)	1(0.5)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.7)
うつ病及び自殺関連有害事象	n (%)	0	4(4.9)	4(5.7)	0	8(4.4)	3(2.2)
自殺念慮	n (%)	0	3(3.7)	1(1.4)	0	4(2.2)	2(1.5)
うつ病	n (%)	0	0	2(2.9)	0	2(1.1)	1(0.7)
抑うつ症状	n (%)	0	1(1.2)	0	0	1(0.5)	0
自殺企図	n (%)	0	0	1(1.4)	0	1(0.5)	0
嚥下障害関連有害事象	n (%)	0	1(1.2)	0	0	1(0.5)	0
嚥下障害	n (%)	0	1(1.2)	0	0	1(0.5)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	2(2.4)	1(1.4)	2(7.4)	5(2.7)	3(2.2)
疲労	n (%)	0	2(2.4)	1(1.4)	2(7.4)	5(2.7)	3(2.2)
肝障害関連有害事象	n (%)	0	0	1(1.4)	0	1(0.5)	0
急性肝炎	n (%)	0	0	1(1.4)	0	1(0.5)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－177　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=82)	80 mg (N=70)	100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
低血圧関連有害事象	n (%)	0	3(3.7)	2(2.9)	1(3.7)	6(3.3)	3(2.2)
転倒・転落	n (%)	0	2(2.4)	1(1.4)	0	3(1.6)	0
浮動性めまい	n (%)	0	1(1.2)	0	0	1(0.5)	3(2.2)
低血圧	n (%)	0	0	1(1.4)	0	1(0.5)	0
失神	n (%)	0	0	0	1(3.7)	1(0.5)	0
パーキンソニズム関連有害事象	n (%)	0	0	1(1.4)	0	1(0.5)	0
振戦	n (%)	0	0	1(1.4)	0	1(0.5)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	3(3.7)	4(5.7)	1(3.7)	8(4.4)	4(3.0)
傾眠	n (%)	0	2(2.4)	3(4.3)	1(3.7)	6(3.3)	3(2.2)
鎮静	n (%)	0	1(1.2)	1(1.4)	0	2(1.1)	1(0.7)
基礎疾患の悪化に関連する有害事象	n (%)	0	6(7.3)	6(8.6)	0	12(6.6)	9(6.7)
自殺念慮	n (%)	0	3(3.7)	1(1.4)	0	4(2.2)	2(1.5)
うつ病	n (%)	0	0	2(2.9)	0	2(1.1)	1(0.7)
抑うつ症状	n (%)	0	1(1.2)	0	0	1(0.5)	0
敵意	n (%)	0	1(1.2)	0	0	1(0.5)	0
軽躁	n (%)	0	1(1.2)	0	0	1(0.5)	0
精神病性障害	n (%)	0	0	1(1.4)	0	1(0.5)	2(1.5)
統合失調感情障害	n (%)	0	0	1(1.4)	0	1(0.5)	1(0.7)
統合失調症	n (%)	0	1(1.2)	0	0	1(0.5)	1(0.7)
自殺企図	n (%)	0	0	1(1.4)	0	1(0.5)	0
易刺激性	n (%)	0	0	0	0	0	1(0.7)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－177　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=4)	40 mg (N=82)	80 mg (N=70)	100 mg (N=27)	All NBI-98854 (N=183)	Placebo (N=134)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.7)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－177　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	40 mg (N=28)	80 mg (N=42)	100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
Any Adverse Event of Special Interest	n (%)	1(100.0)	13(46.4)	7(16.7)	0	21(29.6)	6(13.6)
アカシジア関連有害事象	n (%)	0	2(7.1)	2(4.8)	0	4(5.6)	0
アカシジア	n (%)	0	2(7.1)	2(4.8)	0	4(5.6)	0
不安	n (%)	0	1(3.6)	2(4.8)	0	3(4.2)	0
不安	n (%)	0	1(3.6)	2(4.8)	0	3(4.2)	0
うつ病及び自殺関連有害事象	n (%)	1(100.0)	1(3.6)	0	0	2(2.8)	3(6.8)
抑うつ気分	n (%)	1(100.0)	0	0	0	1(1.4)	0
自殺念慮	n (%)	0	1(3.6)	0	0	1(1.4)	2(4.5)
うつ病	n (%)	0	0	0	0	0	1(2.3)
抑うつ症状	n (%)	0	0	0	0	0	1(2.3)
嚥下障害関連有害事象	n (%)	0	1(3.6)	0	0	1(1.4)	0
嚥下障害	n (%)	0	1(3.6)	0	0	1(1.4)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	3(10.7)	2(4.8)	0	5(7.0)	0
疲労	n (%)	0	3(10.7)	2(4.8)	0	5(7.0)	0
低血圧関連有害事象	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
浮動性めまい	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
パーキンソニズム関連有害事象	n (%)	0	0	1(2.4)	0	1(1.4)	0

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－177　基礎疾患区分ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] <40 mg (N=1)	40 mg (N=28)	80 mg (N=42)	100 mg (N=0)	All NBI-98854 (N=71)	Placebo (N=44)
振戦	n (%)	0	0	1(2.4)	0	1(1.4)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	7(25.0)	2(4.8)	0	9(12.7)	1(2.3)
傾眠	n (%)	0	7(25.0)	1(2.4)	0	8(11.3)	1(2.3)
鎮静	n (%)	0	0	1(2.4)	0	1(1.4)	0
基礎疾患の悪化に関連する有害事象	n (%)	1(100.0)	4(14.3)	0	0	5(7.0)	4(9.1)
双極１型障害	n (%)	0	1(3.6)	0	0	1(1.4)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(1.4)	0
易刺激性	n (%)	0	1(3.6)	0	0	1(1.4)	1(2.3)
妄想症	n (%)	0	1(3.6)	0	0	1(1.4)	0
自殺念慮	n (%)	0	1(3.6)	0	0	1(1.4)	2(4.5)
うつ病	n (%)	0	0	0	0	0	1(2.3)
抑うつ症状	n (%)	0	0	0	0	0	1(2.3)
躁病	n (%)	0	0	0	0	0	1(2.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.3より引用（一部改変）

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
Any Adverse Event	n (%)	87(57.6)	93(60.0)	86(58.1)	180(58.8)
血液およびリンパ系障害	n (%)	4(2.6)	3(1.9)	3(2.0)	7(2.3)
貧血	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
好中球減少症	n (%)	2(1.3)	1(0.6)	1(0.7)	3(1.0)
血小板血症	n (%)	1(0.7)	0	0	1(0.3)
心臓障害	n (%)	4(2.6)	3(1.9)	3(2.0)	7(2.3)
上室性不整脈	n (%)	1(0.7)	0	0	1(0.3)
心房細動	n (%)	1(0.7)	0	0	1(0.3)
心不全	n (%)	0	1(0.6)	1(0.7)	1(0.3)
冠動脈疾患	n (%)	1(0.7)	0	0	1(0.3)
僧帽弁閉鎖不全症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
頻脈	n (%)	1(0.7)	0	0	1(0.3)
三尖弁閉鎖不全症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
心室性期外収縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
耳および迷路障害	n (%)	2(1.3)	0	0	2(0.7)
聴覚障害	n (%)	1(0.7)	0	0	1(0.3)
耳鳴	n (%)	1(0.7)	0	0	1(0.3)
胃腸障害	n (%)	19(12.6)	22(14.2)	16(10.8)	41(13.4)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
便秘	n (%)	5(3.3)	4(2.6)	2(1.4)	9(2.9)
下痢	n (%)	3(2.0)	6(3.9)	5(3.4)	9(2.9)
口内乾燥	n (%)	6(4.0)	2(1.3)	2(1.4)	8(2.6)
嘔吐	n (%)	5(3.3)	3(1.9)	3(2.0)	8(2.6)
流涎過多	n (%)	2(1.3)	5(3.2)	2(1.4)	7(2.3)
悪心	n (%)	1(0.7)	3(1.9)	3(2.0)	4(1.3)
腹痛	n (%)	1(0.7)	1(0.6)	0	2(0.7)
上腹部痛	n (%)	1(0.7)	1(0.6)	0	2(0.7)
嚥下障害	n (%)	2(1.3)	0	0	2(0.7)
歯痛	n (%)	1(0.7)	1(0.6)	0	2(0.7)
腹部圧痛	n (%)	1(0.7)	0	0	1(0.3)
結腸ポリープ	n (%)	1(0.7)	0	0	1(0.3)
消化不良	n (%)	1(0.7)	0	0	1(0.3)
変色便	n (%)	1(0.7)	0	0	1(0.3)
食中毒	n (%)	0	1(0.6)	1(0.7)	1(0.3)
胃炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
痔核	n (%)	1(0.7)	0	0	1(0.3)
裂孔ヘルニア	n (%)	0	1(0.6)	1(0.7)	1(0.3)
歯の脱落	n (%)	1(0.7)	0	0	1(0.3)
臍ヘルニア	n (%)	1(0.7)	0	0	1(0.3)
全身障害および投与局所様態	n (%)	12(7.9)	12(7.7)	10(6.8)	24(7.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
疲労	n (%)	8(5.3)	5(3.2)	5(3.4)	13(4.2)
歩行障害	n (%)	3(2.0)	1(0.6)	0	4(1.3)
末梢性浮腫	n (%)	2(1.3)	1(0.6)	1(0.7)	3(1.0)
易刺激性	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
非心臓性胸痛	n (%)	1(0.7)	1(0.6)	0	2(0.7)
胸痛	n (%)	1(0.7)	0	0	1(0.3)
空腹	n (%)	1(0.7)	0	0	1(0.3)
倦怠感	n (%)	0	1(0.6)	1(0.7)	1(0.3)
発熱	n (%)	0	1(0.6)	1(0.7)	1(0.3)
突然死	n (%)	0	1(0.6)	1(0.7)	1(0.3)
肝胆道系障害	n (%)	0	2(1.3)	2(1.4)	2(0.7)
肝不全	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性肝炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
黄疸	n (%)	0	1(0.6)	1(0.7)	1(0.3)
免疫系障害	n (%)	0	1(0.6)	1(0.7)	1(0.3)
過敏症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
感染症および寄生虫症	n (%)	24(15.9)	21(13.5)	19(12.8)	45(14.7)
尿路感染	n (%)	7(4.6)	6(3.9)	6(4.1)	13(4.2)
鼻咽頭炎	n (%)	4(2.6)	8(5.2)	7(4.7)	12(3.9)
上気道感染	n (%)	3(2.0)	1(0.6)	1(0.7)	4(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
蜂巣炎	n (%)	0	3(1.9)	2(1.4)	3(1.0)
ウイルス性胃腸炎	n (%)	3(2.0)	0	0	3(1.0)
ダニ皮膚炎	n (%)	2(1.3)	0	0	2(0.7)
気管支炎	n (%)	2(1.3)	0	0	2(0.7)
胃腸炎	n (%)	0	2(1.3)	2(1.4)	2(0.7)
インフルエンザ	n (%)	2(1.3)	0	0	2(0.7)
外陰膣真菌感染	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
四肢膿瘍	n (%)	0	1(0.6)	0	1(0.3)
軟部組織膿瘍	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性副鼻腔炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
体部白癬	n (%)	1(0.7)	0	0	1(0.3)
耳感染	n (%)	1(0.7)	0	0	1(0.3)
眼感染	n (%)	1(0.7)	0	0	1(0.3)
せつ	n (%)	1(0.7)	0	0	1(0.3)
咬傷感染	n (%)	0	1(0.6)	1(0.7)	1(0.3)
肺炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性腎盂腎炎	n (%)	1(0.7)	0	0	1(0.3)
皮下組織膿瘍	n (%)	1(0.7)	0	0	1(0.3)
傷害、中毒および処置合併症	n (%)	12(7.9)	11(7.1)	8(5.4)	23(7.5)
転倒・転落	n (%)	5(3.3)	2(1.3)	1(0.7)	7(2.3)
関節脱臼	n (%)	0	2(1.3)	1(0.7)	2(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
動物咬傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)
節足動物咬傷	n (%)	0	1(0.6)	0	1(0.3)
第２度熱傷	n (%)	1(0.7)	0	0	1(0.3)
皮膚化学熱傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)
擦過傷	n (%)	1(0.7)	0	0	1(0.3)
足骨折	n (%)	0	1(0.6)	1(0.7)	1(0.3)
頭部損傷	n (%)	1(0.7)	0	0	1(0.3)
関節損傷	n (%)	1(0.7)	0	0	1(0.3)
四肢損傷	n (%)	0	1(0.6)	0	1(0.3)
四肢外傷性切断	n (%)	1(0.7)	0	0	1(0.3)
橈骨骨折	n (%)	0	1(0.6)	1(0.7)	1(0.3)
腎損傷	n (%)	1(0.7)	0	0	1(0.3)
肋骨骨折	n (%)	0	1(0.6)	0	1(0.3)
交通事故	n (%)	0	1(0.6)	1(0.7)	1(0.3)
引っかき傷	n (%)	1(0.7)	0	0	1(0.3)
皮下血腫	n (%)	0	1(0.6)	1(0.7)	1(0.3)
熱傷	n (%)	1(0.7)	0	0	1(0.3)
臨床検査	n (%)	15(9.9)	21(13.5)	19(12.8)	36(11.8)
体重増加	n (%)	2(1.3)	3(1.9)	3(2.0)	5(1.6)
血中クレアチンホスホキナーゼ増加	n (%)	2(1.3)	2(1.3)	2(1.4)	4(1.3)
ヘモグロビン減少	n (%)	1(0.7)	3(1.9)	3(2.0)	4(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
血中クレアチニン増加	n (%)	1(0.7)	2(1.3)	1(0.7)	3(1.0)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
尿中ブドウ糖陽性	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
体重減少	n (%)	3(2.0)	0	0	3(1.0)
血中ブドウ糖増加	n (%)	0	2(1.3)	2(1.4)	2(0.7)
血圧上昇	n (%)	0	2(1.3)	2(1.4)	2(0.7)
血中プロラクチン増加	n (%)	2(1.3)	0	0	2(0.7)
血中尿素増加	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
ヘマトクリット減少	n (%)	0	2(1.3)	2(1.4)	2(0.7)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.7)	0	0	1(0.3)
抗精神病薬濃度治療量以上	n (%)	0	1(0.6)	0	1(0.3)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.7)	0	0	1(0.3)
血中トリグリセリド増加	n (%)	1(0.7)	0	0	1(0.3)
尿中結晶陽性	n (%)	0	1(0.6)	1(0.7)	1(0.3)
心電図ＱＴ延長	n (%)	0	1(0.6)	1(0.7)	1(0.3)
グリコヘモグロビン増加	n (%)	0	1(0.6)	1(0.7)	1(0.3)
心拍数減少	n (%)	0	1(0.6)	1(0.7)	1(0.3)
肝酵素上昇	n (%)	1(0.7)	0	0	1(0.3)
便潜血陽性	n (%)	0	1(0.6)	1(0.7)	1(0.3)
血小板数減少	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
総蛋白減少	n (%)	0	1(0.6)	1(0.7)	1(0.3)
赤血球数減少	n (%)	0	1(0.6)	1(0.7)	1(0.3)
赤血球数増加	n (%)	0	1(0.6)	1(0.7)	1(0.3)
代謝および栄養障害	n (%)	6(4.0)	7(4.5)	6(4.1)	13(4.2)
食欲減退	n (%)	3(2.0)	0	0	3(1.0)
低ナトリウム血症	n (%)	0	3(1.9)	2(1.4)	3(1.0)
糖尿病	n (%)	0	1(0.6)	1(0.7)	1(0.3)
耐糖能障害	n (%)	1(0.7)	0	0	1(0.3)
高血糖	n (%)	0	1(0.6)	1(0.7)	1(0.3)
高カリウム血症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
高トリグリセリド血症	n (%)	1(0.7)	0	0	1(0.3)
低アルブミン血症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
低カリウム血症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
低ナトリウム血症候群	n (%)	0	1(0.6)	1(0.7)	1(0.3)
代謝性アシドーシス	n (%)	0	1(0.6)	1(0.7)	1(0.3)
多飲症	n (%)	1(0.7)	0	0	1(0.3)
筋骨格系および結合組織障害	n (%)	9(6.0)	11(7.1)	8(5.4)	20(6.5)
骨関節炎	n (%)	2(1.3)	2(1.3)	2(1.4)	4(1.3)
関節痛	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
関節炎	n (%)	1(0.7)	1(0.6)	0	2(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
背部痛	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
筋肉痛	n (%)	2(1.3)	0	0	2(0.7)
頚部痛	n (%)	1(0.7)	1(0.6)	0	2(0.7)
四肢痛	n (%)	0	2(1.3)	0	2(0.7)
椎間板変性症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
関節腫脹	n (%)	0	1(0.6)	1(0.7)	1(0.3)
筋力低下	n (%)	1(0.7)	0	0	1(0.3)
筋骨格系胸痛	n (%)	1(0.7)	0	0	1(0.3)
筋骨格痛	n (%)	0	1(0.6)	1(0.7)	1(0.3)
顎痛	n (%)	1(0.7)	0	0	1(0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	2(1.3)	2(1.4)	2(0.7)
副腎腺腫	n (%)	0	1(0.6)	1(0.7)	1(0.3)
乳癌	n (%)	0	1(0.6)	1(0.7)	1(0.3)
神経系障害	n (%)	30(19.9)	27(17.4)	22(14.9)	57(18.6)
頭痛	n (%)	6(4.0)	9(5.8)	7(4.7)	15(4.9)
傾眠	n (%)	10(6.6)	5(3.2)	5(3.4)	15(4.9)
浮動性めまい	n (%)	4(2.6)	6(3.9)	6(4.1)	10(3.3)
振戦	n (%)	3(2.0)	2(1.3)	1(0.7)	5(1.6)
アカシジア	n (%)	4(2.6)	0	0	4(1.3)
鎮静	n (%)	2(1.3)	2(1.3)	2(1.4)	4(1.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
失神	n (%)	2(1.3)	2(1.3)	1(0.7)	4(1.3)
錐体外路障害	n (%)	0	2(1.3)	2(1.4)	2(0.7)
平衡障害	n (%)	1(0.7)	0	0	1(0.3)
歯車様固縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
認知症	n (%)	1(0.7)	0	0	1(0.3)
構語障害	n (%)	0	1(0.6)	0	1(0.3)
ジスキネジー	n (%)	1(0.7)	0	0	1(0.3)
顔面神経麻痺	n (%)	0	1(0.6)	1(0.7)	1(0.3)
感覚鈍麻	n (%)	1(0.7)	0	0	1(0.3)
嗜眠	n (%)	0	1(0.6)	0	1(0.3)
神経痛	n (%)	1(0.7)	0	0	1(0.3)
遅発性ジスキネジー	n (%)	1(0.7)	0	0	1(0.3)
一過性脳虚血発作	n (%)	0	1(0.6)	1(0.7)	1(0.3)
妊娠、産褥および周産期の状態	n (%)	0	1(0.6)	1(0.7)	1(0.3)
自然流産	n (%)	0	1(0.6)	1(0.7)	1(0.3)
精神障害	n (%)	26(17.2)	23(14.8)	20(13.5)	49(16.0)
自殺念慮	n (%)	7(4.6)	6(3.9)	6(4.1)	13(4.2)
うつ病	n (%)	5(3.3)	4(2.6)	4(2.7)	9(2.9)
統合失調症	n (%)	4(2.6)	4(2.6)	4(2.7)	8(2.6)
不眠症	n (%)	4(2.6)	3(1.9)	3(2.0)	7(2.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
不安	n (%)	2(1.3)	3(1.9)	1(0.7)	5(1.6)
抑うつ症状	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
精神状態変化	n (%)	2(1.3)	0	0	2(0.7)
精神病性障害	n (%)	1(0.7)	1(0.6)	0	2(0.7)
落ち着きのなさ	n (%)	0	2(1.3)	0	2(0.7)
統合失調感情障害	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
自殺企図	n (%)	0	2(1.3)	2(1.4)	2(0.7)
激越	n (%)	1(0.7)	0	0	1(0.3)
アルコール症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
死別反応	n (%)	1(0.7)	0	0	1(0.3)
錯乱状態	n (%)	0	1(0.6)	1(0.7)	1(0.3)
敵意	n (%)	1(0.7)	0	0	1(0.3)
軽躁	n (%)	1(0.7)	0	0	1(0.3)
リビドー減退	n (%)	1(0.7)	0	0	1(0.3)
神経過敏	n (%)	0	1(0.6)	1(0.7)	1(0.3)
妄想症	n (%)	1(0.7)	0	0	1(0.3)
精神運動制止遅滞	n (%)	1(0.7)	0	0	1(0.3)
自殺行為	n (%)	0	1(0.6)	1(0.7)	1(0.3)
トランス	n (%)	1(0.7)	0	0	1(0.3)
腎および尿路障害	n (%)	4(2.6)	5(3.2)	5(3.4)	9(2.9)
血尿	n (%)	2(1.3)	1(0.6)	1(0.7)	3(1.0)
尿失禁	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
糖尿	n (%)	0	1(0.6)	1(0.7)	1(0.3)
腎結石症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
頻尿	n (%)	0	1(0.6)	1(0.7)	1(0.3)
腎嚢胞	n (%)	1(0.7)	0	0	1(0.3)
生殖系および乳房障害	n (%)	2(1.3)	3(1.9)	3(2.0)	5(1.6)
良性前立腺肥大症	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
月経過多	n (%)	0	1(0.6)	1(0.7)	1(0.3)
前立腺炎	n (%)	1(0.7)	0	0	1(0.3)
精巣捻転	n (%)	0	1(0.6)	1(0.7)	1(0.3)
呼吸器、胸郭および縦隔障害	n (%)	7(4.6)	14(9.0)	13(8.8)	21(6.9)
咳嗽	n (%)	3(2.0)	3(1.9)	3(2.0)	6(2.0)
慢性閉塞性肺疾患	n (%)	2(1.3)	2(1.3)	2(1.4)	4(1.3)
喘息	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
鼻閉	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
アレルギー性副鼻腔炎	n (%)	1(0.7)	0	0	1(0.3)
慢性気管支炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
嚢胞性肺疾患	n (%)	0	1(0.6)	1(0.7)	1(0.3)
呼吸困難	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
口腔咽頭痛	n (%)	0	1(0.6)	0	1(0.3)
胸水	n (%)	0	1(0.6)	1(0.7)	1(0.3)
胸膜線維症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
アレルギー性鼻炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
鼻漏	n (%)	1(0.7)	0	0	1(0.3)
副鼻腔うっ血	n (%)	1(0.7)	0	0	1(0.3)
くしゃみ	n (%)	0	1(0.6)	1(0.7)	1(0.3)
皮膚および皮下組織障害	n (%)	9(6.0)	5(3.2)	5(3.4)	14(4.6)
そう痒症	n (%)	2(1.3)	0	0	2(0.7)
発疹	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
斑状丘疹状皮疹	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
水疱	n (%)	1(0.7)	0	0	1(0.3)
アレルギー性皮膚炎	n (%)	1(0.7)	0	0	1(0.3)
過角化	n (%)	1(0.7)	0	0	1(0.3)
全身性皮疹	n (%)	1(0.7)	0	0	1(0.3)
丘疹	n (%)	0	1(0.6)	1(0.7)	1(0.3)
皮膚剥脱	n (%)	0	1(0.6)	1(0.7)	1(0.3)
皮膚病変	n (%)	0	1(0.6)	1(0.7)	1(0.3)
蕁麻疹	n (%)	1(0.7)	0	0	1(0.3)
社会環境	n (%)	1(0.7)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
社会的入院	n (%)	1(0.7)	0	0	1(0.3)
外科および内科処置	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
抜歯	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
四肢再接合手術	n (%)	0	1(0.6)	1(0.7)	1(0.3)
Unknown	n (%)	1(0.7)	0	0	1(0.3)
皮膚嚢腫	n (%)	1(0.7)	0	0	1(0.3)
血管障害	n (%)	5(3.3)	8(5.2)	8(5.4)	13(4.2)
高血圧	n (%)	2(1.3)	4(2.6)	4(2.7)	6(2.0)
深部静脈血栓症	n (%)	0	2(1.3)	2(1.4)	2(0.7)
本態性高血圧症	n (%)	1(0.7)	0	0	1(0.3)
ほてり	n (%)	0	1(0.6)	1(0.7)	1(0.3)
低血圧	n (%)	0	1(0.6)	1(0.7)	1(0.3)
起立性低血圧	n (%)	1(0.7)	0	0	1(0.3)
末梢動脈閉塞性疾患	n (%)	1(0.7)	0	0	1(0.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
Any Adverse Event	n (%)	30(65.2)	49(65.3)	40(60.6)	79(65.3)
血液およびリンパ系障害	n (%)	0	2(2.7)	2(3.0)	2(1.7)
貧血	n (%)	0	1(1.3)	1(1.5)	1(0.8)
白血球増加症	n (%)	0	1(1.3)	1(1.5)	1(0.8)
白血球減少症	n (%)	0	1(1.3)	1(1.5)	1(0.8)
心臓障害	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
心房細動	n (%)	0	1(1.3)	1(1.5)	1(0.8)
左脚ブロック	n (%)	0	1(1.3)	1(1.5)	1(0.8)
洞性頻脈	n (%)	1(2.2)	0	0	1(0.8)
先天性、家族性および遺伝性障害	n (%)	0	1(1.3)	1(1.5)	1(0.8)
弯足	n (%)	0	1(1.3)	1(1.5)	1(0.8)
耳および迷路障害	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
耳介軟骨膜炎	n (%)	0	1(1.3)	1(1.5)	1(0.8)
耳痛	n (%)	0	1(1.3)	1(1.5)	1(0.8)
耳鳴	n (%)	1(2.2)	0	0	1(0.8)
内分泌障害	n (%)	1(2.2)	0	0	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
甲状腺機能低下症	n (%)	1(2.2)	0	0	1(0.8)
眼障害	n (%)	0	3(4.0)	3(4.5)	3(2.5)
核性白内障	n (%)	0	1(1.3)	1(1.5)	1(0.8)
複視	n (%)	0	1(1.3)	1(1.5)	1(0.8)
兎眼	n (%)	0	1(1.3)	1(1.5)	1(0.8)
黄斑浮腫	n (%)	0	1(1.3)	1(1.5)	1(0.8)
網膜静脈閉塞	n (%)	0	1(1.3)	1(1.5)	1(0.8)
胃腸障害	n (%)	11(23.9)	20(26.7)	17(25.8)	31(25.6)
下痢	n (%)	3(6.5)	5(6.7)	5(7.6)	8(6.6)
悪心	n (%)	3(6.5)	4(5.3)	4(6.1)	7(5.8)
嘔吐	n (%)	2(4.3)	4(5.3)	2(3.0)	6(5.0)
腹痛	n (%)	1(2.2)	3(4.0)	3(4.5)	4(3.3)
便秘	n (%)	1(2.2)	3(4.0)	2(3.0)	4(3.3)
上腹部痛	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
口内乾燥	n (%)	2(4.3)	1(1.3)	1(1.5)	3(2.5)
胃食道逆流性疾患	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
歯痛	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
嚥下障害	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
腹部膨満	n (%)	0	1(1.3)	1(1.5)	1(0.8)
結腸ポリープ	n (%)	1(2.2)	0	0	1(0.8)
細菌叢異常症	n (%)	0	1(1.3)	1(1.5)	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
憩室	n (%)	1(2.2)	0	0	1(0.8)
消化不良	n (%)	0	1(1.3)	1(1.5)	1(0.8)
胃炎	n (%)	0	1(1.3)	0	1(0.8)
びらん性胃炎	n (%)	0	1(1.3)	0	1(0.8)
胃腸出血	n (%)	1(2.2)	0	0	1(0.8)
痔核	n (%)	1(2.2)	0	0	1(0.8)
メレナ	n (%)	1(2.2)	0	0	1(0.8)
食道食物嵌入	n (%)	1(2.2)	0	0	1(0.8)
食道狭窄	n (%)	1(2.2)	0	0	1(0.8)
食道炎	n (%)	1(2.2)	0	0	1(0.8)
流涎過多	n (%)	0	1(1.3)	1(1.5)	1(0.8)
全身障害および投与局所様態	n (%)	6(13.0)	15(20.0)	10(15.2)	21(17.4)
疲労	n (%)	5(10.9)	3(4.0)	3(4.5)	8(6.6)
無力症	n (%)	1(2.2)	4(5.3)	0	5(4.1)
胸痛	n (%)	2(4.3)	3(4.0)	3(4.5)	5(4.1)
治癒不良	n (%)	1(2.2)	0	0	1(0.8)
易刺激性	n (%)	0	1(1.3)	1(1.5)	1(0.8)
非心臓性胸痛	n (%)	0	1(1.3)	1(1.5)	1(0.8)
末梢性浮腫	n (%)	0	1(1.3)	1(1.5)	1(0.8)
疼痛	n (%)	0	1(1.3)	1(1.5)	1(0.8)
発熱	n (%)	0	1(1.3)	0	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178 基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
口渇	n (%)	1(2.2)	0	0	1(0.8)
肝胆道系障害	n (%)	0	1(1.3)	1(1.5)	1(0.8)
胆石症	n (%)	0	1(1.3)	1(1.5)	1(0.8)
免疫系障害	n (%)	0	1(1.3)	1(1.5)	1(0.8)
季節性アレルギー	n (%)	0	1(1.3)	1(1.5)	1(0.8)
感染症および寄生虫症	n (%)	8(17.4)	23(30.7)	20(30.3)	31(25.6)
尿路感染	n (%)	4(8.7)	8(10.7)	7(10.6)	12(9.9)
気管支炎	n (%)	0	6(8.0)	5(7.6)	6(5.0)
上気道感染	n (%)	1(2.2)	3(4.0)	3(4.5)	4(3.3)
鼻咽頭炎	n (%)	2(4.3)	1(1.3)	1(1.5)	3(2.5)
胃腸炎	n (%)	0	2(2.7)	2(3.0)	2(1.7)
副鼻腔炎	n (%)	0	2(2.7)	1(1.5)	2(1.7)
急性副鼻腔炎	n (%)	1(2.2)	0	0	1(0.8)
急性扁桃炎	n (%)	0	1(1.3)	1(1.5)	1(0.8)
蜂巣炎	n (%)	0	1(1.3)	1(1.5)	1(0.8)
ブドウ球菌性蜂巣炎	n (%)	1(2.2)	0	0	1(0.8)
憩室炎	n (%)	0	1(1.3)	1(1.5)	1(0.8)
耳感染	n (%)	0	1(1.3)	1(1.5)	1(0.8)
爪真菌症	n (%)	1(2.2)	0	0	1(0.8)
咽頭炎	n (%)	1(2.2)	0	0	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
皮下組織膿瘍	n (%)	0	1(1.3)	1(1.5)	1(0.8)
股部白癬	n (%)	1(2.2)	0	0	1(0.8)
歯膿瘍	n (%)	0	1(1.3)	1(1.5)	1(0.8)
傷害、中毒および処置合併症	n (%)	4(8.7)	10(13.3)	9(13.6)	14(11.6)
挫傷	n (%)	2(4.3)	1(1.3)	1(1.5)	3(2.5)
擦過傷	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
転倒・転落	n (%)	0	3(4.0)	3(4.5)	3(2.5)
足骨折	n (%)	0	2(2.7)	1(1.5)	2(1.7)
筋挫傷	n (%)	0	2(2.7)	2(3.0)	2(1.7)
皮膚裂傷	n (%)	0	2(2.7)	2(3.0)	2(1.7)
頚椎骨折	n (%)	0	1(1.3)	1(1.5)	1(0.8)
異物による損傷	n (%)	0	1(1.3)	1(1.5)	1(0.8)
関節捻挫	n (%)	1(2.2)	0	0	1(0.8)
口腔内損傷	n (%)	0	1(1.3)	1(1.5)	1(0.8)
膝蓋骨骨折	n (%)	0	1(1.3)	1(1.5)	1(0.8)
交通事故	n (%)	0	1(1.3)	1(1.5)	1(0.8)
臨床検査	n (%)	4(8.7)	13(17.3)	10(15.2)	17(14.0)
体重減少	n (%)	1(2.2)	3(4.0)	2(3.0)	4(3.3)
体重増加	n (%)	0	4(5.3)	4(6.1)	4(3.3)
血中トリグリセリド増加	n (%)	0	2(2.7)	2(3.0)	2(1.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178 基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
グリコヘモグロビン増加	n (%)	1(2.2)	1(1.3)	0	2(1.7)
血中コレステロール増加	n (%)	0	1(1.3)	1(1.5)	1(0.8)
血中ブドウ糖減少	n (%)	0	1(1.3)	0	1(0.8)
血中ブドウ糖増加	n (%)	0	1(1.3)	1(1.5)	1(0.8)
血中プロラクチン増加	n (%)	0	1(1.3)	0	1(0.8)
握力低下	n (%)	1(2.2)	0	0	1(0.8)
代謝および栄養障害	n (%)	3(6.5)	9(12.0)	7(10.6)	12(9.9)
食欲減退	n (%)	1(2.2)	3(4.0)	2(3.0)	4(3.3)
食欲亢進	n (%)	0	3(4.0)	2(3.0)	3(2.5)
食欲不振	n (%)	2(4.3)	0	0	2(1.7)
食欲障害	n (%)	0	1(1.3)	1(1.5)	1(0.8)
脱水	n (%)	0	1(1.3)	1(1.5)	1(0.8)
糖尿病	n (%)	0	1(1.3)	1(1.5)	1(0.8)
筋骨格系および結合組織障害	n (%)	9(19.6)	10(13.3)	8(12.1)	19(15.7)
背部痛	n (%)	5(10.9)	3(4.0)	3(4.5)	8(6.6)
関節痛	n (%)	1(2.2)	4(5.3)	3(4.5)	5(4.1)
四肢痛	n (%)	1(2.2)	2(2.7)	2(3.0)	3(2.5)
滑液包炎	n (%)	1(2.2)	0	0	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
尾骨痛	n (%)	0	1(1.3)	1(1.5)	1(0.8)
筋固縮	n (%)	0	1(1.3)	0	1(0.8)
筋痙縮	n (%)	0	1(1.3)	1(1.5)	1(0.8)
筋肉痛	n (%)	0	1(1.3)	1(1.5)	1(0.8)
骨減少症	n (%)	1(2.2)	0	0	1(0.8)
良性、悪性および詳細不明の新生物 （嚢胞およびポリープを含む）	n (%)	2(4.3)	1(1.3)	1(1.5)	3(2.5)
脂肪腫	n (%)	1(2.2)	0	0	1(0.8)
肺新生物	n (%)	1(2.2)	0	0	1(0.8)
甲状腺新生物	n (%)	0	1(1.3)	1(1.5)	1(0.8)
神経系障害	n (%)	16(34.8)	22(29.3)	15(22.7)	38(31.4)
頭痛	n (%)	4(8.7)	7(9.3)	5(7.6)	11(9.1)
傾眠	n (%)	5(10.9)	4(5.3)	1(1.5)	9(7.4)
浮動性めまい	n (%)	2(4.3)	4(5.3)	4(6.1)	6(5.0)
アカシジア	n (%)	3(6.5)	1(1.3)	1(1.5)	4(3.3)
ジスキネジー	n (%)	0	4(5.3)	3(4.5)	4(3.3)
よだれ	n (%)	0	3(4.0)	3(4.5)	3(2.5)
平衡障害	n (%)	0	2(2.7)	1(1.5)	2(1.7)
ジストニー	n (%)	2(4.3)	0	0	2(1.7)
パーキンソニズム	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
鎮静	n (%)	0	2(2.7)	1(1.5)	2(1.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
失神	n (%)	2(4.3)	0	0	2(1.7)
振戦	n (%)	1(2.2)	1(1.3)	0	2(1.7)
健忘	n (%)	0	1(1.3)	1(1.5)	1(0.8)
注意力障害	n (%)	0	1(1.3)	1(1.5)	1(0.8)
脳症	n (%)	0	1(1.3)	1(1.5)	1(0.8)
企図振戦	n (%)	1(2.2)	0	0	1(0.8)
片頭痛	n (%)	1(2.2)	0	0	1(0.8)
ミオクローヌス	n (%)	1(2.2)	0	0	1(0.8)
末梢性ニューロパチー	n (%)	0	1(1.3)	1(1.5)	1(0.8)
遅発性ジスキネジー	n (%)	0	1(1.3)	1(1.5)	1(0.8)
咬舌	n (%)	1(2.2)	0	0	1(0.8)
一過性脳虚血発作	n (%)	1(2.2)	0	0	1(0.8)
精神障害	n (%)	15(32.6)	12(16.0)	8(12.1)	27(22.3)
不安	n (%)	4(8.7)	4(5.3)	2(3.0)	8(6.6)
自殺念慮	n (%)	2(4.3)	4(5.3)	4(6.1)	6(5.0)
うつ病	n (%)	4(8.7)	1(1.3)	0	5(4.1)
激越	n (%)	0	2(2.7)	2(3.0)	2(1.7)
抑うつ気分	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
不眠症	n (%)	0	2(2.7)	1(1.5)	2(1.7)
躁病	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
双極１型障害	n (%)	1(2.2)	0	0	1(0.8)
ディスフェミア	n (%)	1(2.2)	0	0	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
気分動揺	n (%)	0	1(1.3)	0	1(0.8)
パニック発作	n (%)	1(2.2)	0	0	1(0.8)
妄想症	n (%)	1(2.2)	0	0	1(0.8)
外傷後ストレス障害	n (%)	1(2.2)	0	0	1(0.8)
精神運動制止遅滞	n (%)	0	1(1.3)	1(1.5)	1(0.8)
落ち着きのなさ	n (%)	1(2.2)	0	0	1(0.8)
腎および尿路障害	n (%)	2(4.3)	1(1.3)	1(1.5)	3(2.5)
排尿困難	n (%)	0	1(1.3)	1(1.5)	1(0.8)
頻尿	n (%)	1(2.2)	0	0	1(0.8)
急性腎不全	n (%)	1(2.2)	0	0	1(0.8)
尿臭異常	n (%)	1(2.2)	0	0	1(0.8)
生殖系および乳房障害	n (%)	1(2.2)	0	0	1(0.8)
乳房圧痛	n (%)	1(2.2)	0	0	1(0.8)
乳汁漏出症	n (%)	1(2.2)	0	0	1(0.8)
膣分泌物	n (%)	1(2.2)	0	0	1(0.8)
呼吸器、胸郭および縦隔障害	n (%)	1(2.2)	13(17.3)	10(15.2)	14(11.6)
咳嗽	n (%)	0	4(5.3)	2(3.0)	4(3.3)
鼻閉	n (%)	0	4(5.3)	4(6.1)	4(3.3)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
慢性閉塞性肺疾患	n (%)	0	3(4.0)	3(4.5)	3(2.5)
呼吸困難	n (%)	1(2.2)	2(2.7)	1(1.5)	3(2.5)
喘息	n (%)	0	2(2.7)	1(1.5)	2(1.7)
鼻出血	n (%)	1(2.2)	0	0	1(0.8)
口腔咽頭痛	n (%)	0	1(1.3)	1(1.5)	1(0.8)
気道うっ血	n (%)	0	1(1.3)	0	1(0.8)
アレルギー性鼻炎	n (%)	0	1(1.3)	1(1.5)	1(0.8)
副鼻腔うっ血	n (%)	0	1(1.3)	0	1(0.8)
皮膚および皮下組織障害	n (%)	2(4.3)	2(2.7)	1(1.5)	4(3.3)
発疹	n (%)	1(2.2)	2(2.7)	1(1.5)	3(2.5)
過角化	n (%)	0	1(1.3)	1(1.5)	1(0.8)
そう痒症	n (%)	1(2.2)	0	0	1(0.8)
外科および内科処置	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
鼓膜切開	n (%)	0	1(1.3)	1(1.5)	1(0.8)
抜歯	n (%)	1(2.2)	0	0	1(0.8)
血管障害	n (%)	1(2.2)	6(8.0)	5(7.6)	7(5.8)
血腫	n (%)	0	2(2.7)	2(3.0)	2(1.7)
ほてり	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－178　基礎疾患区分ごとの有害事象の内訳：MT-5199長期投与期間（海外試験 ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	 All NBI-98854 (N=121)
高血圧	n (%)	0	2(2.7)	1(1.5)	2(1.7)
レイノー現象	n (%)	0	1(1.3)	1(1.5)	1(0.8)

