表 2.7.4.7-70　　IM デポ群で発現した重篤な副作用［二重盲検試験の二重盲検期（Phase D）］

OPC14597　　1 OF 1

PROTOCOL 31-08-250

5.3.5.3-14

Incidence of Potentially Drug Related Serious Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
精神障害	躁病	0	(0.0)	4	(3.0)	4	(1.5)
	双極性障害	1	(0.8)	1	(0.8)	2	(0.8)
神経系障害	アカシジア	1	(0.8)	0	(0.0)	1	(0.4)
TOTAL1)		2	(1.5)	5	(3.8)	7	(2.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE25AB.LIS, RUN: [redacted]20[redacted] 16:53; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE25.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-14　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-14＞

表 2.7.4.7-71　重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.2
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
(Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
感染症および寄生虫症	腎盂腎炎	0	(0.0)	1	(0.2)
	敗血症	0	(0.0)	1	(0.2)
	外陰部膿瘍	0	(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）	乳癌	0	(0.0)	1	(0.2)
精神障害	不安	0	(0.0)	1	(0.2)
	双極１型障害	1	(0.2)	4	(0.9)
	抑うつ気分	1	(0.2)	0	(0.0)
	うつ病	4	(0.7)	8	(1.9)
	不眠症	1	(0.2)	0	(0.0)
	躁病	17	(2.8)	7	(1.6)
	自殺念慮	3	(0.5)	3	(0.7)
	自殺企図	0	(0.0)	1	(0.2)
	抑うつ症状	2	(0.3)	1	(0.2)
	双極性障害	2	(0.3)	0	(0.0)
	大うつ病	1	(0.2)	0	(0.0)
神経系障害	アカシジア	1	(0.2)	0	(0.0)
	神経根障害	0	(0.0)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BDB.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.2　FINAL

表 2.7.4.7-71　重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.2
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
(Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
神経系障害	振戦	0	(0.0)	1	(0.2)
心臓障害	急性心筋梗塞	0	(0.0)	1	(0.2)
	心房細動	0	(0.0)	1	(0.2)
	心筋梗塞	1	(0.2)	0	(0.0)
血管障害	血栓症	0	(0.0)	1	(0.2)
呼吸器、胸郭および縦隔障害	喘息	0	(0.0)	1	(0.2)
胃腸障害	腹痛	0	(0.0)	1	(0.2)
	食中毒	1	(0.2)	0	(0.0)
肝胆道系障害	胆汁うっ滞	1	(0.2)	0	(0.0)
筋骨格系および結合組織障害	横紋筋融解症	0	(0.0)	1	(0.2)
腎および尿路障害	腎結石症	0	(0.0)	1	(0.2)
	腎尿細管壊死	0	(0.0)	1	(0.2)
	急性腎障害	0	(0.0)	1	(0.2)
傷害、中毒および処置合併症	偶発的過量投与	1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BDB.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.2　FINAL

表 2.7.4.7-71　重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.2
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
(Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
傷害、中毒および処置合併症	頭部損傷	0	(0.0)	1	(0.2)
TOTAL1)		35	(5.7)	36	(8.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BDB.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.2　FINAL

＜資料番号 5.3.5.1-01：CT-21.5.2 より作成＞

表 2.7.4.7-72　器官別大分類別重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.1
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class
(Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
感染症および寄生虫症	0	(0.0)	2	(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）	0	(0.0)	1	(0.2)
精神障害	30	(4.9)	24	(5.6)
神経系障害	1	(0.2)	2	(0.5)
心臓障害	1	(0.2)	2	(0.5)
血管障害	0	(0.0)	1	(0.2)
呼吸器、胸郭および縦隔障害	0	(0.0)	1	(0.2)
胃腸障害	1	(0.2)	1	(0.2)
肝胆道系障害	1	(0.2)	0	(0.0)
筋骨格系および結合組織障害	0	(0.0)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BDA.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.1　FINAL

表 2.7.4.7-72　器官別大分類別重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.1
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class
(Phase B Safety Sample and Phase C Safety Sample)

	PHASE B (N=614)		PHASE C (N=425)	
SYSTEM ORGAN CLASS	n	(%)	n	(%)
腎および尿路障害	0	(0.0)	1	(0.2)
傷害、中毒および処置合併症	1	(0.2)	2	(0.5)
TOTAL1)	35	(5.7)	36	(8.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BDA.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.1　FINAL