[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.3より引用（一部改変）

表2.7.4.7－179　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	 80 mg (N=155)	 80 mg Only[b] (N=148)	All NBI-98854 (N=306)
Any Adverse Event of Special Interest	n (%)	49(32.5)	44(28.4)	38(25.7)	93(30.4)
アカシジア関連有害事象	n (%)	4(2.6)	0	0	4(1.3)
アカシジア	n (%)	4(2.6)	0	0	4(1.3)
不安	n (%)	2(1.3)	3(1.9)	1(0.7)	5(1.6)
不安	n (%)	2(1.3)	3(1.9)	1(0.7)	5(1.6)
心血管系及びQT間隔延長関連有害事象	n (%)	3(2.0)	5(3.2)	4(2.7)	8(2.6)
失神	n (%)	2(1.3)	2(1.3)	1(0.7)	4(1.3)
心不全	n (%)	0	1(0.6)	1(0.7)	1(0.3)
胸痛	n (%)	1(0.7)	0	0	1(0.3)
心電図QT延長	n (%)	0	1(0.6)	1(0.7)	1(0.3)
突然死	n (%)	0	1(0.6)	1(0.7)	1(0.3)
うつ病及び自殺関連有害事象	n (%)	13(8.6)	12(7.7)	12(8.1)	25(8.2)
自殺念慮	n (%)	7(4.6)	6(3.9)	6(4.1)	13(4.2)
うつ病	n (%)	5(3.3)	4(2.6)	4(2.7)	9(2.9)
抑うつ症状	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
自殺企図	n (%)	0	2(1.3)	2(1.4)	2(0.7)
自殺行為	n (%)	0	1(0.6)	1(0.7)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－179 基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	80 mg (N=155)	80 mg Only[b] (N=148)	All NBI-98854 (N=306)
嚥下障害関連有害事象	n (%)	2(1.3)	0	0	2(0.7)
嚥下障害	n (%)	2(1.3)	0	0	2(0.7)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	8(5.3)	7(4.5)	6(4.1)	15(4.9)
疲労	n (%)	8(5.3)	5(3.2)	5(3.4)	13(4.2)
嗜眠	n (%)	0	1(0.6)	0	1(0.3)
倦怠感	n (%)	0	1(0.6)	1(0.7)	1(0.3)
肝障害関連有害事象	n (%)	0	2(1.3)	2(1.4)	2(0.7)
肝不全	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性肝炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
高プロラクチン血症関連有害事象	n (%)	2(1.3)	0	0	2(0.7)
血中プロラクチン増加	n (%)	2(1.3)	0	0	2(0.7)
低血圧関連有害事象	n (%)	11(7.3)	9(5.8)	8(5.4)	20(6.5)
浮動性めまい	n (%)	4(2.6)	6(3.9)	6(4.1)	10(3.3)
転倒・転落	n (%)	5(3.3)	2(1.3)	1(0.7)	7(2.3)
失神	n (%)	2(1.3)	2(1.3)	1(0.7)	4(1.3)
低血圧	n (%)	0	1(0.6)	1(0.7)	1(0.3)
起立性低血圧	n (%)	1(0.7)	0	0	1(0.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－179　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Schizophrenia or Schizoaffective Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=151)	80 mg (N=155)	80 mg Only[b] (N=148)	All NBI-98854 (N=306)
パーキンソニズム関連有害事象	n (%)	3(2.0)	2(1.3)	1(0.7)	5(1.6)
振戦	n (%)	3(2.0)	2(1.3)	1(0.7)	5(1.6)
歯車様固縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	12(7.9)	7(4.5)	7(4.7)	19(6.2)
傾眠	n (%)	10(6.6)	5(3.2)	5(3.4)	15(4.9)
鎮静	n (%)	2(1.3)	2(1.3)	2(1.4)	4(1.3)
基礎疾患の悪化に関連する有害事象	n (%)	17(11.3)	17(11.0)	16(10.8)	34(11.1)
自殺念慮	n (%)	7(4.6)	6(3.9)	6(4.1)	13(4.2)
うつ病	n (%)	5(3.3)	4(2.6)	4(2.7)	9(2.9)
統合失調症	n (%)	4(2.6)	4(2.6)	4(2.7)	8(2.6)
抑うつ症状	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
易刺激性	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
精神病性障害	n (%)	1(0.7)	1(0.6)	0	2(0.7)
統合失調感情障害	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
自殺企図	n (%)	0	2(1.3)	2(1.4)	2(0.7)
敵意	n (%)	1(0.7)	0	0	1(0.3)
軽躁	n (%)	1(0.7)	0	0	1(0.3)
妄想症	n (%)	1(0.7)	0	0	1(0.3)
自殺行為	n (%)	0	1(0.6)	1(0.7)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－179　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	 80 mg (N=75)	 80 mg Only[b] (N=66)	All NBI-98854 (N=121)
Any Adverse Event of Special Interest	n (%)	21(45.7)	27(36.0)	18(27.3)	48(39.7)
アカシジア関連有害事象	n (%)	3(6.5)	1(1.3)	1(1.5)	4(3.3)
アカシジア	n (%)	3(6.5)	1(1.3)	1(1.5)	4(3.3)
不安	n (%)	4(8.7)	4(5.3)	2(3.0)	8(6.6)
不安	n (%)	4(8.7)	4(5.3)	2(3.0)	8(6.6)
心血管系及びQT間隔延長関連有害事象	n (%)	3(6.5)	3(4.0)	3(4.5)	6(5.0)
胸痛	n (%)	2(4.3)	3(4.0)	3(4.5)	5(4.1)
失神	n (%)	2(4.3)	0	0	2(1.7)
うつ病及び自殺関連有害事象	n (%)	6(13.0)	6(8.0)	5(7.6)	12(9.9)
自殺念慮	n (%)	2(4.3)	4(5.3)	4(6.1)	6(5.0)
うつ病	n (%)	4(8.7)	1(1.3)	0	5(4.1)
抑うつ気分	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
嚥下障害関連有害事象	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
嚥下障害	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
食道食物嵌入	n (%)	1(2.2)	0	0	1(0.8)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	5(10.9)	7(9.3)	3(4.5)	12(9.9)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－179　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	80 mg (N=75)	80 mg Only[b] (N=66)	All NBI-98854 (N=121)
疲労	n (%)	5(10.9)	3(4.0)	3(4.5)	8(6.6)
無力症	n (%)	1(2.2)	4(5.3)	0	5(4.1)
高プロラクチン血症関連有害事象	n (%)	1(2.2)	1(1.3)	0	2(1.7)
血中プロラクチン増加	n (%)	0	1(1.3)	0	1(0.8)
乳汁漏出症	n (%)	1(2.2)	0	0	1(0.8)
低血圧関連有害事象	n (%)	3(6.5)	7(9.3)	7(10.6)	10(8.3)
浮動性めまい	n (%)	2(4.3)	4(5.3)	4(6.1)	6(5.0)
転倒・転落	n (%)	0	3(4.0)	3(4.5)	3(2.5)
失神	n (%)	2(4.3)	0	0	2(1.7)
パーキンソニズム関連有害事象	n (%)	2(4.3)	3(4.0)	1(1.5)	5(4.1)
パーキンソニズム	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
振戦	n (%)	1(2.2)	1(1.3)	0	2(1.7)
筋固縮	n (%)	0	1(1.3)	0	1(0.8)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	5(10.9)	6(8.0)	2(3.0)	11(9.1)
傾眠	n (%)	5(10.9)	4(5.3)	1(1.5)	9(7.4)
鎮静	n (%)	0	2(2.7)	1(1.5)	2(1.7)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－179　基礎疾患区分ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Psychiatric Diagnosis Group: Mood Disorder

AESI Preferred Term	Statistic	NBI-98854 Dose[a] 40 mg (N=46)	80 mg (N=75)	80 mg Only[b] (N=66)	All NBI-98854 (N=121)
基礎疾患の悪化に関連する有害事象	n (%)	10(21.7)	8(10.7)	7(10.6)	18(14.9)
自殺念慮	n (%)	2(4.3)	4(5.3)	4(6.1)	6(5.0)
うつ病	n (%)	4(8.7)	1(1.3)	0	5(4.1)
抑うつ気分	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
躁病	n (%)	1(2.2)	1(1.3)	1(1.5)	2(1.7)
双極１型障害	n (%)	1(2.2)	0	0	1(0.8)
易刺激性	n (%)	0	1(1.3)	1(1.5)	1(0.8)
気分動揺	n (%)	0	1(1.3)	0	1(0.8)
妄想症	n (%)	1(2.2)	0	0	1(0.8)
外傷後ストレス障害	n (%)	1(2.2)	0	0	1(0.8)

AESI = Adverse Event of Special Interest.
[a] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[b] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.3より引用（一部改変）

表 2.7.4.7－180　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=33) n(%)	80 mg (N=38) n(%)	All MT-5199 (N=71) n(%)	Placebo (N=32) n(%)	40 mg (N=52) n(%)	80 mg (N=46) n(%)	All MT-5199 (N=98) n(%)	Placebo (N=52) n(%)
Any AESI		17 (51.5)	23 (60.5)	40 (56.3)	6 (18.8)	19 (36.5)	30 (65.2)	49 (50.0)	9 (17.3)
Somnolence	傾眠関連有害事象	8 (24.2)	11 (28.9)	19 (26.8)	0 (0.0)	8 (15.4)	13 (28.3)	21 (21.4)	2 (3.8)
Somnolence	傾眠	4 (12.1)	9 (23.7)	13 (18.3)	0 (0.0)	6 (11.5)	12 (26.1)	18 (18.4)	2 (3.8)
Malaise	倦怠感	3 (9.1)	3 (7.9)	6 (8.5)	0 (0.0)	2 (3.8)	1 (2.2)	3 (3.1)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (5.3)	2 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Hypersomnia	過眠症	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	2 (6.1)	3 (7.9)	5 (7.0)	2 (6.3)	3 (5.8)	4 (8.7)	7 (7.1)	4 (7.7)
Urticaria	蕁麻疹	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	2 (3.8)	1 (2.2)	3 (3.1)	0 (0.0)
Eczema	湿疹	1 (3.0)	1 (2.6)	2 (2.8)	1 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)
Blister	水疱	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Dermatitis	皮膚炎	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－180　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=33) n(%)	80 mg (N=38) n(%)	All MT-5199 (N=71) n(%)	Placebo (N=32) n(%)	40 mg (N=52) n(%)	80 mg (N=46) n(%)	All MT-5199 (N=98) n(%)	Placebo (N=52) n(%)
Parkinsonism	パーキンソニズム関連有害事象	2 (6.1)	5 (13.2)	7 (9.9)	1 (3.1)	3 (5.8)	13 (28.3)	16 (16.3)	0 (0.0)
Salivary hypersecretion	流涎過多	1 (3.0)	3 (7.9)	4 (5.6)	1 (3.1)	2 (3.8)	6 (13.0)	8 (8.2)	0 (0.0)
Tremor	振戦	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	0 (0.0)	4 (8.7)	4 (4.1)	0 (0.0)
Drooling	よだれ	1 (3.0)	1 (2.6)	2 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.3)	2 (2.0)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	1 (2.2)	2 (2.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	4 (12.1)	2 (5.3)	6 (8.5)	1 (3.1)	2 (3.8)	1 (2.2)	3 (3.1)	0 (0.0)
Depression	うつ病	1 (3.0)	2 (5.3)	3 (4.2)	1 (3.1)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Suicide attempt	自殺企図	1 (3.0)	0 (0.0)	1 (1.4)	1 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Akathisia	アカシジア関連有害事象	4 (12.1)	5 (13.2)	9 (12.7)	0 (0.0)	0 (0.0)	3 (6.5)	3 (3.1)	1 (1.9)
Akathisia	アカシジア	4 (12.1)	5 (13.2)	9 (12.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.3)	2 (2.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (5.3)	2 (2.8)	0 (0.0)	1 (1.9)	2 (4.3)	3 (3.1)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (5.3)	2 (2.8)	0 (0.0)	1 (1.9)	2 (4.3)	3 (3.1)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－180　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=33) n(%)	80 mg (N=38) n(%)	All MT-5199 (N=71) n(%)	Placebo (N=32) n(%)	40 mg (N=52) n(%)	80 mg (N=46) n(%)	All MT-5199 (N=98) n(%)	Placebo (N=52) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	5 (15.2)	4 (10.5)	9 (12.7)	3 (9.4)	6 (11.5)	2 (4.3)	8 (8.2)	0 (0.0)
Schizophrenia	統合失調症	2 (6.1)	0 (0.0)	2 (2.8)	1 (3.1)	5 (9.6)	0 (0.0)	5 (5.1)	0 (0.0)
Depression	うつ病	1 (3.0)	2 (5.3)	3 (4.2)	1 (3.1)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	1 (2.6)	1 (1.4)	1 (3.1)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Suicide attempt	自殺企図	1 (3.0)	0 (0.0)	1 (1.4)	1 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Dysphagia	嚥下障害	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.8)	1 (2.2)	3 (3.1)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (1.0)	0 (0.0)
Hypotension	低血圧関連有害事象	1 (3.0)	1 (2.6)	2 (2.8)	0 (0.0)	0 (0.0)	3 (6.5)	3 (3.1)	2 (3.8)
Dizziness	浮動性めまい	0 (0.0)	1 (2.6)	1 (1.4)	0 (0.0)	0 (0.0)	2 (4.3)	2 (2.0)	1 (1.9)
Fall	転倒	1 (3.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (2.2)	1 (1.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.9.1.2 より引用

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=50) n(%)	Yes MT-5199 80 mg (N=51) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=38) n(%)	Yes All MT-5199 (N=101) n(%)	No MT-5199 40 mg (N=76) n(%)	No MT-5199 80 mg (N=72) n(%)	No MT-5199 80 mg (no dose reduction) (N=46) n(%)	No All MT-5199 (N=148) n(%)
Any AESI		37 (74.0)	43 (84.3)	31 (81.6)	80 (79.2)	51 (67.1)	65 (90.3)	39 (84.8)	116 (78.4)
Somnolence	傾眠関連有害事象	14 (28.0)	15 (29.4)	11 (28.9)	29 (28.7)	18 (23.7)	25 (34.7)	11 (23.9)	43 (29.1)
Somnolence	傾眠	8 (16.0)	12 (23.5)	9 (23.7)	20 (19.8)	11 (14.5)	16 (22.2)	9 (19.6)	27 (18.2)
Malaise	倦怠感	5 (10.0)	4 (7.8)	4 (10.5)	9 (8.9)	5 (6.6)	6 (8.3)	1 (2.2)	11 (7.4)
Fatigue	疲労	1 (2.0)	3 (5.9)	2 (5.3)	4 (4.0)	1 (1.3)	1 (1.4)	1 (2.2)	2 (1.4)
Sedation complication	鎮静合併症	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	2 (2.6)	1 (1.4)	0 (0.0)	3 (2.0)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	1 (2.2)	2 (1.4)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Hypersomnia	過眠症	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=50) n(%)	Yes MT-5199 80 mg (N=51) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=38) n(%)	Yes All MT-5199 (N=101) n(%)	No MT-5199 40 mg (N=76) n(%)	No MT-5199 80 mg (N=72) n(%)	No MT-5199 80 mg (no dose reduction) (N=46) n(%)	No All MT-5199 (N=148) n(%)
Hypersensitivity	過敏症関連有害事象	7 (14.0)	7 (13.7)	6 (15.8)	14 (13.9)	16 (21.1)	11 (15.3)	8 (17.4)	27 (18.2)
Eczema	湿疹	3 (6.0)	1 (2.0)	1 (2.6)	4 (4.0)	1 (1.3)	2 (2.8)	1 (2.2)	3 (2.0)
Stomatitis	口内炎	1 (2.0)	1 (2.0)	1 (2.6)	2 (2.0)	3 (3.9)	2 (2.8)	2 (4.3)	5 (3.4)
Urticaria	蕁麻疹	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	3 (3.9)	1 (1.4)	0 (0.0)	4 (2.7)
Dermatitis contact	接触皮膚炎	1 (2.0)	1 (2.0)	1 (2.6)	2 (2.0)	1 (1.3)	1 (1.4)	0 (0.0)	2 (1.4)
Pruritus	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.8)	2 (4.3)	4 (2.7)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	2 (2.8)	2 (4.3)	3 (2.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.4)	1 (2.2)	2 (1.4)
Dermatitis	皮膚炎	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Blister	水疱	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (2.2)	1 (0.7)
Erythema	紅斑	0 (0.0)	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=50) n(%)	Yes MT-5199 80 mg (N=51) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=38) n(%)	Yes All MT-5199 (N=101) n(%)	No MT-5199 40 mg (N=76) n(%)	No MT-5199 80 mg (N=72) n(%)	No MT-5199 80 mg (no dose reduction) (N=46) n(%)	No All MT-5199 (N=148) n(%)
Parkinsonism	パーキンソニズム関連有害事象	8 (16.0)	20 (39.2)	9 (23.7)	28 (27.7)	16 (21.1)	30 (41.7)	16 (34.8)	46 (31.1)
Salivary hypersecretion	流涎過多	4 (8.0)	8 (15.7)	4 (10.5)	12 (11.9)	5 (6.6)	13 (18.1)	6 (13.0)	18 (12.2)
Tremor	振戦	2 (4.0)	8 (15.7)	4 (10.5)	10 (9.9)	3 (3.9)	8 (11.1)	5 (10.9)	11 (7.4)
Parkinsonism	パーキンソニズム	1 (2.0)	2 (3.9)	1 (2.6)	3 (3.0)	4 (5.3)	1 (1.4)	1 (2.2)	5 (3.4)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	2 (3.9)	0 (0.0)	2 (2.0)	2 (2.6)	2 (2.8)	2 (4.3)	4 (2.7)
Drooling	よだれ	1 (2.0)	1 (2.0)	1 (2.6)	2 (2.0)	1 (1.3)	2 (2.8)	1 (2.2)	3 (2.0)
Bradykinesia	運動緩慢	0 (0.0)	1 (2.0)	0 (0.0)	1 (1.0)	1 (1.3)	1 (1.4)	0 (0.0)	2 (1.4)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)
Muscle rigidity	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Musculoskeletal stiffness	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)
Propulsive gait	突進性歩行	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (2.2)	1 (0.7)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=50) n(%)	Yes MT-5199 80 mg (N=51) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=38) n(%)	Yes All MT-5199 (N=101) n(%)	No MT-5199 40 mg (N=76) n(%)	No MT-5199 80 mg (N=72) n(%)	No MT-5199 80 mg (no dose reduction) (N=46) n(%)	No All MT-5199 (N=148) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	13 (26.0)	10 (19.6)	8 (21.1)	23 (22.8)	6 (7.9)	9 (12.5)	7 (15.2)	15 (10.1)
Depression	うつ病	5 (10.0)	6 (11.8)	5 (13.2)	11 (10.9)	1 (1.3)	4 (5.6)	4 (8.7)	5 (3.4)
Suicidal ideation	自殺念慮	4 (8.0)	1 (2.0)	1 (2.6)	5 (5.0)	2 (2.6)	2 (2.8)	1 (2.2)	4 (2.7)
Suicide attempt	自殺企図	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.3)	1 (1.4)	1 (2.2)	2 (1.4)
Middle insomnia	中期不眠症	2 (4.0)	1 (2.0)	1 (2.6)	3 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	2 (1.4)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (2.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Intentional self-injury	故意の自傷行為	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (2.2)	1 (0.7)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac events	心血管系及びQT間隔延長関連有害事象	3 (6.0)	0 (0.0)	0 (0.0)	3 (3.0)	1 (1.3)	1 (1.4)	1 (2.2)	2 (1.4)
Death	死亡	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (1.4)	1 (2.2)	1 (0.7)
Long QT syndrome	ＱＴ延長症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Loss of consciousness	意識消失	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperprolactinemia	高プロラクチン血症関連有害事象	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=50) n(%)	80 mg (N=51) n(%)	80 mg (no dose reduction) (N=38) n(%)	All MT-5199 (N=101) n(%)	40 mg (N=76) n(%)	80 mg (N=72) n(%)	80 mg (no dose reduction) (N=46) n(%)	All MT-5199 (N=148) n(%)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=50) n(%)	80 mg (N=51) n(%)	80 mg (no dose reduction) (N=38) n(%)	All MT-5199 (N=101) n(%)	40 mg (N=76) n(%)	80 mg (N=72) n(%)	80 mg (no dose reduction) (N=46) n(%)	All MT-5199 (N=148) n(%)
Akathisia	アカシジア関連有害事象	7 (14.0)	12 (23.5)	7 (18.4)	19 (18.8)	5 (6.6)	7 (9.7)	4 (8.7)	12 (8.1)
Akathisia	アカシジア	7 (14.0)	10 (19.6)	7 (18.4)	17 (16.8)	1 (1.3)	2 (2.8)	1 (2.2)	3 (2.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	2 (3.9)	0 (0.0)	2 (2.0)	2 (2.6)	2 (2.8)	2 (4.3)	4 (2.7)
Restlessness	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.8)	1 (2.2)	4 (2.7)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.7)
Anxiety	不安	3 (6.0)	4 (7.8)	4 (10.5)	7 (6.9)	2 (2.6)	5 (6.9)	3 (6.5)	7 (4.7)
Anxiety	不安	3 (6.0)	4 (7.8)	4 (10.5)	7 (6.9)	2 (2.6)	5 (6.9)	3 (6.5)	7 (4.7)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	18 (36.0)	13 (25.5)	10 (26.3)	31 (30.7)	17 (22.4)	16 (22.2)	9 (19.6)	33 (22.3)
Schizophrenia	統合失調症	8 (16.0)	5 (9.8)	3 (7.9)	13 (12.9)	13 (17.1)	8 (11.1)	2 (4.3)	21 (14.2)
Depression	うつ病	5 (10.0)	6 (11.8)	5 (13.2)	11 (10.9)	1 (1.3)	4 (5.6)	4 (8.7)	5 (3.4)
Suicidal ideation	自殺念慮	4 (8.0)	1 (2.0)	1 (2.6)	5 (5.0)	2 (2.6)	2 (2.8)	1 (2.2)	4 (2.7)
Suicide attempt	自殺企図	2 (4.0)	0 (0.0)	0 (0.0)	2 (2.0)	1 (1.3)	1 (1.4)	1 (2.2)	2 (1.4)
Bipolar disorder	双極性障害	2 (4.0)	1 (2.0)	1 (2.6)	3 (3.0)	0 (0.0)	1 (1.4)	1 (2.2)	1 (0.7)
Depressed mood	抑うつ気分	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	1 (2.0)	1 (2.6)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (2.2)	1 (0.7)
Dysphagia	嚥下障害関連有害事象	1 (2.0)	3 (5.9)	3 (7.9)	4 (4.0)	4 (5.3)	2 (2.8)	0 (0.0)	6 (4.1)
Dysphagia	嚥下障害	1 (2.0)	3 (5.9)	3 (7.9)	4 (4.0)	4 (5.3)	2 (2.8)	0 (0.0)	6 (4.1)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－181　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=50) n(%)	Yes MT-5199 80 mg (N=51) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=38) n(%)	Yes All MT-5199 (N=101) n(%)	No MT-5199 40 mg (N=76) n(%)	No MT-5199 80 mg (N=72) n(%)	No MT-5199 80 mg (no dose reduction) (N=46) n(%)	No All MT-5199 (N=148) n(%)
Hepatotoxicity	肝障害関連有害事象	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	4 (5.3)	3 (4.2)	2 (4.3)	7 (4.7)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	2 (1.4)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.8)	2 (4.3)	2 (1.4)
Liver function test increased	肝機能検査値上昇	1 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Hypotension	低血圧関連有害事象	3 (6.0)	5 (9.8)	4 (10.5)	8 (7.9)	4 (5.3)	8 (11.1)	7 (15.2)	12 (8.1)
Dizziness	浮動性めまい	2 (4.0)	3 (5.9)	2 (5.3)	5 (5.0)	2 (2.6)	4 (5.6)	4 (8.7)	6 (4.1)
Fall	転倒	1 (2.0)	2 (3.9)	2 (5.3)	3 (3.0)	1 (1.3)	5 (6.9)	4 (8.7)	6 (4.1)
Hypotension	低血圧	0 (0.0)	2 (3.9)	2 (5.3)	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)
Cognitive disorder	認知機能低下関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.4)	0 (0.0)	3 (2.0)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	2 (1.4)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.7)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.9.2.2 より引用

表 2.7.4.7－182　自殺念慮又は自殺企図の既往ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Yes (N=103) n (%)	No (N=151) n (%)	Yes (N=65) n (%)	No (N=113) n (%)	Yes (N=170) n (%)	No (N=257) n (%)
At Least 1 AE	61 (59.2)	50 (33.1)	37 (56.9)	34 (30.1)	115 (67.6)	144 (56.0)
At Least 1 SAE	5 (4.9)	7 (4.6)	2 (3.1)	4 (3.5)	26 (15.3)	28 (10.9)
At Least 1 AE Leading to Study Discontinuation	2 (1.9)	8 (5.3)	2 (3.1)	6 (5.3)	27 (15.9)	31 (12.1)
At Least 1 AE Leading to Dose Reduction	2 (1.9)	5 (3.3)	0	4 (3.5)	10 (5.9)	16 (6.2)

AE: adverse event, SAE: serious adverse event
Note: Suicidality was measured by the Columbia-Suicide Severity Rating Scale. If a subject experienced more than 1 event in a given category, that subject is counted once for that category.

5.3.5.3－2 Table 104 より引用（一部改変）

表2.7.4.7－183　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=49)	80 mg (N=44)	100 mg (N=8)	All NBI-98854 (N=103)	Placebo (N=65)
Any Adverse Event of Special Interest	n (%)	1(50.0)	16(32.7)	12(27.3)	1(12.5)	30(29.1)	11(16.9)
アカシジア関連有害事象	n (%)	0	2(4.1)	2(4.5)	0	4(3.9)	1(1.5)
アカシジア	n (%)	0	2(4.1)	2(4.5)	0	4(3.9)	1(1.5)
不安	n (%)	0	0	1(2.3)	0	1(1.0)	0
不安	n (%)	0	0	1(2.3)	0	1(1.0)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(2.0)	0	0	1(1.0)	0
胸痛	n (%)	0	1(2.0)	0	0	1(1.0)	0
うつ病及び自殺関連有害事象	n (%)	1(50.0)	5(10.2)	3(6.8)	0	9(8.7)	3(4.6)
自殺念慮	n (%)	0	4(8.2)	0	0	4(3.9)	1(1.5)
うつ病	n (%)	0	0	2(4.5)	0	2(1.9)	1(1.5)
抑うつ気分	n (%)	1(50.0)	0	0	0	1(1.0)	0
抑うつ症状	n (%)	0	1(2.0)	0	0	1(1.0)	1(1.5)
自殺企図	n (%)	0	0	1(2.3)	0	1(1.0)	0
嚥下障害関連有害事象	n (%)	0	2(4.1)	0	0	2(1.9)	0
嚥下障害	n (%)	0	2(4.1)	0	0	2(1.9)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	2(4.1)	3(6.8)	1(12.5)	6(5.8)	2(3.1)
疲労	n (%)	0	2(4.1)	3(6.8)	1(12.5)	6(5.8)	2(3.1)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－183　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=49)	80 mg (N=44)	100 mg (N=8)	All NBI-98854 (N=103)	Placebo (N=65)
肝障害関連有害事象	n (%)	0	0	1(2.3)	0	1(1.0)	0
急性肝炎	n (%)	0	0	1(2.3)	0	1(1.0)	0
低血圧関連有害事象	n (%)	0	0	1(2.3)	0	1(1.0)	1(1.5)
低血圧	n (%)	0	0	1(2.3)	0	1(1.0)	0
浮動性めまい	n (%)	0	0	0	0	0	1(1.5)
パーキンソニズム関連有害事象	n (%)	0	0	1(2.3)	0	1(1.0)	0
振戦	n (%)	0	0	1(2.3)	0	1(1.0)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	6(12.2)	3(6.8)	0	9(8.7)	3(4.6)
傾眠	n (%)	0	5(10.2)	1(2.3)	0	6(5.8)	3(4.6)
鎮静	n (%)	0	1(2.0)	2(4.5)	0	3(2.9)	0
基礎疾患の悪化に関連する有害事象	n (%)	1(50.0)	7(14.3)	3(6.8)	0	11(10.7)	6(9.2)
自殺念慮	n (%)	0	4(8.2)	0	0	4(3.9)	1(1.5)
うつ病	n (%)	0	0	2(4.5)	0	2(1.9)	1(1.5)
抑うつ気分	n (%)	1(50.0)	0	0	0	1(1.0)	0
抑うつ症状	n (%)	0	1(2.0)	0	0	1(1.0)	1(1.5)
軽躁	n (%)	0	1(2.0)	0	0	1(1.0)	0
妄想症	n (%)	0	1(2.0)	0	0	1(1.0)	0
統合失調症	n (%)	0	1(2.0)	0	0	1(1.0)	1(1.5)
自殺企図	n (%)	0	0	1(2.3)	0	1(1.0)	0

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－183　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=49)	80 mg (N=44)	100 mg (N=8)	All NBI-98854 (N=103)	Placebo (N=65)
易刺激性	n (%)	0	0	0	0	0	1(1.5)
統合失調感情障害	n (%)	0	0	0	0	0	1(1.5)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－183　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=3)	40 mg (N=61)	80 mg (N=68)	100 mg (N=19)	All NBI-98854 (N=151)	Placebo (N=113)
Any Adverse Event of Special Interest	n (%)	0	12(19.7)	11(16.2)	2(10.5)	25(16.6)	13(11.5)
アカシジア関連有害事象	n (%)	0	1(1.6)	1(1.5)	0	2(1.3)	0
アカシジア	n (%)	0	1(1.6)	1(1.5)	0	2(1.3)	0
不安	n (%)	0	1(1.6)	1(1.5)	0	2(1.3)	0
不安	n (%)	0	1(1.6)	1(1.5)	0	2(1.3)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	1(1.5)	1(5.3)	2(1.3)	1(0.9)
突然死	n (%)	0	0	1(1.5)	0	1(0.7)	0
失神	n (%)	0	0	0	1(5.3)	1(0.7)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.9)
うつ病及び自殺関連有害事象	n (%)	0	0	1(1.5)	0	1(0.7)	3(2.7)
自殺念慮	n (%)	0	0	1(1.5)	0	1(0.7)	3(2.7)
うつ病	n (%)	0	0	0	0	0	1(0.9)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	3(4.9)	0	1(5.3)	4(2.6)	1(0.9)
疲労	n (%)	0	3(4.9)	0	1(5.3)	4(2.6)	1(0.9)
低血圧関連有害事象	n (%)	0	4(6.6)	1(1.5)	1(5.3)	6(4.0)	3(2.7)
転倒・転落	n (%)	0	2(3.3)	1(1.5)	0	3(2.0)	0
浮動性めまい	n (%)	0	2(3.3)	0	0	2(1.3)	3(2.7)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－183　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=3)	40 mg (N=61)	80 mg (N=68)	100 mg (N=19)	All NBI-98854 (N=151)	Placebo (N=113)
失神	n (%)	0	0	0	1(5.3)	1(0.7)	0
パーキンソニズム関連有害事象	n (%)	0	0	1(1.5)	0	1(0.7)	0
振戦	n (%)	0	0	1(1.5)	0	1(0.7)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	4(6.6)	3(4.4)	1(5.3)	8(5.3)	2(1.8)
傾眠	n (%)	0	4(6.6)	3(4.4)	1(5.3)	8(5.3)	1(0.9)
鎮静	n (%)	0	0	0	0	0	1(0.9)
基礎疾患の悪化に関連する有害事象	n (%)	0	3(4.9)	3(4.4)	0	6(4.0)	7(6.2)
双極１型障害	n (%)	0	1(1.6)	0	0	1(0.7)	0
敵意	n (%)	0	1(1.6)	0	0	1(0.7)	0
易刺激性	n (%)	0	1(1.6)	0	0	1(0.7)	1(0.9)
精神病性障害	n (%)	0	0	1(1.5)	0	1(0.7)	2(1.8)
統合失調感情障害	n (%)	0	0	1(1.5)	0	1(0.7)	0
自殺念慮	n (%)	0	0	1(1.5)	0	1(0.7)	3(2.7)
うつ病	n (%)	0	0	0	0	0	1(0.9)
躁病	n (%)	0	0	0	0	0	1(0.9)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.9)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.1.1.8.1より引用（一部改変）

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=77)	80 mg (N=93)	80 mg Only[c] (N=87)	All NBI-98854 (N=170)
Any Adverse Event of Special Interest	n (%)	34(44.2)	35(37.6)	29(33.3)	69(40.6)
アカシジア関連有害事象	n (%)	5(6.5)	1(1.1)	1(1.1)	6(3.5)
アカシジア	n (%)	5(6.5)	1(1.1)	1(1.1)	6(3.5)
不安	n (%)	4(5.2)	4(4.3)	2(2.3)	8(4.7)
不安	n (%)	4(5.2)	4(4.3)	2(2.3)	8(4.7)
心血管系及びQT間隔延長関連有害事象	n (%)	4(5.2)	3(3.2)	3(3.4)	7(4.1)
胸痛	n (%)	3(3.9)	3(3.2)	3(3.4)	6(3.5)
失神	n (%)	2(2.6)	0	0	2(1.2)
うつ病及び自殺関連有害事象	n (%)	11(14.3)	12(12.9)	11(12.6)	23(13.5)
自殺念慮	n (%)	7(9.1)	6(6.5)	6(6.9)	13(7.6)
うつ病	n (%)	4(5.2)	4(4.3)	3(3.4)	8(4.7)
抑うつ症状	n (%)	1(1.3)	1(1.1)	1(1.1)	2(1.2)
抑うつ気分	n (%)	0	1(1.1)	1(1.1)	1(0.6)
自殺行為	n (%)	0	1(1.1)	1(1.1)	1(0.6)
自殺企図	n (%)	0	1(1.1)	1(1.1)	1(0.6)
嚥下障害関連有害事象	n (%)	2(2.6)	1(1.1)	1(1.1)	3(1.8)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=77)	80 mg (N=93)	80 mg Only[c] (N=87)	All NBI-98854 (N=170)
嚥下障害	n (%)	2(2.6)	1(1.1)	1(1.1)	3(1.8)
食道食物嵌入	n (%)	1(1.3)	0	0	1(0.6)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	6(7.8)	6(6.5)	5(5.7)	12(7.1)
疲労	n (%)	6(7.8)	5(5.4)	5(5.7)	11(6.5)
無力症	n (%)	1(1.3)	1(1.1)	0	2(1.2)
肝障害関連有害事象	n (%)	0	1(1.1)	1(1.1)	1(0.6)
急性肝炎	n (%)	0	1(1.1)	1(1.1)	1(0.6)
高プロラクチン血症関連有害事象	n (%)	1(1.3)	0	0	1(0.6)
乳汁漏出症	n (%)	1(1.3)	0	0	1(0.6)
低血圧関連有害事象	n (%)	4(5.2)	7(7.5)	7(8.0)	11(6.5)
浮動性めまい	n (%)	2(2.6)	5(5.4)	5(5.7)	7(4.1)
失神	n (%)	2(2.6)	0	0	2(1.2)
転倒・転落	n (%)	0	1(1.1)	1(1.1)	1(0.6)
低血圧	n (%)	0	1(1.1)	1(1.1)	1(0.6)
起立性低血圧	n (%)	1(1.3)	0	0	1(0.6)
パーキンソニズム関連有害事象	n (%)	3(3.9)	3(3.2)	0	6(3.5)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=77)	80 mg (N=93)	80 mg Only[c] (N=87)	All NBI-98854 (N=170)
振戦	n (%)	3(3.9)	2(2.2)	0	5(2.9)
筋固縮	n (%)	0	1(1.1)	0	1(0.6)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	10(13.0)	7(7.5)	6(6.9)	17(10.0)
傾眠	n (%)	8(10.4)	3(3.2)	3(3.4)	11(6.5)
鎮静	n (%)	2(2.6)	4(4.3)	3(3.4)	6(3.5)
基礎疾患の悪化に関連する有害事象	n (%)	15(19.5)	15(16.1)	14(16.1)	30(17.6)
自殺念慮	n (%)	7(9.1)	6(6.5)	6(6.9)	13(7.6)
うつ病	n (%)	4(5.2)	4(4.3)	3(3.4)	8(4.7)
統合失調症	n (%)	2(2.6)	2(2.2)	2(2.3)	4(2.4)
易刺激性	n (%)	1(1.3)	2(2.2)	2(2.3)	3(1.8)
抑うつ症状	n (%)	1(1.3)	1(1.1)	1(1.1)	2(1.2)
躁病	n (%)	1(1.3)	1(1.1)	1(1.1)	2(1.2)
抑うつ気分	n (%)	0	1(1.1)	1(1.1)	1(0.6)
軽躁	n (%)	1(1.3)	0	0	1(0.6)
気分動揺	n (%)	0	1(1.1)	0	1(0.6)
妄想症	n (%)	1(1.3)	0	0	1(0.6)
精神病性障害	n (%)	1(1.3)	0	0	1(0.6)
統合失調感情障害	n (%)	1(1.3)	0	0	1(0.6)
自殺行為	n (%)	0	1(1.1)	1(1.1)	1(0.6)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=77)	80 mg (N=93)	80 mg Only[c] (N=87)	All NBI-98854 (N=170)
自殺企図	n (%)	0	1(1.1)	1(1.1)	1(0.6)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=120)	80 mg (N=137)	80 mg Only[c] (N=127)	All NBI-98854 (N=257)
Any Adverse Event of Special Interest	n (%)	36(30.0)	36(26.3)	27(21.3)	72(28.0)
アカシジア関連有害事象	n (%)	2(1.7)	0	0	2(0.8)
アカシジア	n (%)	2(1.7)	0	0	2(0.8)
不安	n (%)	2(1.7)	3(2.2)	1(0.8)	5(1.9)
不安	n (%)	2(1.7)	3(2.2)	1(0.8)	5(1.9)
心血管系及びQT間隔延長関連有害事象	n (%)	2(1.7)	5(3.6)	4(3.1)	7(2.7)
失神	n (%)	2(1.7)	2(1.5)	1(0.8)	4(1.6)
心不全	n (%)	0	1(0.7)	1(0.8)	1(0.4)
心電図QT延長	n (%)	0	1(0.7)	1(0.8)	1(0.4)
突然死	n (%)	0	1(0.7)	1(0.8)	1(0.4)
うつ病及び自殺関連有害事象	n (%)	8(6.7)	6(4.4)	6(4.7)	14(5.4)
うつ病	n (%)	5(4.2)	1(0.7)	1(0.8)	6(2.3)
自殺念慮	n (%)	2(1.7)	4(2.9)	4(3.1)	6(2.3)
抑うつ気分	n (%)	1(0.8)	0	0	1(0.4)
自殺企図	n (%)	0	1(0.7)	1(0.8)	1(0.4)
嚥下障害関連有害事象	n (%)	1(0.8)	0	0	1(0.4)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=120)	80 mg (N=137)	80 mg Only[c] (N=127)	All NBI-98854 (N=257)
嚥下障害	n (%)	1(0.8)	0	0	1(0.4)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	7(5.8)	8(5.8)	4(3.1)	15(5.8)
疲労	n (%)	7(5.8)	3(2.2)	3(2.4)	10(3.9)
無力症	n (%)	0	3(2.2)	0	3(1.2)
嗜眠	n (%)	0	1(0.7)	0	1(0.4)
倦怠感	n (%)	0	1(0.7)	1(0.8)	1(0.4)
肝障害関連有害事象	n (%)	0	1(0.7)	1(0.8)	1(0.4)
肝不全	n (%)	0	1(0.7)	1(0.8)	1(0.4)
高プロラクチン血症関連有害事象	n (%)	2(1.7)	1(0.7)	0	3(1.2)
血中プロラクチン増加	n (%)	2(1.7)	1(0.7)	0	3(1.2)
低血圧関連有害事象	n (%)	10(8.3)	9(6.6)	8(6.3)	19(7.4)
浮動性めまい	n (%)	4(3.3)	5(3.6)	5(3.9)	9(3.5)
転倒・転落	n (%)	5(4.2)	4(2.9)	3(2.4)	9(3.5)
失神	n (%)	2(1.7)	2(1.5)	1(0.8)	4(1.6)
パーキンソニズム関連有害事象	n (%)	2(1.7)	2(1.5)	2(1.6)	4(1.6)
パーキンソニズム	n (%)	1(0.8)	1(0.7)	1(0.8)	2(0.8)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－184　自殺念慮又は自殺企図の既往ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) During Lifetime: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=120)	80 mg (N=137)	80 mg Only[c] (N=127)	All NBI-98854 (N=257)
振戦	n (%)	1(0.8)	1(0.7)	1(0.8)	2(0.8)
歯車様固縮	n (%)	0	1(0.7)	1(0.8)	1(0.4)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	7(5.8)	6(4.4)	3(2.4)	13(5.1)
傾眠	n (%)	7(5.8)	6(4.4)	3(2.4)	13(5.1)
基礎疾患の悪化に関連する有害事象	n (%)	12(10.0)	10(7.3)	9(7.1)	22(8.6)
うつ病	n (%)	5(4.2)	1(0.7)	1(0.8)	6(2.3)
自殺念慮	n (%)	2(1.7)	4(2.9)	4(3.1)	6(2.3)
統合失調症	n (%)	2(1.7)	2(1.5)	2(1.6)	4(1.6)
双極Ⅰ型障害	n (%)	1(0.8)	0	0	1(0.4)
抑うつ気分	n (%)	1(0.8)	0	0	1(0.4)
敵意	n (%)	1(0.8)	0	0	1(0.4)
妄想症	n (%)	1(0.8)	0	0	1(0.4)
外傷後ストレス障害	n (%)	1(0.8)	0	0	1(0.4)
精神病性障害	n (%)	0	1(0.7)	0	1(0.4)
統合失調感情障害	n (%)	0	1(0.7)	1(0.8)	1(0.4)
自殺企図	n (%)	0	1(0.7)	1(0.8)	1(0.4)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.8.1より引用（一部改変）

表 2.7.4.7－185　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=9) n(%)	80 mg (N=6) n(%)	All MT-5199 (N=15) n(%)	Placebo (N=4) n(%)	40 mg (N=76) n(%)	80 mg (N=78) n(%)	All MT-5199 (N=154) n(%)	Placebo (N=80) n(%)
Any AESI		6 (66.7)	3 (50.0)	9 (60.0)	0 (0.0)	30 (39.5)	50 (64.1)	80 (51.9)	15 (18.8)
Somnolence	傾眠関連有害事象	3 (33.3)	2 (33.3)	5 (33.3)	0 (0.0)	13 (17.1)	22 (28.2)	35 (22.7)	2 (2.5)
Somnolence	傾眠	1 (11.1)	2 (33.3)	3 (20.0)	0 (0.0)	9 (11.8)	19 (24.4)	28 (18.2)	2 (2.5)
Malaise	倦怠感	2 (22.2)	0 (0.0)	2 (13.3)	0 (0.0)	3 (3.9)	4 (5.1)	7 (4.5)	0 (0.0)
Fatigue	疲労	0 (0.0)	1 (16.7)	1 (6.7)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.6)	7 (9.0)	12 (7.8)	6 (7.5)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (2.6)	4 (2.6)	0 (0.0)
Eczema	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (1.3)	3 (3.8)
Blister	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－185　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=9) n(%)	80 mg (N=6) n(%)	All MT-5199 (N=15) n(%)	Placebo (N=4) n(%)	40 mg (N=76) n(%)	80 mg (N=78) n(%)	All MT-5199 (N=154) n(%)	Placebo (N=80) n(%)
Parkinsonism	パーキンソニズム関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.6)	18 (23.1)	23 (14.9)	1 (1.3)
Salivary hypersecretion	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.9)	9 (11.5)	12 (7.8)	1 (1.3)
Tremor	振戦	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (6.4)	5 (3.2)	0 (0.0)
Drooling	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (1.3)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (1.3)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (1.3)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	3 (33.3)	1 (16.7)	4 (26.7)	0 (0.0)	3 (3.9)	2 (2.6)	5 (3.2)	1 (1.3)
Depression	うつ病	1 (11.1)	1 (16.7)	2 (13.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (1.3)	1 (1.3)
Depressed mood	抑うつ気分	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Suicide attempt	自殺企図	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Akathisia	アカシジア関連有害事象	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	3 (3.9)	8 (10.3)	11 (7.1)	1 (1.3)
Akathisia	アカシジア	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	3 (3.9)	5 (6.4)	8 (5.2)	1 (1.3)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (1.3)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Anxiety	不安	0 (0.0)	1 (16.7)	1 (6.7)	0 (0.0)	1 (1.3)	3 (3.8)	4 (2.6)	0 (0.0)
Anxiety	不安	0 (0.0)	1 (16.7)	1 (6.7)	0 (0.0)	1 (1.3)	3 (3.8)	4 (2.6)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－185　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=9) n(%)	80 mg (N=6) n(%)	All MT-5199 (N=15) n(%)	Placebo (N=4) n(%)	40 mg (N=76) n(%)	80 mg (N=78) n(%)	All MT-5199 (N=154) n(%)	Placebo (N=80) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	3 (33.3)	1 (16.7)	4 (26.7)	0 (0.0)	8 (10.5)	5 (6.4)	13 (8.4)	3 (3.8)
Schizophrenia	統合失調症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (9.2)	0 (0.0)	7 (4.5)	1 (1.3)
Depression	うつ病	1 (11.1)	1 (16.7)	2 (13.3)	0 (0.0)	0 (0.0)	2 (2.6)	2 (1.3)	1 (1.3)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	2 (1.3)	1 (1.3)
Depressed mood	抑うつ気分	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Suicide attempt	自殺企図	1 (11.1)	0 (0.0)	1 (6.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (1.3)	0 (0.0)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (1.3)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.6)	1 (1.3)	3 (1.9)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.6)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.6)	0 (0.0)
Hypotension	低血圧関連有害事象	0 (0.0)	1 (16.7)	1 (6.7)	0 (0.0)	1 (1.3)	3 (3.8)	4 (2.6)	2 (2.5)
Dizziness	浮動性めまい	0 (0.0)	1 (16.7)	1 (6.7)	0 (0.0)	0 (0.0)	2 (2.6)	2 (1.3)	1 (1.3)
Fall	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (1.3)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.10.1.2 より引用

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：

MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=13) n(%)	Yes MT-5199 80 mg (N=6) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=6) n(%)	Yes All MT-5199 (N=19) n(%)	No MT-5199 40 mg (N=113) n(%)	No MT-5199 80 mg (N=117) n(%)	No MT-5199 80 mg (no dose reduction) (N=78) n(%)	No All MT-5199 (N=230) n(%)
Any AESI		10 (76.9)	4 (66.7)	4 (66.7)	14 (73.7)	78 (69.0)	104 (88.9)	66 (84.6)	182 (79.1)
Somnolence	傾眠関連有害事象	3 (23.1)	3 (50.0)	3 (50.0)	6 (31.6)	29 (25.7)	37 (31.6)	19 (24.4)	66 (28.7)
Somnolence	傾眠	1 (7.7)	3 (50.0)	3 (50.0)	4 (21.1)	18 (15.9)	25 (21.4)	15 (19.2)	43 (18.7)
Malaise	倦怠感	2 (15.4)	0 (0.0)	0 (0.0)	2 (10.5)	8 (7.1)	10 (8.5)	5 (6.4)	18 (7.8)
Fatigue	疲労	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	2 (1.8)	3 (2.6)	2 (2.6)	5 (2.2)
Sedation complication	鎮静合併症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.7)	1 (0.9)	0 (0.0)	4 (1.7)
Asthenia	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.7)	1 (1.3)	2 (0.9)
Decreased activity	活動性低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Sedation	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=13) n(%)	Yes MT-5199 80 mg (N=6) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=6) n(%)	Yes All MT-5199 (N=19) n(%)	No MT-5199 40 mg (N=113) n(%)	No MT-5199 80 mg (N=117) n(%)	No MT-5199 80 mg (no dose reduction) (N=78) n(%)	No All MT-5199 (N=230) n(%)
Hypersensitivity	過敏症関連有害事象	1 (7.7)	1 (16.7)	1 (16.7)	2 (10.5)	22 (19.5)	17 (14.5)	13 (16.7)	39 (17.0)
Eczema	湿疹	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.3)	3 (2.7)	3 (2.6)	2 (2.6)	6 (2.6)
Stomatitis	口内炎	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	4 (3.5)	2 (1.7)	2 (2.6)	6 (2.6)
Urticaria	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.7)	2 (1.7)	1 (1.3)	5 (2.2)
Dermatitis contact	接触皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.7)	1 (1.3)	4 (1.7)
Pruritus	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.7)	2 (2.6)	4 (1.7)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (1.7)	2 (2.6)	3 (1.3)
Conjunctivitis	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)	1 (1.3)	2 (0.9)
Dermatitis	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (0.9)
Blister	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Conjunctival oedema	結膜浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Dermatitis atopic	アトピー性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Erythema	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
Rash erythematous	紅斑性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Rhinitis allergic	アレルギー性鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Skin exfoliation	皮膚剥脱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Swelling face	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：

MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=13) n(%)	Yes MT-5199 80 mg (N=6) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=6) n(%)	Yes All MT-5199 (N=19) n(%)	No MT-5199 40 mg (N=113) n(%)	No MT-5199 80 mg (N=117) n(%)	No MT-5199 80 mg (no dose reduction) (N=78) n(%)	No All MT-5199 (N=230) n(%)
Parkinsonism	パーキンソニズム関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	24 (21.2)	50 (42.7)	25 (32.1)	74 (32.2)
Salivary hypersecretion	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (8.0)	21 (17.9)	10 (12.8)	30 (13.0)
Tremor	振戦	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.4)	16 (13.7)	9 (11.5)	21 (9.1)
Parkinsonism	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.4)	3 (2.6)	2 (2.6)	8 (3.5)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	4 (3.4)	2 (2.6)	6 (2.6)
Drooling	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	3 (2.6)	2 (2.6)	5 (2.2)
Bradykinesia	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (1.7)	0 (0.0)	3 (1.3)
Gait disturbance	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
Muscle rigidity	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Musculoskeletal stiffness	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Reduced facial expression	表情減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
Propulsive gait	突進性歩行	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：

MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=13) n(%)	Yes MT-5199 80 mg (N=6) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=6) n(%)	Yes All MT-5199 (N=19) n(%)	No MT-5199 40 mg (N=113) n(%)	No MT-5199 80 mg (N=117) n(%)	No MT-5199 80 mg (no dose reduction) (N=78) n(%)	No All MT-5199 (N=230) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	5 (38.5)	3 (50.0)	3 (50.0)	8 (42.1)	14 (12.4)	16 (13.7)	12 (15.4)	30 (13.0)
Depression	うつ病	2 (15.4)	1 (16.7)	1 (16.7)	3 (15.8)	4 (3.5)	9 (7.7)	8 (10.3)	13 (5.7)
Suicidal ideation	自殺念慮	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	6 (5.3)	2 (1.7)	1 (1.3)	8 (3.5)
Suicide attempt	自殺企図	2 (15.4)	0 (0.0)	0 (0.0)	2 (10.5)	1 (0.9)	1 (0.9)	1 (1.3)	2 (0.9)
Middle insomnia	中期不眠症	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.3)	1 (0.9)	1 (0.9)	1 (1.3)	2 (0.9)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)	0 (0.0)	2 (0.9)
Alcohol abuse	アルコール乱用	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
Depressed mood	抑うつ気分	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Intentional overdose	企図的過量投与	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Intentional self-injury	故意の自傷行為	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac events	心血管系及びQT間隔延長関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.5)	1 (0.9)	1 (1.3)	5 (2.2)
Death	死亡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)	1 (1.3)	2 (0.9)
Long QT syndrome	ＱＴ延長症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Loss of consciousness	意識消失	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Hyperprolactinemia	高プロラクチン血症関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)	1 (1.3)	2 (0.9)
Galactorrhoea	乳汁漏出症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=13) n(%)	Yes MT-5199 80 mg (N=6) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=6) n(%)	Yes All MT-5199 (N=19) n(%)	No MT-5199 40 mg (N=113) n(%)	No MT-5199 80 mg (N=117) n(%)	No MT-5199 80 mg (no dose reduction) (N=78) n(%)	No All MT-5199 (N=230) n(%)
Menstruation irregular	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=13) n(%)	Yes MT-5199 80 mg (N=6) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=6) n(%)	Yes All MT-5199 (N=19) n(%)	No MT-5199 40 mg (N=113) n(%)	No MT-5199 80 mg (N=117) n(%)	No MT-5199 80 mg (no dose reduction) (N=78) n(%)	No All MT-5199 (N=230) n(%)
Akathisia	アカシジア関連有害事象	2 (15.4)	1 (16.7)	1 (16.7)	3 (15.8)	10 (8.8)	18 (15.4)	10 (12.8)	28 (12.2)
Akathisia	アカシジア	2 (15.4)	1 (16.7)	1 (16.7)	3 (15.8)	6 (5.3)	11 (9.4)	7 (9.0)	17 (7.4)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	4 (3.4)	2 (2.6)	6 (2.6)
Restlessness	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.7)	1 (1.3)	4 (1.7)
Movement disorder	運動障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
Anxiety	不安	1 (7.7)	1 (16.7)	1 (16.7)	2 (10.5)	4 (3.5)	8 (6.8)	6 (7.7)	12 (5.2)
Anxiety	不安	1 (7.7)	1 (16.7)	1 (16.7)	2 (10.5)	4 (3.5)	8 (6.8)	6 (7.7)	12 (5.2)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	6 (46.2)	2 (33.3)	2 (33.3)	8 (42.1)	29 (25.7)	27 (23.1)	17 (21.8)	56 (24.3)
Schizophrenia	統合失調症	2 (15.4)	1 (16.7)	1 (16.7)	3 (15.8)	19 (16.8)	12 (10.3)	4 (5.1)	31 (13.5)
Depression	うつ病	2 (15.4)	1 (16.7)	1 (16.7)	3 (15.8)	4 (3.5)	9 (7.7)	8 (10.3)	13 (5.7)
Suicidal ideation	自殺念慮	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	6 (5.3)	2 (1.7)	1 (1.3)	8 (3.5)
Suicide attempt	自殺企図	2 (15.4)	0 (0.0)	0 (0.0)	2 (10.5)	1 (0.9)	1 (0.9)	1 (1.3)	2 (0.9)
Bipolar disorder	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	2 (1.7)	2 (2.6)	4 (1.7)
Depressed mood	抑うつ気分	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Intentional self-injury	故意の自傷行為	1 (7.7)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (1.3)	1 (0.4)
Dysphagia	嚥下障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.4)	5 (4.3)	3 (3.8)	10 (4.3)
Dysphagia	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.4)	5 (4.3)	3 (3.8)	10 (4.3)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－186　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：
MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=13) n(%)	80 mg (N=6) n(%)	80 mg (no dose reduction) (N=6) n(%)	All MT-5199 (N=19) n(%)	40 mg (N=113) n(%)	80 mg (N=117) n(%)	80 mg (no dose reduction) (N=78) n(%)	All MT-5199 (N=230) n(%)
Hepatotoxicity	肝障害関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.4)	3 (2.6)	2 (2.6)	8 (3.5)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)	0 (0.0)	2 (0.9)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.7)	2 (2.6)	2 (0.9)
Liver function test increased	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	0 (0.0)	0 (0.0)	2 (0.9)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Hypotension	低血圧関連有害事象	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	7 (6.2)	12 (10.3)	10 (12.8)	19 (8.3)
Dizziness	浮動性めまい	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	4 (3.5)	6 (5.1)	5 (6.4)	10 (4.3)
Fall	転倒	0 (0.0)	1 (16.7)	1 (16.7)	1 (5.3)	2 (1.8)	6 (5.1)	5 (6.4)	8 (3.5)
Hypotension	低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.7)	2 (2.6)	2 (0.9)
Blood pressure decreased	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)
Cognitive disorder	認知機能低下関連有害事象	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.8)	1 (0.9)	0 (0.0)	3 (1.3)
Disturbance in attention	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.9)	0 (0.0)	2 (0.9)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.10.2.2 より引用

表 2.7.4.7－187　ベースライン前 3 ケ月以内の自殺念慮又は自殺企図の有無ごとの有害事象の要約：
プラセボ対照二重盲検期・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Yes (N=12) n (%)	No (N=242) n (%)	Yes (N=5) n (%)	No (N=173) n (%)	Yes (N=15) n (%)	No (N=412) n (%)
At Least 1 AE	9 (75.0)	102 (42.1)	3 (60.0)	68 (39.3)	10 (66.7)	249 (60.4)
At Least 1 SAE	0	12 (5.0)	0	6 (3.5)	3 (20.0)	51 (12.4)
At Least 1 AE Leading to Study Discontinuation	0	10 (4.1)	0	8 (4.6)	3 (20.0)	55 (13.3)
At Least 1 AE Leading to Dose Reduction	0	7 (2.9)	0	4 (2.3)	0	26 (6.3)

AE: adverse event, SAE: serious adverse event
Note: Suicidality was measured by the Columbia-Suicide Severity Rating Scale. If a subject experienced more than 1 event in a given category, that subject is counted once for that category.

5.3.5.3－2 Table 105 より引用（一部改変）

表2.7.4.7－188　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	40 mg (N=8)	80 mg (N=2)	100 mg (N=1)	All NBI-98854 (N=12)	Placebo (N=5)
Any Adverse Event of Special Interest	n (%)	0	5(62.5)	0	1(100.0)	6(50.0)	1(20.0)
アカシジア関連有害事象	n (%)	0	1(12.5)	0	0	1(8.3)	0
アカシジア	n (%)	0	1(12.5)	0	0	1(8.3)	0
うつ病及び自殺関連有害事象	n (%)	0	2(25.0)	0	0	2(16.7)	1(20.0)
自殺念慮	n (%)	0	2(25.0)	0	0	2(16.7)	1(20.0)
嚥下障害関連有害事象	n (%)	0	1(12.5)	0	0	1(8.3)	0
嚥下障害	n (%)	0	1(12.5)	0	0	1(8.3)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(12.5)	0	1(100.0)	2(16.7)	0
疲労	n (%)	0	1(12.5)	0	1(100.0)	2(16.7)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	3(37.5)	0	0	3(25.0)	0
傾眠	n (%)	0	3(37.5)	0	0	3(25.0)	0
基礎疾患の悪化に関連する有害事象	n (%)	0	2(25.0)	0	0	2(16.7)	1(20.0)
自殺念慮	n (%)	0	2(25.0)	0	0	2(16.7)	1(20.0)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－188　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	NBI-98854 Dose[b] 40 mg (N=102)	NBI-98854 Dose[b] 80 mg (N=110)	NBI-98854 Dose[b] 100 mg (N=26)	All NBI-98854 (N=242)	Placebo (N=173)
Any Adverse Event of Special Interest	n (%)	1(25.0)	23(22.5)	23(20.9)	2(7.7)	49(20.2)	23(13.3)
アカシジア関連有害事象	n (%)	0	2(2.0)	3(2.7)	0	5(2.1)	1(0.6)
アカシジア	n (%)	0	2(2.0)	3(2.7)	0	5(2.1)	1(0.6)
不安	n (%)	0	1(1.0)	2(1.8)	0	3(1.2)	0
不安	n (%)	0	1(1.0)	2(1.8)	0	3(1.2)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(1.0)	1(0.9)	1(3.8)	3(1.2)	1(0.6)
胸痛	n (%)	0	1(1.0)	0	0	1(0.4)	0
突然死	n (%)	0	0	1(0.9)	0	1(0.4)	0
失神	n (%)	0	0	0	1(3.8)	1(0.4)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.6)
うつ病及び自殺関連有害事象	n (%)	1(25.0)	3(2.9)	4(3.6)	0	8(3.3)	5(2.9)
自殺念慮	n (%)	0	2(2.0)	1(0.9)	0	3(1.2)	3(1.7)
うつ病	n (%)	0	0	2(1.8)	0	2(0.8)	2(1.2)
抑うつ気分	n (%)	1(25.0)	0	0	0	1(0.4)	0
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
自殺企図	n (%)	0	0	1(0.9)	0	1(0.4)	0
嚥下障害関連有害事象	n (%)	0	1(1.0)	0	0	1(0.4)	0
嚥下障害	n (%)	0	1(1.0)	0	0	1(0.4)	0

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－188　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=102)	80 mg (N=110)	100 mg (N=26)	All NBI-98854 (N=242)	Placebo (N=173)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	4(3.9)	3(2.7)	1(3.8)	8(3.3)	3(1.7)
疲労	n (%)	0	4(3.9)	3(2.7)	1(3.8)	8(3.3)	3(1.7)
肝障害関連有害事象	n (%)	0	0	1(0.9)	0	1(0.4)	0
急性肝炎	n (%)	0	0	1(0.9)	0	1(0.4)	0
低血圧関連有害事象	n (%)	0	4(3.9)	2(1.8)	1(3.8)	7(2.9)	4(2.3)
転倒・転落	n (%)	0	2(2.0)	1(0.9)	0	3(1.2)	0
浮動性めまい	n (%)	0	2(2.0)	0	0	2(0.8)	4(2.3)
低血圧	n (%)	0	0	1(0.9)	0	1(0.4)	0
失神	n (%)	0	0	0	1(3.8)	1(0.4)	0
パーキンソニズム関連有害事象	n (%)	0	0	2(1.8)	0	2(0.8)	0
振戦	n (%)	0	0	2(1.8)	0	2(0.8)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	7(6.9)	6(5.5)	1(3.8)	14(5.8)	5(2.9)
傾眠	n (%)	0	6(5.9)	4(3.6)	1(3.8)	11(4.5)	4(2.3)
鎮静	n (%)	0	1(1.0)	2(1.8)	0	3(1.2)	1(0.6)
基礎疾患の悪化に関連する有害事象	n (%)	1(25.0)	8(7.8)	6(5.5)	0	15(6.2)	12(6.9)
自殺念慮	n (%)	0	2(2.0)	1(0.9)	0	3(1.2)	3(1.7)
うつ病	n (%)	0	0	2(1.8)	0	2(0.8)	2(1.2)
双極１型障害	n (%)	0	1(1.0)	0	0	1(0.4)	0

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－188　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=102)	80 mg (N=110)	100 mg (N=26)	All NBI-98854 (N=242)	Placebo (N=173)
抑うつ気分	n (%)	1(25.0)	0	0	0	1(0.4)	0
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
敵意	n (%)	0	1(1.0)	0	0	1(0.4)	0
軽躁	n (%)	0	1(1.0)	0	0	1(0.4)	0
易刺激性	n (%)	0	1(1.0)	0	0	1(0.4)	2(1.2)
妄想症	n (%)	0	1(1.0)	0	0	1(0.4)	0
精神病性障害	n (%)	0	0	1(0.9)	0	1(0.4)	2(1.2)
統合失調感情障害	n (%)	0	0	1(0.9)	0	1(0.4)	1(0.6)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.4)	1(0.6)
自殺企図	n (%)	0	0	1(0.9)	0	1(0.4)	0
躁病	n (%)	0	0	0	0	0	1(0.6)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.6)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.8.2より引用（一部改変）

表2.7.4.7－189　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=10)	80 mg (N=5)	80 mg Only[c] (N=5)	All NBI-98854 (N=15)
Any Adverse Event of Special Interest	n (%)	6(60.0)	3(60.0)	3(60.0)	9(60.0)
アカシジア関連有害事象	n (%)	1(10.0)	0	0	1(6.7)
アカシジア	n (%)	1(10.0)	0	0	1(6.7)
心血管系及びQT間隔延長関連有害事象	n (%)	2(20.0)	0	0	2(13.3)
失神	n (%)	2(20.0)	0	0	2(13.3)
胸痛	n (%)	1(10.0)	0	0	1(6.7)
うつ病及び自殺関連有害事象	n (%)	3(30.0)	2(40.0)	2(40.0)	5(33.3)
自殺念慮	n (%)	3(30.0)	2(40.0)	2(40.0)	5(33.3)
うつ病	n (%)	1(10.0)	0	0	1(6.7)
嚥下障害関連有害事象	n (%)	1(10.0)	0	0	1(6.7)
嚥下障害	n (%)	1(10.0)	0	0	1(6.7)
食道食物嵌入	n (%)	1(10.0)	0	0	1(6.7)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	2(20.0)	1(20.0)	1(20.0)	3(20.0)
疲労	n (%)	2(20.0)	1(20.0)	1(20.0)	3(20.0)
無力症	n (%)	1(10.0)	0	0	1(6.7)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－189　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=10)	80 mg (N=5)	80 mg Only[c] (N=5)	All NBI-98854 (N=15)
低血圧関連有害事象	n (%)	2(20.0)	0	0	2(13.3)
失神	n (%)	2(20.0)	0	0	2(13.3)
浮動性めまい	n (%)	1(10.0)	0	0	1(6.7)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	3(30.0)	1(20.0)	1(20.0)	4(26.7)
傾眠	n (%)	3(30.0)	1(20.0)	1(20.0)	4(26.7)
基礎疾患の悪化に関連する有害事象	n (%)	3(30.0)	2(40.0)	2(40.0)	5(33.3)
自殺念慮	n (%)	3(30.0)	2(40.0)	2(40.0)	5(33.3)
うつ病	n (%)	1(10.0)	0	0	1(6.7)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－189　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=187)	80 mg (N=225)	80 mg Only[c] (N=209)	All NBI-98854 (N=412)
Any Adverse Event of Special Interest	n (%)	64(34.2)	68(30.2)	53(25.4)	132(32.0)
アカシジア関連有害事象	n (%)	6(3.2)	1(0.4)	1(0.5)	7(1.7)
アカシジア	n (%)	6(3.2)	1(0.4)	1(0.5)	7(1.7)
不安	n (%)	6(3.2)	7(3.1)	3(1.4)	13(3.2)
不安	n (%)	6(3.2)	7(3.1)	3(1.4)	13(3.2)
心血管系及びQT間隔延長関連有害事象	n (%)	4(2.1)	8(3.6)	7(3.3)	12(2.9)
胸痛	n (%)	2(1.1)	3(1.3)	3(1.4)	5(1.2)
失神	n (%)	2(1.1)	2(0.9)	1(0.5)	4(1.0)
心不全	n (%)	0	1(0.4)	1(0.5)	1(0.2)
心電図QT延長	n (%)	0	1(0.4)	1(0.5)	1(0.2)
突然死	n (%)	0	1(0.4)	1(0.5)	1(0.2)
うつ病及び自殺関連有害事象	n (%)	16(8.6)	16(7.1)	15(7.2)	32(7.8)
自殺念慮	n (%)	6(3.2)	8(3.6)	8(3.8)	14(3.4)
うつ病	n (%)	8(4.3)	5(2.2)	4(1.9)	13(3.2)
抑うつ気分	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)
抑うつ症状	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(0.9)	2(1.0)	2(0.5)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－189　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=187)	80 mg (N=225)	80 mg Only[c] (N=209)	All NBI-98854 (N=412)
自殺行為	n (%)	0	1(0.4)	1(0.5)	1(0.2)
嚥下障害関連有害事象	n (%)	2(1.1)	1(0.4)	1(0.5)	3(0.7)
嚥下障害	n (%)	2(1.1)	1(0.4)	1(0.5)	3(0.7)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	11(5.9)	13(5.8)	8(3.8)	24(5.8)
疲労	n (%)	11(5.9)	7(3.1)	7(3.3)	18(4.4)
無力症	n (%)	0	4(1.8)	0	4(1.0)
嗜眠	n (%)	0	1(0.4)	0	1(0.2)
倦怠感	n (%)	0	1(0.4)	1(0.5)	1(0.2)
肝障害関連有害事象	n (%)	0	2(0.9)	2(1.0)	2(0.5)
肝不全	n (%)	0	1(0.4)	1(0.5)	1(0.2)
急性肝炎	n (%)	0	1(0.4)	1(0.5)	1(0.2)
高プロラクチン血症関連有害事象	n (%)	3(1.6)	1(0.4)	0	4(1.0)
血中プロラクチン増加	n (%)	2(1.1)	1(0.4)	0	3(0.7)
乳汁漏出症	n (%)	1(0.5)	0	0	1(0.2)
低血圧関連有害事象	n (%)	12(6.4)	16(7.1)	15(7.2)	28(6.8)
浮動性めまい	n (%)	5(2.7)	10(4.4)	10(4.8)	15(3.6)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－189　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=187)	80 mg (N=225)	80 mg Only[c] (N=209)	All NBI-98854 (N=412)
転倒・転落	n (%)	5(2.7)	5(2.2)	4(1.9)	10(2.4)
失神	n (%)	2(1.1)	2(0.9)	1(0.5)	4(1.0)
低血圧	n (%)	0	1(0.4)	1(0.5)	1(0.2)
起立性低血圧	n (%)	1(0.5)	0	0	1(0.2)
パーキンソニズム関連有害事象	n (%)	5(2.7)	5(2.2)	2(1.0)	10(2.4)
振戦	n (%)	4(2.1)	3(1.3)	1(0.5)	7(1.7)
パーキンソニズム	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)
歯車様固縮	n (%)	0	1(0.4)	1(0.5)	1(0.2)
筋固縮	n (%)	0	1(0.4)	0	1(0.2)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	14(7.5)	12(5.3)	8(3.8)	26(6.3)
傾眠	n (%)	12(6.4)	8(3.6)	5(2.4)	20(4.9)
鎮静	n (%)	2(1.1)	4(1.8)	3(1.4)	6(1.5)
基礎疾患の悪化に関連する有害事象	n (%)	24(12.8)	23(10.2)	21(10.0)	47(11.4)
自殺念慮	n (%)	6(3.2)	8(3.6)	8(3.8)	14(3.4)
うつ病	n (%)	8(4.3)	5(2.2)	4(1.9)	13(3.2)
統合失調症	n (%)	4(2.1)	4(1.8)	4(1.9)	8(1.9)
易刺激性	n (%)	1(0.5)	2(0.9)	2(1.0)	3(0.7)
抑うつ気分	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－189　ベースライン前3ケ月以内の自殺念慮又は自殺企図の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Suicidality[a](Suicidal Behavior and/or Ideation) Within 3 Months Prior to Screening: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=187)	80 mg (N=225)	80 mg Only[c] (N=209)	All NBI-98854 (N=412)
抑うつ症状	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)
躁病	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)
妄想症	n (%)	2(1.1)	0	0	2(0.5)
精神病性障害	n (%)	1(0.5)	1(0.4)	0	2(0.5)
統合失調感情障害	n (%)	1(0.5)	1(0.4)	1(0.5)	2(0.5)
自殺企図	n (%)	0	2(0.9)	2(1.0)	2(0.5)
双極１型障害	n (%)	1(0.5)	0	0	1(0.2)
敵意	n (%)	1(0.5)	0	0	1(0.2)
軽躁	n (%)	1(0.5)	0	0	1(0.2)
気分動揺	n (%)	0	1(0.4)	0	1(0.2)
外傷後ストレス障害	n (%)	1(0.5)	0	0	1(0.2)
自殺行為	n (%)	0	1(0.4)	1(0.5)	1(0.2)

AESI = Adverse Event of Special Interest.
[a] As measured by the Columbia-Suicide Severity Rating Scale (C-SSRS).
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.8.2より引用（一部改変）

表 2.7.4.7－190　MT-5199 未変化体の曝露量区分別の主要な人口統計学的特性：海外臨床試験

	Statistics	MT-5199 Cmax Upper 25% (N=49)	MT-5199 Cmax Lower 75% (N=146)	MT-5199 AUC Upper 25% (N=49)	MT-5199 AUC Lower 75% (N=146)
Age (years)	n	49	146	49	146
	Mean	59.0	55.0	56.7	55.8
	SD	10.5	9.1	11.3	8.9
	Median	59.0	55.0	58.0	55.0
	(Min, Max)	(28, 77)	(32, 83)	(28, 77)	(32, 83)
<65	n(%)	35 (71.4)	127 (87.0)	37 (75.5)	125 (85.6)
>=65	n(%)	14 (28.6)	19 (13.0)	12 (24.5)	21 (14.4)
Gender					
Male	n(%)	24 (49.0)	89 (61.0)	26 (53.1)	87 (59.6)
Female	n(%)	25 (51.0)	57 (39.0)	23 (46.9)	59 (40.4)
Race					
American Indian or Alaska Native	n(%)	0 (0.0)	2 (1.4)	0 (0.0)	2 (1.4)
Asian	n(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Black or African American	n(%)	16 (32.7)	54 (37.0)	19 (38.8)	51 (34.9)
White	n(%)	31 (63.3)	86 (58.9)	29 (59.2)	88 (60.3)
Native Hawaiian or Other Pacific Islander	n(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Multiple	n(%)	1 (2.0)	2 (1.4)	1 (2.0)	2 (1.4)
Other	n(%)	1 (2.0)	2 (1.4)	0 (0.0)	3 (2.1)
Ethnicity					
Hispanic or Latino	n(%)	17 (34.7)	30 (20.5)	9 (18.4)	38 (26.0)
Not Hispanic or Latino	n(%)	32 (65.3)	116 (79.5)	40 (81.6)	108 (74.0)
Body Mass Index (kg/m2)	n	49	146	49	146
	Mean	26.4	29.1	25.7	29.3
	SD	5.3	5.8	4.9	5.8
	Median	26.6	28.1	25.6	28.3
	(Min, Max)	(17, 38)	(19, 47)	(17, 38)	(18, 47)
<18.5	n(%)	3 (6.1)	0 (0.0)	2 (4.1)	1 (0.7)
18.5 to <25	n(%)	16 (32.7)	39 (26.7)	20 (40.8)	35 (24.0)
25 to <30	n(%)	17 (34.7)	43 (29.5)	16 (32.7)	44 (30.1)
>=30	n(%)	13 (26.5)	64 (43.8)	11 (22.4)	66 (45.2)
CYP2D6 Genotype					
Poor Metabolizer	n(%)	2 (4.1)	10 (6.8)	2 (4.1)	10 (6.8)
Ultra Rapid	n(%)	0 (0.0)	6 (4.1)	0 (0.0)	6 (4.1)
Extensive	n(%)	33 (67.3)	75 (51.4)	31 (63.3)	77 (52.7)
Intermediate	n(%)	13 (26.5)	49 (33.6)	15 (30.6)	47 (32.2)
Intermediate or Extensive	n(%)	1 (2.0)	2 (1.4)	1 (2.0)	2 (1.4)
Extensive or Ultra Rapid	n(%)	0 (0.0)	4 (2.7)	0 (0.0)	4 (2.7)

Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.

表 2.7.4.7－190　MT-5199 未変化体の曝露量区分別の主要な人口統計学的特性：海外臨床試験（続き）

	Statistics	MT-5199 Cmax Upper 25% (N=49)	MT-5199 Cmax Lower 75% (N=146)	MT-5199 AUC Upper 25% (N=49)	MT-5199 AUC Lower 75% (N=146)
Hepatic Abnormality					
Yes	n(%)	6 (12.2)	16 (11.0)	6 (12.2)	16 (11.0)
No	n(%)	43 (87.8)	130 (89.0)	43 (87.8)	130 (89.0)

Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.

5.3.5.3－5 Table 1.2.3.1.1 より引用

表 2.7.4.7－191　MT-5199 未変化体の曝露量区分別のベースライン疾患特性：海外臨床試験

	Statistics	MT-5199 Cmax Upper 25% (N=49)	MT-5199 Cmax Lower 75% (N=146)	MT-5199 AUC Upper 25% (N=49)	MT-5199 AUC Lower 75% (N=146)
Age at Tardive Dyskinesia Diagnosis (years)	n	38	116	40	114
	Mean	51.4	46.4	49.3	47.0
	SD	12.1	10.9	13.0	10.8
	Median	52.5	46.5	51.5	48.0
	(Min, Max)	(22, 73)	(17, 69)	(22, 73)	(17, 67)
Psychiatric Diagnosis Group					
Schizophrenia or Schizoaffective Disorder	n(%)	35 (71.4)	104 (71.2)	33 (67.3)	106 (72.6)
Mood Disorder	n(%)	14 (28.6)	42 (28.8)	16 (32.7)	40 (27.4)
Age at Schizophrenia or Schizoaffective Disorder (years)	n	28	96	27	97
	Mean	35.1	28.9	32.0	29.8
	SD	14.5	11.6	13.5	12.3
	Median	31.0	25.5	29.0	27.0
	(Min, Max)	(17, 68)	(9, 66)	(9, 68)	(10, 66)
Age at Mood Disorder (years)	n	13	37	14	36
	Mean	42.1	33.5	39.3	34.4
	SD	11.7	13.8	12.5	14.0
	Median	44.0	32.0	38.5	35.5
	(Min, Max)	(26, 60)	(12, 56)	(21, 60)	(12, 56)
Use of Antipsychotic Medication at Baseline					
Yes	n(%)	40 (81.6)	121 (82.9)	38 (77.6)	123 (84.2)
No	n(%)	9 (18.4)	25 (17.1)	11 (22.4)	23 (15.8)
Atypical vs Typical Antipsychotic Medication					
Atypical only	n(%)	33 (67.3)	91 (62.3)	33 (67.3)	91 (62.3)
Typical or both Typical and Atypical	n(%)	7 (14.3)	30 (20.5)	5 (10.2)	32 (21.9)
Suicidality During Lifetime					
Yes	n(%)	18 (36.7)	66 (45.2)	19 (38.8)	65 (44.5)
No	n(%)	31 (63.3)	80 (54.8)	30 (61.2)	81 (55.5)
Suicidality Within 3 Months Prior to Screening					
Yes	n(%)	0 (0.0)	10 (6.8)	1 (2.0)	9 (6.2)
No	n(%)	49 (100.0)	136 (93.2)	48 (98.0)	137 (93.8)

5.3.5.3－5 Table 1.2.3.2.1 より引用

表 2.7.4.7－192　NBI-98782 の曝露量区分別の主要な人口統計学的特性：海外臨床試験

	Statistics	NBI-98782 Cmax Upper 25% (N=50)	NBI-98782 Cmax Lower 75% (N=147)	NBI-98782 AUC Upper 25% (N=50)	NBI-98782 AUC Lower 75% (N=147)
Age (years)	n	50	147	50	147
	Mean	58.6	55.0	58.5	55.1
	SD	10.2	9.2	10.6	9.1
	Median	59.5	55.0	59.5	55.0
	(Min, Max)	(28, 83)	(32, 78)	(28, 83)	(32, 78)
<65	n(%)	39 (78.0)	125 (85.0)	39 (78.0)	125 (85.0)
>=65	n(%)	11 (22.0)	22 (15.0)	11 (22.0)	22 (15.0)
Gender					
Male	n(%)	21 (42.0)	93 (63.3)	21 (42.0)	93 (63.3)
Female	n(%)	29 (58.0)	54 (36.7)	29 (58.0)	54 (36.7)
Race					
American Indian or Alaska Native	n(%)	0 (0.0)	2 (1.4)	0 (0.0)	2 (1.4)
Asian	n(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Black or African American	n(%)	15 (30.0)	56 (38.1)	14 (28.0)	57 (38.8)
White	n(%)	33 (66.0)	85 (57.8)	35 (70.0)	83 (56.5)
Native Hawaiian or Other Pacific Islander	n(%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Multiple	n(%)	1 (2.0)	2 (1.4)	1 (2.0)	2 (1.4)
Other	n(%)	1 (2.0)	2 (1.4)	0 (0.0)	3 (2.0)
Ethnicity					
Hispanic or Latino	n(%)	11 (22.0)	37 (25.2)	12 (24.0)	36 (24.5)
Not Hispanic or Latino	n(%)	39 (78.0)	110 (74.8)	38 (76.0)	111 (75.5)
Body Mass Index (kg/m2)	n	50	147	50	147
	Mean	27.6	28.7	28.3	28.5
	SD	5.8	5.8	5.9	5.8
	Median	26.8	28.0	27.4	27.6
	(Min, Max)	(17, 47)	(18, 43)	(17, 47)	(18, 43)
<18.5	n(%)	2 (4.0)	1 (0.7)	2 (4.0)	1 (0.7)
18.5 to <25	n(%)	12 (24.0)	43 (29.3)	10 (20.0)	45 (30.6)
25 to <30	n(%)	19 (38.0)	42 (28.6)	18 (36.0)	43 (29.3)
>=30	n(%)	17 (34.0)	61 (41.5)	20 (40.0)	58 (39.5)
CYP2D6 Genotype					
Poor Metabolizer	n(%)	6 (12.0)	6 (4.1)	6 (12.0)	6 (4.1)
Ultra Rapid	n(%)	0 (0.0)	6 (4.1)	0 (0.0)	6 (4.1)
Extensive	n(%)	25 (50.0)	83 (56.5)	24 (48.0)	84 (57.1)
Intermediate	n(%)	18 (36.0)	46 (31.3)	19 (38.0)	45 (30.6)
Intermediate or Extensive	n(%)	1 (2.0)	2 (1.4)	1 (2.0)	2 (1.4)
Extensive or Ultra Rapid	n(%)	0 (0.0)	4 (2.7)	0 (0.0)	4 (2.7)

Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.

表 2.7.4.7－192　NBI-98782 の曝露量区分別の主要な人口統計学的特性：海外臨床試験（続き）

	Statistics	NBI-98782 Cmax Upper 25% (N=50)	NBI-98782 Cmax Lower 75% (N=147)	NBI-98782 AUC Upper 25% (N=50)	NBI-98782 AUC Lower 75% (N=147)
Hepatic Abnormality					
Yes	n(%)	9 (18.0)	13 (8.8)	7 (14.0)	15 (10.2)
No	n(%)	41 (82.0)	134 (91.2)	43 (86.0)	132 (89.8)

Hepatic abnormality is defined as baseline GGT, ALT, or AST > ULN.

5.3.5.3－5 Table 1.2.3.1.2 より引用

表 2.7.4.7－193　NBI-98782 の曝露量区分別のベースライン疾患特性：海外臨床試験

	Statistics	NBI-98782 Cmax Upper 25% (N=50)	NBI-98782 Cmax Lower 75% (N=147)	NBI-98782 AUC Upper 25% (N=50)	NBI-98782 AUC Lower 75% (N=147)
Age at Tardive Dyskinesia Diagnosis (years)	n	40	114	43	111
	Mean	51.4	46.3	50.7	46.4
	SD	12.8	10.6	12.7	10.6
	Median	53.0	46.5	53.0	47.0
	(Min, Max)	(22, 73)	(17, 67)	(22, 73)	(17, 67)
Psychiatric Diagnosis Group					
Schizophrenia or Schizoaffective Disorder	n(%)	31 (62.0)	109 (74.1)	33 (66.0)	107 (72.8)
Mood Disorder	n(%)	19 (38.0)	38 (25.9)	17 (34.0)	40 (27.2)
Age at Schizophrenia or Schizoaffective Disorder (years)	n	25	100	28	97
	Mean	31.5	29.9	31.2	29.9
	SD	14.1	12.2	13.3	12.4
	Median	30.0	26.5	28.0	27.0
	(Min, Max)	(9, 68)	(10, 66)	(9, 68)	(10, 66)
Age at Mood Disorder (years)	n	17	34	15	36
	Mean	41.5	33.0	41.3	33.6
	SD	12.8	13.2	13.7	13.1
	Median	42.0	32.0	42.0	33.5
	(Min, Max)	(19, 60)	(12, 56)	(19, 60)	(12, 56)
Use of Antipsychotic Medication at Baseline					
Yes	n(%)	35 (70.0)	128 (87.1)	34 (68.0)	129 (87.8)
No	n(%)	15 (30.0)	19 (12.9)	16 (32.0)	18 (12.2)
Atypical vs Typical Antipsychotic Medication					
Atypical only	n(%)	31 (62.0)	95 (64.6)	30 (60.0)	96 (65.3)
Typical or both Typical and Atypical	n(%)	4 (8.0)	33 (22.4)	4 (8.0)	33 (22.4)
Suicidality During Lifetime					
Yes	n(%)	19 (38.0)	65 (44.2)	19 (38.0)	65 (44.2)
No	n(%)	31 (62.0)	82 (55.8)	31 (62.0)	82 (55.8)
Suicidality Within 3 Months Prior to Screening					
Yes	n(%)	2 (4.0)	8 (5.4)	2 (4.0)	8 (5.4)
No	n(%)	48 (96.0)	139 (94.6)	48 (96.0)	139 (94.6)

5.3.5.3－5 Table 1.2.3.2.2 より引用

表 2.7.4.7－194　MT-5199 未変化体の曝露量区分別の注目すべき有害事象の発現割合：海外臨床試験

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	MT-5199 Cmax Upper 25% (N=49)	MT-5199 Cmax Lower 75% (N=146)	MT-5199 AUC Upper 25% (N=49)	MT-5199 AUC Lower 75% (N=146)
Any AESI		6 (12.2)	26 (17.8)	10 (20.4)	22 (15.1)
Sedation/Somnolence	傾眠関連有害事象	3 (6.1)	20 (13.7)	6 (12.2)	17 (11.6)
Sedation	鎮静	1 (2.0)	3 (2.1)	3 (6.1)	1 (0.7)
Somnolence	傾眠	2 (4.1)	17 (11.6)	3 (6.1)	16 (11.0)
Parkinsonism	パーキンソニズム関連有害事象	3 (6.1)	1 (0.7)	2 (4.1)	2 (1.4)
Muscle rigidity	筋固縮	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.7)
Parkinsonism	パーキンソニズム	1 (2.0)	0 (0.0)	0 (0.0)	1 (0.7)
Tremor	振戦	2 (4.1)	0 (0.0)	2 (4.1)	0 (0.0)
Akathisia	アカシジア関連有害事象	0 (0.0)	5 (3.4)	2 (4.1)	3 (2.1)
Akathisia	アカシジア	0 (0.0)	5 (3.4)	2 (4.1)	3 (2.1)

MedDRA Version 12.0.

5.3.5.3－5 Table 3.4.1 より引用

表 2.7.4.7－195　NBI-98782 の曝露量区分別の注目すべき有害事象の発現割合：海外臨床試験

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	NBI-98782 Cmax Upper 25% (N=50)	NBI-98782 Cmax Lower 75% (N=147)	NBI-98782 AUC Upper 25% (N=50)	NBI-98782 AUC Lower 75% (N=147)
Any AESI		10 (20.0)	22 (15.0)	11 (22.0)	21 (14.3)
Sedation/Somnolence	傾眠関連有害事象	7 (14.0)	16 (10.9)	7 (14.0)	16 (10.9)
Sedation	鎮静	3 (6.0)	1 (0.7)	3 (6.0)	1 (0.7)
Somnolence	傾眠	4 (8.0)	15 (10.2)	4 (8.0)	15 (10.2)
Parkinsonism	パーキンソニズム関連有害事象	3 (6.0)	1 (0.7)	3 (6.0)	1 (0.7)
Muscle rigidity	筋固縮	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.7)
Parkinsonism	パーキンソニズム	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)
Tremor	振戦	2 (4.0)	0 (0.0)	2 (4.0)	0 (0.0)
Akathisia	アカシジア関連有害事象	0 (0.0)	5 (3.4)	1 (2.0)	4 (2.7)
Akathisia	アカシジア	0 (0.0)	5 (3.4)	1 (2.0)	4 (2.7)

MedDRA Version 12.0.