＜資料番号 5.3.5.1-01：CT-21.5.1 より作成＞

表 2.7.4.7-73　重症度別重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.3
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)				PHASE C (N=425)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	腎盂腎炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	敗血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	外陰部膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	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）	乳癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
精神障害	不安	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	双極１型障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	3 (0.7)	4 (0.9)
	抑うつ気分	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	0 (0.0)	4 (0.7)	0 (0.0)	4 (0.7)	0 (0.0)	6 (1.4)	2 (0.5)	8 (1.9)
	不眠症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	16 (2.6)	1 (0.2)	17 (2.8)	0 (0.0)	3 (0.7)	4 (0.9)	7 (1.6)
	自殺念慮	0 (0.0)	3 (0.5)	0 (0.0)	3 (0.5)	1 (0.2)	2 (0.5)	0 (0.0)	3 (0.7)
	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	抑うつ症状	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	双極性障害	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経根障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2BDC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.3　FINAL

表 2.7.4.7-73　重症度別重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.3
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)				PHASE C (N=425)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
神経系障害	振戦	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
心臓障害	急性心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	心房細動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	心筋梗塞	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
胃腸障害	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	食中毒	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	胆汁うっ滞	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
筋骨格系および結合組織障害	横紋筋融解症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
腎および尿路障害	腎結石症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腎尿細管壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	急性腎障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2BDC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.3　FINAL

表 2.7.4.7-73　重症度別重篤な有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.5.3
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)				PHASE C (N=425)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症	偶発的過量投与	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	頭部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2BDC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.3　FINAL
＜資料番号 5.3.5.1-01：CT-21.5.3 より作成＞

表 2.7.4.7-74　　重篤な副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-20

Incidence of Potentially Drug Related Serious Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
(Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
精神障害	不安	0	(0.0)	1	(0.2)
	うつ病	0	(0.0)	2	(0.5)
	不眠症	1	(0.2)	0	(0.0)
	躁病	1	(0.2)	0	(0.0)
	抑うつ症状	0	(0.0)	1	(0.2)
神経系障害	アカシジア	1	(0.2)	0	(0.0)
	振戦	0	(0.0)	1	(0.2)
TOTAL1)		3	(0.5)	5	(1.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE25BB.LIS, RUN: [redacted]20[redacted] 16:53; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE25.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-20　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-20＞

表 2.7.4.7-75　器官別大分類別重篤な有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.5.1
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	1	(0.3)	0	(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）	1	(0.3)	0	(0.0)	1	(0.2)
内分泌障害	1	(0.3)	0	(0.0)	1	(0.2)
代謝および栄養障害	2	(0.5)	1	(1.2)	3	(0.6)
精神障害	14	(3.7)	2	(2.4)	16	(3.4)
神経系障害	2	(0.5)	0	(0.0)	2	(0.4)
心臓障害	3	(0.8)	0	(0.0)	3	(0.6)
呼吸器、胸郭および縦隔障害	1	(0.3)	0	(0.0)	1	(0.2)
肝胆道系障害	1	(0.3)	0	(0.0)	1	(0.2)
一般・全身障害および投与部位の状態	2	(0.5)	0	(0.0)	2	(0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ADA.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.5.1　FINAL

表 2.7.4.7-75　器官別大分類別重篤な有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.5.1
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
傷害、中毒および処置合併症	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL1)	27	(7.1)	3	(3.5)	30	(6.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ADA.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.5.1　FINAL

＜資料番号 5.3.5.2-01：CT-8.5.1 より作成＞

表 2.7.4.7-76　　重症度別重篤な有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
(Phase C Safety Sample)

		DE NOVO (N=379)				ROLLOVER (N=85)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	腎感染	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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）	乳癌	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
内分泌障害	高プロラクチン血症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
	コントロール不良の糖尿病	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肥満	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	攻撃性	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	2 (0.5)	2 (0.5)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	0 (0.0)	2 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	0 (0.0)	1 (0.3)	2 (0.5)	3 (0.8)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	自殺企図	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2ADC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.5.3　FINAL

表 2.7.4.7-76　　重症度別重篤な有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
(Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	腎感染	0 (0.0)	0 (0.0)	1 (0.2)	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）	乳癌	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
内分泌障害	高プロラクチン血症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
代謝および栄養障害	糖尿病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	コントロール不良の糖尿病	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	肥満	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
精神障害	攻撃性	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	双極１型障害	0 (0.0)	2 (0.4)	2 (0.4)	4 (0.9)
	躁病	0 (0.0)	0 (0.0)	3 (0.6)	3 (0.6)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	自殺念慮	1 (0.2)	1 (0.2)	2 (0.4)	4 (0.9)
	自殺企図	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	双極性障害	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.4)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2ADC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.5.3　FINAL

表 2.7.4.7-76　　重症度別重篤な有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
(Phase C Safety Sample)