5.3.5.3－5 Table 3.4.2 より引用

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Any System Organ Class		41 (67.2)	53 (82.8)	94 (75.2)	29 (43.3)	13 (54.2)	14 (70.0)	27 (61.4)	8 (47.1)
Infections and infestations	感染症および寄生虫症	7 (11.5)	6 (9.4)	13 (10.4)	4 (6.0)	3 (12.5)	3 (15.0)	6 (13.6)	3 (17.6)
Nasopharyngitis	上咽頭炎	3 (4.9)	3 (4.7)	6 (4.8)	4 (6.0)	3 (12.5)	1 (5.0)	4 (9.1)	2 (11.8)
Pneumonia	肺炎	1 (1.6)	2 (3.1)	3 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Influenza	インフルエンザ	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periodontitis	歯周炎	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Upper respiratory tract infection	上気道感染	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	1 (5.9)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Blepharal papilloma	眼瞼乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	4 (6.6)	3 (4.7)	7 (5.6)	1 (1.5)	2 (8.3)	1 (5.0)	3 (6.8)	1 (5.9)
Decreased appetite	食欲減退	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Dehydration	脱水	0 (0.0)	2 (3.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperuricaemia	高尿酸血症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polydipsia	多飲症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Psychiatric disorders	精神障害	13 (21.3)	12 (18.8)	25 (20.0)	3 (4.5)	4 (16.7)	4 (20.0)	8 (18.2)	2 (11.8)
Insomnia	不眠症	2 (3.3)	5 (7.8)	7 (5.6)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Schizophrenia	統合失調症	7 (11.5)	0 (0.0)	7 (5.6)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	4 (6.3)	4 (3.2)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Depression	うつ病	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	2 (10.0)	2 (4.5)	1 (5.9)
Disinhibition	脱抑制	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Suicidal ideation	自殺念慮	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Somatic symptom disorder	身体症状症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Nervous system disorders	神経系障害	14 (23.0)	30 (46.9)	44 (35.2)	5 (7.5)	6 (25.0)	8 (40.0)	14 (31.8)	1 (5.9)
Somnolence	傾眠	6 (9.8)	18 (28.1)	24 (19.2)	2 (3.0)	4 (16.7)	3 (15.0)	7 (15.9)	0 (0.0)
Akathisia	アカシジア	4 (6.6)	4 (6.3)	8 (6.4)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Headache	頭痛	1 (1.6)	4 (6.3)	5 (4.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Tremor	振戦	0 (0.0)	4 (6.3)	4 (3.2)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	2 (3.1)	2 (1.6)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Drooling	よだれ	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	2 (3.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Sciatica	坐骨神経痛	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Seizure	痙攣発作	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Eye disorders	眼障害	1 (1.6)	2 (3.1)	3 (2.4)	2 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blepharitis	眼瞼炎	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Deafness neurosensory	感音性難聴	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Cardiac disorders	心臓障害	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	動悸	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	1 (1.6)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertension	高血圧	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	1 (1.6)	3 (4.7)	4 (3.2)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Asthma	喘息	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Gastrointestinal disorders	胃腸障害	5 (8.2)	13 (20.3)	18 (14.4)	6 (9.0)	3 (12.5)	7 (35.0)	10 (22.7)	1 (5.9)
Salivary hypersecretion	流涎過多	3 (4.9)	6 (9.4)	9 (7.2)	1 (1.5)	0 (0.0)	3 (15.0)	3 (6.8)	0 (0.0)
Constipation	便秘	1 (1.6)	1 (1.6)	2 (1.6)	1 (1.5)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Nausea	悪心	0 (0.0)	2 (3.1)	2 (1.6)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Diarrhoea	下痢	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.5)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Dry mouth	口内乾燥	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Dysphagia	嚥下障害	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastritis	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	歯痛	1 (1.6)	0 (0.0)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	5 (8.2)	6 (9.4)	11 (8.8)	5 (7.5)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Urticaria	蕁麻疹	2 (3.3)	2 (3.1)	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	湿疹	0 (0.0)	1 (1.6)	1 (0.8)	3 (4.5)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Alopecia areata	円形脱毛症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry skin	皮膚乾燥	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (1.6)	4 (6.3)	5 (4.0)	4 (6.0)	3 (12.5)	1 (5.0)	4 (9.1)	1 (5.9)
Back pain	背部痛	0 (0.0)	2 (3.1)	2 (1.6)	2 (3.0)	3 (12.5)	0 (0.0)	3 (6.8)	0 (0.0)
Neck pain	頚部痛	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Posture abnormal	姿勢異常	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle spasms	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Renal and urinary disorders	腎および尿路障害	1 (1.6)	0 (0.0)	1 (0.8)	1 (1.5)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Polyuria	多尿	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	8 (13.1)	10 (15.6)	18 (14.4)	1 (1.5)	2 (8.3)	1 (5.0)	3 (6.8)	1 (5.9)
Malaise	倦怠感	4 (6.6)	3 (4.7)	7 (5.6)	0 (0.0)	1 (4.2)	1 (5.0)	2 (4.5)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (3.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	口渇	2 (3.3)	0 (0.0)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling abnormal	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Oedema	浮腫	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Pyrexia	発熱	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inflammation	炎症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Investigations	臨床検査	4 (6.6)	2 (3.1)	6 (4.8)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1 (1.6)	1 (1.6)	2 (1.6)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Weight increased	体重増加	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－196　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	3 (4.9)	2 (3.1)	5 (4.0)	3 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fall	転倒	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contusion	挫傷	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.7.1.1 より引用

表 2.7.4.7－197　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Any AESI		29 (47.5)	42 (65.6)	71 (56.8)	13 (19.4)	7 (29.2)	11 (55.0)	18 (40.9)	2 (11.8)
Somnolence	傾眠関連有害事象	12 (19.7)	20 (31.3)	32 (25.6)	2 (3.0)	4 (16.7)	4 (20.0)	8 (18.2)	0 (0.0)
Somnolence	傾眠	6 (9.8)	18 (28.1)	24 (19.2)	2 (3.0)	4 (16.7)	3 (15.0)	7 (15.9)	0 (0.0)
Malaise	倦怠感	4 (6.6)	3 (4.7)	7 (5.6)	0 (0.0)	1 (4.2)	1 (5.0)	2 (4.5)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (3.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	4 (6.6)	6 (9.4)	10 (8.0)	5 (7.5)	1 (4.2)	1 (5.0)	2 (4.5)	1 (5.9)
Urticaria	蕁麻疹	2 (3.3)	2 (3.1)	4 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	湿疹	0 (0.0)	1 (1.6)	1 (0.8)	3 (4.5)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Rash	発疹	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stomatitis	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－197　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Parkinsonism	パーキンソニズム関連有害事象	4 (6.6)	14 (21.9)	18 (14.4)	1 (1.5)	1 (4.2)	4 (20.0)	5 (11.4)	0 (0.0)
Salivary hypersecretion	流涎過多	3 (4.9)	6 (9.4)	9 (7.2)	1 (1.5)	0 (0.0)	3 (15.0)	3 (6.8)	0 (0.0)
Tremor	振戦	0 (0.0)	4 (6.3)	4 (3.2)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Drooling	よだれ	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	2 (3.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	5 (8.2)	1 (1.6)	6 (4.8)	0 (0.0)	1 (4.2)	2 (10.0)	3 (6.8)	1 (5.9)
Depression	うつ病	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	2 (10.0)	2 (4.5)	1 (5.9)
Depressed mood	抑うつ気分	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Akathisia	アカシジア関連有害事象	4 (6.6)	7 (10.9)	11 (8.8)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Akathisia	アカシジア	4 (6.6)	4 (6.3)	8 (6.4)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	2 (3.1)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	4 (6.3)	4 (3.2)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Anxiety	不安	0 (0.0)	4 (6.3)	4 (3.2)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－197 ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=61) n(%)	80 mg (N=64) n(%)	All MT-5199 (N=125) n(%)	Placebo (N=67) n(%)	40 mg (N=24) n(%)	80 mg (N=20) n(%)	All MT-5199 (N=44) n(%)	Placebo (N=17) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	10 (16.4)	2 (3.1)	12 (9.6)	2 (3.0)	1 (4.2)	4 (20.0)	5 (11.4)	1 (5.9)
Schizophrenia	統合失調症	7 (11.5)	0 (0.0)	7 (5.6)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	2 (10.0)	2 (4.5)	1 (5.9)
Bipolar disorder	双極性障害	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicidal ideation	自殺念慮	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Dysphagia	嚥下障害	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (2.3)	0 (0.0)
Hypotension	低血圧関連有害事象	1 (1.6)	3 (4.7)	4 (3.2)	2 (3.0)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	2 (3.1)	2 (1.6)	1 (1.5)	0 (0.0)	1 (5.0)	1 (2.3)	0 (0.0)
Fall	転倒	1 (1.6)	1 (1.6)	2 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.7.1.2 より引用

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Any System Organ Class		85 (92.4)	92 (94.8)	57 (91.9)	177 (93.7)	28 (82.4)	24 (92.3)	20 (90.9)	52 (86.7)
Infections and infestations	感染症および寄生虫症	33 (35.9)	32 (33.0)	21 (33.9)	65 (34.4)	13 (38.2)	8 (30.8)	8 (36.4)	21 (35.0)
Nasopharyngitis	上咽頭炎	20 (21.7)	19 (19.6)	11 (17.7)	39 (20.6)	10 (29.4)	4 (15.4)	4 (18.2)	14 (23.3)
Cystitis	膀胱炎	1 (1.1)	2 (2.1)	2 (3.2)	3 (1.6)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Pneumonia	肺炎	1 (1.1)	2 (2.1)	2 (3.2)	3 (1.6)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Bronchitis	気管支炎	2 (2.2)	1 (1.0)	1 (1.6)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza	インフルエンザ	1 (1.1)	2 (2.1)	2 (3.2)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	上気道感染	2 (2.2)	1 (1.0)	0 (0.0)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cellulitis	蜂巣炎	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Conjunctivitis	結膜炎	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatophytosis of nail	爪の皮膚糸状菌症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Folliculitis	毛包炎	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	胃腸炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Otitis externa	外耳炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Periodontitis	歯周炎	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pharyngitis	咽頭炎	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Gingivitis	歯肉炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	帯状疱疹	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Mastitis	乳腺炎	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal vestibulitis	鼻前庭炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis media	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subcutaneous abscess	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Tonsillitis	扁桃炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary tract infection	尿路感染	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal infection	膣感染	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Varicella	水痘	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部膣カンジダ症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin candida	皮膚カンジダ	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nail infection	爪感染	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Acarodermatitis	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Cystitis bacterial	細菌性膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Infected dermal cyst	感染性皮膚嚢腫	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial vulvovaginitis	細菌性外陰膣炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Skin papilloma	皮膚乳頭腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Metabolism and nutrition disorders	代謝および栄養障害	10 (10.9)	9 (9.3)	5 (8.1)	19 (10.1)	6 (17.6)	3 (11.5)	3 (13.6)	9 (15.0)
Decreased appetite	食欲減退	2 (2.2)	3 (3.1)	0 (0.0)	5 (2.6)	3 (8.8)	1 (3.8)	1 (4.5)	4 (6.7)
Dehydration	脱水	1 (1.1)	3 (3.1)	3 (4.8)	4 (2.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Hyperuricaemia	高尿酸血症	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Diabetes mellitus	糖尿病	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Increased appetite	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Dyslipidaemia	脂質異常症	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Electrolyte imbalance	電解質失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Hypokalaemia	低カリウム血症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypouricaemia	低尿酸血症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marasmus	マラスムス	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polydipsia	多飲症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Psychiatric disorders	精神障害	40 (43.5)	44 (45.4)	28 (45.2)	84 (44.4)	12 (35.3)	13 (50.0)	12 (54.5)	25 (41.7)
Schizophrenia	統合失調症	20 (21.7)	13 (13.4)	5 (8.1)	33 (17.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Insomnia	不眠症	9 (9.8)	13 (13.4)	9 (14.5)	22 (11.6)	1 (2.9)	3 (11.5)	3 (13.6)	4 (6.7)
Depression	うつ病	4 (4.3)	6 (6.2)	5 (8.1)	10 (5.3)	2 (5.9)	4 (15.4)	4 (18.2)	6 (10.0)
Anxiety	不安	3 (3.3)	8 (8.2)	7 (11.3)	11 (5.8)	2 (5.9)	1 (3.8)	0 (0.0)	3 (5.0)
Suicidal ideation	自殺念慮	4 (4.3)	3 (3.1)	2 (3.2)	7 (3.7)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Restlessness	落ち着きのなさ	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Suicide attempt	自殺企図	3 (3.3)	1 (1.0)	1 (1.6)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bipolar disorder	双極性障害	2 (2.2)	1 (1.0)	1 (1.6)	3 (1.6)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Middle insomnia	中期不眠症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Bruxism	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Delirium	譫妄	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disinhibition	脱抑制	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Flat affect	感情の平板化	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination, auditory	幻聴	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sleep disorder	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Agitation	激越	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Intentional self-injury	故意の自傷行為	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurosis	神経症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Panic attack	パニック発作	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abulia	無為	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Abnormal behaviour	異常行動	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Somatic hallucination	体感幻覚	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Nervous system disorders	神経系障害	40 (43.5)	55 (56.7)	32 (51.6)	95 (50.3)	11 (32.4)	14 (53.8)	12 (54.5)	25 (41.7)
Somnolence	傾眠	13 (14.1)	23 (23.7)	15 (24.2)	36 (19.0)	6 (17.6)	5 (19.2)	3 (13.6)	11 (18.3)
Tremor	振戦	4 (4.3)	14 (14.4)	7 (11.3)	18 (9.5)	1 (2.9)	2 (7.7)	2 (9.1)	3 (5.0)
Akathisia	アカシジア	8 (8.7)	8 (8.2)	4 (6.5)	16 (8.5)	0 (0.0)	4 (15.4)	4 (18.2)	4 (6.7)
Headache	頭痛	4 (4.3)	8 (8.2)	5 (8.1)	12 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	浮動性めまい	4 (4.3)	5 (5.2)	4 (6.5)	9 (4.8)	0 (0.0)	2 (7.7)	2 (9.1)	2 (3.3)
Parkinsonism	パーキンソニズム	3 (3.3)	3 (3.1)	2 (3.2)	6 (3.2)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Extrapyramidal disorder	錐体外路障害	1 (1.1)	4 (4.1)	2 (3.2)	5 (2.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Drooling	よだれ	2 (2.2)	2 (2.1)	1 (1.6)	4 (2.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Tardive dyskinesia	遅発性ジスキネジア	2 (2.2)	2 (2.1)	2 (3.2)	4 (2.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Hypoaesthesia	感覚鈍麻	2 (2.2)	1 (1.0)	1 (1.6)	3 (1.6)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Bradykinesia	運動緩慢	1 (1.1)	2 (2.1)	0 (0.0)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyskinesia	ジスキネジア	2 (2.2)	1 (1.0)	1 (1.6)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	2 (2.1)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dystonia	ジストニア	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Seizure	痙攣発作	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Coordination abnormal	協調運動異常	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Hypersomnia	過眠症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	神経痛	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Radial nerve palsy	橈骨神経麻痺	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stupor	昏迷	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intercostal neuralgia	肋間神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Cervical radiculopathy	頚髄神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Cognitive disorder	認知障害	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vagus nerve disorder	迷走神経障害	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Eye disorders	眼障害	2 (2.2)	5 (5.2)	2 (3.2)	7 (3.7)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Blepharitis	眼瞼炎	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Cataract	白内障	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye discharge	眼脂	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	眼痛	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Deafness neurosensory	感音性難聴	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo	回転性めまい	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo positional	頭位性回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Cardiac disorders	心臓障害	3 (3.3)	4 (4.1)	3 (4.8)	7 (3.7)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Palpitations	動悸	2 (2.2)	1 (1.0)	0 (0.0)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradycardia	徐脈	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Sinus bradycardia	洞性徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Tachycardia	頻脈	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	3 (3.3)	2 (2.1)	1 (1.6)	5 (2.6)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Hypertension	高血圧	2 (2.2)	1 (1.0)	0 (0.0)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Hypotension	低血圧	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Deep vein thrombosis	深部静脈血栓症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	7 (7.6)	10 (10.3)	2 (3.2)	17 (9.0)	1 (2.9)	2 (7.7)	2 (9.1)	3 (5.0)
Asthma	喘息	1 (1.1)	3 (3.1)	1 (1.6)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Dyspnoea	呼吸困難	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleural effusion	胸水	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Upper respiratory tract inflammation	上気道の炎症	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	2 (2.1)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough	咳嗽	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Interstitial lung disease	間質性肺疾患	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleurisy	胸膜炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Productive cough	湿性咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Pulmonary embolism	肺塞栓症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory failure	呼吸不全	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough variant asthma	咳喘息	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Throat clearing	咳払い	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Gastrointestinal disorders	胃腸障害	26 (28.3)	40 (41.2)	19 (30.6)	66 (34.9)	13 (38.2)	11 (42.3)	9 (40.9)	24 (40.0)
Salivary hypersecretion	流涎過多	9 (9.8)	15 (15.5)	6 (9.7)	24 (12.7)	0 (0.0)	6 (23.1)	4 (18.2)	6 (10.0)
Constipation	便秘	7 (7.6)	8 (8.2)	5 (8.1)	15 (7.9)	2 (5.9)	1 (3.8)	0 (0.0)	3 (5.0)
Dysphagia	嚥下障害	4 (4.3)	4 (4.1)	2 (3.2)	8 (4.2)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Diarrhoea	下痢	4 (4.3)	3 (3.1)	2 (3.2)	7 (3.7)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Nausea	悪心	1 (1.1)	3 (3.1)	2 (3.2)	4 (2.1)	1 (2.9)	2 (7.7)	2 (9.1)	3 (5.0)
Stomatitis	口内炎	3 (3.3)	3 (3.1)	3 (4.8)	6 (3.2)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Vomiting	嘔吐	2 (2.2)	5 (5.2)	1 (1.6)	7 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abdominal discomfort	腹部不快感	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	3 (8.8)	0 (0.0)	0 (0.0)	3 (5.0)
Dental caries	齲歯	1 (1.1)	2 (2.1)	0 (0.0)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Abdominal pain	腹痛	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Dry mouth	口内乾燥	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Gastritis	胃炎	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Toothache	歯痛	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Abdominal distension	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Abdominal pain lower	下腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Abdominal pain upper	上腹部痛	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aphthous ulcer	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eructation	おくび	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorder	胃腸障害	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingival bleeding	歯肉出血	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia oral	口の感覚鈍麻	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal pruritus	肛門そう痒症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Hepatic function abnormal	肝機能異常	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	19 (20.7)	22 (22.7)	13 (21.0)	41 (21.7)	4 (11.8)	1 (3.8)	1 (4.5)	5 (8.3)
Eczema	湿疹	2 (2.2)	3 (3.1)	2 (3.2)	5 (2.6)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Urticaria	蕁麻疹	3 (3.3)	2 (2.1)	1 (1.6)	5 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	3 (3.1)	2 (3.2)	3 (1.6)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Dermatitis contact	接触皮膚炎	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Dry skin	皮膚乾燥	2 (2.2)	2 (2.1)	0 (0.0)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	そう痒症	2 (2.2)	2 (2.1)	2 (3.2)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	2 (2.2)	1 (1.0)	0 (0.0)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Alopecia areata	円形脱毛症	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperhidrosis	多汗症	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhage subcutaneous	皮下出血	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ingrowing nail	嵌入爪	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Skin fissures	皮膚亀裂	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin ulcer	皮膚潰瘍	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	18 (19.6)	20 (20.6)	13 (21.0)	38 (20.1)	9 (26.5)	3 (11.5)	3 (13.6)	12 (20.0)
Back pain	背部痛	3 (3.3)	6 (6.2)	4 (6.5)	9 (4.8)	4 (11.8)	0 (0.0)	0 (0.0)	4 (6.7)
Arthralgia	関節痛	1 (1.1)	5 (5.2)	4 (6.5)	6 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	1 (1.1)	4 (4.1)	2 (3.2)	5 (2.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Muscular weakness	筋力低下	2 (2.2)	3 (3.1)	2 (3.2)	5 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain in extremity	四肢痛	2 (2.2)	3 (3.1)	3 (4.8)	5 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myalgia	筋肉痛	4 (4.3)	0 (0.0)	0 (0.0)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal pain	筋骨格痛	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Neck pain	頚部痛	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Posture abnormal	姿勢異常	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc protrusion	椎間板突出	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Osteoporosis	骨粗鬆症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Periarthritis	関節周囲炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Tenosynovitis	腱鞘炎	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mastication disorder	咀嚼障害	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Temporomandibular joint syndrome	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Trigger finger	弾発指	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)

MedDRA Version 23.0.

表 2.7.4.7－198 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Extremity contracture	四肢拘縮	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot deformity	足変形	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal stenosis	脊柱管狭窄症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Renal and urinary disorders	腎および尿路障害	2 (2.2)	3 (3.1)	2 (3.2)	5 (2.6)	2 (5.9)	1 (3.8)	1 (4.5)	3 (5.0)
Dysuria	排尿困難	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertonic bladder	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Neurogenic bladder	神経因性膀胱	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	夜間頻尿	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal glycosuria	腎性糖尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Urinary incontinence	尿失禁	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention	尿閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Bladder prolapse	膀胱脱	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Reproductive system and breast disorders	生殖系および乳房障害	4 (4.3)	1 (1.0)	1 (1.6)	5 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal discharge	膣分泌物	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Prostatomegaly	前立腺腫大	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	19 (20.7)	22 (22.7)	12 (19.4)	41 (21.7)	8 (23.5)	3 (11.5)	3 (13.6)	11 (18.3)
Malaise	倦怠感	7 (7.6)	9 (9.3)	4 (6.5)	16 (8.5)	3 (8.8)	1 (3.8)	1 (4.5)	4 (6.7)
Thirst	口渇	3 (3.3)	2 (2.1)	1 (1.6)	5 (2.6)	4 (11.8)	0 (0.0)	0 (0.0)	4 (6.7)
Fatigue	疲労	0 (0.0)	3 (3.1)	2 (3.2)	3 (1.6)	2 (5.9)	1 (3.8)	1 (4.5)	3 (5.0)
Pyrexia	発熱	3 (3.3)	2 (2.1)	1 (1.6)	5 (2.6)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Feeling abnormal	異常感	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Asthenia	無力症	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	死亡	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Calcinosis	石灰沈着症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chest discomfort	胸部不快感	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	熱感	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Inflammation	炎症	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Investigations	臨床検査	17 (18.5)	12 (12.4)	8 (12.9)	29 (15.3)	5 (14.7)	3 (11.5)	2 (9.1)	8 (13.3)
Weight decreased	体重減少	5 (5.4)	4 (4.1)	2 (3.2)	9 (4.8)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Weight increased	体重増加	3 (3.3)	3 (3.1)	2 (3.2)	6 (3.2)	3 (8.8)	0 (0.0)	0 (0.0)	3 (5.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	2 (2.2)	4 (4.1)	4 (6.5)	6 (3.2)	0 (0.0)	1 (3.8)	0 (0.0)	1 (1.7)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Blood creatinine increased	血中クレアチニン増加	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Blood pressure increased	血圧上昇	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Liver function test increased	肝機能検査値上昇	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Blood pressure decreased	血圧低下	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood triglycerides increased	血中トリグリセリド増加	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood uric acid increased	血中尿酸増加	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	18 (19.6)	18 (18.6)	11 (17.7)	36 (19.0)	3 (8.8)	4 (15.4)	4 (18.2)	7 (11.7)
Contusion	挫傷	5 (5.4)	7 (7.2)	4 (6.5)	12 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fall	転倒	2 (2.2)	5 (5.2)	4 (6.5)	7 (3.7)	0 (0.0)	2 (7.7)	2 (9.1)	2 (3.3)
Skin abrasion	皮膚擦過傷	2 (2.2)	2 (2.1)	2 (3.2)	4 (2.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Sedation complication	鎮静合併症	3 (3.3)	1 (1.0)	0 (0.0)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thermal burn	熱傷	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Animal bite	動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Ankle fracture	足関節部骨折	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Concussion	脳振盪	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femoral neck fracture	大腿骨頚部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Femur fracture	大腿骨骨折	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot fracture	足骨折	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fractured sacrum	仙骨骨折	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand fracture	手骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Head injury	頭部損傷	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint dislocation	関節脱臼	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ligament sprain	靱帯捻挫	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Road traffic accident	交通事故	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－198　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Spinal compression fracture	脊椎圧迫骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Face injury	顔面損傷	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Tooth fracture	歯牙破折	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid injury	眼瞼損傷	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin wound	皮膚創傷	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.7.2.1 より引用

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Any AESI		66 (71.7)	87 (89.7)	53 (85.5)	153 (81.0)	22 (64.7)	21 (80.8)	17 (77.3)	43 (71.7)
Somnolence	傾眠関連有害事象	24 (26.1)	34 (35.1)	18 (29.0)	58 (30.7)	8 (23.5)	6 (23.1)	4 (18.2)	14 (23.3)
Somnolence	傾眠	13 (14.1)	23 (23.7)	15 (24.2)	36 (19.0)	6 (17.6)	5 (19.2)	3 (13.6)	11 (18.3)
Malaise	倦怠感	7 (7.6)	9 (9.3)	4 (6.5)	16 (8.5)	3 (8.8)	1 (3.8)	1 (4.5)	4 (6.7)
Fatigue	疲労	0 (0.0)	3 (3.1)	2 (3.2)	3 (1.6)	2 (5.9)	1 (3.8)	1 (4.5)	3 (5.0)
Sedation complication	鎮静合併症	3 (3.3)	1 (1.0)	0 (0.0)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	2 (2.1)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Hypersensitivity	過敏症関連有害事象	18 (19.6)	17 (17.5)	13 (21.0)	35 (18.5)	5 (14.7)	1 (3.8)	1 (4.5)	6 (10.0)
Eczema	湿疹	2 (2.2)	3 (3.1)	2 (3.2)	5 (2.6)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Stomatitis	口内炎	3 (3.3)	3 (3.1)	3 (4.8)	6 (3.2)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Urticaria	蕁麻疹	3 (3.3)	2 (2.1)	1 (1.6)	5 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	接触皮膚炎	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Pruritus	そう痒症	2 (2.2)	2 (2.1)	2 (3.2)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Conjunctivitis	結膜炎	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	2 (2.2)	0 (0.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis infected	感染性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Erythema	紅斑	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Parkinsonism	パーキンソニズム関連有害事象	20 (21.7)	41 (42.3)	18 (29.0)	61 (32.3)	4 (11.8)	9 (34.6)	7 (31.8)	13 (21.7)
Salivary hypersecretion	流涎過多	9 (9.8)	15 (15.5)	6 (9.7)	24 (12.7)	0 (0.0)	6 (23.1)	4 (18.2)	6 (10.0)
Tremor	振戦	4 (4.3)	14 (14.4)	7 (11.3)	18 (9.5)	1 (2.9)	2 (7.7)	2 (9.1)	3 (5.0)
Parkinsonism	パーキンソニズム	3 (3.3)	3 (3.1)	2 (3.2)	6 (3.2)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Extrapyramidal disorder	錐体外路障害	1 (1.1)	4 (4.1)	2 (3.2)	5 (2.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Drooling	よだれ	2 (2.2)	2 (2.1)	1 (1.6)	4 (2.1)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Bradykinesia	運動緩慢	1 (1.1)	2 (2.1)	0 (0.0)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	13 (14.1)	12 (12.4)	8 (12.9)	25 (13.2)	6 (17.6)	7 (26.9)	7 (31.8)	13 (21.7)
Depression	うつ病	4 (4.3)	6 (6.2)	5 (8.1)	10 (5.3)	2 (5.9)	4 (15.4)	4 (18.2)	6 (10.0)
Suicidal ideation	自殺念慮	4 (4.3)	3 (3.1)	2 (3.2)	7 (3.7)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Suicide attempt	自殺企図	3 (3.3)	1 (1.0)	1 (1.6)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Middle insomnia	中期不眠症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Disturbance in attention	注意力障害	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Terminal insomnia	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Cardiac events	心血管系及びQT間隔延長関連有害事象	3 (3.3)	0 (0.0)	0 (0.0)	3 (1.6)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Death	死亡	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Long QT syndrome	ＱＴ延長症候群	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Myocardial ischaemia	心筋虚血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Hyperprolactinemia	高プロラクチン血症関連有害事象	1 (1.1)	1 (1.0)	1 (1.6)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Menstruation irregular	不規則月経	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes				No			
		MT-5199				MT-5199			
		40 mg (N=92) n(%)	80 mg (N=97) n(%)	80 mg (no dose reduction) (N=62) n(%)	All MT-5199 (N=189) n(%)	40 mg (N=34) n(%)	80 mg (N=26) n(%)	80 mg (no dose reduction) (N=22) n(%)	All MT-5199 (N=60) n(%)
Akathisia	アカシジア関連有害事象	10 (10.9)	15 (15.5)	7 (11.3)	25 (13.2)	2 (5.9)	4 (15.4)	4 (18.2)	6 (10.0)
Akathisia	アカシジア	8 (8.7)	8 (8.2)	4 (6.5)	16 (8.5)	0 (0.0)	4 (15.4)	4 (18.2)	4 (6.7)
Extrapyramidal disorder	錐体外路障害	1 (1.1)	4 (4.1)	2 (3.2)	5 (2.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Restlessness	落ち着きのなさ	1 (1.1)	2 (2.1)	1 (1.6)	3 (1.6)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Movement disorder	運動障害	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	3 (3.3)	8 (8.2)	7 (11.3)	11 (5.8)	2 (5.9)	1 (3.8)	0 (0.0)	3 (5.0)
Anxiety	不安	3 (3.3)	8 (8.2)	7 (11.3)	11 (5.8)	2 (5.9)	1 (3.8)	0 (0.0)	3 (5.0)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	29 (31.5)	22 (22.7)	12 (19.4)	51 (27.0)	6 (17.6)	7 (26.9)	7 (31.8)	13 (21.7)
Schizophrenia	統合失調症	20 (21.7)	13 (13.4)	5 (8.1)	33 (17.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Depression	うつ病	4 (4.3)	6 (6.2)	5 (8.1)	10 (5.3)	2 (5.9)	4 (15.4)	4 (18.2)	6 (10.0)
Suicidal ideation	自殺念慮	4 (4.3)	3 (3.1)	2 (3.2)	7 (3.7)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Suicide attempt	自殺企図	3 (3.3)	1 (1.0)	1 (1.6)	4 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bipolar disorder	双極性障害	2 (2.2)	1 (1.0)	1 (1.6)	3 (1.6)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Depressed mood	抑うつ気分	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypomania	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Intentional self-injury	故意の自傷行為	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressive symptom	抑うつ症状	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Major depression	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Dysphagia	嚥下障害関連有害事象	4 (4.3)	4 (4.1)	2 (3.2)	8 (4.2)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)
Dysphagia	嚥下障害	4 (4.3)	4 (4.1)	2 (3.2)	8 (4.2)	1 (2.9)	1 (3.8)	1 (4.5)	2 (3.3)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－199　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Yes MT-5199 40 mg (N=92) n(%)	Yes MT-5199 80 mg (N=97) n(%)	Yes MT-5199 80 mg (no dose reduction) (N=62) n(%)	Yes All MT-5199 (N=189) n(%)	No MT-5199 40 mg (N=34) n(%)	No MT-5199 80 mg (N=26) n(%)	No MT-5199 80 mg (no dose reduction) (N=22) n(%)	No All MT-5199 (N=60) n(%)
Hepatotoxicity	肝障害関連有害事象	3 (3.3)	3 (3.1)	2 (3.2)	6 (3.2)	2 (5.9)	0 (0.0)	0 (0.0)	2 (3.3)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	2 (2.1)	2 (3.2)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Liver function test increased	肝機能検査値上昇	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Hepatic steatosis	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (1.7)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	7 (7.6)	10 (10.3)	8 (12.9)	17 (9.0)	0 (0.0)	3 (11.5)	3 (13.6)	3 (5.0)
Dizziness	浮動性めまい	4 (4.3)	5 (5.2)	4 (6.5)	9 (4.8)	0 (0.0)	2 (7.7)	2 (9.1)	2 (3.3)
Fall	転倒	2 (2.2)	5 (5.2)	4 (6.5)	7 (3.7)	0 (0.0)	2 (7.7)	2 (9.1)	2 (3.3)
Hypotension	低血圧	0 (0.0)	1 (1.0)	1 (1.6)	1 (0.5)	0 (0.0)	1 (3.8)	1 (4.5)	1 (1.7)
Blood pressure decreased	血圧低下	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知機能低下関連有害事象	2 (2.2)	1 (1.0)	0 (0.0)	3 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disturbance in attention	注意力障害	1 (1.1)	1 (1.0)	0 (0.0)	2 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知障害	1 (1.1)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.7.2.2 より引用

表 2.7.4.7－200　ベースライン時の抗精神病薬投与の有無ごとの有害事象の要約：プラセボ対照二重盲検期間・長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Yes (N=211) n (%)	No (N=43) n (%)	Yes (N=149) n (%)	No (N=29) n (%)	Yes (N=365) n (%)	No (N=62) n (%)
At Least 1 AE	89 (42.2)	22 (51.2)	57 (38.3)	14 (48.3)	215 (58.9)	44 (71.0)
At Least 1 SAE	11 (5.2)	1 (2.3)	6 (4.0)	0	48 (13.2)	6 (9.7)
At Least 1 AE Leading to Study Discontinuation	9 (4.3)	1 (2.3)	8 (5.4)	0	47 (12.9)	11 (17.7)
At Least 1 AE Leading to Dose Reduction	5 (2.4)	2 (4.7)	2 (1.3)	2 (6.9)	20 (5.5)	6 (9.7)

AE: adverse event, SAE: serious adverse event
Note: If a subject experienced more than 1 event in a given category, that subject is counted once.

5.3.5.3－2 Table 102 より引用（一部改変）

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	 Placebo (N=149)
Any Adverse Event	n (%)	1(25.0)	39(40.2)	41(47.7)	8(33.3)	89(42.2)	57(38.3)
心臓障害	n (%)	0	0	0	0	0	1(0.7)
心筋梗塞	n (%)	0	0	0	0	0	1(0.7)
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(0.7)
トゥレット病	n (%)	0	0	0	0	0	1(0.7)
耳および迷路障害	n (%)	0	1(1.0)	0	0	1(0.5)	1(0.7)
耳鳴	n (%)	0	1(1.0)	0	0	1(0.5)	0
耳痛	n (%)	0	0	0	0	0	1(0.7)
眼障害	n (%)	0	0	0	1(4.2)	1(0.5)	1(0.7)
霧視	n (%)	0	0	0	1(4.2)	1(0.5)	0
結膜出血	n (%)	0	0	0	0	0	1(0.7)
胃腸障害	n (%)	0	10(10.3)	5(5.8)	1(4.2)	16(7.6)	13(8.7)
口内乾燥	n (%)	0	5(5.2)	0	1(4.2)	6(2.8)	3(2.0)
嘔吐	n (%)	0	1(1.0)	3(3.5)	0	4(1.9)	1(0.7)
悪心	n (%)	0	1(1.0)	2(2.3)	0	3(1.4)	3(2.0)
流涎過多	n (%)	0	0	2(2.3)	1(4.2)	3(1.4)	0
腹部圧痛	n (%)	0	1(1.0)	0	0	1(0.5)	0
便秘	n (%)	0	1(1.0)	0	0	1(0.5)	1(0.7)
下痢	n (%)	0	1(1.0)	0	0	1(0.5)	0

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	 Placebo (N=149)
嚥下障害	n (%)	0	1(1.0)	0	0	1(0.5)	0
メレナ	n (%)	0	1(1.0)	0	0	1(0.5)	0
臍ヘルニア	n (%)	0	1(1.0)	0	0	1(0.5)	0
排便回数増加	n (%)	0	0	0	0	0	1(0.7)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(0.7)
歯肉炎	n (%)	0	0	0	0	0	1(0.7)
舌痛	n (%)	0	0	0	0	0	1(0.7)
歯痛	n (%)	0	0	0	0	0	1(0.7)
全身障害および投与局所様態	n (%)	0	7(7.2)	5(5.8)	2(8.3)	14(6.6)	6(4.0)
疲労	n (%)	0	4(4.1)	3(3.5)	2(8.3)	9(4.3)	3(2.0)
歩行障害	n (%)	0	1(1.0)	0	1(4.2)	2(0.9)	0
末梢性浮腫	n (%)	0	2(2.1)	0	0	2(0.9)	1(0.7)
胸痛	n (%)	0	1(1.0)	0	0	1(0.5)	0
空腹	n (%)	0	1(1.0)	0	0	1(0.5)	0
発熱	n (%)	0	0	1(1.2)	0	1(0.5)	0
突然死	n (%)	0	0	1(1.2)	0	1(0.5)	0
口渇	n (%)	0	1(1.0)	0	0	1(0.5)	0
易刺激性	n (%)	0	0	0	0	0	2(1.3)
肝胆道系障害	n (%)	0	0	1(1.2)	0	1(0.5)	0
急性肝炎	n (%)	0	0	1(1.2)	0	1(0.5)	0
黄疸	n (%)	0	0	1(1.2)	0	1(0.5)	0

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	Placebo (N=149)
感染症および寄生虫症	n (%)	0	9(9.3)	3(3.5)	3(12.5)	15(7.1)	10(6.7)
尿路感染	n (%)	0	3(3.1)	1(1.2)	1(4.2)	5(2.4)	6(4.0)
鼻咽頭炎	n (%)	0	0	1(1.2)	1(4.2)	2(0.9)	1(0.7)
上気道感染	n (%)	0	0	1(1.2)	1(4.2)	2(0.9)	1(0.7)
ダニ皮膚炎	n (%)	0	1(1.0)	0	0	1(0.5)	0
体部白癬	n (%)	0	1(1.0)	0	0	1(0.5)	0
せつ	n (%)	0	1(1.0)	0	0	1(0.5)	0
ウイルス性胃腸炎	n (%)	0	1(1.0)	0	0	1(0.5)	0
インフルエンザ	n (%)	0	1(1.0)	0	0	1(0.5)	0
急性腎盂腎炎	n (%)	0	1(1.0)	0	0	1(0.5)	0
副鼻腔炎	n (%)	0	1(1.0)	0	0	1(0.5)	0
外陰腟真菌感染	n (%)	0	1(1.0)	0	0	1(0.5)	0
気管支炎	n (%)	0	0	0	0	0	1(0.7)
耳感染	n (%)	0	0	0	0	0	1(0.7)
傷害、中毒および処置合併症	n (%)	0	4(4.1)	4(4.7)	1(4.2)	9(4.3)	2(1.3)
転倒・転落	n (%)	0	2(2.1)	1(1.2)	0	3(1.4)	0
動物咬傷	n (%)	0	0	1(1.2)	0	1(0.5)	0
節足動物咬傷	n (%)	0	0	0	1(4.2)	1(0.5)	1(0.7)
第２度熱傷	n (%)	0	0	1(1.2)	0	1(0.5)	0
関節損傷	n (%)	0	1(1.0)	0	0	1(0.5)	0
四肢損傷	n (%)	0	0	1(1.2)	0	1(0.5)	0
筋挫傷	n (%)	0	1(1.0)	0	0	1(0.5)	0
足骨折	n (%)	0	0	0	0	0	1(0.7)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	 Placebo (N=149)
臨床検査	n (%)	0	4(4.1)	9(10.5)	1(4.2)	14(6.6)	3(2.0)
体重増加	n (%)	0	1(1.0)	2(2.3)	0	3(1.4)	1(0.7)
血中クレアチニン増加	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	0
血中ブドウ糖増加	n (%)	0	0	2(2.3)	0	2(0.9)	0
血中クレアチンホスホキナーゼ増加	n (%)	0	1(1.0)	0	0	1(0.5)	0
血圧上昇	n (%)	0	0	1(1.2)	0	1(0.5)	0
血中トリグリセリド増加	n (%)	0	0	0	1(4.2)	1(0.5)	0
血中尿素増加	n (%)	0	1(1.0)	0	0	1(0.5)	0
尿中結晶陽性	n (%)	0	0	1(1.2)	0	1(0.5)	0
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	1(1.2)	0	1(0.5)	0
尿中ブドウ糖陽性	n (%)	0	0	1(1.2)	0	1(0.5)	0
グリコヘモグロビン増加	n (%)	0	0	1(1.2)	0	1(0.5)	1(0.7)
握力低下	n (%)	0	1(1.0)	0	0	1(0.5)	0
ヘマトクリット減少	n (%)	0	0	1(1.2)	0	1(0.5)	0
ヘモグロビン減少	n (%)	0	0	1(1.2)	0	1(0.5)	0
便潜血陽性	n (%)	0	0	1(1.2)	0	1(0.5)	0
赤血球数減少	n (%)	0	0	1(1.2)	0	1(0.5)	0
赤血球数増加	n (%)	0	0	1(1.2)	0	1(0.5)	0
血中ビリルビン増加	n (%)	0	0	0	0	0	1(0.7)
肝酵素上昇	n (%)	0	0	0	0	0	1(0.7)
代謝および栄養障害	n (%)	0	1(1.0)	4(4.7)	0	5(2.4)	4(2.7)
食欲減退	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	1(0.7)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	 Placebo (N=149)
食欲亢進	n (%)	0	0	2(2.3)	0	2(0.9)	1(0.7)
低ナトリウム血症	n (%)	0	0	1(1.2)	0	1(0.5)	0
異常体重減少	n (%)	0	0	0	0	0	1(0.7)
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(0.7)
低血糖症	n (%)	0	0	0	0	0	1(0.7)
筋骨格系および結合組織障害	n (%)	0	6(6.2)	4(4.7)	1(4.2)	11(5.2)	4(2.7)
関節痛	n (%)	0	3(3.1)	2(2.3)	0	5(2.4)	0
背部痛	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	0
関節炎	n (%)	0	1(1.0)	0	0	1(0.5)	0
筋痙縮	n (%)	0	0	1(1.2)	0	1(0.5)	0
筋力低下	n (%)	0	1(1.0)	0	0	1(0.5)	0
筋肉痛	n (%)	0	0	0	1(4.2)	1(0.5)	0
滑液包炎	n (%)	0	0	0	0	0	1(0.7)
関節腫脹	n (%)	0	0	0	0	0	1(0.7)
筋骨格硬直	n (%)	0	0	0	0	0	1(0.7)
四肢痛	n (%)	0	0	0	0	0	1(0.7)
神経系障害	n (%)	0	12(12.4)	13(15.1)	3(12.5)	28(13.3)	11(7.4)
傾眠	n (%)	0	6(6.2)	3(3.5)	1(4.2)	10(4.7)	3(2.0)
頭痛	n (%)	0	3(3.1)	4(4.7)	1(4.2)	8(3.8)	2(1.3)
アカシジア	n (%)	0	3(3.1)	1(1.2)	0	4(1.9)	1(0.7)
鎮静	n (%)	0	1(1.0)	2(2.3)	0	3(1.4)	1(0.7)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	 Placebo (N=149)
浮動性めまい	n (%)	0	2(2.1)	0	0	2(0.9)	4(2.7)
ジスキネジー	n (%)	0	0	2(2.3)	0	2(0.9)	0
振戦	n (%)	0	0	2(2.3)	0	2(0.9)	0
感覚鈍麻	n (%)	0	0	1(1.2)	0	1(0.5)	0
ミオクローヌス	n (%)	0	1(1.0)	0	0	1(0.5)	0
失神	n (%)	0	0	0	1(4.2)	1(0.5)	0
咬舌	n (%)	0	1(1.0)	0	0	1(0.5)	0
痙攣	n (%)	0	0	0	0	0	1(0.7)
精神障害	n (%)	1(25.0)	10(10.3)	9(10.5)	0	20(9.5)	12(8.1)
自殺念慮	n (%)	0	3(3.1)	1(1.2)	0	4(1.9)	3(2.0)
不眠症	n (%)	0	1(1.0)	2(2.3)	0	3(1.4)	1(0.7)
不安	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	0
うつ病	n (%)	0	0	2(2.3)	0	2(0.9)	1(0.7)
歯ぎしり	n (%)	0	1(1.0)	0	0	1(0.5)	0
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.5)	0
ディスフェミア	n (%)	0	1(1.0)	0	0	1(0.5)	0
敵意	n (%)	0	1(1.0)	0	0	1(0.5)	0
軽躁	n (%)	0	1(1.0)	0	0	1(0.5)	0
精神状態変化	n (%)	0	1(1.0)	0	0	1(0.5)	1(0.7)
神経過敏	n (%)	0	0	1(1.2)	0	1(0.5)	0
パニック発作	n (%)	1(25.0)	0	0	0	1(0.5)	0
落ち着きのなさ	n (%)	0	1(1.0)	0	0	1(0.5)	0
統合失調感情障害	n (%)	0	0	1(1.2)	0	1(0.5)	1(0.7)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.5)	1(0.7)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	 Placebo (N=149)
自殺企図	n (%)	0	0	1(1.2)	0	1(0.5)	0
激越	n (%)	0	0	0	0	0	1(0.7)
精神病性障害	n (%)	0	0	0	0	0	2(1.3)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.7)
睡眠障害	n (%)	0	0	0	0	0	1(0.7)
腎および尿路障害	n (%)	0	0	0	0	0	3(2.0)
糖尿	n (%)	0	0	0	0	0	1(0.7)
血尿	n (%)	0	0	0	0	0	1(0.7)
尿閉	n (%)	0	0	0	0	0	1(0.7)
生殖系および乳房障害	n (%)	0	0	1(1.2)	0	1(0.5)	2(1.3)
月経過多	n (%)	0	0	1(1.2)	0	1(0.5)	0
腟出血	n (%)	0	0	0	0	0	2(1.3)
呼吸器、胸郭および縦隔障害	n (%)	0	1(1.0)	1(1.2)	1(4.2)	3(1.4)	2(1.3)
慢性閉塞性肺疾患	n (%)	0	1(1.0)	0	1(4.2)	2(0.9)	1(0.7)
鼻閉	n (%)	0	0	1(1.2)	0	1(0.5)	0
咳嗽	n (%)	0	0	0	0	0	1(0.7)
皮膚および皮下組織障害	n (%)	0	1(1.0)	2(2.3)	0	3(1.4)	4(2.7)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	 40 mg (N=97)	 80 mg (N=86)	 100 mg (N=24)	All NBI-98854 (N=211)	Placebo (N=149)
そう痒症	n (%)	0	1(1.0)	0	0	1(0.5)	2(1.3)
発疹	n (%)	0	0	1(1.2)	0	1(0.5)	1(0.7)
斑状丘疹状皮疹	n (%)	0	0	1(1.2)	0	1(0.5)	0
多汗症	n (%)	0	0	0	0	0	1(0.7)
外科および内科処置	n (%)	0	0	1(1.2)	0	1(0.5)	0
抜歯	n (%)	0	0	1(1.2)	0	1(0.5)	0
血管障害	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	1(0.7)
高血圧	n (%)	0	1(1.0)	0	0	1(0.5)	1(0.7)
低血圧	n (%)	0	0	1(1.2)	0	1(0.5)	0

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=13)	 80 mg (N=26)	 100 mg (N=3)	All NBI-98854 (N=43)	 Placebo (N=29)
Any Adverse Event	n (%)	1(100.0)	9(69.2)	12(46.2)	0	22(51.2)	14(48.3)
血液およびリンパ系障害	n (%)	0	0	1(3.8)	0	1(2.3)	0
白血球減少症	n (%)	0	0	1(3.8)	0	1(2.3)	0
心臓障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
徐脈	n (%)	0	1(7.7)	0	0	1(2.3)	0
胃腸障害	n (%)	0	4(30.8)	2(7.7)	0	6(14.0)	8(27.6)
口内乾燥	n (%)	0	2(15.4)	0	0	2(4.7)	0
嘔吐	n (%)	0	1(7.7)	1(3.8)	0	2(4.7)	0
便秘	n (%)	0	1(7.7)	0	0	1(2.3)	4(13.8)
消化不良	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
嚥下障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
びらん性胃炎	n (%)	0	0	1(3.8)	0	1(2.3)	0
悪心	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
口腔知覚不全	n (%)	0	1(7.7)	0	0	1(2.3)	0
上腹部痛	n (%)	0	0	0	0	0	1(3.4)
下痢	n (%)	0	0	0	0	0	3(10.3)
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(3.4)
全身障害および投与局所様態	n (%)	0	3(23.1)	0	0	3(7.0)	1(3.4)
疲労	n (%)	0	1(7.7)	0	0	1(2.3)	0

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=13)	 80 mg (N=26)	 100 mg (N=3)	All NBI-98854 (N=43)	 Placebo (N=29)
歩行障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
易刺激性	n (%)	0	1(7.7)	0	0	1(2.3)	0
末梢性浮腫	n (%)	0	1(7.7)	0	0	1(2.3)	0
疼痛	n (%)	0	1(7.7)	0	0	1(2.3)	0
発熱	n (%)	0	0	0	0	0	1(3.4)
感染症および寄生虫症	n (%)	0	1(7.7)	0	0	1(2.3)	4(13.8)
鼻咽頭炎	n (%)	0	1(7.7)	0	0	1(2.3)	0
尿路感染	n (%)	0	1(7.7)	0	0	1(2.3)	2(6.9)
口腔ヘルペス	n (%)	0	0	0	0	0	1(3.4)
ウイルス感染	n (%)	0	0	0	0	0	1(3.4)
傷害、中毒および処置合併症	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
交通事故	n (%)	0	1(7.7)	0	0	1(2.3)	0
むち打ち損傷	n (%)	0	1(7.7)	0	0	1(2.3)	0
処置による疼痛	n (%)	0	0	0	0	0	1(3.4)
臨床検査	n (%)	1(100.0)	1(7.7)	1(3.8)	0	3(7.0)	3(10.3)
血中ブドウ糖増加	n (%)	0	1(7.7)	0	0	1(2.3)	0
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	1(3.8)	0	1(2.3)	1(3.4)
肝酵素上昇	n (%)	1(100.0)	0	0	0	1(2.3)	0
血中カリウム増加	n (%)	0	0	0	0	0	1(3.4)
好中球数増加	n (%)	0	0	0	0	0	1(3.4)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=13)	 80 mg (N=26)	 100 mg (N=3)	All NBI-98854 (N=43)	Placebo (N=29)
白血球数増加	n (%)	0	0	0	0	0	1(3.4)
代謝および栄養障害	n (%)	0	2(15.4)	1(3.8)	0	3(7.0)	1(3.4)
食欲減退	n (%)	0	1(7.7)	1(3.8)	0	2(4.7)	1(3.4)
食欲亢進	n (%)	0	1(7.7)	0	0	1(2.3)	0
筋骨格系および結合組織障害	n (%)	0	3(23.1)	2(7.7)	0	5(11.6)	1(3.4)
関節痛	n (%)	0	0	1(3.8)	0	1(2.3)	1(3.4)
背部痛	n (%)	0	1(7.7)	0	0	1(2.3)	0
四肢不快感	n (%)	0	1(7.7)	0	0	1(2.3)	0
筋力低下	n (%)	0	1(7.7)	0	0	1(2.3)	0
筋肉痛	n (%)	0	0	1(3.8)	0	1(2.3)	0
顎関節症候群	n (%)	0	1(7.7)	0	0	1(2.3)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	0	0	0	0	0	1(3.4)
口腔乳頭腫	n (%)	0	0	0	0	0	1(3.4)
神経系障害	n (%)	0	5(38.5)	6(23.1)	0	11(25.6)	5(17.2)
傾眠	n (%)	0	3(23.1)	1(3.8)	0	4(9.3)	1(3.4)
アカシジア	n (%)	0	0	2(7.7)	0	2(4.7)	0
よだれ	n (%)	0	0	2(7.7)	0	2(4.7)	0
頭痛	n (%)	0	1(7.7)	1(3.8)	0	2(4.7)	2(6.9)
平衡障害	n (%)	0	0	1(3.8)	0	1(2.3)	0

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=13)	 80 mg (N=26)	 100 mg (N=3)	All NBI-98854 (N=43)	 Placebo (N=29)
注意力障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
ジスキネジー	n (%)	0	0	1(3.8)	0	1(2.3)	0
ジストニー	n (%)	0	0	1(3.8)	0	1(2.3)	0
睡眠の質低下	n (%)	0	1(7.7)	0	0	1(2.3)	0
感覚鈍麻	n (%)	0	0	0	0	0	1(3.4)
片頭痛	n (%)	0	0	0	0	0	1(3.4)
遅発性ジスキネジー	n (%)	0	0	0	0	0	1(3.4)
精神障害	n (%)	1(100.0)	4(30.8)	3(11.5)	0	8(18.6)	2(6.9)
不安	n (%)	0	0	1(3.8)	0	1(2.3)	0
双極１型障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(2.3)	0
不眠症	n (%)	0	1(7.7)	0	0	1(2.3)	0
パニック発作	n (%)	0	0	1(3.8)	0	1(2.3)	0
妄想症	n (%)	0	1(7.7)	0	0	1(2.3)	0
精神運動制止遅滞	n (%)	0	1(7.7)	0	0	1(2.3)	0
精神病性障害	n (%)	0	0	1(3.8)	0	1(2.3)	0
自殺念慮	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
うつ病	n (%)	0	0	0	0	0	1(3.4)
抑うつ症状	n (%)	0	0	0	0	0	1(3.4)
躁病	n (%)	0	0	0	0	0	1(3.4)
呼吸器、胸郭および縦隔障害	n (%)	0	0	1(3.8)	0	1(2.3)	0
鼻閉	n (%)	0	0	1(3.8)	0	1(2.3)	0

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－201　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	 40 mg (N=13)	 80 mg (N=26)	 100 mg (N=3)	All NBI-98854 (N=43)	Placebo (N=29)
皮膚および皮下組織障害	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
網状皮斑	n (%)	0	1(7.7)	0	0	1(2.3)	0
ケラトアカントーマ	n (%)	0	0	0	0	0	1(3.4)
乾癬	n (%)	0	0	0	0	0	1(3.4)
外科および内科処置	n (%)	0	0	0	0	0	1(3.4)
鼓膜切開	n (%)	0	0	0	0	0	1(3.4)
血管障害	n (%)	0	0	2(7.7)	0	2(4.7)	1(3.4)
血腫	n (%)	0	0	1(3.8)	0	1(2.3)	0
ほてり	n (%)	0	0	1(3.8)	0	1(2.3)	1(3.4)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.6より引用（一部改変）

表2.7.4.7－202　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=97)	80 mg (N=86)	100 mg (N=24)	All NBI-98854 (N=211)	Placebo (N=149)
Any Adverse Event of Special Interest	n (%)	0	22(22.7)	19(22.1)	3(12.5)	44(20.9)	21(14.1)
アカシジア関連有害事象	n (%)	0	3(3.1)	1(1.2)	0	4(1.9)	1(0.7)
アカシジア	n (%)	0	3(3.1)	1(1.2)	0	4(1.9)	1(0.7)
不安	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	0
不安	n (%)	0	1(1.0)	1(1.2)	0	2(0.9)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(1.0)	1(1.2)	1(4.2)	3(1.4)	1(0.7)
胸痛	n (%)	0	1(1.0)	0	0	1(0.5)	0
突然死	n (%)	0	0	1(1.2)	0	1(0.5)	0
失神	n (%)	0	0	0	1(4.2)	1(0.5)	0
心筋梗塞	n (%)	0	0	0	0	0	1(0.7)
うつ病及び自殺関連有害事象	n (%)	0	4(4.1)	4(4.7)	0	8(3.8)	4(2.7)
自殺念慮	n (%)	0	3(3.1)	1(1.2)	0	4(1.9)	3(2.0)
うつ病	n (%)	0	0	2(2.3)	0	2(0.9)	1(0.7)
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.5)	0
自殺企図	n (%)	0	0	1(1.2)	0	1(0.5)	0
嚥下障害関連有害事象	n (%)	0	1(1.0)	0	0	1(0.5)	0
嚥下障害	n (%)	0	1(1.0)	0	0	1(0.5)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	4(4.1)	3(3.5)	2(8.3)	9(4.3)	3(2.0)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－202　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=97)	80 mg (N=86)	100 mg (N=24)	All NBI-98854 (N=211)	Placebo (N=149)
疲労	n (%)	0	4(4.1)	3(3.5)	2(8.3)	9(4.3)	3(2.0)
肝障害関連有害事象	n (%)	0	0	1(1.2)	0	1(0.5)	0
急性肝炎	n (%)	0	0	1(1.2)	0	1(0.5)	0
低血圧関連有害事象	n (%)	0	4(4.1)	2(2.3)	1(4.2)	7(3.3)	4(2.7)
転倒・転落	n (%)	0	2(2.1)	1(1.2)	0	3(1.4)	0
浮動性めまい	n (%)	0	2(2.1)	0	0	2(0.9)	4(2.7)
低血圧	n (%)	0	0	1(1.2)	0	1(0.5)	0
失神	n (%)	0	0	0	1(4.2)	1(0.5)	0
パーキンソニズム関連有害事象	n (%)	0	0	2(2.3)	0	2(0.9)	0
振戦	n (%)	0	0	2(2.3)	0	2(0.9)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	7(7.2)	5(5.8)	1(4.2)	13(6.2)	4(2.7)
傾眠	n (%)	0	6(6.2)	3(3.5)	1(4.2)	10(4.7)	3(2.0)
鎮静	n (%)	0	1(1.0)	2(2.3)	0	3(1.4)	1(0.7)
基礎疾患の悪化に関連する有害事象	n (%)	0	6(6.2)	5(5.8)	0	11(5.2)	11(7.4)
自殺念慮	n (%)	0	3(3.1)	1(1.2)	0	4(1.9)	3(2.0)
うつ病	n (%)	0	0	2(2.3)	0	2(0.9)	1(0.7)
抑うつ症状	n (%)	0	1(1.0)	0	0	1(0.5)	0
敵意	n (%)	0	1(1.0)	0	0	1(0.5)	0

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－202　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=4)	40 mg (N=97)	80 mg (N=86)	100 mg (N=24)	All NBI-98854 (N=211)	Placebo (N=149)
軽躁	n (%)	0	1(1.0)	0	0	1(0.5)	0
統合失調感情障害	n (%)	0	0	1(1.2)	0	1(0.5)	1(0.7)
統合失調症	n (%)	0	1(1.0)	0	0	1(0.5)	1(0.7)
自殺企図	n (%)	0	0	1(1.2)	0	1(0.5)	0
易刺激性	n (%)	0	0	0	0	0	2(1.3)
精神病性障害	n (%)	0	0	0	0	0	2(1.3)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.7)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－202　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	40 mg (N=13)	80 mg (N=26)	100 mg (N=3)	All NBI-98854 (N=43)	Placebo (N=29)
Any Adverse Event of Special Interest	n (%)	1(100.0)	6(46.2)	4(15.4)	0	11(25.6)	3(10.3)
アカシジア関連有害事象	n (%)	0	0	2(7.7)	0	2(4.7)	0
アカシジア	n (%)	0	0	2(7.7)	0	2(4.7)	0
不安	n (%)	0	0	1(3.8)	0	1(2.3)	0
不安	n (%)	0	0	1(3.8)	0	1(2.3)	0
うつ病及び自殺関連有害事象	n (%)	1(100.0)	1(7.7)	0	0	2(4.7)	2(6.9)
抑うつ気分	n (%)	1(100.0)	0	0	0	1(2.3)	0
自殺念慮	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
うつ病	n (%)	0	0	0	0	0	1(3.4)
抑うつ症状	n (%)	0	0	0	0	0	1(3.4)
嚥下障害関連有害事象	n (%)	0	1(7.7)	0	0	1(2.3)	0
嚥下障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(7.7)	0	0	1(2.3)	0
疲労	n (%)	0	1(7.7)	0	0	1(2.3)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	3(23.1)	1(3.8)	0	4(9.3)	1(3.4)
傾眠	n (%)	0	3(23.1)	1(3.8)	0	4(9.3)	1(3.4)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－202　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=1)	40 mg (N=13)	80 mg (N=26)	100 mg (N=3)	All NBI-98854 (N=43)	Placebo (N=29)
基礎疾患の悪化に関連する有害事象	n (%)	1(100.0)	4(30.8)	1(3.8)	0	6(14.0)	2(6.9)
双極１型障害	n (%)	0	1(7.7)	0	0	1(2.3)	0
抑うつ気分	n (%)	1(100.0)	0	0	0	1(2.3)	0
易刺激性	n (%)	0	1(7.7)	0	0	1(2.3)	0
妄想症	n (%)	0	1(7.7)	0	0	1(2.3)	0
精神病性障害	n (%)	0	0	1(3.8)	0	1(2.3)	0
自殺念慮	n (%)	0	1(7.7)	0	0	1(2.3)	1(3.4)
うつ病	n (%)	0	0	0	0	0	1(3.4)
抑うつ症状	n (%)	0	0	0	0	0	1(3.4)
躁病	n (%)	0	0	0	0	0	1(3.4)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.6より引用（一部改変）

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
Any Adverse Event	n (%)	100(57.5)	115(60.2)	104(57.8)	215(58.9)
血液およびリンパ系障害	n (%)	3(1.7)	4(2.1)	4(2.2)	7(1.9)
貧血	n (%)	1(0.6)	3(1.6)	3(1.7)	4(1.1)
好中球減少症	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
白血球増加症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
血小板血症	n (%)	1(0.6)	0	0	1(0.3)
心臓障害	n (%)	3(1.7)	5(2.6)	5(2.8)	8(2.2)
上室性不整脈	n (%)	1(0.6)	0	0	1(0.3)
心房細動	n (%)	0	1(0.5)	1(0.6)	1(0.3)
左脚ブロック	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
冠動脈疾患	n (%)	1(0.6)	0	0	1(0.3)
僧帽弁閉鎖不全症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
頻脈	n (%)	1(0.6)	0	0	1(0.3)
三尖弁閉鎖不全症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心室性期外収縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
耳および迷路障害	n (%)	3(1.7)	0	0	3(0.8)
耳鳴	n (%)	2(1.1)	0	0	2(0.5)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
聴覚障害	n (%)	1(0.6)	0	0	1(0.3)
眼障害	n (%)	0	1(0.5)	1(0.6)	1(0.3)
兎眼	n (%)	0	1(0.5)	1(0.6)	1(0.3)
胃腸障害	n (%)	25(14.4)	31(16.2)	24(13.3)	56(15.3)
下痢	n (%)	5(2.9)	9(4.7)	8(4.4)	14(3.8)
便秘	n (%)	6(3.4)	5(2.6)	3(1.7)	11(3.0)
嘔吐	n (%)	6(3.4)	5(2.6)	4(2.2)	11(3.0)
口内乾燥	n (%)	7(4.0)	3(1.6)	3(1.7)	10(2.7)
流涎過多	n (%)	2(1.1)	6(3.1)	3(1.7)	8(2.2)
悪心	n (%)	3(1.7)	4(2.1)	4(2.2)	7(1.9)
腹痛	n (%)	2(1.1)	4(2.1)	3(1.7)	6(1.6)
嚥下障害	n (%)	3(1.7)	1(0.5)	1(0.6)	4(1.1)
歯痛	n (%)	2(1.1)	2(1.0)	1(0.6)	4(1.1)
上腹部痛	n (%)	1(0.6)	2(1.0)	1(0.6)	3(0.8)
結腸ポリープ	n (%)	2(1.1)	0	0	2(0.5)
胃食道逆流性疾患	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
痔核	n (%)	2(1.1)	0	0	2(0.5)
腹部膨満	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腹部圧痛	n (%)	1(0.6)	0	0	1(0.3)
細菌叢異常症	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
憩室	n (%)	1(0.6)	0	0	1(0.3)
消化不良	n (%)	1(0.6)	0	0	1(0.3)
胃炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
胃腸出血	n (%)	1(0.6)	0	0	1(0.3)
裂孔ヘルニア	n (%)	0	1(0.5)	1(0.6)	1(0.3)
メレナ	n (%)	1(0.6)	0	0	1(0.3)
食道食物嵌入	n (%)	1(0.6)	0	0	1(0.3)
食道狭窄	n (%)	1(0.6)	0	0	1(0.3)
食道炎	n (%)	1(0.6)	0	0	1(0.3)
臍ヘルニア	n (%)	1(0.6)	0	0	1(0.3)
全身障害および投与局所様態	n (%)	17(9.8)	16(8.4)	13(7.2)	33(9.0)
疲労	n (%)	12(6.9)	5(2.6)	5(2.8)	17(4.7)
胸痛	n (%)	3(1.7)	2(1.0)	2(1.1)	5(1.4)
歩行障害	n (%)	3(1.7)	1(0.5)	0	4(1.1)
末梢性浮腫	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)
無力症	n (%)	1(0.6)	1(0.5)	0	2(0.5)
易刺激性	n (%)	0	2(1.0)	2(1.1)	2(0.5)
非心臓性胸痛	n (%)	1(0.6)	1(0.5)	0	2(0.5)
空腹	n (%)	1(0.6)	0	0	1(0.3)
治癒不良	n (%)	1(0.6)	0	0	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
倦怠感	n (%)	0	1(0.5)	1(0.6)	1(0.3)
発熱	n (%)	0	1(0.5)	1(0.6)	1(0.3)
突然死	n (%)	0	1(0.5)	1(0.6)	1(0.3)
口渇	n (%)	1(0.6)	0	0	1(0.3)
肝胆道系障害	n (%)	0	3(1.6)	3(1.7)	3(0.8)
胆石症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
肝不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
急性肝炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
黄疸	n (%)	0	1(0.5)	1(0.6)	1(0.3)
免疫系障害	n (%)	0	2(1.0)	2(1.1)	2(0.5)
過敏症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
季節性アレルギー	n (%)	0	1(0.5)	1(0.6)	1(0.3)
感染症および寄生虫症	n (%)	28(16.1)	35(18.3)	32(17.8)	63(17.3)
尿路感染	n (%)	10(5.7)	12(6.3)	11(6.1)	22(6.0)
鼻咽頭炎	n (%)	5(2.9)	9(4.7)	8(4.4)	14(3.8)
上気道感染	n (%)	4(2.3)	3(1.6)	3(1.7)	7(1.9)
気管支炎	n (%)	2(1.1)	4(2.1)	4(2.2)	6(1.6)
蜂巣炎	n (%)	0	3(1.6)	2(1.1)	3(0.8)
胃腸炎	n (%)	0	3(1.6)	3(1.7)	3(0.8)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
ダニ皮膚炎	n (%)	2(1.1)	0	0	2(0.5)
急性副鼻腔炎	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
ウイルス性胃腸炎	n (%)	2(1.1)	0	0	2(0.5)
インフルエンザ	n (%)	2(1.1)	0	0	2(0.5)
四肢膿瘍	n (%)	0	1(0.5)	0	1(0.3)
軟部組織膿瘍	n (%)	0	1(0.5)	1(0.6)	1(0.3)
急性扁桃炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
体部白癬	n (%)	1(0.6)	0	0	1(0.3)
憩室炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
耳感染	n (%)	1(0.6)	0	0	1(0.3)
眼感染	n (%)	1(0.6)	0	0	1(0.3)
せつ	n (%)	1(0.6)	0	0	1(0.3)
咬傷感染	n (%)	0	1(0.5)	1(0.6)	1(0.3)
爪真菌症	n (%)	1(0.6)	0	0	1(0.3)
咽頭炎	n (%)	1(0.6)	0	0	1(0.3)
肺炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
急性腎盂腎炎	n (%)	1(0.6)	0	0	1(0.3)
副鼻腔炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
歯膿瘍	n (%)	0	1(0.5)	1(0.6)	1(0.3)
外陰腟真菌感染	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
傷害、中毒および処置合併症	n (%)	14(8.0)	17(8.9)	14(7.8)	31(8.5)
転倒・転落	n (%)	4(2.3)	4(2.1)	3(1.7)	8(2.2)
擦過傷	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)
挫傷	n (%)	2(1.1)	0	0	2(0.5)
関節脱臼	n (%)	0	2(1.0)	1(0.6)	2(0.5)
交通事故	n (%)	0	2(1.0)	2(1.1)	2(0.5)
皮膚裂傷	n (%)	0	2(1.0)	2(1.1)	2(0.5)
動物咬傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
節足動物咬傷	n (%)	0	1(0.5)	0	1(0.3)
第２度熱傷	n (%)	1(0.6)	0	0	1(0.3)
頚椎骨折	n (%)	0	1(0.5)	1(0.6)	1(0.3)
皮膚化学熱傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
足骨折	n (%)	0	1(0.5)	1(0.6)	1(0.3)
異物による損傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
頭部損傷	n (%)	1(0.6)	0	0	1(0.3)
関節損傷	n (%)	1(0.6)	0	0	1(0.3)
四肢損傷	n (%)	0	1(0.5)	0	1(0.3)
四肢外傷性切断	n (%)	1(0.6)	0	0	1(0.3)
口腔内損傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋挫傷	n (%)	0	1(0.5)	1(0.6)	1(0.3)
橈骨骨折	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
腎損傷	n (%)	1(0.6)	0	0	1(0.3)
肋骨骨折	n (%)	0	1(0.5)	0	1(0.3)
引っかき傷	n (%)	1(0.6)	0	0	1(0.3)
皮下血腫	n (%)	0	1(0.5)	1(0.6)	1(0.3)
熱傷	n (%)	1(0.6)	0	0	1(0.3)
臨床検査	n (%)	16(9.2)	25(13.1)	22(12.2)	41(11.2)
体重増加	n (%)	2(1.1)	6(3.1)	6(3.3)	8(2.2)
ヘモグロビン減少	n (%)	1(0.6)	3(1.6)	3(1.7)	4(1.1)
血中クレアチンホスホキナーゼ増加	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)
血中クレアチニン増加	n (%)	1(0.6)	2(1.0)	1(0.6)	3(0.8)
血中ブドウ糖増加	n (%)	0	3(1.6)	3(1.7)	3(0.8)
血中プロラクチン増加	n (%)	2(1.1)	1(0.5)	0	3(0.8)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(0.6)	2(1.0)	2(1.1)	3(0.8)
尿中ブドウ糖陽性	n (%)	1(0.6)	2(1.0)	2(1.1)	3(0.8)
体重減少	n (%)	3(1.7)	0	0	3(0.8)
血圧上昇	n (%)	0	2(1.0)	2(1.1)	2(0.5)
血中トリグリセリド増加	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
血中尿素増加	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
ヘマトクリット減少	n (%)	0	2(1.0)	2(1.1)	2(0.5)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
抗精神病薬濃度治療量以上	n (%)	0	1(0.5)	0	1(0.3)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.6)	0	0	1(0.3)
血中コレステロール増加	n (%)	0	1(0.5)	1(0.6)	1(0.3)
尿中結晶陽性	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心電図ＱＴ延長	n (%)	0	1(0.5)	1(0.6)	1(0.3)
グリコヘモグロビン増加	n (%)	0	1(0.5)	1(0.6)	1(0.3)
握力低下	n (%)	1(0.6)	0	0	1(0.3)
肝酵素上昇	n (%)	1(0.6)	0	0	1(0.3)
便潜血陽性	n (%)	0	1(0.5)	1(0.6)	1(0.3)
総蛋白減少	n (%)	0	1(0.5)	1(0.6)	1(0.3)
赤血球数減少	n (%)	0	1(0.5)	1(0.6)	1(0.3)
赤血球数増加	n (%)	0	1(0.5)	1(0.6)	1(0.3)
代謝および栄養障害	n (%)	5(2.9)	12(6.3)	10(5.6)	17(4.7)
低ナトリウム血症	n (%)	0	3(1.6)	2(1.1)	3(0.8)
食欲亢進	n (%)	0	3(1.6)	2(1.1)	3(0.8)
食欲減退	n (%)	2(1.1)	0	0	2(0.5)
食欲不振	n (%)	1(0.6)	0	0	1(0.3)
食欲障害	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
脱水	n (%)	0	1(0.5)	1(0.6)	1(0.3)
糖尿病	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高血糖	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高カリウム血症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高トリグリセリド血症	n (%)	1(0.6)	0	0	1(0.3)
低アルブミン血症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
低カリウム血症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
低ナトリウム血症候群	n (%)	0	1(0.5)	1(0.6)	1(0.3)
代謝性アシドーシス	n (%)	0	1(0.5)	1(0.6)	1(0.3)
多飲症	n (%)	1(0.6)	0	0	1(0.3)
筋骨格系および結合組織障害	n (%)	16(9.2)	14(7.3)	11(6.1)	30(8.2)
背部痛	n (%)	5(2.9)	4(2.1)	4(2.2)	9(2.5)
関節痛	n (%)	2(1.1)	3(1.6)	3(1.7)	5(1.4)
骨関節炎	n (%)	1(0.6)	2(1.0)	2(1.1)	3(0.8)
四肢痛	n (%)	1(0.6)	2(1.0)	0	3(0.8)
関節炎	n (%)	1(0.6)	1(0.5)	0	2(0.5)
筋肉痛	n (%)	2(1.1)	0	0	2(0.5)
頚部痛	n (%)	1(0.6)	1(0.5)	0	2(0.5)
滑液包炎	n (%)	1(0.6)	0	0	1(0.3)
椎間板変性症	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
関節腫脹	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋痙縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
筋力低下	n (%)	1(0.6)	0	0	1(0.3)
筋骨格系胸痛	n (%)	1(0.6)	0	0	1(0.3)
筋骨格痛	n (%)	0	1(0.5)	1(0.6)	1(0.3)
骨減少症	n (%)	1(0.6)	0	0	1(0.3)
顎痛	n (%)	1(0.6)	0	0	1(0.3)
良性、悪性および詳細不明の新生物 （嚢胞およびポリープを含む）	n (%)	2(1.1)	3(1.6)	3(1.7)	5(1.4)
副腎腺腫	n (%)	0	1(0.5)	1(0.6)	1(0.3)
乳癌	n (%)	0	1(0.5)	1(0.6)	1(0.3)
脂肪腫	n (%)	1(0.6)	0	0	1(0.3)
肺新生物	n (%)	1(0.6)	0	0	1(0.3)
甲状腺新生物	n (%)	0	1(0.5)	1(0.6)	1(0.3)
神経系障害	n (%)	42(24.1)	34(17.8)	27(15.0)	76(20.8)
頭痛	n (%)	9(5.2)	10(5.2)	8(4.4)	19(5.2)
傾眠	n (%)	14(8.0)	5(2.6)	4(2.2)	19(5.2)
浮動性めまい	n (%)	6(3.4)	6(3.1)	6(3.3)	12(3.3)
振戦	n (%)	4(2.3)	3(1.6)	1(0.6)	7(1.9)
アカシジア	n (%)	6(3.4)	0	0	6(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
失神	n (%)	4(2.3)	2(1.0)	1(0.6)	6(1.6)
鎮静	n (%)	2(1.1)	2(1.0)	2(1.1)	4(1.1)
ジスキネジー	n (%)	1(0.6)	2(1.0)	2(1.1)	3(0.8)
錐体外路障害	n (%)	0	2(1.0)	2(1.1)	2(0.5)
一過性脳虚血発作	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
健忘	n (%)	0	1(0.5)	1(0.6)	1(0.3)
平衡障害	n (%)	1(0.6)	0	0	1(0.3)
歯車様固縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
認知症	n (%)	1(0.6)	0	0	1(0.3)
よだれ	n (%)	0	1(0.5)	1(0.6)	1(0.3)
構語障害	n (%)	0	1(0.5)	0	1(0.3)
ジストニー	n (%)	1(0.6)	0	0	1(0.3)
脳症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
顔面神経麻痺	n (%)	0	1(0.5)	1(0.6)	1(0.3)
感覚鈍麻	n (%)	1(0.6)	0	0	1(0.3)
企図振戦	n (%)	1(0.6)	0	0	1(0.3)
嗜眠	n (%)	0	1(0.5)	0	1(0.3)
片頭痛	n (%)	1(0.6)	0	0	1(0.3)
ミオクローヌス	n (%)	1(0.6)	0	0	1(0.3)
神経痛	n (%)	1(0.6)	0	0	1(0.3)
末梢性ニューロパチー	n (%)	0	1(0.5)	1(0.6)	1(0.3)
遅発性ジスキネジー	n (%)	1(0.6)	0	0	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
咬舌	n (%)	1(0.6)	0	0	1(0.3)
妊娠、産褥および周産期の状態	n (%)	0	1(0.5)	1(0.6)	1(0.3)
自然流産	n (%)	0	1(0.5)	1(0.6)	1(0.3)
精神障害	n (%)	32(18.4)	26(13.6)	21(11.7)	58(15.9)
自殺念慮	n (%)	7(4.0)	7(3.7)	7(3.9)	14(3.8)
不安	n (%)	5(2.9)	6(3.1)	2(1.1)	11(3.0)
うつ病	n (%)	7(4.0)	4(2.1)	4(2.2)	11(3.0)
統合失調症	n (%)	4(2.3)	4(2.1)	4(2.2)	8(2.2)
不眠症	n (%)	3(1.7)	4(2.1)	4(2.2)	7(1.9)
落ち着きのなさ	n (%)	1(0.6)	2(1.0)	0	3(0.8)
激越	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
抑うつ症状	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
精神状態変化	n (%)	2(1.1)	0	0	2(0.5)
精神運動制止遅滞	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
精神病性障害	n (%)	1(0.6)	1(0.5)	0	2(0.5)
統合失調感情障害	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
自殺企図	n (%)	0	2(1.0)	2(1.1)	2(0.5)
アルコール症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
死別反応	n (%)	1(0.6)	0	0	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
錯乱状態	n (%)	0	1(0.5)	1(0.6)	1(0.3)
ディスフェミア	n (%)	1(0.6)	0	0	1(0.3)
敵意	n (%)	1(0.6)	0	0	1(0.3)
軽躁	n (%)	1(0.6)	0	0	1(0.3)
リビドー減退	n (%)	1(0.6)	0	0	1(0.3)
躁病	n (%)	1(0.6)	0	0	1(0.3)
神経過敏	n (%)	0	1(0.5)	1(0.6)	1(0.3)
妄想症	n (%)	1(0.6)	0	0	1(0.3)
トランス	n (%)	1(0.6)	0	0	1(0.3)
腎および尿路障害	n (%)	5(2.9)	5(2.6)	5(2.8)	10(2.7)
血尿	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)
頻尿	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
尿失禁	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
糖尿	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腎結石症	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腎嚢胞	n (%)	1(0.6)	0	0	1(0.3)
尿臭異常	n (%)	1(0.6)	0	0	1(0.3)
生殖系および乳房障害	n (%)	2(1.1)	3(1.6)	3(1.7)	5(1.4)
良性前立腺肥大症	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
乳房圧痛	n (%)	1(0.6)	0	0	1(0.3)
乳汁漏出症	n (%)	1(0.6)	0	0	1(0.3)
月経過多	n (%)	0	1(0.5)	1(0.6)	1(0.3)
精巣捻転	n (%)	0	1(0.5)	1(0.6)	1(0.3)
腟分泌物	n (%)	1(0.6)	0	0	1(0.3)
呼吸器、胸郭および縦隔障害	n (%)	7(4.0)	19(9.9)	17(9.4)	26(7.1)
咳嗽	n (%)	3(1.7)	5(2.6)	4(2.2)	8(2.2)
慢性閉塞性肺疾患	n (%)	2(1.1)	4(2.1)	4(2.2)	6(1.6)
喘息	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
呼吸困難	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
鼻閉	n (%)	0	2(1.0)	2(1.1)	2(0.5)
アレルギー性鼻炎	n (%)	0	2(1.0)	2(1.1)	2(0.5)
アレルギー性副鼻腔炎	n (%)	1(0.6)	0	0	1(0.3)
慢性気管支炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
嚢胞性肺疾患	n (%)	0	1(0.5)	1(0.6)	1(0.3)
鼻出血	n (%)	1(0.6)	0	0	1(0.3)
口腔咽頭痛	n (%)	0	1(0.5)	0	1(0.3)
胸水	n (%)	0	1(0.5)	1(0.6)	1(0.3)
胸膜線維症	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
鼻漏	n (%)	1(0.6)	0	0	1(0.3)
副鼻腔うっ血	n (%)	1(0.6)	0	0	1(0.3)
くしゃみ	n (%)	0	1(0.5)	1(0.6)	1(0.3)
皮膚および皮下組織障害	n (%)	10(5.7)	4(2.1)	4(2.2)	14(3.8)
そう痒症	n (%)	3(1.7)	0	0	3(0.8)
発疹	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)
斑状丘疹状皮疹	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
水疱	n (%)	1(0.6)	0	0	1(0.3)
過角化	n (%)	1(0.6)	0	0	1(0.3)
全身性皮疹	n (%)	1(0.6)	0	0	1(0.3)
皮膚剥脱	n (%)	0	1(0.5)	1(0.6)	1(0.3)
皮膚病変	n (%)	0	1(0.5)	1(0.6)	1(0.3)
蕁麻疹	n (%)	1(0.6)	0	0	1(0.3)
社会環境	n (%)	1(0.6)	0	0	1(0.3)
社会的入院	n (%)	1(0.6)	0	0	1(0.3)
外科および内科処置	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)
抜歯	n (%)	2(1.1)	1(0.5)	1(0.6)	3(0.8)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	 80 mg (N=191)	 80 mg Only[c] (N=180)	All NBI-98854 (N=365)
血管障害	n (%)	6(3.4)	11(5.8)	10(5.6)	17(4.7)
高血圧	n (%)	2(1.1)	6(3.1)	5(2.8)	8(2.2)
深部静脈血栓症	n (%)	0	2(1.0)	2(1.1)	2(0.5)
ほてり	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
本態性高血圧症	n (%)	1(0.6)	0	0	1(0.3)
低血圧	n (%)	0	1(0.5)	1(0.6)	1(0.3)
起立性低血圧	n (%)	1(0.6)	0	0	1(0.3)
末梢動脈閉塞性疾患	n (%)	1(0.6)	0	0	1(0.3)
レイノー現象	n (%)	0	1(0.5)	1(0.6)	1(0.3)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203 ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	All NBI-98854 (N=62)
Any Adverse Event	n (%)	17(73.9)	27(69.2)	22(64.7)	44(71.0)
血液およびリンパ系障害	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
白血球減少症	n (%)	0	1(2.6)	1(2.9)	1(1.6)
好中球減少症	n (%)	1(4.3)	0	0	1(1.6)
心臓障害	n (%)	2(8.7)	0	0	2(3.2)
心房細動	n (%)	1(4.3)	0	0	1(1.6)
洞性頻脈	n (%)	1(4.3)	0	0	1(1.6)
先天性、家族性および遺伝性障害	n (%)	0	1(2.6)	1(2.9)	1(1.6)
弯足	n (%)	0	1(2.6)	1(2.9)	1(1.6)
耳および迷路障害	n (%)	0	2(5.1)	2(5.9)	2(3.2)
耳介軟骨膜炎	n (%)	0	1(2.6)	1(2.9)	1(1.6)
耳痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
内分泌障害	n (%)	1(4.3)	0	0	1(1.6)
甲状腺機能低下症	n (%)	1(4.3)	0	0	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	All NBI-98854 (N=62)
眼障害	n (%)	0	2(5.1)	2(5.9)	2(3.2)
核性白内障	n (%)	0	1(2.6)	1(2.9)	1(1.6)
複視	n (%)	0	1(2.6)	1(2.9)	1(1.6)
黄斑浮腫	n (%)	0	1(2.6)	1(2.9)	1(1.6)
網膜静脈閉塞	n (%)	0	1(2.6)	1(2.9)	1(1.6)
胃腸障害	n (%)	5(21.7)	11(28.2)	9(26.5)	16(25.8)
悪心	n (%)	1(4.3)	3(7.7)	3(8.8)	4(6.5)
下痢	n (%)	1(4.3)	2(5.1)	2(5.9)	3(4.8)
嘔吐	n (%)	1(4.3)	2(5.1)	1(2.9)	3(4.8)
上腹部痛	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
便秘	n (%)	0	2(5.1)	1(2.9)	2(3.2)
口内乾燥	n (%)	1(4.3)	0	0	1(1.6)
消化不良	n (%)	0	1(2.6)	1(2.9)	1(1.6)
変色便	n (%)	1(4.3)	0	0	1(1.6)
食中毒	n (%)	0	1(2.6)	1(2.9)	1(1.6)
胃炎	n (%)	0	1(2.6)	0	1(1.6)
びらん性胃炎	n (%)	0	1(2.6)	0	1(1.6)
胃食道逆流性疾患	n (%)	0	1(2.6)	1(2.9)	1(1.6)
歯の脱落	n (%)	1(4.3)	0	0	1(1.6)
歯痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	 All NBI-98854 (N=62)
全身障害および投与局所様態	n (%)	1(4.3)	11(28.2)	7(20.6)	12(19.4)
疲労	n (%)	1(4.3)	3(7.7)	3(8.8)	4(6.5)
無力症	n (%)	0	3(7.7)	0	3(4.8)
胸痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
易刺激性	n (%)	1(4.3)	0	0	1(1.6)
非心臓性胸痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
末梢性浮腫	n (%)	0	1(2.6)	1(2.9)	1(1.6)
疼痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
発熱	n (%)	0	1(2.6)	0	1(1.6)
感染症および寄生虫症	n (%)	4(17.4)	9(23.1)	7(20.6)	13(21.0)
尿路感染	n (%)	1(4.3)	2(5.1)	2(5.9)	3(4.8)
気管支炎	n (%)	0	2(5.1)	1(2.9)	2(3.2)
皮下組織膿瘍	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
蜂巣炎	n (%)	0	1(2.6)	1(2.9)	1(1.6)
ブドウ球菌性蜂巣炎	n (%)	1(4.3)	0	0	1(1.6)
耳感染	n (%)	0	1(2.6)	1(2.9)	1(1.6)
胃腸炎	n (%)	0	1(2.6)	1(2.9)	1(1.6)
ウイルス性胃腸炎	n (%)	1(4.3)	0	0	1(1.6)
鼻咽頭炎	n (%)	1(4.3)	0	0	1(1.6)
副鼻腔炎	n (%)	0	1(2.6)	0	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	All NBI-98854 (N=62)
股部白癬	n (%)	1(4.3)	0	0	1(1.6)
上気道感染	n (%)	0	1(2.6)	1(2.9)	1(1.6)
外陰腟真菌感染	n (%)	1(4.3)	0	0	1(1.6)
傷害、中毒および処置合併症	n (%)	2(8.7)	4(10.3)	3(8.8)	6(9.7)
転倒・転落	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
足骨折	n (%)	0	2(5.1)	1(2.9)	2(3.2)
挫傷	n (%)	0	1(2.6)	1(2.9)	1(1.6)
擦過傷	n (%)	0	1(2.6)	1(2.9)	1(1.6)
関節捻挫	n (%)	1(4.3)	0	0	1(1.6)
筋挫傷	n (%)	0	1(2.6)	1(2.9)	1(1.6)
膝蓋骨骨折	n (%)	0	1(2.6)	1(2.9)	1(1.6)
臨床検査	n (%)	3(13.0)	9(23.1)	7(20.6)	12(19.4)
体重減少	n (%)	1(4.3)	3(7.7)	2(5.9)	4(6.5)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
グリコヘモグロビン増加	n (%)	1(4.3)	1(2.6)	0	2(3.2)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(2.6)	1(2.9)	1(1.6)
血中ブドウ糖減少	n (%)	0	1(2.6)	0	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	All NBI-98854 (N=62)
血中トリグリセリド増加	n (%)	0	1(2.6)	1(2.9)	1(1.6)
心拍数減少	n (%)	0	1(2.6)	1(2.9)	1(1.6)
血小板数減少	n (%)	0	1(2.6)	1(2.9)	1(1.6)
体重増加	n (%)	0	1(2.6)	1(2.9)	1(1.6)
代謝および栄養障害	n (%)	4(17.4)	4(10.3)	3(8.8)	8(12.9)
食欲減退	n (%)	2(8.7)	3(7.7)	2(5.9)	5(8.1)
食欲不振	n (%)	1(4.3)	0	0	1(1.6)
糖尿病	n (%)	0	1(2.6)	1(2.9)	1(1.6)
耐糖能障害	n (%)	1(4.3)	0	0	1(1.6)
筋骨格系および結合組織障害	n (%)	2(8.7)	7(17.9)	5(14.7)	9(14.5)
関節痛	n (%)	0	3(7.7)	2(5.9)	3(4.8)
四肢痛	n (%)	0	2(5.1)	2(5.9)	2(3.2)
背部痛	n (%)	1(4.3)	0	0	1(1.6)
尾骨痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
筋固縮	n (%)	0	1(2.6)	0	1(1.6)
筋肉痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
骨関節炎	n (%)	1(4.3)	0	0	1(1.6)
神経系障害	n (%)	4(17.4)	15(38.5)	10(29.4)	19(30.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	 All NBI-98854 (N=62)
頭痛	n (%)	1(4.3)	6(15.4)	4(11.8)	7(11.3)
傾眠	n (%)	1(4.3)	4(10.3)	2(5.9)	5(8.1)
浮動性めまい	n (%)	0	4(10.3)	4(11.8)	4(6.5)
アカシジア	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
平衡障害	n (%)	0	2(5.1)	1(2.9)	2(3.2)
よだれ	n (%)	0	2(5.1)	2(5.9)	2(3.2)
ジスキネジー	n (%)	0	2(5.1)	1(2.9)	2(3.2)
パーキンソニズム	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
鎮静	n (%)	0	2(5.1)	1(2.9)	2(3.2)
注意力障害	n (%)	0	1(2.6)	1(2.9)	1(1.6)
ジストニー	n (%)	1(4.3)	0	0	1(1.6)
遅発性ジスキネジー	n (%)	0	1(2.6)	1(2.9)	1(1.6)
精神障害	n (%)	9(39.1)	9(23.1)	7(20.6)	18(29.0)
自殺念慮	n (%)	2(8.7)	3(7.7)	3(8.8)	5(8.1)
うつ病	n (%)	2(8.7)	1(2.6)	0	3(4.8)
不安	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
抑うつ気分	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
不眠症	n (%)	1(4.3)	1(2.6)	0	2(3.2)
激越	n (%)	0	1(2.6)	1(2.9)	1(1.6)
双極１型障害	n (%)	1(4.3)	0	0	1(1.6)
躁病	n (%)	0	1(2.6)	1(2.9)	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	All NBI-98854 (N=62)
気分動揺	n (%)	0	1(2.6)	0	1(1.6)
パニック発作	n (%)	1(4.3)	0	0	1(1.6)
妄想症	n (%)	1(4.3)	0	0	1(1.6)
外傷後ストレス障害	n (%)	1(4.3)	0	0	1(1.6)
自殺行為	n (%)	0	1(2.6)	1(2.9)	1(1.6)
腎および尿路障害	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
排尿困難	n (%)	0	1(2.6)	1(2.9)	1(1.6)
急性腎不全	n (%)	1(4.3)	0	0	1(1.6)
生殖系および乳房障害	n (%)	1(4.3)	0	0	1(1.6)
前立腺炎	n (%)	1(4.3)	0	0	1(1.6)
呼吸器、胸郭および縦隔障害	n (%)	1(4.3)	8(20.5)	6(17.6)	9(14.5)
鼻閉	n (%)	1(4.3)	3(7.7)	3(8.8)	4(6.5)
喘息	n (%)	0	2(5.1)	1(2.9)	2(3.2)
咳嗽	n (%)	0	2(5.1)	1(2.9)	2(3.2)
呼吸困難	n (%)	0	2(5.1)	1(2.9)	2(3.2)
慢性閉塞性肺疾患	n (%)	0	1(2.6)	1(2.9)	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－203　ベースライン時の抗精神病薬投与の有無ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	 80 mg (N=39)	 80 mg Only[c] (N=34)	All NBI-98854 (N=62)
口腔咽頭痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
気道うっ血	n (%)	0	1(2.6)	0	1(1.6)
副鼻腔うっ血	n (%)	0	1(2.6)	0	1(1.6)
皮膚および皮下組織障害	n (%)	1(4.3)	3(7.7)	2(5.9)	4(6.5)
発疹	n (%)	0	2(5.1)	1(2.9)	2(3.2)
アレルギー性皮膚炎	n (%)	1(4.3)	0	0	1(1.6)
過角化	n (%)	0	1(2.6)	1(2.9)	1(1.6)
丘疹	n (%)	0	1(2.6)	1(2.9)	1(1.6)
外科および内科処置	n (%)	0	2(5.1)	2(5.9)	2(3.2)
四肢再接合手術	n (%)	0	1(2.6)	1(2.9)	1(1.6)
鼓膜切開	n (%)	0	1(2.6)	1(2.9)	1(1.6)
Unknown	n (%)	1(4.3)	0	0	1(1.6)
皮膚嚢腫	n (%)	1(4.3)	0	0	1(1.6)
血管障害	n (%)	0	3(7.7)	3(8.8)	3(4.8)
血腫	n (%)	0	2(5.1)	2(5.9)	2(3.2)
ほてり	n (%)	0	1(2.6)	1(2.9)	1(1.6)

[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.6より引用（一部改変）

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	80 mg (N=191)	80 mg Only[c] (N=180)	All NBI-98854 (N=365)
Any Adverse Event of Special Interest	n (%)	59(33.9)	53(27.7)	43(23.9)	112(30.7)
アカシジア関連有害事象	n (%)	6(3.4)	0	0	6(1.6)
アカシジア	n (%)	6(3.4)	0	0	6(1.6)
不安	n (%)	5(2.9)	6(3.1)	2(1.1)	11(3.0)
不安	n (%)	5(2.9)	6(3.1)	2(1.1)	11(3.0)
心血管系及びQT間隔延長関連有害事象	n (%)	6(3.4)	7(3.7)	6(3.3)	13(3.6)
失神	n (%)	4(2.3)	2(1.0)	1(0.6)	6(1.6)
胸痛	n (%)	3(1.7)	2(1.0)	2(1.1)	5(1.4)
心不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
心電図QT延長	n (%)	0	1(0.5)	1(0.6)	1(0.3)
突然死	n (%)	0	1(0.5)	1(0.6)	1(0.3)
うつ病及び自殺関連有害事象	n (%)	14(8.0)	12(6.3)	12(6.7)	26(7.1)
自殺念慮	n (%)	7(4.0)	7(3.7)	7(3.9)	14(3.8)
うつ病	n (%)	7(4.0)	4(2.1)	4(2.2)	11(3.0)
抑うつ症状	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
自殺企図	n (%)	0	2(1.0)	2(1.1)	2(0.5)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	80 mg (N=191)	80 mg Only[c] (N=180)	All NBI-98854 (N=365)
嚥下障害関連有害事象	n (%)	3(1.7)	1(0.5)	1(0.6)	4(1.1)
嚥下障害	n (%)	3(1.7)	1(0.5)	1(0.6)	4(1.1)
食道食物嵌入	n (%)	1(0.6)	0	0	1(0.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	12(6.9)	8(4.2)	6(3.3)	20(5.5)
疲労	n (%)	12(6.9)	5(2.6)	5(2.8)	17(4.7)
無力症	n (%)	1(0.6)	1(0.5)	0	2(0.5)
嗜眠	n (%)	0	1(0.5)	0	1(0.3)
倦怠感	n (%)	0	1(0.5)	1(0.6)	1(0.3)
肝障害関連有害事象	n (%)	0	2(1.0)	2(1.1)	2(0.5)
肝不全	n (%)	0	1(0.5)	1(0.6)	1(0.3)
急性肝炎	n (%)	0	1(0.5)	1(0.6)	1(0.3)
高プロラクチン血症関連有害事象	n (%)	3(1.7)	1(0.5)	0	4(1.1)
血中プロラクチン増加	n (%)	2(1.1)	1(0.5)	0	3(0.8)
乳汁漏出症	n (%)	1(0.6)	0	0	1(0.3)
低血圧関連有害事象	n (%)	13(7.5)	11(5.8)	10(5.6)	24(6.6)
浮動性めまい	n (%)	6(3.4)	6(3.1)	6(3.3)	12(3.3)
転倒・転落	n (%)	4(2.3)	4(2.1)	3(1.7)	8(2.2)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	80 mg (N=191)	80 mg Only[c] (N=180)	All NBI-98854 (N=365)
失神	n (%)	4(2.3)	2(1.0)	1(0.6)	6(1.6)
低血圧	n (%)	0	1(0.5)	1(0.6)	1(0.3)
起立性低血圧	n (%)	1(0.6)	0	0	1(0.3)
パーキンソニズム関連有害事象	n (%)	4(2.3)	3(1.6)	1(0.6)	7(1.9)
振戦	n (%)	4(2.3)	3(1.6)	1(0.6)	7(1.9)
歯車様固縮	n (%)	0	1(0.5)	1(0.6)	1(0.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	16(9.2)	7(3.7)	6(3.3)	23(6.3)
傾眠	n (%)	14(8.0)	5(2.6)	4(2.2)	19(5.2)
鎮静	n (%)	2(1.1)	2(1.0)	2(1.1)	4(1.1)
基礎疾患の悪化に関連する有害事象	n (%)	19(10.9)	18(9.4)	17(9.4)	37(10.1)
自殺念慮	n (%)	7(4.0)	7(3.7)	7(3.9)	14(3.8)
うつ病	n (%)	7(4.0)	4(2.1)	4(2.2)	11(3.0)
統合失調症	n (%)	4(2.3)	4(2.1)	4(2.2)	8(2.2)
抑うつ症状	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
易刺激性	n (%)	0	2(1.0)	2(1.1)	2(0.5)
精神病性障害	n (%)	1(0.6)	1(0.5)	0	2(0.5)
統合失調感情障害	n (%)	1(0.6)	1(0.5)	1(0.6)	2(0.5)
自殺企図	n (%)	0	2(1.0)	2(1.1)	2(0.5)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: Yes

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=174)	80 mg (N=191)	80 mg Only[c] (N=180)	All NBI-98854 (N=365)
敵意	n (%)	1(0.6)	0	0	1(0.3)
軽躁	n (%)	1(0.6)	0	0	1(0.3)
躁病	n (%)	1(0.6)	0	0	1(0.3)
妄想症	n (%)	1(0.6)	0	0	1(0.3)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	80 mg (N=39)	80 mg Only[c] (N=34)	All NBI-98854 (N=62)
Any Adverse Event of Special Interest	n (%)	11(47.8)	18(46.2)	13(38.2)	29(46.8)
アカシジア関連有害事象	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
アカシジア	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
不安	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
不安	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(2.6)	1(2.9)	1(1.6)
胸痛	n (%)	0	1(2.6)	1(2.9)	1(1.6)
うつ病及び自殺関連有害事象	n (%)	5(21.7)	6(15.4)	5(14.7)	11(17.7)
自殺念慮	n (%)	2(8.7)	3(7.7)	3(8.8)	5(8.1)
うつ病	n (%)	2(8.7)	1(2.6)	0	3(4.8)
抑うつ気分	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
自殺行為	n (%)	0	1(2.6)	1(2.9)	1(1.6)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	1(4.3)	6(15.4)	3(8.8)	7(11.3)
疲労	n (%)	1(4.3)	3(7.7)	3(8.8)	4(6.5)
無力症	n (%)	0	3(7.7)	0	3(4.8)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	80 mg (N=39)	80 mg Only[c] (N=34)	All NBI-98854 (N=62)
低血圧関連有害事象	n (%)	1(4.3)	5(12.8)	5(14.7)	6(9.7)
浮動性めまい	n (%)	0	4(10.3)	4(11.8)	4(6.5)
転倒・転落	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
パーキンソニズム関連有害事象	n (%)	1(4.3)	2(5.1)	1(2.9)	3(4.8)
パーキンソニズム	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
筋固縮	n (%)	0	1(2.6)	0	1(1.6)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	1(4.3)	6(15.4)	3(8.8)	7(11.3)
傾眠	n (%)	1(4.3)	4(10.3)	2(5.9)	5(8.1)
鎮静	n (%)	0	2(5.1)	1(2.9)	2(3.2)
基礎疾患の悪化に関連する有害事象	n (%)	8(34.8)	7(17.9)	6(17.6)	15(24.2)
自殺念慮	n (%)	2(8.7)	3(7.7)	3(8.8)	5(8.1)
うつ病	n (%)	2(8.7)	1(2.6)	0	3(4.8)
抑うつ気分	n (%)	1(4.3)	1(2.6)	1(2.9)	2(3.2)
双極１型障害	n (%)	1(4.3)	0	0	1(1.6)
易刺激性	n (%)	1(4.3)	0	0	1(1.6)
躁病	n (%)	0	1(2.6)	1(2.9)	1(1.6)
気分動揺	n (%)	0	1(2.6)	0	1(1.6)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－204　ベースライン時の抗精神病薬投与の有無ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use[a]: No

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=23)	80 mg (N=39)	80 mg Only[c] (N=34)	All NBI-98854 (N=62)
妄想症	n (%)	1(4.3)	0	0	1(1.6)
外傷後ストレス障害	n (%)	1(4.3)	0	0	1(1.6)
自殺行為	n (%)	0	1(2.6)	1(2.9)	1(1.6)

AESI = Adverse Event of Special Interest.
[a] Antipsychotic medication is defined as use of a dopamine antagonist.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.6より引用（一部改変）

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Any System Organ Class		30 (63.8)	40 (81.6)	70 (72.9)	22 (38.6)	11 (78.6)	13 (86.7)	24 (82.8)	7 (70.0)
Infections and infestations	感染症および寄生虫症	5 (10.6)	5 (10.2)	10 (10.4)	4 (7.0)	2 (14.3)	1 (6.7)	3 (10.3)	0 (0.0)
Nasopharyngitis	上咽頭炎	3 (6.4)	3 (6.1)	6 (6.3)	4 (7.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia	肺炎	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	1 (6.7)	2 (6.9)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Influenza	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Periodontitis	歯周炎	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	上気道感染	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部腟カンジダ症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Metabolism and nutrition disorders	代謝および栄養障害	3 (6.4)	3 (6.1)	6 (6.3)	1 (1.8)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Dehydration	脱水	0 (0.0)	2 (4.1)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased appetite	食欲減退	1 (2.1)	1 (2.0)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperuricaemia	高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypertriglyceridaemia	高トリグリセリド血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Psychiatric disorders	精神障害	9 (19.1)	8 (16.3)	17 (17.7)	3 (5.3)	4 (28.6)	4 (26.7)	8 (27.6)	0 (0.0)
Insomnia	不眠症	1 (2.1)	4 (8.2)	5 (5.2)	1 (1.8)	1 (7.1)	1 (6.7)	2 (6.9)	0 (0.0)
Schizophrenia	統合失調症	7 (14.9)	0 (0.0)	7 (7.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (4.1)	2 (2.1)	0 (0.0)	0 (0.0)	2 (13.3)	2 (6.9)	0 (0.0)
Depression	うつ病	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disinhibition	脱抑制	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Panic attack	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Nervous system disorders	神経系障害	12 (25.5)	23 (46.9)	35 (36.5)	3 (5.3)	2 (14.3)	7 (46.7)	9 (31.0)	2 (20.0)
Somnolence	傾眠	4 (8.5)	14 (28.6)	18 (18.8)	1 (1.8)	2 (14.3)	4 (26.7)	6 (20.7)	1 (10.0)
Akathisia	アカシジア	4 (8.5)	4 (8.2)	8 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Headache	頭痛	1 (2.1)	3 (6.1)	4 (4.2)	1 (1.8)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Tremor	振戦	0 (0.0)	4 (8.2)	4 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Drooling	よだれ	1 (2.1)	1 (2.0)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Seizure	痙攣発作	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Eye disorders	眼障害	0 (0.0)	2 (4.1)	2 (2.1)	2 (3.5)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Blepharitis	眼瞼炎	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	耳および迷路障害	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deafness neurosensory	感音性難聴	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	心臓障害	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Palpitations	動悸	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Hypertension	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	0 (0.0)	2 (4.1)	2 (2.1)	1 (1.8)	1 (7.1)	1 (6.7)	2 (6.9)	0 (0.0)
Asthma	喘息	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Epistaxis	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Gastrointestinal disorders	胃腸障害	5 (10.6)	9 (18.4)	14 (14.6)	4 (7.0)	0 (0.0)	4 (26.7)	4 (13.8)	2 (20.0)
Salivary hypersecretion	流涎過多	3 (6.4)	6 (12.2)	9 (9.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Constipation	便秘	1 (2.1)	1 (2.0)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Nausea	悪心	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Abdominal pain upper	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	下痢	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Dry mouth	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Dysphagia	嚥下障害	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhoids	痔核	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	歯痛	1 (2.1)	0 (0.0)	1 (1.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vomiting	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	4 (8.5)	5 (10.2)	9 (9.4)	3 (5.3)	1 (7.1)	1 (6.7)	2 (6.9)	2 (20.0)
Urticaria	蕁麻疹	1 (2.1)	2 (4.1)	3 (3.1)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Alopecia areata	円形脱毛症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blister	水疱	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry skin	皮膚乾燥	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	湿疹	0 (0.0)	1 (2.0)	1 (1.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Scab	痂皮	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	1 (2.1)	3 (6.1)	4 (4.2)	2 (3.5)	0 (0.0)	1 (6.7)	1 (3.4)	2 (20.0)
Back pain	背部痛	0 (0.0)	1 (2.0)	1 (1.0)	2 (3.5)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Neck pain	頚部痛	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Osteoarthritis	変形性関節症	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Posture abnormal	姿勢異常	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gouty arthritis	痛風性関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Joint swelling	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Renal and urinary disorders	腎および尿路障害	1 (2.1)	0 (0.0)	1 (1.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pollakiuria	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	6 (12.8)	8 (16.3)	14 (14.6)	1 (1.8)	2 (14.3)	2 (13.3)	4 (13.8)	0 (0.0)
Malaise	倦怠感	3 (6.4)	2 (4.1)	5 (5.2)	0 (0.0)	1 (7.1)	1 (6.7)	2 (6.9)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (4.1)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thirst	口渇	2 (4.3)	0 (0.0)	2 (2.1)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Pyrexia	発熱	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Inflammation	炎症	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Investigations	臨床検査	2 (4.3)	1 (2.0)	3 (3.1)	0 (0.0)	2 (14.3)	1 (6.7)	3 (10.3)	1 (10.0)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	1 (6.7)	2 (6.9)	1 (10.0)
Weight increased	体重増加	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－205　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	1 (2.1)	2 (4.1)	3 (3.1)	3 (5.3)	2 (14.3)	0 (0.0)	2 (6.9)	0 (0.0)
Fall	転倒	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Head injury	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Contusion	挫傷	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin laceration	皮膚裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.8.1.1 より引用

表 2.7.4.7－206　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Any AESI		22 (46.8)	32 (65.3)	54 (56.3)	8 (14.0)	7 (50.0)	10 (66.7)	17 (58.6)	5 (50.0)
Somnolence	傾眠関連有害事象	9 (19.1)	15 (30.6)	24 (25.0)	1 (1.8)	3 (21.4)	5 (33.3)	8 (27.6)	1 (10.0)
Somnolence	傾眠	4 (8.5)	14 (28.6)	18 (18.8)	1 (1.8)	2 (14.3)	4 (26.7)	6 (20.7)	1 (10.0)
Malaise	倦怠感	3 (6.4)	2 (4.1)	5 (5.2)	0 (0.0)	1 (7.1)	1 (6.7)	2 (6.9)	0 (0.0)
Fatigue	疲労	0 (0.0)	2 (4.1)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation complication	鎮静合併症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersensitivity	過敏症関連有害事象	3 (6.4)	5 (10.2)	8 (8.3)	3 (5.3)	1 (7.1)	1 (6.7)	2 (6.9)	2 (20.0)
Urticaria	蕁麻疹	1 (2.1)	2 (4.1)	3 (3.1)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Blister	水疱	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema	湿疹	0 (0.0)	1 (2.0)	1 (1.0)	2 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Rash	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis allergic	アレルギー性結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin erosion	皮膚びらん	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－206 ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Parkinsonism	パーキンソニズム関連有害事象	4 (8.5)	13 (26.5)	17 (17.7)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	1 (10.0)
Salivary hypersecretion	流涎過多	3 (6.4)	6 (12.2)	9 (9.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Tremor	振戦	0 (0.0)	4 (8.2)	4 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Drooling	よだれ	1 (2.1)	1 (2.0)	2 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Parkinsonism	パーキンソニズム	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression or Suicidality	うつ病及び自殺関連有害事象	3 (6.4)	1 (2.0)	4 (4.2)	0 (0.0)	2 (14.3)	0 (0.0)	2 (6.9)	0 (0.0)
Depression	うつ病	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Depressed mood	抑うつ気分	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Akathisia	アカシジア関連有害事象	4 (8.5)	5 (10.2)	9 (9.4)	0 (0.0)	0 (0.0)	2 (13.3)	2 (6.9)	1 (10.0)
Akathisia	アカシジア	4 (8.5)	4 (8.2)	8 (8.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)
Extrapyramidal disorder	錐体外路障害	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Restlessness	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (4.1)	2 (2.1)	0 (0.0)	0 (0.0)	2 (13.3)	2 (6.9)	0 (0.0)
Anxiety	不安	0 (0.0)	2 (4.1)	2 (2.1)	0 (0.0)	0 (0.0)	2 (13.3)	2 (6.9)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－206　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=47) n(%)	80 mg (N=49) n(%)	All MT-5199 (N=96) n(%)	Placebo (N=57) n(%)	40 mg (N=14) n(%)	80 mg (N=15) n(%)	All MT-5199 (N=29) n(%)	Placebo (N=10) n(%)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	8 (17.0)	2 (4.1)	10 (10.4)	2 (3.5)	2 (14.3)	0 (0.0)	2 (6.9)	0 (0.0)
Schizophrenia	統合失調症	7 (14.9)	0 (0.0)	7 (7.3)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depression	うつ病	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Depressed mood	抑うつ気分	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Suicidal ideation	自殺念慮	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Suicide attempt	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Bipolar disorder	双極性障害	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害関連有害事象	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatotoxicity	肝障害関連有害事象	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (2.1)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Hypotension	低血圧関連有害事象	0 (0.0)	2 (4.1)	2 (2.1)	2 (3.5)	1 (7.1)	1 (6.7)	2 (6.9)	0 (0.0)
Dizziness	浮動性めまい	0 (0.0)	1 (2.0)	1 (1.0)	1 (1.8)	0 (0.0)	1 (6.7)	1 (3.4)	0 (0.0)
Fall	転倒	0 (0.0)	1 (2.0)	1 (1.0)	0 (0.0)	1 (7.1)	0 (0.0)	1 (3.4)	0 (0.0)
Orthostatic hypotension	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.8.1.2 より引用

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Any System Organ Class		66 (91.7)	75 (94.9)	44 (91.7)	141 (93.4)	19 (95.0)	17 (94.4)	13 (92.9)	36 (94.7)
Infections and infestations	感染症および寄生虫症	25 (34.7)	29 (36.7)	19 (39.6)	54 (35.8)	8 (40.0)	3 (16.7)	2 (14.3)	11 (28.9)
Nasopharyngitis	上咽頭炎	14 (19.4)	17 (21.5)	10 (20.8)	31 (20.5)	6 (30.0)	2 (11.1)	1 (7.1)	8 (21.1)
Bronchitis	気管支炎	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Cystitis	膀胱炎	0 (0.0)	2 (2.5)	2 (4.2)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Influenza	インフルエンザ	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Pneumonia	肺炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Upper respiratory tract infection	上気道感染	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Conjunctivitis	結膜炎	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Folliculitis	毛包炎	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periodontitis	歯周炎	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pharyngitis	咽頭炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Cellulitis	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Dermatophytosis of nail	爪の皮膚糸状菌症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastroenteritis	胃腸炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingivitis	歯肉炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Herpes zoster	帯状疱疹	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mastitis	乳腺炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nasal vestibulitis	鼻前庭炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis externa	外耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=72) n(%)	80 mg (N=79) n(%)	80 mg (no dose reduction) (N=48) n(%)	All MT-5199 (N=151) n(%)	40 mg (N=20) n(%)	80 mg (N=18) n(%)	80 mg (no dose reduction) (N=14) n(%)	All MT-5199 (N=38) n(%)
Pneumonia pneumococcal	肺炎球菌性肺炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinea pedis	足部白癬	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tonsillitis	扁桃炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary tract infection	尿路感染	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal infection	膣感染	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Varicella	水痘	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vulvovaginal candidiasis	外陰部膣カンジダ症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Staphylococcal bacteraemia	ブドウ球菌性菌血症	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema impetiginous	膿痂疹性湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Skin candida	皮膚カンジダ	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia bacterial	細菌性肺炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nail infection	爪感染	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infected dermal cyst	感染性皮膚嚢腫	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bacterial vulvovaginitis	細菌性外陰膣炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only				Typical or both Typical and Atypical			
		MT-5199				MT-5199			
		40 mg (N=72) n(%)	80 mg (N=79) n(%)	80 mg (no dose reduction) (N=48) n(%)	All MT-5199 (N=151) n(%)	40 mg (N=20) n(%)	80 mg (N=18) n(%)	80 mg (no dose reduction) (N=14) n(%)	All MT-5199 (N=38) n(%)
Metabolism and nutrition disorders	代謝および栄養障害	8 (11.1)	9 (11.4)	5 (10.4)	17 (11.3)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Decreased appetite	食欲減退	2 (2.8)	3 (3.8)	0 (0.0)	5 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dehydration	脱水	1 (1.4)	3 (3.8)	3 (6.3)	4 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes mellitus	糖尿病	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperuricaemia	高尿酸血症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Dyslipidaemia	脂質異常症	0 (0.0)	2 (2.5)	2 (4.2)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypokalaemia	低カリウム血症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypouricaemia	低尿酸血症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Marasmus	マラスムス	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Refeeding syndrome	リフィーディング症候群	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperlipidaemia	高脂血症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Type 2 diabetes mellitus	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Psychiatric disorders	精神障害	33 (45.8)	36 (45.6)	23 (47.9)	69 (45.7)	7 (35.0)	8 (44.4)	5 (35.7)	15 (39.5)
Schizophrenia	統合失調症	18 (25.0)	12 (15.2)	5 (10.4)	30 (19.9)	2 (10.0)	1 (5.6)	0 (0.0)	3 (7.9)
Insomnia	不眠症	7 (9.7)	10 (12.7)	7 (14.6)	17 (11.3)	2 (10.0)	3 (16.7)	2 (14.3)	5 (13.2)
Anxiety	不安	3 (4.2)	6 (7.6)	5 (10.4)	9 (6.0)	0 (0.0)	2 (11.1)	2 (14.3)	2 (5.3)
Depression	うつ病	2 (2.8)	6 (7.6)	5 (10.4)	8 (5.3)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Suicidal ideation	自殺念慮	4 (5.6)	2 (2.5)	1 (2.1)	6 (4.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Suicide attempt	自殺企図	2 (2.8)	1 (1.3)	1 (2.1)	3 (2.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Restlessness	落ち着きのなさ	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Bipolar disorder	双極性障害	2 (2.8)	1 (1.3)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delirium	譫妄	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Flat affect	感情の平板化	0 (0.0)	2 (2.5)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hallucination, auditory	幻聴	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Agitation	激越	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Delusion	妄想	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Disinhibition	脱抑制	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Middle insomnia	中期不眠症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurosis	神経症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Panic attack	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Abulia	無為	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Abnormal behaviour	異常行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Somatic hallucination	体感幻覚	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Nervous system disorders	神経系障害	33 (45.8)	46 (58.2)	26 (54.2)	79 (52.3)	7 (35.0)	9 (50.0)	6 (42.9)	16 (42.1)
Somnolence	傾眠	11 (15.3)	19 (24.1)	12 (25.0)	30 (19.9)	2 (10.0)	4 (22.2)	3 (21.4)	6 (15.8)
Tremor	振戦	3 (4.2)	13 (16.5)	6 (12.5)	16 (10.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Akathisia	アカシジア	7 (9.7)	7 (8.9)	4 (8.3)	14 (9.3)	1 (5.0)	1 (5.6)	0 (0.0)	2 (5.3)
Headache	頭痛	4 (5.6)	7 (8.9)	5 (10.4)	11 (7.3)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Dizziness	浮動性めまい	3 (4.2)	4 (5.1)	3 (6.3)	7 (4.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Parkinsonism	パーキンソニズム	3 (4.2)	3 (3.8)	2 (4.2)	6 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	1 (1.4)	3 (3.8)	1 (2.1)	4 (2.6)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Drooling	よだれ	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	1 (5.0)	1 (5.6)	0 (0.0)	2 (5.3)
Tardive dyskinesia	遅発性ジスキネジア	2 (2.8)	2 (2.5)	2 (4.2)	4 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bradykinesia	運動緩慢	1 (1.4)	2 (2.5)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyskinesia	ジスキネジア	2 (2.8)	1 (1.3)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia	感覚鈍麻	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Disturbance in attention	注意力障害	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysarthria	構語障害	0 (0.0)	2 (2.5)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Seizure	痙攣発作	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Coordination abnormal	協調運動異常	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyslalia	構音障害	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dystonia	ジストニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Hypersomnia	過眠症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Loss of consciousness	意識消失	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neuralgia	神経痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Radial nerve palsy	橈骨神経麻痺	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sciatica	坐骨神経痛	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stupor	昏迷	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Restless legs syndrome	下肢静止不能症候群	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vagus nerve disorder	迷走神経障害	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reduced facial expression	表情減少	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye disorders	眼障害	1 (1.4)	5 (6.3)	2 (4.2)	6 (4.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Blepharitis	眼瞼炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cataract	白内障	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye discharge	眼脂	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eye pain	眼痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eyelid ptosis	眼瞼下垂	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Keratitis	角膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Ear and labyrinth disorders	耳および迷路障害	1 (1.4)	2 (2.5)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deafness neurosensory	感音性難聴	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tinnitus	耳鳴	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vertigo	回転性めまい	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	心臓障害	3 (4.2)	2 (2.5)	2 (4.2)	5 (3.3)	0 (0.0)	2 (11.1)	1 (7.1)	2 (5.3)
Palpitations	動悸	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Bradycardia	徐脈	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tachycardia	頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Ventricular extrasystoles	心室性期外収縮	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	血管障害	1 (1.4)	2 (2.5)	1 (2.1)	3 (2.0)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Hypertension	高血圧	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Hypotension	低血圧	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deep vein thrombosis	深部静脈血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	4 (5.6)	8 (10.1)	2 (4.2)	12 (7.9)	3 (15.0)	2 (11.1)	0 (0.0)	5 (13.2)
Asthma	喘息	1 (1.4)	3 (3.8)	1 (2.1)	4 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea	呼吸困難	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Pneumonia aspiration	誤嚥性肺炎	0 (0.0)	2 (2.5)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Upper respiratory tract inflammation	上気道の炎症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Oropharyngeal pain	口腔咽頭痛	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Cough	咳嗽	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dyspnoea exertional	労作性呼吸困難	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Interstitial lung disease	間質性肺疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Pleural effusion	胸水	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pleurisy	胸膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Pulmonary embolism	肺塞栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Respiratory failure	呼吸不全	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cough variant asthma	咳喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Gastrointestinal disorders	胃腸障害	20 (27.8)	35 (44.3)	16 (33.3)	55 (36.4)	6 (30.0)	5 (27.8)	3 (21.4)	11 (28.9)
Salivary hypersecretion	流涎過多	9 (12.5)	15 (19.0)	6 (12.5)	24 (15.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Constipation	便秘	5 (6.9)	7 (8.9)	4 (8.3)	12 (7.9)	2 (10.0)	1 (5.6)	1 (7.1)	3 (7.9)
Dysphagia	嚥下障害	4 (5.6)	4 (5.1)	2 (4.2)	8 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	下痢	4 (5.6)	2 (2.5)	1 (2.1)	6 (4.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Vomiting	嘔吐	1 (1.4)	4 (5.1)	1 (2.1)	5 (3.3)	1 (5.0)	1 (5.6)	0 (0.0)	2 (5.3)
Stomatitis	口内炎	1 (1.4)	3 (3.8)	3 (6.3)	4 (2.6)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Nausea	悪心	1 (1.4)	2 (2.5)	2 (4.2)	3 (2.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Dental caries	齲歯	1 (1.4)	2 (2.5)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dry mouth	口内乾燥	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Gastritis	胃炎	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toothache	歯痛	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Abdominal discomfort	腹部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Abdominal pain	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Abdominal pain upper	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Chronic gastritis	慢性胃炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eructation	おくび	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrooesophageal reflux disease	胃食道逆流性疾患	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorder	胃腸障害	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gingival bleeding	歯肉出血	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Haemorrhoids	痔核	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypoaesthesia oral	口の感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Anal pruritus	肛門そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Anal eczema	肛門湿疹	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	肝胆道系障害	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	14 (19.4)	18 (22.8)	10 (20.8)	32 (21.2)	5 (25.0)	4 (22.2)	3 (21.4)	9 (23.7)
Eczema	湿疹	1 (1.4)	3 (3.8)	2 (4.2)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Urticaria	蕁麻疹	2 (2.8)	2 (2.5)	1 (2.1)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Dry skin	皮膚乾燥	2 (2.8)	2 (2.5)	0 (0.0)	4 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pruritus	そう痒症	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Decubitus ulcer	褥瘡性潰瘍	0 (0.0)	3 (3.8)	2 (4.2)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis contact	接触皮膚炎	1 (1.4)	2 (2.5)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperkeratosis	過角化	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Alopecia areata	円形脱毛症	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperhidrosis	多汗症	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Rash	発疹	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Blister	水疱	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Eczema asteatotic	皮脂欠乏性湿疹	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Haemorrhage subcutaneous	皮下出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Ingrowing nail	嵌入爪	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Rash erythematous	紅斑性皮疹	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Skin fissures	皮膚亀裂	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin ulcer	皮膚潰瘍	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Xeroderma	乾皮症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	12 (16.7)	18 (22.8)	12 (25.0)	30 (19.9)	6 (30.0)	2 (11.1)	1 (7.1)	8 (21.1)
Back pain	背部痛	3 (4.2)	5 (6.3)	3 (6.3)	8 (5.3)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Arthralgia	関節痛	0 (0.0)	4 (5.1)	3 (6.3)	4 (2.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Muscular weakness	筋力低下	1 (1.4)	3 (3.8)	2 (4.2)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Osteoarthritis	変形性関節症	1 (1.4)	4 (5.1)	2 (4.2)	5 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain in extremity	四肢痛	1 (1.4)	2 (2.5)	2 (4.2)	3 (2.0)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Myalgia	筋肉痛	3 (4.2)	0 (0.0)	0 (0.0)	3 (2.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Posture abnormal	姿勢異常	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Musculoskeletal pain	筋骨格痛	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neck pain	頚部痛	0 (0.0)	2 (2.5)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tenosynovitis	腱鞘炎	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc protrusion	椎間板突出	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Mastication disorder	咀嚼障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Muscle rigidity	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Osteoporosis	骨粗鬆症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Periarthritis	関節周囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Rhabdomyolysis	横紋筋融解症	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Spinal osteoarthritis	変形性脊椎症	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extremity contracture	四肢拘縮	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal stiffness	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Foot deformity	足変形	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	椎間板障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	腎および尿路障害	2 (2.8)	3 (3.8)	2 (4.2)	5 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysuria	排尿困難	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurogenic bladder	神経因性膀胱	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nocturia	夜間頻尿	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Polyuria	多尿	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary incontinence	尿失禁	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bladder prolapse	膀胱脱	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reproductive system and breast disorders	生殖系および乳房障害	4 (5.6)	1 (1.3)	1 (2.1)	5 (3.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Benign prostatic hyperplasia	良性前立腺肥大症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal discharge	膣分泌物	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Prostatomegaly	前立腺腫大	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
General disorders and administration site conditions	一般　全身障害および投与部位の状態	13 (18.1)	19 (24.1)	10 (20.8)	32 (21.2)	6 (30.0)	3 (16.7)	2 (14.3)	9 (23.7)
Malaise	倦怠感	5 (6.9)	7 (8.9)	3 (6.3)	12 (7.9)	2 (10.0)	2 (11.1)	1 (7.1)	4 (10.5)
Pyrexia	発熱	2 (2.8)	2 (2.5)	1 (2.1)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Thirst	口渇	2 (2.8)	2 (2.5)	1 (2.1)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Fatigue	疲労	0 (0.0)	3 (3.8)	2 (4.2)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	2 (2.5)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling abnormal	異常感	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Calcinosis	石灰沈着症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Chest discomfort	胸部不快感	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	死亡	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Discomfort	不快感	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Feeling hot	熱感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Gait disturbance	歩行障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema	浮腫	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Oedema peripheral	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Swelling face	顔面腫脹	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Physical deconditioning	体調不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Inflammation	炎症	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Investigations	臨床検査	13 (18.1)	11 (13.9)	7 (14.6)	24 (15.9)	4 (20.0)	1 (5.6)	1 (7.1)	5 (13.2)
Weight decreased	体重減少	4 (5.6)	4 (5.1)	2 (4.2)	8 (5.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	1 (1.4)	3 (3.8)	3 (6.3)	4 (2.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Weight increased	体重増加	2 (2.8)	3 (3.8)	2 (4.2)	5 (3.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Blood pressure increased	血圧上昇	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glucose urine present	尿中ブドウ糖陽性	0 (0.0)	2 (2.5)	2 (4.2)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood creatinine increased	血中クレアチニン増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood pressure decreased	血圧低下	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood triglycerides increased	血中トリグリセリド増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood uric acid increased	血中尿酸増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Liver function test increased	肝機能検査値上昇	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	12 (16.7)	14 (17.7)	8 (16.7)	26 (17.2)	6 (30.0)	4 (22.2)	3 (21.4)	10 (26.3)
Contusion	挫傷	3 (4.2)	5 (6.3)	3 (6.3)	8 (5.3)	2 (10.0)	2 (11.1)	1 (7.1)	4 (10.5)
Fall	転倒	1 (1.4)	3 (3.8)	2 (4.2)	4 (2.6)	1 (5.0)	2 (11.1)	2 (14.3)	3 (7.9)
Skin abrasion	皮膚擦過傷	1 (1.4)	2 (2.5)	2 (4.2)	3 (2.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Sedation complication	鎮静合併症	3 (4.2)	1 (1.3)	0 (0.0)	4 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thermal burn	熱傷	1 (1.4)	2 (2.5)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Heat illness	熱中症	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ankle fracture	足関節部骨折	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Concussion	脳振盪	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Femur fracture	大腿骨骨折	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Foot fracture	足骨折	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fractured sacrum	仙骨骨折	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Head injury	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Intentional overdose	企図的過量投与	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Joint dislocation	関節脱臼	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ligament sprain	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Road traffic accident	交通事故	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Face injury	顔面損傷	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Wound	創傷	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tooth fracture	歯牙破折	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

表 2.7.4.7－207　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

System Organ Class Preferred Term (MedDRA)	System Organ Class Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Eyelid injury	眼瞼損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Skin wound	皮膚創傷	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.8.2.1 より引用

表 2.7.4.7－208　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Any AESI		54 (75.0)	70 (88.6)	40 (83.3)	124 (82.1)	12 (60.0)	17 (94.4)	13 (92.9)	29 (76.3)
Somnolence	傾眠関連有害事象	20 (27.8)	28 (35.4)	14 (29.2)	48 (31.8)	4 (20.0)	6 (33.3)	4 (28.6)	10 (26.3)
Somnolence	傾眠	11 (15.3)	19 (24.1)	12 (25.0)	30 (19.9)	2 (10.0)	4 (22.2)	3 (21.4)	6 (15.8)
Malaise	倦怠感	5 (6.9)	7 (8.9)	3 (6.3)	12 (7.9)	2 (10.0)	2 (11.1)	1 (7.1)	4 (10.5)
Sedation complication	鎮静合併症	3 (4.2)	1 (1.3)	0 (0.0)	4 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue	疲労	0 (0.0)	3 (3.8)	2 (4.2)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Asthenia	無力症	0 (0.0)	2 (2.5)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Decreased activity	活動性低下	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Sedation	鎮静	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－208　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Hypersensitivity	過敏症関連有害事象	14 (19.4)	14 (17.7)	10 (20.8)	28 (18.5)	4 (20.0)	3 (16.7)	3 (21.4)	7 (18.4)
Stomatitis	口内炎	1 (1.4)	3 (3.8)	3 (6.3)	4 (2.6)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Eczema	湿疹	1 (1.4)	3 (3.8)	2 (4.2)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Urticaria	蕁麻疹	2 (2.8)	2 (2.5)	1 (2.1)	4 (2.6)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Pruritus	そう痒症	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Dermatitis contact	接触皮膚炎	1 (1.4)	2 (2.5)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctivitis	結膜炎	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis	皮膚炎	2 (2.8)	0 (0.0)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash	発疹	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Blister	水疱	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conjunctival oedema	結膜浮腫	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dermatitis atopic	アトピー性皮膚炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Erythema	紅斑	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rash erythematous	紅斑性皮疹	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhinitis allergic	アレルギー性鼻炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Skin exfoliation	皮膚剥脱	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Swelling face	顔面腫脹	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic skin eruption	中毒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－208　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Hand dermatitis	手皮膚炎	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anal eczema	肛門湿疹	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Parkinsonism	パーキンソニズム関連有害事象	17 (23.6)	38 (48.1)	16 (33.3)	55 (36.4)	3 (15.0)	3 (16.7)	2 (14.3)	6 (15.8)
Salivary hypersecretion	流涎過多	9 (12.5)	15 (19.0)	6 (12.5)	24 (15.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Tremor	振戦	3 (4.2)	13 (16.5)	6 (12.5)	16 (10.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Parkinsonism	パーキンソニズム	3 (4.2)	3 (3.8)	2 (4.2)	6 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Extrapyramidal disorder	錐体外路障害	1 (1.4)	3 (3.8)	1 (2.1)	4 (2.6)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Drooling	よだれ	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	1 (5.0)	1 (5.6)	0 (0.0)	2 (5.3)
Bradykinesia	運動緩慢	1 (1.4)	2 (2.5)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gait disturbance	歩行障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Movement disorder	運動障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Muscle rigidity	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Musculoskeletal stiffness	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Reduced facial expression	表情減少	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Propulsive gait	突進性歩行	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－208　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Depression or Suicidality	うつ病及び自殺関連有害事象	10 (13.9)	11 (13.9)	7 (14.6)	21 (13.9)	3 (15.0)	1 (5.6)	1 (7.1)	4 (10.5)
Depression	うつ病	2 (2.8)	6 (7.6)	5 (10.4)	8 (5.3)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Suicidal ideation	自殺念慮	4 (5.6)	2 (2.5)	1 (2.1)	6 (4.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Suicide attempt	自殺企図	2 (2.8)	1 (1.3)	1 (2.1)	3 (2.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Disturbance in attention	注意力障害	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Alcohol abuse	アルコール乱用	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypersomnia	過眠症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional overdose	企図的過量投与	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Middle insomnia	中期不眠症	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac events	心血管系及びQT間隔延長関連有害事象	3 (4.2)	0 (0.0)	0 (0.0)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Death	死亡	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Long QT syndrome	ＱＴ延長症候群	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Loss of consciousness	意識消失	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hyperprolactinemia	高プロラクチン血症関連有害事象	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Galactorrhoea	乳汁漏出症	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Menstruation irregular	不規則月経	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－208　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Akathisia	アカシジア関連有害事象	9 (12.5)	12 (15.2)	6 (12.5)	21 (13.9)	1 (5.0)	3 (16.7)	1 (7.1)	4 (10.5)
Akathisia	アカシジア	7 (9.7)	7 (8.9)	4 (8.3)	14 (9.3)	1 (5.0)	1 (5.6)	0 (0.0)	2 (5.3)
Extrapyramidal disorder	錐体外路障害	1 (1.4)	3 (3.8)	1 (2.1)	4 (2.6)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Restlessness	落ち着きのなさ	1 (1.4)	1 (1.3)	1 (2.1)	2 (1.3)	0 (0.0)	1 (5.6)	0 (0.0)	1 (2.6)
Movement disorder	運動障害	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Anxiety	不安	3 (4.2)	6 (7.6)	5 (10.4)	9 (6.0)	0 (0.0)	2 (11.1)	2 (14.3)	2 (5.3)
Anxiety	不安	3 (4.2)	6 (7.6)	5 (10.4)	9 (6.0)	0 (0.0)	2 (11.1)	2 (14.3)	2 (5.3)
Worsening of Underlying Psychiatric Condition	基礎疾患の悪化に関連する有害事象	24 (33.3)	20 (25.3)	11 (22.9)	44 (29.1)	5 (25.0)	2 (11.1)	1 (7.1)	7 (18.4)
Schizophrenia	統合失調症	18 (25.0)	12 (15.2)	5 (10.4)	30 (19.9)	2 (10.0)	1 (5.6)	0 (0.0)	3 (7.9)
Depression	うつ病	2 (2.8)	6 (7.6)	5 (10.4)	8 (5.3)	2 (10.0)	0 (0.0)	0 (0.0)	2 (5.3)
Suicidal ideation	自殺念慮	4 (5.6)	2 (2.5)	1 (2.1)	6 (4.0)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Suicide attempt	自殺企図	2 (2.8)	1 (1.3)	1 (2.1)	3 (2.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Bipolar disorder	双極性障害	2 (2.8)	1 (1.3)	1 (2.1)	3 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Depressed mood	抑うつ気分	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intentional self-injury	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Dysphagia	嚥下障害関連有害事象	4 (5.6)	4 (5.1)	2 (4.2)	8 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Dysphagia	嚥下障害	4 (5.6)	4 (5.1)	2 (4.2)	8 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

AESI: adverse events of special interest, MedDRA Version 23.0.

表 2.7.4.7－208　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199 長期投与期間（MT-5199-J02 試験）（続き）

AESI Preferred Term (MedDRA)	AESI Preferred Term (MedDRA) in Japanese	Atypical only MT-5199 40 mg (N=72) n(%)	Atypical only MT-5199 80 mg (N=79) n(%)	Atypical only MT-5199 80 mg (no dose reduction) (N=48) n(%)	Atypical only All MT-5199 (N=151) n(%)	Typical or both Typical and Atypical MT-5199 40 mg (N=20) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (N=18) n(%)	Typical or both Typical and Atypical MT-5199 80 mg (no dose reduction) (N=14) n(%)	Typical or both Typical and Atypical All MT-5199 (N=38) n(%)
Hepatotoxicity	肝障害関連有害事象	2 (2.8)	2 (2.5)	1 (2.1)	4 (2.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Gamma-glutamyltransferase increased	γ－グルタミルトランスフェラーゼ増加	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatic function abnormal	肝機能異常	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	1 (5.6)	1 (7.1)	1 (2.6)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Liver function test increased	肝機能検査値上昇	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧関連有害事象	5 (6.9)	7 (8.9)	5 (10.4)	12 (7.9)	2 (10.0)	3 (16.7)	3 (21.4)	5 (13.2)
Dizziness	浮動性めまい	3 (4.2)	4 (5.1)	3 (6.3)	7 (4.6)	1 (5.0)	1 (5.6)	1 (7.1)	2 (5.3)
Fall	転倒	1 (1.4)	3 (3.8)	2 (4.2)	4 (2.6)	1 (5.0)	2 (11.1)	2 (14.3)	3 (7.9)
Blood pressure decreased	血圧低下	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Hypotension	低血圧	0 (0.0)	1 (1.3)	1 (2.1)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知機能低下関連有害事象	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)
Disturbance in attention	注意力障害	1 (1.4)	1 (1.3)	0 (0.0)	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	認知障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	1 (2.6)

AESI: adverse events of special interest, MedDRA Version 23.0.

5.3.5.1－1 Table 14.3.1.6.2.8.2.2 より引用

表 2.7.4.7－209　ベースライン時投与の抗精神病薬分類ごとの有害事象の要約：プラセボ対照二重盲検期間・ 長期投与期間（海外試験_ISS）

AE Category	Controlled Studies				Long-term Exposure	
	NBI-98854		Placebo		NBI-98854	
	Typical[a] (N=49) n (%)	Atypical Only (N=162) n (%)	Typical[a] (N=34) n (%)	Atypical Only (N=115) n (%)	Typical[a] (N=67) n (%)	Atypical Only (N=298) n (%)
At Least 1 AE	14 (28.6)	75 (46.3)	15 (44.1)	42 (36.5)	35 (52.2)	180 (60.4)
At Least 1 SAE	3 (6.1)	8 (4.9)	2 (5.9)	4 (3.5)	10 (14.9)	38 (12.8)
At Least 1 AE Leading to Study Discontinuation	3 (6.1)	6 (3.7)	3 (8.8)	5 (4.3)	9 (13.4)	38 (12.8)
At Least 1 AE Leading to Dose Reduction	2 (4.1)	3 (1.9)	1 (2.9)	1 (0.9)	3 (4.5)	17 (5.7)

AE: adverse event, SAE: serious adverse event
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
Note: If a subject experienced more than 1 event in a given category, that subject is counted once.

5.3.5.3－2 Table 103 より引用（一部改変）

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
Any Adverse Event	n (%)	1(50.0)	33(45.2)	34(50.0)	7(36.8)	75(46.3)	42(36.5)
耳および迷路障害	n (%)	0	1(1.4)	0	0	1(0.6)	1(0.9)
耳鳴	n (%)	0	1(1.4)	0	0	1(0.6)	0
耳痛	n (%)	0	0	0	0	0	1(0.9)
眼障害	n (%)	0	0	0	1(5.3)	1(0.6)	1(0.9)
霧視	n (%)	0	0	0	1(5.3)	1(0.6)	0
結膜出血	n (%)	0	0	0	0	0	1(0.9)
胃腸障害	n (%)	0	9(12.3)	3(4.4)	1(5.3)	13(8.0)	8(7.0)
口内乾燥	n (%)	0	4(5.5)	0	1(5.3)	5(3.1)	1(0.9)
嘔吐	n (%)	0	1(1.4)	2(2.9)	0	3(1.9)	1(0.9)
悪心	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	1(0.9)
流涎過多	n (%)	0	0	1(1.5)	1(5.3)	2(1.2)	0
腹部圧痛	n (%)	0	1(1.4)	0	0	1(0.6)	0
便秘	n (%)	0	1(1.4)	0	0	1(0.6)	1(0.9)
下痢	n (%)	0	1(1.4)	0	0	1(0.6)	0
嚥下障害	n (%)	0	1(1.4)	0	0	1(0.6)	0
メレナ	n (%)	0	1(1.4)	0	0	1(0.6)	0
臍ヘルニア	n (%)	0	1(1.4)	0	0	1(0.6)	0
胃食道逆流性疾患	n (%)	0	0	0	0	0	1(0.9)
歯肉炎	n (%)	0	0	0	0	0	1(0.9)
舌痛	n (%)	0	0	0	0	0	1(0.9)
歯痛	n (%)	0	0	0	0	0	1(0.9)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	 Placebo (N=115)
全身障害および投与局所様態	n (%)	0	6(8.2)	4(5.9)	2(10.5)	12(7.4)	5(4.3)
疲労	n (%)	0	3(4.1)	3(4.4)	2(10.5)	8(4.9)	2(1.7)
歩行障害	n (%)	0	1(1.4)	0	1(5.3)	2(1.2)	0
末梢性浮腫	n (%)	0	2(2.7)	0	0	2(1.2)	1(0.9)
胸痛	n (%)	0	1(1.4)	0	0	1(0.6)	0
空腹	n (%)	0	1(1.4)	0	0	1(0.6)	0
発熱	n (%)	0	0	1(1.5)	0	1(0.6)	0
口渇	n (%)	0	1(1.4)	0	0	1(0.6)	0
易刺激性	n (%)	0	0	0	0	0	2(1.7)
肝胆道系障害	n (%)	0	0	1(1.5)	0	1(0.6)	0
急性肝炎	n (%)	0	0	1(1.5)	0	1(0.6)	0
黄疸	n (%)	0	0	1(1.5)	0	1(0.6)	0
感染症および寄生虫症	n (%)	0	8(11.0)	3(4.4)	2(10.5)	13(8.0)	9(7.8)
尿路感染	n (%)	0	2(2.7)	1(1.5)	0	3(1.9)	6(5.2)
鼻咽頭炎	n (%)	0	0	1(1.5)	1(5.3)	2(1.2)	1(0.9)
上気道感染	n (%)	0	0	1(1.5)	1(5.3)	2(1.2)	1(0.9)
ダニ皮膚炎	n (%)	0	1(1.4)	0	0	1(0.6)	0
体部白癬	n (%)	0	1(1.4)	0	0	1(0.6)	0
せつ	n (%)	0	1(1.4)	0	0	1(0.6)	0
ウイルス性胃腸炎	n (%)	0	1(1.4)	0	0	1(0.6)	0
インフルエンザ	n (%)	0	1(1.4)	0	0	1(0.6)	0
急性腎盂腎炎	n (%)	0	1(1.4)	0	0	1(0.6)	0

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
副鼻腔炎	n (%)	0	1(1.4)	0	0	1(0.6)	0
外陰腟真菌感染	n (%)	0	1(1.4)	0	0	1(0.6)	0
耳感染	n (%)	0	0	0	0	0	1(0.9)
傷害、中毒および処置合併症	n (%)	0	3(4.1)	3(4.4)	1(5.3)	7(4.3)	1(0.9)
転倒・転落	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	0
動物咬傷	n (%)	0	0	1(1.5)	0	1(0.6)	0
節足動物咬傷	n (%)	0	0	0	1(5.3)	1(0.6)	0
第２度熱傷	n (%)	0	0	1(1.5)	0	1(0.6)	0
関節損傷	n (%)	0	1(1.4)	0	0	1(0.6)	0
筋挫傷	n (%)	0	1(1.4)	0	0	1(0.6)	0
足骨折	n (%)	0	0	0	0	0	1(0.9)
臨床検査	n (%)	0	4(5.5)	7(10.3)	1(5.3)	12(7.4)	1(0.9)
体重増加	n (%)	0	1(1.4)	2(2.9)	0	3(1.9)	0
血中クレアチンホスホキナーゼ増加	n (%)	0	1(1.4)	0	0	1(0.6)	0
血中クレアチニン増加	n (%)	0	1(1.4)	0	0	1(0.6)	0
血中ブドウ糖増加	n (%)	0	0	1(1.5)	0	1(0.6)	0
血圧上昇	n (%)	0	0	1(1.5)	0	1(0.6)	0
血中トリグリセリド増加	n (%)	0	0	0	1(5.3)	1(0.6)	0
血中尿素増加	n (%)	0	1(1.4)	0	0	1(0.6)	0
尿中結晶陽性	n (%)	0	0	1(1.5)	0	1(0.6)	0

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210 ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
γ－グルタミルトランスフェラーゼ増加	n (%)	0	0	1(1.5)	0	1(0.6)	0
握力低下	n (%)	0	1(1.4)	0	0	1(0.6)	0
ヘマトクリット減少	n (%)	0	0	1(1.5)	0	1(0.6)	0
ヘモグロビン減少	n (%)	0	0	1(1.5)	0	1(0.6)	0
便潜血陽性	n (%)	0	0	1(1.5)	0	1(0.6)	0
赤血球数減少	n (%)	0	0	1(1.5)	0	1(0.6)	0
赤血球数増加	n (%)	0	0	1(1.5)	0	1(0.6)	0
グリコヘモグロビン増加	n (%)	0	0	0	0	0	1(0.9)
代謝および栄養障害	n (%)	0	1(1.4)	2(2.9)	0	3(1.9)	3(2.6)
食欲減退	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	1(0.9)
食欲亢進	n (%)	0	0	1(1.5)	0	1(0.6)	0
コントロール不良の糖尿病	n (%)	0	0	0	0	0	1(0.9)
低血糖症	n (%)	0	0	0	0	0	1(0.9)
筋骨格系および結合組織障害	n (%)	0	6(8.2)	4(5.9)	1(5.3)	11(6.8)	4(3.5)
関節痛	n (%)	0	3(4.1)	2(2.9)	0	5(3.1)	0
背部痛	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	0
関節炎	n (%)	0	1(1.4)	0	0	1(0.6)	0
筋痙縮	n (%)	0	0	1(1.5)	0	1(0.6)	0
筋力低下	n (%)	0	1(1.4)	0	0	1(0.6)	0
筋肉痛	n (%)	0	0	0	1(5.3)	1(0.6)	0

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
滑液包炎	n (%)	0	0	0	0	0	1(0.9)
関節腫脹	n (%)	0	0	0	0	0	1(0.9)
筋骨格硬直	n (%)	0	0	0	0	0	1(0.9)
四肢痛	n (%)	0	0	0	0	0	1(0.9)
神経系障害	n (%)	0	10(13.7)	9(13.2)	2(10.5)	21(13.0)	6(5.2)
頭痛	n (%)	0	3(4.1)	3(4.4)	1(5.3)	7(4.3)	2(1.7)
傾眠	n (%)	0	4(5.5)	1(1.5)	1(5.3)	6(3.7)	1(0.9)
アカシジア	n (%)	0	3(4.1)	0	0	3(1.9)	0
鎮静	n (%)	0	1(1.4)	2(2.9)	0	3(1.9)	1(0.9)
浮動性めまい	n (%)	0	2(2.7)	0	0	2(1.2)	3(2.6)
ジスキネジー	n (%)	0	0	2(2.9)	0	2(1.2)	0
振戦	n (%)	0	0	2(2.9)	0	2(1.2)	0
ミオクローヌス	n (%)	0	1(1.4)	0	0	1(0.6)	0
咬舌	n (%)	0	1(1.4)	0	0	1(0.6)	0
精神障害	n (%)	1(50.0)	8(11.0)	9(13.2)	0	18(11.1)	8(7.0)
自殺念慮	n (%)	0	3(4.1)	1(1.5)	0	4(2.5)	1(0.9)
不安	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	0
うつ病	n (%)	0	0	2(2.9)	0	2(1.2)	1(0.9)
不眠症	n (%)	0	0	2(2.9)	0	2(1.2)	1(0.9)
歯ぎしり	n (%)	0	1(1.4)	0	0	1(0.6)	0
抑うつ症状	n (%)	0	1(1.4)	0	0	1(0.6)	0
ディスフェミア	n (%)	0	1(1.4)	0	0	1(0.6)	0
軽躁	n (%)	0	1(1.4)	0	0	1(0.6)	0

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
神経過敏	n (%)	0	0	1(1.5)	0	1(0.6)	0
パニック発作	n (%)	1(50.0)	0	0	0	1(0.6)	0
落ち着きのなさ	n (%)	0	1(1.4)	0	0	1(0.6)	0
統合失調感情障害	n (%)	0	0	1(1.5)	0	1(0.6)	1(0.9)
統合失調症	n (%)	0	1(1.4)	0	0	1(0.6)	0
自殺企図	n (%)	0	0	1(1.5)	0	1(0.6)	0
激越	n (%)	0	0	0	0	0	1(0.9)
精神状態変化	n (%)	0	0	0	0	0	1(0.9)
精神病性障害	n (%)	0	0	0	0	0	2(1.7)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.9)
腎および尿路障害	n (%)	0	0	0	0	0	3(2.6)
糖尿	n (%)	0	0	0	0	0	1(0.9)
血尿	n (%)	0	0	0	0	0	1(0.9)
尿閉	n (%)	0	0	0	0	0	1(0.9)
生殖系および乳房障害	n (%)	0	0	1(1.5)	0	1(0.6)	1(0.9)
月経過多	n (%)	0	0	1(1.5)	0	1(0.6)	0
腟出血	n (%)	0	0	0	0	0	1(0.9)
呼吸器、胸郭および縦隔障害	n (%)	0	1(1.4)	1(1.5)	1(5.3)	3(1.9)	2(1.7)
慢性閉塞性肺疾患	n (%)	0	1(1.4)	0	1(5.3)	2(1.2)	1(0.9)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=73)	 80 mg (N=68)	 100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
鼻閉	n (%)	0	0	1(1.5)	0	1(0.6)	0
咳嗽	n (%)	0	0	0	0	0	1(0.9)
皮膚および皮下組織障害	n (%)	0	1(1.4)	2(2.9)	0	3(1.9)	3(2.6)
そう痒症	n (%)	0	1(1.4)	0	0	1(0.6)	1(0.9)
発疹	n (%)	0	0	1(1.5)	0	1(0.6)	1(0.9)
斑状丘疹状皮疹	n (%)	0	0	1(1.5)	0	1(0.6)	0
多汗症	n (%)	0	0	0	0	0	1(0.9)
外科および内科処置	n (%)	0	0	1(1.5)	0	1(0.6)	0
抜歯	n (%)	0	0	1(1.5)	0	1(0.6)	0
血管障害	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	1(0.9)
高血圧	n (%)	0	1(1.4)	0	0	1(0.6)	1(0.9)
低血圧	n (%)	0	0	1(1.5)	0	1(0.6)	0

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=24)	 80 mg (N=18)	 100 mg (N=5)	All NBI-98854 (N=49)	Placebo (N=34)
Any Adverse Event	n (%)	0	6(25.0)	7(38.9)	1(20.0)	14(28.6)	15(44.1)
心臓障害	n (%)	0	0	0	0	0	1(2.9)
心筋梗塞	n (%)	0	0	0	0	0	1(2.9)
先天性、家族性および遺伝性障害	n (%)	0	0	0	0	0	1(2.9)
トゥレット病	n (%)	0	0	0	0	0	1(2.9)
胃腸障害	n (%)	0	1(4.2)	2(11.1)	0	3(6.1)	5(14.7)
口内乾燥	n (%)	0	1(4.2)	0	0	1(2.0)	2(5.9)
悪心	n (%)	0	0	1(5.6)	0	1(2.0)	2(5.9)
流涎過多	n (%)	0	0	1(5.6)	0	1(2.0)	0
嘔吐	n (%)	0	0	1(5.6)	0	1(2.0)	0
排便回数増加	n (%)	0	0	0	0	0	1(2.9)
全身障害および投与局所様態	n (%)	0	1(4.2)	1(5.6)	0	2(4.1)	1(2.9)
疲労	n (%)	0	1(4.2)	0	0	1(2.0)	1(2.9)
突然死	n (%)	0	0	1(5.6)	0	1(2.0)	0
感染症および寄生虫症	n (%)	0	1(4.2)	0	1(20.0)	2(4.1)	1(2.9)
尿路感染	n (%)	0	1(4.2)	0	1(20.0)	2(4.1)	0
気管支炎	n (%)	0	0	0	0	0	1(2.9)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=24)	 80 mg (N=18)	 100 mg (N=5)	All NBI-98854 (N=49)	Placebo (N=34)
傷害、中毒および処置合併症	n (%)	0	1(4.2)	1(5.6)	0	2(4.1)	1(2.9)
転倒・転落	n (%)	0	1(4.2)	0	0	1(2.0)	0
四肢損傷	n (%)	0	0	1(5.6)	0	1(2.0)	0
節足動物咬傷	n (%)	0	0	0	0	0	1(2.9)
臨床検査	n (%)	0	0	2(11.1)	0	2(4.1)	2(5.9)
血中クレアチニン増加	n (%)	0	0	1(5.6)	0	1(2.0)	0
血中ブドウ糖増加	n (%)	0	0	1(5.6)	0	1(2.0)	0
尿中ブドウ糖陽性	n (%)	0	0	1(5.6)	0	1(2.0)	0
グリコヘモグロビン増加	n (%)	0	0	1(5.6)	0	1(2.0)	0
血中ビリルビン増加	n (%)	0	0	0	0	0	1(2.9)
肝酵素上昇	n (%)	0	0	0	0	0	1(2.9)
体重増加	n (%)	0	0	0	0	0	1(2.9)
代謝および栄養障害	n (%)	0	0	2(11.1)	0	2(4.1)	1(2.9)
低ナトリウム血症	n (%)	0	0	1(5.6)	0	1(2.0)	0
食欲亢進	n (%)	0	0	1(5.6)	0	1(2.0)	1(2.9)
異常体重減少	n (%)	0	0	0	0	0	1(2.9)
神経系障害	n (%)	0	2(8.3)	4(22.2)	1(20.0)	7(14.3)	5(14.7)
傾眠	n (%)	0	2(8.3)	2(11.1)	0	4(8.2)	2(5.9)
アカシジア	n (%)	0	0	1(5.6)	0	1(2.0)	1(2.9)
頭痛	n (%)	0	0	1(5.6)	0	1(2.0)	0
感覚鈍麻	n (%)	0	0	1(5.6)	0	1(2.0)	0

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－210　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	 40 mg (N=24)	 80 mg (N=18)	 100 mg (N=5)	All NBI-98854 (N=49)	Placebo (N=34)
失神	n (%)	0	0	0	1(20.0)	1(2.0)	0
痙攣	n (%)	0	0	0	0	0	1(2.9)
浮動性めまい	n (%)	0	0	0	0	0	1(2.9)
精神障害	n (%)	0	2(8.3)	0	0	2(4.1)	4(11.8)
敵意	n (%)	0	1(4.2)	0	0	1(2.0)	0
不眠症	n (%)	0	1(4.2)	0	0	1(2.0)	0
精神状態変化	n (%)	0	1(4.2)	0	0	1(2.0)	0
統合失調症	n (%)	0	0	0	0	0	1(2.9)
睡眠障害	n (%)	0	0	0	0	0	1(2.9)
自殺念慮	n (%)	0	0	0	0	0	2(5.9)
生殖系および乳房障害	n (%)	0	0	0	0	0	1(2.9)
腟出血	n (%)	0	0	0	0	0	1(2.9)
皮膚および皮下組織障害	n (%)	0	0	0	0	0	1(2.9)
そう痒症	n (%)	0	0	0	0	0	1(2.9)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.1.7より引用（一部改変）

表2.7.4.7－211　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=73)	80 mg (N=68)	100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
Any Adverse Event of Special Interest	n (%)	0	18(24.7)	15(22.1)	2(10.5)	35(21.6)	15(13.0)
アカシジア関連有害事象	n (%)	0	3(4.1)	0	0	3(1.9)	0
アカシジア	n (%)	0	3(4.1)	0	0	3(1.9)	0
不安	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	0
不安	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	0
心血管系及びQT間隔延長関連有害事象	n (%)	0	1(1.4)	0	0	1(0.6)	0
胸痛	n (%)	0	1(1.4)	0	0	1(0.6)	0
うつ病及び自殺関連有害事象	n (%)	0	4(5.5)	4(5.9)	0	8(4.9)	2(1.7)
自殺念慮	n (%)	0	3(4.1)	1(1.5)	0	4(2.5)	1(0.9)
うつ病	n (%)	0	0	2(2.9)	0	2(1.2)	1(0.9)
抑うつ症状	n (%)	0	1(1.4)	0	0	1(0.6)	0
自殺企図	n (%)	0	0	1(1.5)	0	1(0.6)	0
嚥下障害関連有害事象	n (%)	0	1(1.4)	0	0	1(0.6)	0
嚥下障害	n (%)	0	1(1.4)	0	0	1(0.6)	0
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	3(4.1)	3(4.4)	2(10.5)	8(4.9)	2(1.7)
疲労	n (%)	0	3(4.1)	3(4.4)	2(10.5)	8(4.9)	2(1.7)
肝障害関連有害事象	n (%)	0	0	1(1.5)	0	1(0.6)	0

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－211　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=73)	80 mg (N=68)	100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
急性肝炎	n (%)	0	0	1(1.5)	0	1(0.6)	0
低血圧関連有害事象	n (%)	0	3(4.1)	2(2.9)	0	5(3.1)	3(2.6)
浮動性めまい	n (%)	0	2(2.7)	0	0	2(1.2)	3(2.6)
転倒・転落	n (%)	0	1(1.4)	1(1.5)	0	2(1.2)	0
低血圧	n (%)	0	0	1(1.5)	0	1(0.6)	0
パーキンソニズム関連有害事象	n (%)	0	0	2(2.9)	0	2(1.2)	0
振戦	n (%)	0	0	2(2.9)	0	2(1.2)	0
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	5(6.8)	3(4.4)	1(5.3)	9(5.6)	2(1.7)
傾眠	n (%)	0	4(5.5)	1(1.5)	1(5.3)	6(3.7)	1(0.9)
鎮静	n (%)	0	1(1.4)	2(2.9)	0	3(1.9)	1(0.9)
基礎疾患の悪化に関連する有害事象	n (%)	0	5(6.8)	5(7.4)	0	10(6.2)	8(7.0)
自殺念慮	n (%)	0	3(4.1)	1(1.5)	0	4(2.5)	1(0.9)
うつ病	n (%)	0	0	2(2.9)	0	2(1.2)	1(0.9)
抑うつ症状	n (%)	0	1(1.4)	0	0	1(0.6)	0
軽躁	n (%)	0	1(1.4)	0	0	1(0.6)	0
統合失調感情障害	n (%)	0	0	1(1.5)	0	1(0.6)	1(0.9)
統合失調症	n (%)	0	1(1.4)	0	0	1(0.6)	0
自殺企図	n (%)	0	0	1(1.5)	0	1(0.6)	0
易刺激性	n (%)	0	0	0	0	0	2(1.7)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－211　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=73)	80 mg (N=68)	100 mg (N=19)	All NBI-98854 (N=162)	Placebo (N=115)
精神病性障害	n (%)	0	0	0	0	0	2(1.7)
統合失調症、妄想型	n (%)	0	0	0	0	0	1(0.9)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－211　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=24)	80 mg (N=18)	100 mg (N=5)	All NBI-98854 (N=49)	Placebo (N=34)
Any Adverse Event of Special Interest	n (%)	0	4(16.7)	4(22.2)	1(20.0)	9(18.4)	6(17.6)
アカシジア関連有害事象	n (%)	0	0	1(5.6)	0	1(2.0)	1(2.9)
アカシジア	n (%)	0	0	1(5.6)	0	1(2.0)	1(2.9)
心血管系及びQT間隔延長関連有害事象	n (%)	0	0	1(5.6)	1(20.0)	2(4.1)	1(2.9)
突然死	n (%)	0	0	1(5.6)	0	1(2.0)	0
失神	n (%)	0	0	0	1(20.0)	1(2.0)	0
心筋梗塞	n (%)	0	0	0	0	0	1(2.9)
うつ病及び自殺関連有害事象	n (%)	0	0	0	0	0	2(5.9)
自殺念慮	n (%)	0	0	0	0	0	2(5.9)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(4.2)	0	0	1(2.0)	1(2.9)
疲労	n (%)	0	1(4.2)	0	0	1(2.0)	1(2.9)
低血圧関連有害事象	n (%)	0	1(4.2)	0	1(20.0)	2(4.1)	1(2.9)
転倒・転落	n (%)	0	1(4.2)	0	0	1(2.0)	0
失神	n (%)	0	0	0	1(20.0)	1(2.0)	0
浮動性めまい	n (%)	0	0	0	0	0	1(2.9)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	0	2(8.3)	2(11.1)	0	4(8.2)	2(5.9)
傾眠	n (%)	0	2(8.3)	2(11.1)	0	4(8.2)	2(5.9)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－211　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：プラセボ対照二重盲検期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

AESI Preferred Term	Statistic	NBI-98854 Dose[b] <40 mg (N=2)	40 mg (N=24)	80 mg (N=18)	100 mg (N=5)	All NBI-98854 (N=49)	Placebo (N=34)
基礎疾患の悪化に関連する有害事象	n (%)	0	1(4.2)	0	0	1(2.0)	3(8.8)
敵意	n (%)	0	1(4.2)	0	0	1(2.0)	0
統合失調症	n (%)	0	0	0	0	0	1(2.9)
自殺念慮	n (%)	0	0	0	0	0	2(5.9)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854 and the 80 mg column includes doses of 75 mg and 80 mg NBI-98854.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.1.7より引用（一部改変）

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
Any Adverse Event	n (%)	81(57.4)	99(63.1)	89(60.5)	180(60.4)
血液およびリンパ系障害	n (%)	2(1.4)	4(2.5)	4(2.7)	6(2.0)
貧血	n (%)	1(0.7)	3(1.9)	3(2.0)	4(1.3)
白血球増加症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
好中球減少症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
血小板血症	n (%)	1(0.7)	0	0	1(0.3)
心臓障害	n (%)	2(1.4)	4(2.5)	4(2.7)	6(2.0)
心房細動	n (%)	0	1(0.6)	1(0.7)	1(0.3)
左脚ブロック	n (%)	0	1(0.6)	1(0.7)	1(0.3)
冠動脈疾患	n (%)	1(0.7)	0	0	1(0.3)
僧帽弁閉鎖不全症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
頻脈	n (%)	1(0.7)	0	0	1(0.3)
三尖弁閉鎖不全症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
心室性期外収縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
耳および迷路障害	n (%)	2(1.4)	0	0	2(0.7)
聴覚障害	n (%)	1(0.7)	0	0	1(0.3)
耳鳴	n (%)	1(0.7)	0	0	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
胃腸障害	n (%)	20(14.2)	27(17.2)	21(14.3)	47(15.8)
下痢	n (%)	4(2.8)	8(5.1)	7(4.8)	12(4.0)
口内乾燥	n (%)	6(4.3)	3(1.9)	3(2.0)	9(3.0)
便秘	n (%)	3(2.1)	4(2.5)	2(1.4)	7(2.3)
流涎過多	n (%)	2(1.4)	5(3.2)	3(2.0)	7(2.3)
嘔吐	n (%)	4(2.8)	3(1.9)	2(1.4)	7(2.3)
腹痛	n (%)	1(0.7)	4(2.5)	3(2.0)	5(1.7)
悪心	n (%)	2(1.4)	2(1.3)	2(1.4)	4(1.3)
歯痛	n (%)	2(1.4)	2(1.3)	1(0.7)	4(1.3)
上腹部痛	n (%)	1(0.7)	2(1.3)	1(0.7)	3(1.0)
嚥下障害	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)
結腸ポリープ	n (%)	2(1.4)	0	0	2(0.7)
胃食道逆流性疾患	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
痔核	n (%)	2(1.4)	0	0	2(0.7)
腹部膨満	n (%)	0	1(0.6)	1(0.7)	1(0.3)
腹部圧痛	n (%)	1(0.7)	0	0	1(0.3)
細菌叢異常症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
憩室	n (%)	1(0.7)	0	0	1(0.3)
消化不良	n (%)	1(0.7)	0	0	1(0.3)
胃炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
胃腸出血	n (%)	1(0.7)	0	0	1(0.3)
裂孔ヘルニア	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
メレナ	n (%)	1(0.7)	0	0	1(0.3)
食道食物嵌入	n (%)	1(0.7)	0	0	1(0.3)
食道狭窄	n (%)	1(0.7)	0	0	1(0.3)
食道炎	n (%)	1(0.7)	0	0	1(0.3)
臍ヘルニア	n (%)	1(0.7)	0	0	1(0.3)
全身障害および投与局所様態	n (%)	15(10.6)	13(8.3)	10(6.8)	28(9.4)
疲労	n (%)	12(8.5)	4(2.5)	4(2.7)	16(5.4)
胸痛	n (%)	3(2.1)	2(1.3)	2(1.4)	5(1.7)
歩行障害	n (%)	2(1.4)	1(0.6)	0	3(1.0)
末梢性浮腫	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)
無力症	n (%)	1(0.7)	1(0.6)	0	2(0.7)
空腹	n (%)	1(0.7)	0	0	1(0.3)
治癒不良	n (%)	1(0.7)	0	0	1(0.3)
易刺激性	n (%)	0	1(0.6)	1(0.7)	1(0.3)
倦怠感	n (%)	0	1(0.6)	1(0.7)	1(0.3)
非心臓性胸痛	n (%)	0	1(0.6)	0	1(0.3)
発熱	n (%)	0	1(0.6)	1(0.7)	1(0.3)
口渇	n (%)	1(0.7)	0	0	1(0.3)
肝胆道系障害	n (%)	0	2(1.3)	2(1.4)	2(0.7)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
胆石症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性肝炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
黄疸	n (%)	0	1(0.6)	1(0.7)	1(0.3)
免疫系障害	n (%)	0	2(1.3)	2(1.4)	2(0.7)
過敏症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
季節性アレルギー	n (%)	0	1(0.6)	1(0.7)	1(0.3)
感染症および寄生虫症	n (%)	22(15.6)	30(19.1)	27(18.4)	52(17.4)
尿路感染	n (%)	7(5.0)	10(6.4)	9(6.1)	17(5.7)
鼻咽頭炎	n (%)	5(3.5)	8(5.1)	7(4.8)	13(4.4)
上気道感染	n (%)	3(2.1)	3(1.9)	3(2.0)	6(2.0)
気管支炎	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
蜂巣炎	n (%)	0	3(1.9)	2(1.4)	3(1.0)
胃腸炎	n (%)	0	3(1.9)	3(2.0)	3(1.0)
ダニ皮膚炎	n (%)	2(1.4)	0	0	2(0.7)
急性副鼻腔炎	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
四肢膿瘍	n (%)	0	1(0.6)	0	1(0.3)
軟部組織膿瘍	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性扁桃炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
体部白癬	n (%)	1(0.7)	0	0	1(0.3)
憩室炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
眼感染	n (%)	1(0.7)	0	0	1(0.3)
せつ	n (%)	1(0.7)	0	0	1(0.3)
ウイルス性胃腸炎	n (%)	1(0.7)	0	0	1(0.3)
咬傷感染	n (%)	0	1(0.6)	1(0.7)	1(0.3)
インフルエンザ	n (%)	1(0.7)	0	0	1(0.3)
爪真菌症	n (%)	1(0.7)	0	0	1(0.3)
咽頭炎	n (%)	1(0.7)	0	0	1(0.3)
肺炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性腎盂腎炎	n (%)	1(0.7)	0	0	1(0.3)
副鼻腔炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
歯膿瘍	n (%)	0	1(0.6)	1(0.7)	1(0.3)
外陰膣真菌感染	n (%)	0	1(0.6)	1(0.7)	1(0.3)
傷害、中毒および処置合併症	n (%)	11(7.8)	15(9.6)	13(8.8)	26(8.7)
転倒・転落	n (%)	2(1.4)	4(2.5)	3(2.0)	6(2.0)
擦過傷	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)
挫傷	n (%)	2(1.4)	0	0	2(0.7)
関節脱臼	n (%)	0	2(1.3)	1(0.7)	2(0.7)
交通事故	n (%)	0	2(1.3)	2(1.4)	2(0.7)
皮膚裂傷	n (%)	0	2(1.3)	2(1.4)	2(0.7)
動物咬傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
節足動物咬傷	n (%)	0	1(0.6)	0	1(0.3)
第２度熱傷	n (%)	1(0.7)	0	0	1(0.3)
頚椎骨折	n (%)	0	1(0.6)	1(0.7)	1(0.3)
皮膚化学熱傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)
足骨折	n (%)	0	1(0.6)	1(0.7)	1(0.3)
異物による損傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)
頭部損傷	n (%)	1(0.7)	0	0	1(0.3)
関節損傷	n (%)	1(0.7)	0	0	1(0.3)
四肢外傷性切断	n (%)	1(0.7)	0	0	1(0.3)
口腔内損傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)
筋挫傷	n (%)	0	1(0.6)	1(0.7)	1(0.3)
橈骨骨折	n (%)	0	1(0.6)	1(0.7)	1(0.3)
肋骨骨折	n (%)	0	1(0.6)	0	1(0.3)
引っかき傷	n (%)	1(0.7)	0	0	1(0.3)
熱傷	n (%)	1(0.7)	0	0	1(0.3)
臨床検査	n (%)	16(11.3)	21(13.4)	19(12.9)	37(12.4)
体重増加	n (%)	2(1.4)	6(3.8)	6(4.1)	8(2.7)
ヘモグロビン減少	n (%)	1(0.7)	3(1.9)	3(2.0)	4(1.3)
血中プロラクチン増加	n (%)	2(1.4)	1(0.6)	0	3(1.0)
γ－グルタミルトランスフェラーゼ増加	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
体重減少	n (%)	3(2.1)	0	0	3(1.0)
血中クレアチンホスホキナーゼ増加	n (%)	2(1.4)	0	0	2(0.7)
血中クレアチニン増加	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
血中ブドウ糖増加	n (%)	0	2(1.3)	2(1.4)	2(0.7)
血圧上昇	n (%)	0	2(1.3)	2(1.4)	2(0.7)
血中トリグリセリド増加	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
血中尿素増加	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
ヘマトクリット減少	n (%)	0	2(1.3)	2(1.4)	2(0.7)
アラニン・アミノトランスフェラーゼ増加	n (%)	1(0.7)	0	0	1(0.3)
抗精神病薬濃度治療量以上	n (%)	0	1(0.6)	0	1(0.3)
アスパラギン酸アミノトランスフェラーゼ増加	n (%)	1(0.7)	0	0	1(0.3)
血中コレステロール増加	n (%)	0	1(0.6)	1(0.7)	1(0.3)
尿中結晶陽性	n (%)	0	1(0.6)	1(0.7)	1(0.3)
心電図ＱＴ延長	n (%)	0	1(0.6)	1(0.7)	1(0.3)
尿中ブドウ糖陽性	n (%)	1(0.7)	0	0	1(0.3)
握力低下	n (%)	1(0.7)	0	0	1(0.3)
肝酵素上昇	n (%)	1(0.7)	0	0	1(0.3)
便潜血陽性	n (%)	0	1(0.6)	1(0.7)	1(0.3)
総蛋白減少	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
赤血球数減少	n (%)	0	1(0.6)	1(0.7)	1(0.3)
赤血球数増加	n (%)	0	1(0.6)	1(0.7)	1(0.3)
代謝および栄養障害	n (%)	4(2.8)	10(6.4)	9(6.1)	14(4.7)
食欲亢進	n (%)	0	3(1.9)	2(1.4)	3(1.0)
低ナトリウム血症	n (%)	0	2(1.3)	2(1.4)	2(0.7)
食欲不振	n (%)	1(0.7)	0	0	1(0.3)
食欲障害	n (%)	0	1(0.6)	1(0.7)	1(0.3)
食欲減退	n (%)	1(0.7)	0	0	1(0.3)
脱水	n (%)	0	1(0.6)	1(0.7)	1(0.3)
高血糖	n (%)	0	1(0.6)	1(0.7)	1(0.3)
高トリグリセリド血症	n (%)	1(0.7)	0	0	1(0.3)
低アルブミン血症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
低カリウム血症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
低ナトリウム血症候群	n (%)	0	1(0.6)	1(0.7)	1(0.3)
多飲症	n (%)	1(0.7)	0	0	1(0.3)
筋骨格系および結合組織障害	n (%)	15(10.6)	12(7.6)	10(6.8)	27(9.1)
背部痛	n (%)	5(3.5)	4(2.5)	4(2.7)	9(3.0)
関節痛	n (%)	2(1.4)	3(1.9)	3(2.0)	5(1.7)
骨関節炎	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
四肢痛	n (%)	1(0.7)	2(1.3)	0	3(1.0)
筋肉痛	n (%)	2(1.4)	0	0	2(0.7)
関節炎	n (%)	1(0.7)	0	0	1(0.3)
滑液包炎	n (%)	1(0.7)	0	0	1(0.3)
椎間板変性症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
筋痙縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
筋力低下	n (%)	1(0.7)	0	0	1(0.3)
筋骨格系胸痛	n (%)	1(0.7)	0	0	1(0.3)
筋骨格痛	n (%)	0	1(0.6)	1(0.7)	1(0.3)
骨減少症	n (%)	1(0.7)	0	0	1(0.3)
顎痛	n (%)	1(0.7)	0	0	1(0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	n (%)	2(1.4)	3(1.9)	3(2.0)	5(1.7)
副腎腺腫	n (%)	0	1(0.6)	1(0.7)	1(0.3)
乳癌	n (%)	0	1(0.6)	1(0.7)	1(0.3)
脂肪腫	n (%)	1(0.7)	0	0	1(0.3)
肺新生物	n (%)	1(0.7)	0	0	1(0.3)
甲状腺新生物	n (%)	0	1(0.6)	1(0.7)	1(0.3)
神経系障害	n (%)	32(22.7)	29(18.5)	23(15.6)	61(20.5)
頭痛	n (%)	9(6.4)	7(4.5)	6(4.1)	16(5.4)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
傾眠	n (%)	9(6.4)	4(2.5)	3(2.0)	13(4.4)
浮動性めまい	n (%)	6(4.3)	6(3.8)	6(4.1)	12(4.0)
アカシジア	n (%)	5(3.5)	0	0	5(1.7)
失神	n (%)	3(2.1)	2(1.3)	1(0.7)	5(1.7)
振戦	n (%)	2(1.4)	3(1.9)	1(0.7)	5(1.7)
ジスキネジー	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
鎮静	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
一過性脳虚血発作	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
健忘	n (%)	0	1(0.6)	1(0.7)	1(0.3)
平衡障害	n (%)	1(0.7)	0	0	1(0.3)
歯車様固縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
よだれ	n (%)	0	1(0.6)	1(0.7)	1(0.3)
構語障害	n (%)	0	1(0.6)	0	1(0.3)
ジストニー	n (%)	1(0.7)	0	0	1(0.3)
脳症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
錐体外路障害	n (%)	0	1(0.6)	1(0.7)	1(0.3)
顔面神経麻痺	n (%)	0	1(0.6)	1(0.7)	1(0.3)
感覚鈍麻	n (%)	1(0.7)	0	0	1(0.3)
企図振戦	n (%)	1(0.7)	0	0	1(0.3)
嗜眠	n (%)	0	1(0.6)	0	1(0.3)
片頭痛	n (%)	1(0.7)	0	0	1(0.3)
ミオクローヌス	n (%)	1(0.7)	0	0	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
末梢性ニューロパチー	n (%)	0	1(0.6)	1(0.7)	1(0.3)
遅発性ジスキネジー	n (%)	1(0.7)	0	0	1(0.3)
咬舌	n (%)	1(0.7)	0	0	1(0.3)
妊娠、産褥および周産期の状態	n (%)	0	1(0.6)	1(0.7)	1(0.3)
自然流産	n (%)	0	1(0.6)	1(0.7)	1(0.3)
精神障害	n (%)	23(16.3)	20(12.7)	16(10.9)	43(14.4)
不安	n (%)	4(2.8)	6(3.8)	2(1.4)	10(3.4)
自殺念慮	n (%)	6(4.3)	3(1.9)	3(2.0)	9(3.0)
うつ病	n (%)	5(3.5)	3(1.9)	3(2.0)	8(2.7)
不眠症	n (%)	2(1.4)	4(2.5)	4(2.7)	6(2.0)
統合失調症	n (%)	3(2.1)	3(1.9)	3(2.0)	6(2.0)
落ち着きのなさ	n (%)	1(0.7)	2(1.3)	0	3(1.0)
激越	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
抑うつ症状	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
統合失調感情障害	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
アルコール症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
死別反応	n (%)	1(0.7)	0	0	1(0.3)
錯乱状態	n (%)	0	1(0.6)	1(0.7)	1(0.3)
ディスフェミア	n (%)	1(0.7)	0	0	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
軽躁	n (%)	1(0.7)	0	0	1(0.3)
躁病	n (%)	1(0.7)	0	0	1(0.3)
神経過敏	n (%)	0	1(0.6)	1(0.7)	1(0.3)
妄想症	n (%)	1(0.7)	0	0	1(0.3)
精神運動制止遅滞	n (%)	1(0.7)	0	0	1(0.3)
精神病性障害	n (%)	1(0.7)	0	0	1(0.3)
自殺企図	n (%)	0	1(0.6)	1(0.7)	1(0.3)
トランス	n (%)	1(0.7)	0	0	1(0.3)
腎および尿路障害	n (%)	4(2.8)	5(3.2)	5(3.4)	9(3.0)
血尿	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)
頻尿	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
尿失禁	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
糖尿	n (%)	0	1(0.6)	1(0.7)	1(0.3)
腎結石症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
尿臭異常	n (%)	1(0.7)	0	0	1(0.3)
生殖系および乳房障害	n (%)	2(1.4)	2(1.3)	2(1.4)	4(1.3)
良性前立腺肥大症	n (%)	1(0.7)	0	0	1(0.3)
乳房圧痛	n (%)	1(0.7)	0	0	1(0.3)
乳汁漏出症	n (%)	1(0.7)	0	0	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
月経過多	n (%)	0	1(0.6)	1(0.7)	1(0.3)
精巣捻転	n (%)	0	1(0.6)	1(0.7)	1(0.3)
腟分泌物	n (%)	1(0.7)	0	0	1(0.3)
呼吸器、胸郭および縦隔障害	n (%)	6(4.3)	15(9.6)	13(8.8)	21(7.0)
咳嗽	n (%)	2(1.4)	4(2.5)	3(2.0)	6(2.0)
慢性閉塞性肺疾患	n (%)	2(1.4)	3(1.9)	3(2.0)	5(1.7)
鼻閉	n (%)	0	2(1.3)	2(1.4)	2(0.7)
アレルギー性鼻炎	n (%)	0	2(1.3)	2(1.4)	2(0.7)
アレルギー性副鼻腔炎	n (%)	1(0.7)	0	0	1(0.3)
喘息	n (%)	0	1(0.6)	1(0.7)	1(0.3)
慢性気管支炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
嚢胞性肺疾患	n (%)	0	1(0.6)	1(0.7)	1(0.3)
呼吸困難	n (%)	1(0.7)	0	0	1(0.3)
鼻出血	n (%)	1(0.7)	0	0	1(0.3)
口腔咽頭痛	n (%)	0	1(0.6)	0	1(0.3)
胸膜線維症	n (%)	0	1(0.6)	1(0.7)	1(0.3)
鼻漏	n (%)	1(0.7)	0	0	1(0.3)
副鼻腔うっ血	n (%)	1(0.7)	0	0	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
皮膚および皮下組織障害	n (%)	10(7.1)	4(2.5)	4(2.7)	14(4.7)
そう痒症	n (%)	3(2.1)	0	0	3(1.0)
発疹	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)
斑状丘疹状皮疹	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
水疱	n (%)	1(0.7)	0	0	1(0.3)
過角化	n (%)	1(0.7)	0	0	1(0.3)
全身性皮疹	n (%)	1(0.7)	0	0	1(0.3)
皮膚剥脱	n (%)	0	1(0.6)	1(0.7)	1(0.3)
皮膚病変	n (%)	0	1(0.6)	1(0.7)	1(0.3)
蕁麻疹	n (%)	1(0.7)	0	0	1(0.3)
社会環境	n (%)	1(0.7)	0	0	1(0.3)
社会的入院	n (%)	1(0.7)	0	0	1(0.3)
外科および内科処置	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
抜歯	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
血管障害	n (%)	4(2.8)	10(6.4)	9(6.1)	14(4.7)
高血圧	n (%)	2(1.4)	5(3.2)	4(2.7)	7(2.3)
深部静脈血栓症	n (%)	0	2(1.3)	2(1.4)	2(0.7)
ほてり	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	 80 mg (N=157)	 80 mg Only[c] (N=147)	All NBI-98854 (N=298)
低血圧	n (%)	0	1(0.6)	1(0.7)	1(0.3)
末梢動脈閉塞性疾患	n (%)	1(0.7)	0	0	1(0.3)
レイノー現象	n (%)	0	1(0.6)	1(0.7)	1(0.3)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212 ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	 80 mg (N=34)	 80 mg Only[c] (N=33)	All NBI-98854 (N=67)
Any Adverse Event	n (%)	19(57.6)	16(47.1)	15(45.5)	35(52.2)
血液およびリンパ系障害	n (%)	1(3.0)	0	0	1(1.5)
好中球減少症	n (%)	1(3.0)	0	0	1(1.5)
心臓障害	n (%)	1(3.0)	1(2.9)	1(3.0)	2(3.0)
上室性不整脈	n (%)	1(3.0)	0	0	1(1.5)
心不全	n (%)	0	1(2.9)	1(3.0)	1(1.5)
耳および迷路障害	n (%)	1(3.0)	0	0	1(1.5)
耳鳴	n (%)	1(3.0)	0	0	1(1.5)
眼障害	n (%)	0	1(2.9)	1(3.0)	1(1.5)
兎眼	n (%)	0	1(2.9)	1(3.0)	1(1.5)
胃腸障害	n (%)	5(15.2)	4(11.8)	3(9.1)	9(13.4)
便秘	n (%)	3(9.1)	1(2.9)	1(3.0)	4(6.0)
嘔吐	n (%)	2(6.1)	2(5.9)	2(6.1)	4(6.0)
悪心	n (%)	1(3.0)	2(5.9)	2(6.1)	3(4.5)
下痢	n (%)	1(3.0)	1(2.9)	1(3.0)	2(3.0)
腹痛	n (%)	1(3.0)	0	0	1(1.5)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	 80 mg (N=34)	 80 mg Only[c] (N=33)	All NBI-98854 (N=67)
口内乾燥	n (%)	1(3.0)	0	0	1(1.5)
嚥下障害	n (%)	1(3.0)	0	0	1(1.5)
流涎過多	n (%)	0	1(2.9)	0	1(1.5)
全身障害および投与局所様態	n (%)	2(6.1)	3(8.8)	3(9.1)	5(7.5)
疲労	n (%)	0	1(2.9)	1(3.0)	1(1.5)
歩行障害	n (%)	1(3.0)	0	0	1(1.5)
易刺激性	n (%)	0	1(2.9)	1(3.0)	1(1.5)
非心臓性胸痛	n (%)	1(3.0)	0	0	1(1.5)
突然死	n (%)	0	1(2.9)	1(3.0)	1(1.5)
肝胆道系障害	n (%)	0	1(2.9)	1(3.0)	1(1.5)
肝不全	n (%)	0	1(2.9)	1(3.0)	1(1.5)
感染症および寄生虫症	n (%)	6(18.2)	5(14.7)	5(15.2)	11(16.4)
尿路感染	n (%)	3(9.1)	2(5.9)	2(6.1)	5(7.5)
気管支炎	n (%)	1(3.0)	2(5.9)	2(6.1)	3(4.5)
耳感染	n (%)	1(3.0)	0	0	1(1.5)
ウイルス性胃腸炎	n (%)	1(3.0)	0	0	1(1.5)
インフルエンザ	n (%)	1(3.0)	0	0	1(1.5)
鼻咽頭炎	n (%)	0	1(2.9)	1(3.0)	1(1.5)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	 80 mg (N=34)	 80 mg Only[c] (N=33)	All NBI-98854 (N=67)
上気道感染	n (%)	1(3.0)	0	0	1(1.5)
傷害、中毒および処置合併症	n (%)	3(9.1)	2(5.9)	1(3.0)	5(7.5)
転倒・転落	n (%)	2(6.1)	0	0	2(3.0)
四肢損傷	n (%)	0	1(2.9)	0	1(1.5)
腎損傷	n (%)	1(3.0)	0	0	1(1.5)
皮下血腫	n (%)	0	1(2.9)	1(3.0)	1(1.5)
臨床検査	n (%)	0	4(11.8)	3(9.1)	4(6.0)
尿中ブドウ糖陽性	n (%)	0	2(5.9)	2(6.1)	2(3.0)
血中クレアチンホスホキナーゼ増加	n (%)	0	1(2.9)	1(3.0)	1(1.5)
血中クレアチニン増加	n (%)	0	1(2.9)	0	1(1.5)
血中ブドウ糖増加	n (%)	0	1(2.9)	1(3.0)	1(1.5)
グリコヘモグロビン増加	n (%)	0	1(2.9)	1(3.0)	1(1.5)
代謝および栄養障害	n (%)	1(3.0)	2(5.9)	1(3.0)	3(4.5)
食欲減退	n (%)	1(3.0)	0	0	1(1.5)
糖尿病	n (%)	0	1(2.9)	1(3.0)	1(1.5)
高カリウム血症	n (%)	0	1(2.9)	1(3.0)	1(1.5)
低ナトリウム血症	n (%)	0	1(2.9)	0	1(1.5)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	 80 mg (N=34)	 80 mg Only[c] (N=33)	All NBI-98854 (N=67)
代謝性アシドーシス	n (%)	0	1(2.9)	1(3.0)	1(1.5)
筋骨格系および結合組織障害	n (%)	1(3.0)	2(5.9)	1(3.0)	3(4.5)
頚部痛	n (%)	1(3.0)	1(2.9)	0	2(3.0)
関節炎	n (%)	0	1(2.9)	0	1(1.5)
関節腫脹	n (%)	0	1(2.9)	1(3.0)	1(1.5)
神経系障害	n (%)	10(30.3)	5(14.7)	4(12.1)	15(22.4)
傾眠	n (%)	5(15.2)	1(2.9)	1(3.0)	6(9.0)
頭痛	n (%)	0	3(8.8)	2(6.1)	3(4.5)
振戦	n (%)	2(6.1)	0	0	2(3.0)
アカシジア	n (%)	1(3.0)	0	0	1(1.5)
認知症	n (%)	1(3.0)	0	0	1(1.5)
錐体外路障害	n (%)	0	1(2.9)	1(3.0)	1(1.5)
神経痛	n (%)	1(3.0)	0	0	1(1.5)
鎮静	n (%)	1(3.0)	0	0	1(1.5)
失神	n (%)	1(3.0)	0	0	1(1.5)
精神障害	n (%)	9(27.3)	6(17.6)	5(15.2)	15(22.4)
自殺念慮	n (%)	1(3.0)	4(11.8)	4(12.1)	5(7.5)
うつ病	n (%)	2(6.1)	1(2.9)	1(3.0)	3(4.5)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	 80 mg (N=34)	 80 mg Only[c] (N=33)	All NBI-98854 (N=67)
精神状態変化	n (%)	2(6.1)	0	0	2(3.0)
統合失調症	n (%)	1(3.0)	1(2.9)	1(3.0)	2(3.0)
不安	n (%)	1(3.0)	0	0	1(1.5)
敵意	n (%)	1(3.0)	0	0	1(1.5)
不眠症	n (%)	1(3.0)	0	0	1(1.5)
リビドー減退	n (%)	1(3.0)	0	0	1(1.5)
精神運動制止遅滞	n (%)	0	1(2.9)	1(3.0)	1(1.5)
精神病性障害	n (%)	0	1(2.9)	0	1(1.5)
自殺企図	n (%)	0	1(2.9)	1(3.0)	1(1.5)
腎および尿路障害	n (%)	1(3.0)	0	0	1(1.5)
腎嚢胞	n (%)	1(3.0)	0	0	1(1.5)
生殖系および乳房障害	n (%)	0	1(2.9)	1(3.0)	1(1.5)
良性前立腺肥大症	n (%)	0	1(2.9)	1(3.0)	1(1.5)
呼吸器、胸郭および縦隔障害	n (%)	1(3.0)	4(11.8)	4(12.1)	5(7.5)
咳嗽	n (%)	1(3.0)	1(2.9)	1(3.0)	2(3.0)
喘息	n (%)	1(3.0)	0	0	1(1.5)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

表2.7.4.7－212　ベースライン時投与の抗精神病薬分類ごとの有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

MedDRA System Organ Class Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	 80 mg (N=34)	 80 mg Only[c] (N=33)	All NBI-98854 (N=67)
慢性閉塞性肺疾患	n (%)	0	1(2.9)	1(3.0)	1(1.5)
呼吸困難	n (%)	0	1(2.9)	1(3.0)	1(1.5)
胸水	n (%)	0	1(2.9)	1(3.0)	1(1.5)
くしゃみ	n (%)	0	1(2.9)	1(3.0)	1(1.5)
外科および内科処置	n (%)	1(3.0)	0	0	1(1.5)
抜歯	n (%)	1(3.0)	0	0	1(1.5)
血管障害	n (%)	2(6.1)	1(2.9)	1(3.0)	3(4.5)
本態性高血圧症	n (%)	1(3.0)	0	0	1(1.5)
高血圧	n (%)	0	1(2.9)	1(3.0)	1(1.5)
起立性低血圧	n (%)	1(3.0)	0	0	1(1.5)

[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event in a given System Organ Class, that subject is counted once for the class. If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.

5.3.5.3－2 Table 1.3.1.2.7より引用（一部改変）

表2.7.4.7－213　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	80 mg (N=157)	80 mg Only[c] (N=147)	All NBI-98854 (N=298)
Any Adverse Event of Special Interest	n (%)	43(30.5)	43(27.4)	34(23.1)	86(28.9)
アカシジア関連有害事象	n (%)	5(3.5)	0	0	5(1.7)
アカシジア	n (%)	5(3.5)	0	0	5(1.7)
不安	n (%)	4(2.8)	6(3.8)	2(1.4)	10(3.4)
不安	n (%)	4(2.8)	6(3.8)	2(1.4)	10(3.4)
心血管系及びQT間隔延長関連有害事象	n (%)	5(3.5)	5(3.2)	4(2.7)	10(3.4)
胸痛	n (%)	3(2.1)	2(1.3)	2(1.4)	5(1.7)
失神	n (%)	3(2.1)	2(1.3)	1(0.7)	5(1.7)
心電図QT延長	n (%)	0	1(0.6)	1(0.7)	1(0.3)
うつ病及び自殺関連有害事象	n (%)	11(7.8)	7(4.5)	7(4.8)	18(6.0)
自殺念慮	n (%)	6(4.3)	3(1.9)	3(2.0)	9(3.0)
うつ病	n (%)	5(3.5)	3(1.9)	3(2.0)	8(2.7)
抑うつ症状	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
自殺企図	n (%)	0	1(0.6)	1(0.7)	1(0.3)
嚥下障害関連有害事象	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)
嚥下障害	n (%)	2(1.4)	1(0.6)	1(0.7)	3(1.0)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－213 ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	80 mg (N=157)	80 mg Only[c] (N=147)	All NBI-98854 (N=298)
食道食物嵌入	n (%)	1(0.7)	0	0	1(0.3)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	12(8.5)	7(4.5)	5(3.4)	19(6.4)
疲労	n (%)	12(8.5)	4(2.5)	4(2.7)	16(5.4)
無力症	n (%)	1(0.7)	1(0.6)	0	2(0.7)
嗜眠	n (%)	0	1(0.6)	0	1(0.3)
倦怠感	n (%)	0	1(0.6)	1(0.7)	1(0.3)
肝障害関連有害事象	n (%)	0	1(0.6)	1(0.7)	1(0.3)
急性肝炎	n (%)	0	1(0.6)	1(0.7)	1(0.3)
高プロラクチン血症関連有害事象	n (%)	3(2.1)	1(0.6)	0	4(1.3)
血中プロラクチン増加	n (%)	2(1.4)	1(0.6)	0	3(1.0)
乳汁漏出症	n (%)	1(0.7)	0	0	1(0.3)
低血圧関連有害事象	n (%)	9(6.4)	11(7.0)	10(6.8)	20(6.7)
浮動性めまい	n (%)	6(4.3)	6(3.8)	6(4.1)	12(4.0)
転倒・転落	n (%)	2(1.4)	4(2.5)	3(2.0)	6(2.0)
失神	n (%)	3(2.1)	2(1.3)	1(0.7)	5(1.7)
低血圧	n (%)	0	1(0.6)	1(0.7)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－213　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Atypical Antipsychotic only

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=141)	80 mg (N=157)	80 mg Only[c] (N=147)	All NBI-98854 (N=298)
パーキンソニズム関連有害事象	n (%)	2(1.4)	3(1.9)	1(0.7)	5(1.7)
振戦	n (%)	2(1.4)	3(1.9)	1(0.7)	5(1.7)
歯車様固縮	n (%)	0	1(0.6)	1(0.7)	1(0.3)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	10(7.1)	6(3.8)	5(3.4)	16(5.4)
傾眠	n (%)	9(6.4)	4(2.5)	3(2.0)	13(4.4)
鎮静	n (%)	1(0.7)	2(1.3)	2(1.4)	3(1.0)
基礎疾患の悪化に関連する有害事象	n (%)	14(9.9)	12(7.6)	12(8.2)	26(8.7)
自殺念慮	n (%)	6(4.3)	3(1.9)	3(2.0)	9(3.0)
うつ病	n (%)	5(3.5)	3(1.9)	3(2.0)	8(2.7)
統合失調症	n (%)	3(2.1)	3(1.9)	3(2.0)	6(2.0)
抑うつ症状	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
統合失調感情障害	n (%)	1(0.7)	1(0.6)	1(0.7)	2(0.7)
軽躁	n (%)	1(0.7)	0	0	1(0.3)
易刺激性	n (%)	0	1(0.6)	1(0.7)	1(0.3)
躁病	n (%)	1(0.7)	0	0	1(0.3)
妄想症	n (%)	1(0.7)	0	0	1(0.3)
精神病性障害	n (%)	1(0.7)	0	0	1(0.3)
自殺企図	n (%)	0	1(0.6)	1(0.7)	1(0.3)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－213　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	80 mg (N=34)	80 mg Only[c] (N=33)	All NBI-98854 (N=67)
Any Adverse Event of Special Interest	n (%)	16(48.5)	10(29.4)	9(27.3)	26(38.8)
アカシジア関連有害事象	n (%)	1(3.0)	0	0	1(1.5)
アカシジア	n (%)	1(3.0)	0	0	1(1.5)
不安	n (%)	1(3.0)	0	0	1(1.5)
不安	n (%)	1(3.0)	0	0	1(1.5)
心血管系及びQT間隔延長関連有害事象	n (%)	1(3.0)	2(5.9)	2(6.1)	3(4.5)
心不全	n (%)	0	1(2.9)	1(3.0)	1(1.5)
突然死	n (%)	0	1(2.9)	1(3.0)	1(1.5)
失神	n (%)	1(3.0)	0	0	1(1.5)
うつ病及び自殺関連有害事象	n (%)	3(9.1)	5(14.7)	5(15.2)	8(11.9)
自殺念慮	n (%)	1(3.0)	4(11.8)	4(12.1)	5(7.5)
うつ病	n (%)	2(6.1)	1(2.9)	1(3.0)	3(4.5)
自殺企図	n (%)	0	1(2.9)	1(3.0)	1(1.5)
嚥下障害関連有害事象	n (%)	1(3.0)	0	0	1(1.5)
嚥下障害	n (%)	1(3.0)	0	0	1(1.5)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－213　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	80 mg (N=34)	80 mg Only[c] (N=33)	All NBI-98854 (N=67)
傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）	n (%)	0	1(2.9)	1(3.0)	1(1.5)
疲労	n (%)	0	1(2.9)	1(3.0)	1(1.5)
肝障害関連有害事象	n (%)	0	1(2.9)	1(3.0)	1(1.5)
肝不全	n (%)	0	1(2.9)	1(3.0)	1(1.5)
低血圧関連有害事象	n (%)	4(12.1)	0	0	4(6.0)
転倒・転落	n (%)	2(6.1)	0	0	2(3.0)
起立性低血圧	n (%)	1(3.0)	0	0	1(1.5)
失神	n (%)	1(3.0)	0	0	1(1.5)
パーキンソニズム関連有害事象	n (%)	2(6.1)	0	0	2(3.0)
振戦	n (%)	2(6.1)	0	0	2(3.0)
傾眠関連有害事象（傾眠又は鎮静）	n (%)	6(18.2)	1(2.9)	1(3.0)	7(10.4)
傾眠	n (%)	5(15.2)	1(2.9)	1(3.0)	6(9.0)
鎮静	n (%)	1(3.0)	0	0	1(1.5)
基礎疾患の悪化に関連する有害事象	n (%)	5(15.2)	6(17.6)	5(15.2)	11(16.4)
自殺念慮	n (%)	1(3.0)	4(11.8)	4(12.1)	5(7.5)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

表2.7.4.7－213　ベースライン時投与の抗精神病薬分類ごとの注目すべき有害事象の内訳：MT-5199長期投与期間（海外試験_ISS）（続き）

Antipsychotic Medication Use Category: Typical Antipsychotic[a]

AESI Preferred Term	Statistic	NBI-98854 Dose[b] 40 mg (N=33)	80 mg (N=34)	80 mg Only[c] (N=33)	All NBI-98854 (N=67)
うつ病	n (%)	2(6.1)	1(2.9)	1(3.0)	3(4.5)
統合失調症	n (%)	1(3.0)	1(2.9)	1(3.0)	2(3.0)
敵意	n (%)	1(3.0)	0	0	1(1.5)
易刺激性	n (%)	0	1(2.9)	1(3.0)	1(1.5)
精神病性障害	n (%)	0	1(2.9)	0	1(1.5)
自殺企図	n (%)	0	1(2.9)	1(3.0)	1(1.5)

AESI = Adverse Event of Special Interest.
[a] Typical Antipsychotic includes typical alone or both atypical and typical.
[b] 40 mg column includes doses of 40 mg and 50 mg NBI-98854.
[c] Subjects in the NBI-98854 80 mg column who did not have a dose reduction during the study. For Study 1304, includes subjects in the 80 mg NBI-98854 arm (double-blind and/or extension period) with no dose reduction. For Study 1402, includes subjects with a dose increase to 80 mg NBI-98854 after Week 4 with no dose reduction. These subjects are counted only once in the All NBI-98854 column.
Note: If a subject experienced more than 1 event within a given preferred term, that subject is counted only once for that term.
傾眠関連有害事象を傾眠関連有害事象（傾眠又は鎮静）と傾眠関連有害事象（疲労，無力症，嗜眠又は倦怠感）に分けて集計した

5.3.5.3－2 Table 1.3.6.2.7より引用（一部改変）

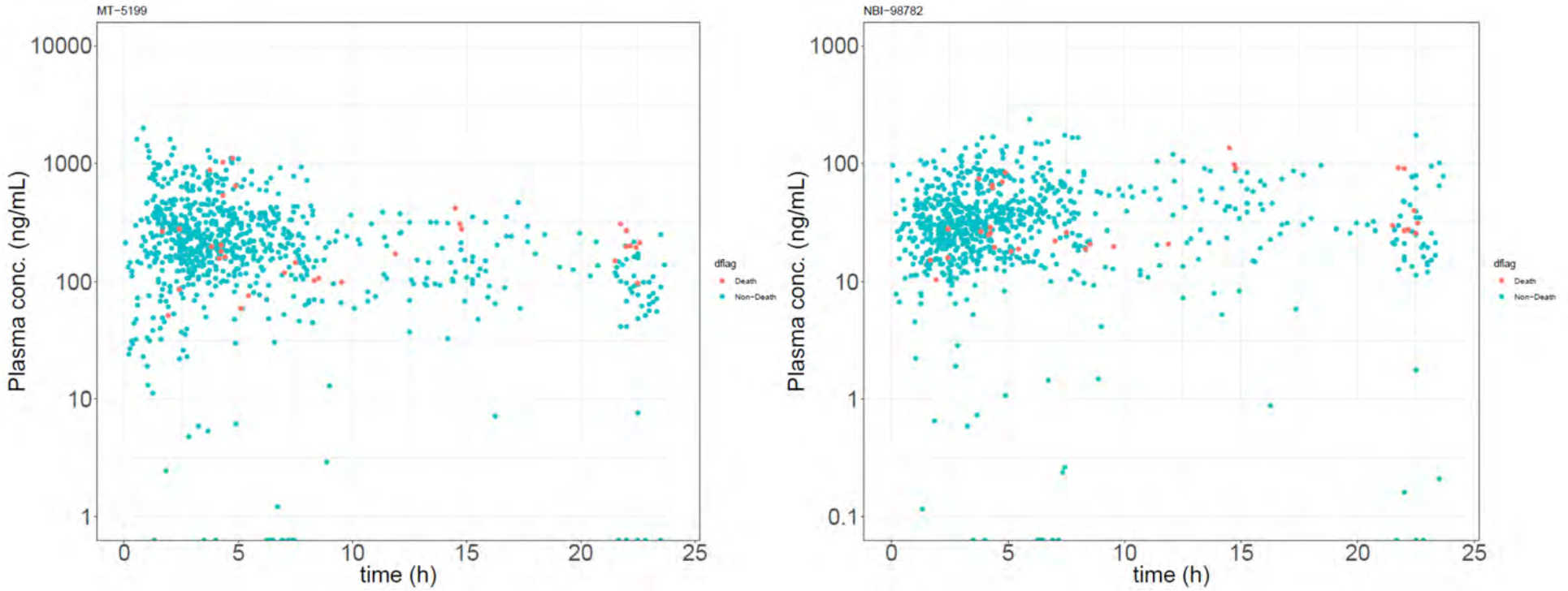


図 2.7.4.7－1　死亡例と非死亡例の MT-5199 及び NBI-98782 の血漿中濃度：MT-5199-J02 試験

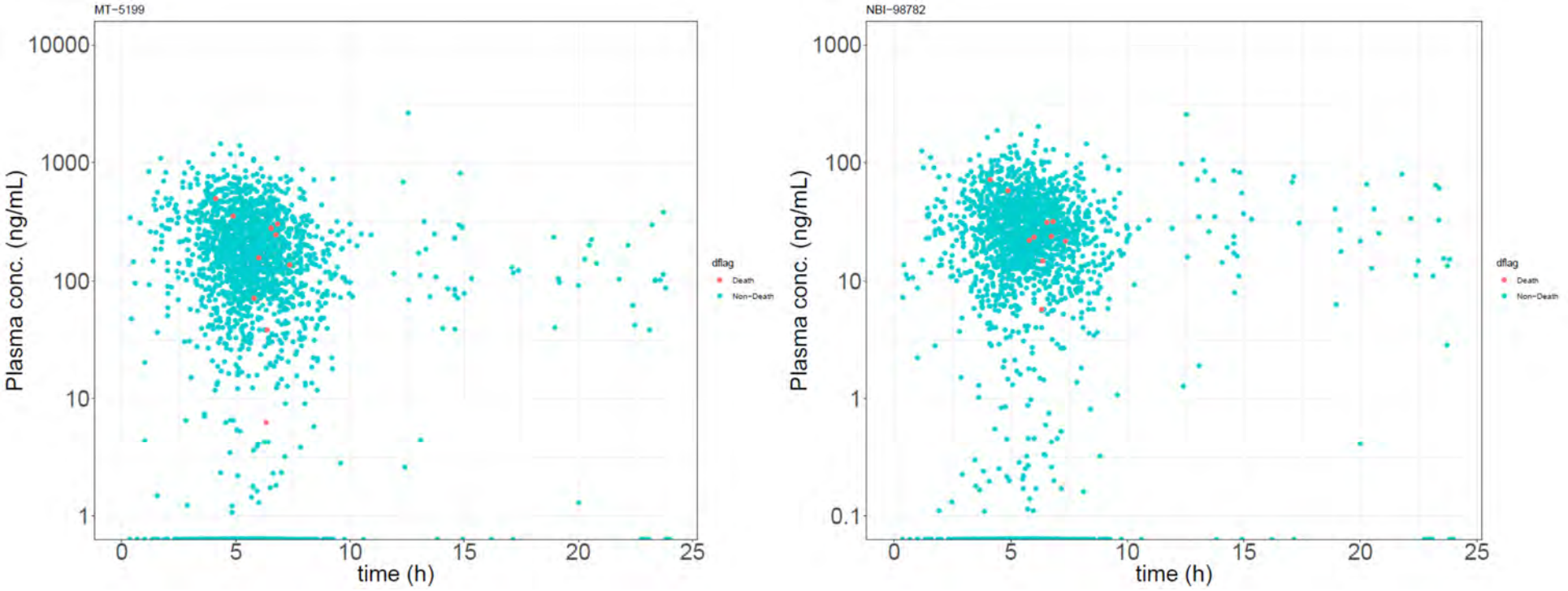


図 2.7.4.7－2　死亡例と非死亡例の MT-5199 及び NBI-98782 の血漿中濃度：海外臨床試験

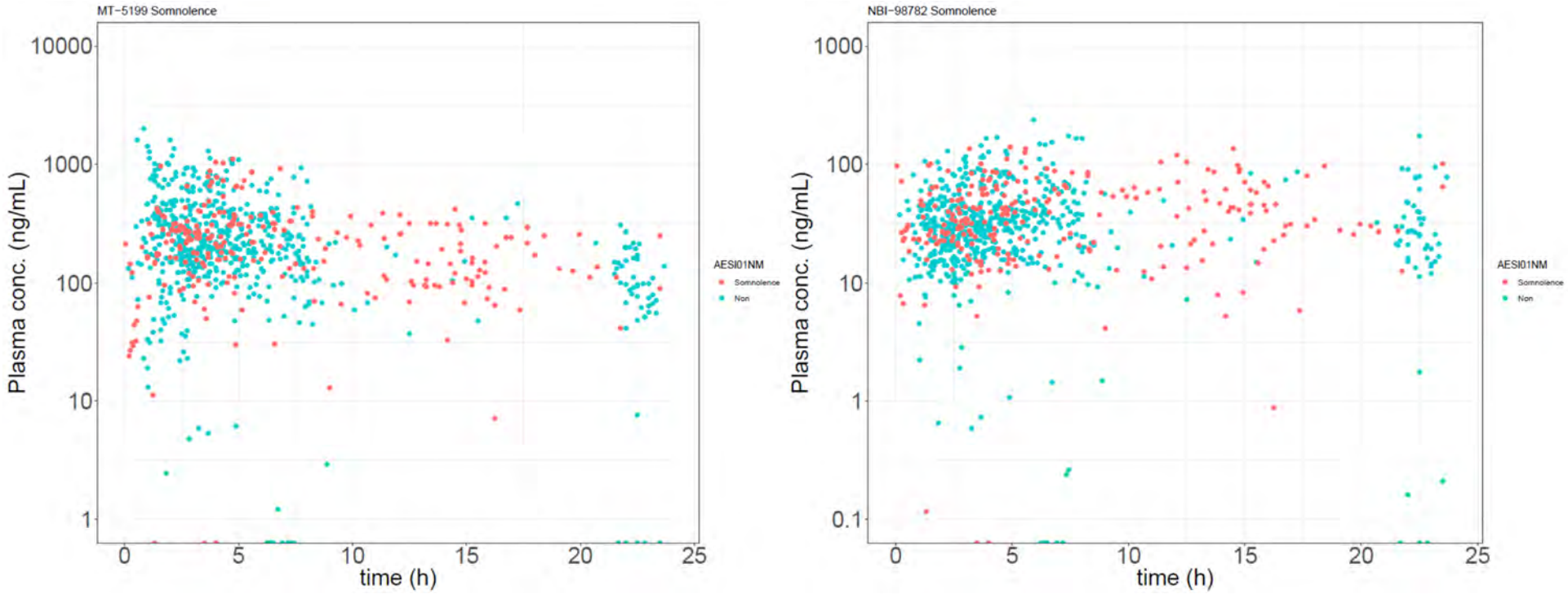


図 2.7.4.7－3　傾眠関連有害事象発現有無別の MT-5199 及び NBI-98782 の血漿中濃度：MT-5199-J02 試験

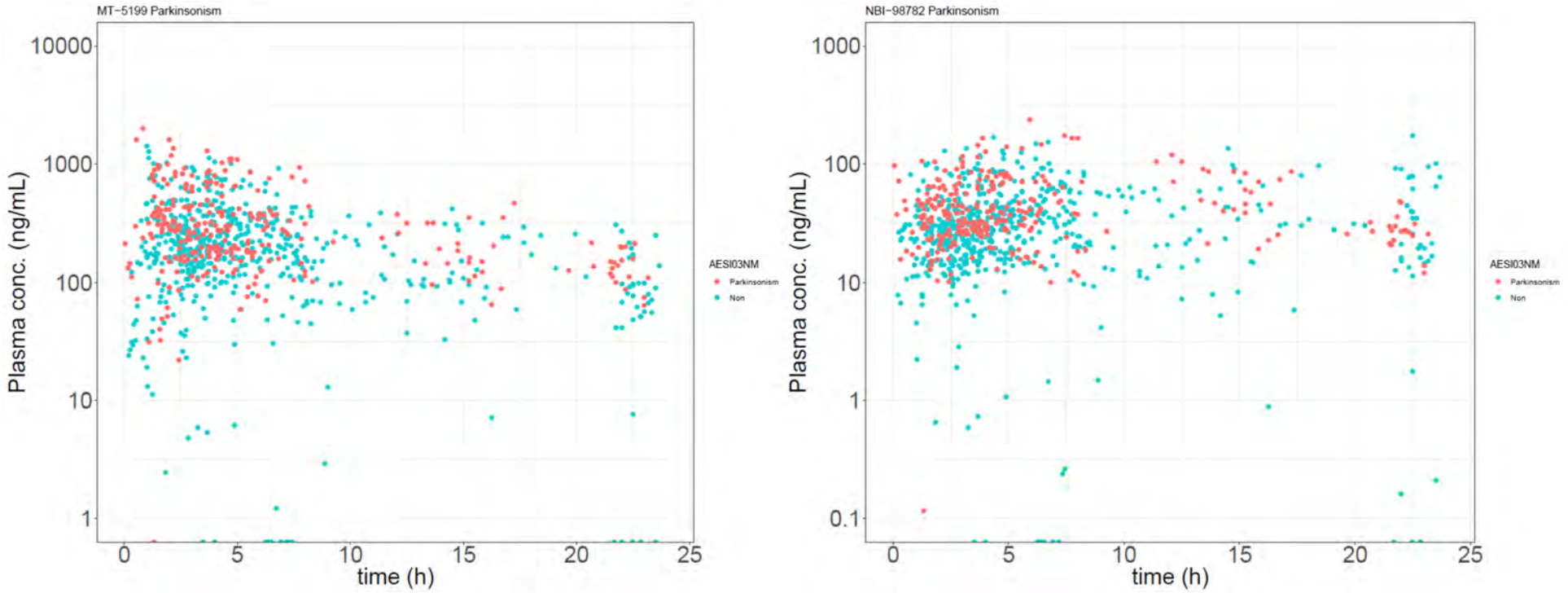


図 2.7.4.7－4　パーキンソニズム関連有害事象発現有無別の MT-5199 及び NBI-98782 の血漿中濃度：MT-5199-J02 試験

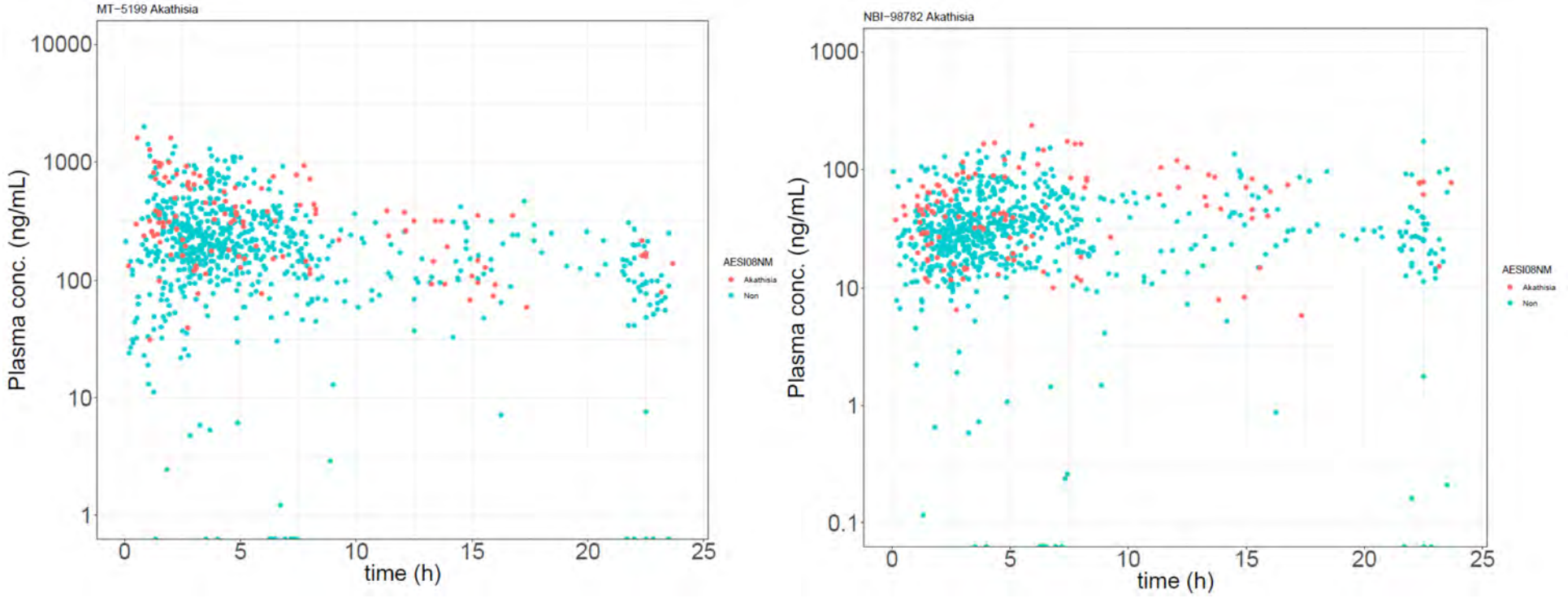


図 2.7.4.7－5　アカシジア関連有害事象発現有無別の MT-5199 及び NBI-98782 の血漿中濃度：MT-5199-J02 試験

ジスバルカプセル 40mg
製造販売承認申請書添付資料

第 2 部（モジュール 2）

2.7　臨床概要
2.7.5　参考文献

田辺三菱製薬株式会社

目次

2.7.5　参考文献..... 3

2.7.5　参考文献

1) Uchida Y, Ohtsuki S, Kamiie J, Ohmine K, Iwase R, Terasaki T. Quantitative targeted absolute proteomics for 28 human transporters in plasma membrane of Caco-2 cell monolayer cultured for 2, 3, and 4 weeks. Drug Metab Pharmacokinet. 2015;30(2):205-8.（資料番号：5.4―38）
2) Parkinson A, Ogilvie BW, Buckley DB, Kazmi F, Czerwinski M, Parkinson O. Biotransformation of xenobiotics. In: Klaassen CD, editor. Casarett & Doull's toxicology: The basic science of poisons. 8th ed. New York: Mcgraw-Hill Education; 2013. p. 185-366.（資料番号：5.4―39）
3) Gong J, Gan J, Masson E, Syed S, Xia YQ, Williams D, et al. Metabolic chiral inversion of brivanib and its relevance to safety and pharmacology. Drug Metab Dispos. 2012;40(12):2374-80.（資料番号：5.4―40）
4) Davies B, Morris T. Physiological parameters in laboratory animals and humans. Pharm Res. 1993;10(7):1093-5.（資料番号：5.4―41）
5) Rowland M, Matin SB. Kinetics of drug-drug interactions. J Pharmacokinet Biopharm. 1973;1(6):553-67.（資料番号：5.4―42）
6) Ito K, Hallifax D, Obach RS, Houston JB. Impact of parallel pathways of drug elimination and multiple cytochrome P450 involvement on drug-drug interactions: CYP2D6 paradigm. Drug Metab Dispos. 2005;33(6):837-44.（資料番号：5.4―43）
7) Bohnert T, Patel A, Templeton I, Chen Y, Lu C, Lai G, et al. Evaluation of a new molecular entity as a victim of metabolic drug-drug interactions--an industry perspective. Drug Metab Dispos. 2016;44(8):1399-423.（資料番号：5.4―44）
8) Johnson TN, Boussery K, Rowland-Yeo K, Tucker GT, Rostami-Hodjegan A. A semi-mechanistic model to predict the effects of liver cirrhosis on drug clearance. Clin Pharmacokinet. 2010;49(3):189-206.（資料番号：5.4―45）
9) Janno S, Holi MM, Tuisku K, Wahlbeck K. Validity of Simpson-Angus Scale (SAS) in a naturalistic schizophrenia population. BMC Neurology. 2005;5(1):p.5.（資料番号：5.4―46）
10) Ondo WG, Hanna PA, Jankovic J. Tetrabenazine treatment for tardive dyskinesia: assessment by randomized videotape protocol. Am J Psychiatry. 1999;156(8):1279-81.（資料番号：5.4―23）
11) Anderson KE, Stamler D, Davis MD, Factor SA, Hauser RA, Isojärvi J, et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomised, placebo-controlled, phase 3 trial. Lancet Psychiatry. 2017;4:595-604.（資料番号：5.4―24）
12) Stacy M, Sajatovic M, Kane JM, Cutler AJ, Liang GS., O'Brien CF, et al. Abnormal involuntary movement scale in tardive dyskinesia: minimal clinically important difference. Mov Disord. 2019;34(8):1203-9.（資料番号：5.4―25）