		DE NOVO (N=379)				ROLLOVER (N=85)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
神経系障害	傾眠	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	急性心筋梗塞	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心停止	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心筋梗塞	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	呼吸困難	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	急性胆嚢炎	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	胸痛	0 (0.0)	0 (0.0)	2 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	節足動物咬傷	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2ADC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.5.3　FINAL

表 2.7.4.7-76　　重症度別重篤な有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
(Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
神経系障害	傾眠	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
心臓障害	急性心筋梗塞	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	心停止	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	心筋梗塞	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
呼吸器、胸郭および縦隔障害	呼吸困難	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
肝胆道系障害	急性胆嚢炎	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
一般・全身障害および投与部位の状態	胸痛	0 (0.0)	0 (0.0)	2 (0.4)	2 (0.4)
傷害、中毒および処置合併症	節足動物咬傷	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2ADC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.5.3　FINAL

＜資料番号 5.3.5.2-01：CT-8.5.3 より作成＞

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/M/CAUC.	椎間板障害*/DISCOPATHY	筋骨格系および結合組織障害	2C[redacted]-01-28 14:00	同年*-01-30	27	MILD
		[redacted]	5[redacted]/M/ASIAN	死亡*/DEATH,CAUSE UNKNOWN	一般・全身障害および投与部位の状態	2C[redacted]-10-13	同年*-10-13	20	SEVERE
		[redacted]	5[redacted]/M/CAUC.	悪性症候群*/NEUROLEPTIC MALIGNANT SYNDROME	神経系障害	2C[redacted]-11-10	同年*-12-04	47	SEVERE
		[redacted]	2[redacted]/F/CAUC.	躁病*/MANIA AGGRAVATED	精神障害	2C[redacted]-01-31 16:30	同年*-02-02 16:30	9	SEVERE
				抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	2C[redacted]-02-10 14:00	同年*-02-12 14:00	19	SEVERE
		[redacted]	2[redacted]/F/BLACK	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	2C[redacted]-11-06	ONGOING	14	SEVERE
		[redacted]	5[redacted]/F/CAUC.	肺腺癌*/BRONCHOGENIC ADENOCARCINOMA	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）	2C[redacted]-09-11	同年*-10-10	27	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]2C[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]2C[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/M/CAUC.	椎間板障害*/DISCOPATHY	筋骨格系および結合組織障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	死亡*/DEATH,CAUSE UNKNOWN	一般・全身障害および投与部位の状態	DEATH	NOT LIKELY	NOT APPLICABLE	FATAL
		[redacted]	5[redacted]/M/CAUC.	悪性症候群*/NEUROLEPTIC MALIGNANT SYNDROME	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	躁病*/MANIA AGGRAVATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/BLACK	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
		[redacted]	5[redacted]/F/CAUC.	肺腺癌*/BRONCHOGENIC ADENOCARCINOMA	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）	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	1[redacted]/M/CAUC.	膵炎*/PANCREATITIS	胃腸障害	20[redacted]-10-07	同年*-10-09	-18	SEVERE
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL THOUGHTS	精神障害	20[redacted]-11-29	同年*-11-29	17	MODERATE
		[redacted]	3[redacted]/F/CAUC.	胃炎*/GASTRITIS	胃腸障害	20[redacted]-10-09	ONGOING	20	MODERATE
				好酸球性食道炎*/EOSINOPHILIC ESOPHAGITIS	胃腸障害	20[redacted]-10-09	ONGOING	20	MODERATE
				甲状腺機能低下症*/HYPOTHYROIDISM, SUBCLINICAL	内分泌障害	20[redacted]-10-09	同年*-11-04	20	MODERATE
				十二指腸炎*/DUODENITIS	胃腸障害	20[redacted]-10-09	ONGOING	20	MODERATE
				乳汁漏出症*/GALACTORRHEA	生殖系および乳房障害	20[redacted]-10-09	同年*-11-04	20	MODERATE
				便秘*/CONSTIPATION EXACERBATION	胃腸障害	20[redacted]-10-09	同年*-10-12	20	MODERATE

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Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	1[redacted]/M/CAUC.	膵炎*/PANCREATITIS	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL THOUGHTS	精神障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	胃炎*/GASTRITIS	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	UNKNOWN
				好酸球性食道炎*/EOSINOPHILIC ESOPHAGITIS	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	UNKNOWN
				甲状腺機能低下症*/HYPOTHYROIDISM, SUBCLINICAL	内分泌障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				十二指腸炎*/DUODENITIS	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	UNKNOWN
				乳汁漏出症*/GALACTORRHEA	生殖系および乳房障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				便秘*/CONSTIPATION EXACERBATION	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED

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CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	6[redacted]/M/CAUC.	前立腺癌*/PROSTATE CANCER	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）	2O[redacted]-10-16	同年*-11	35	MODERATE
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	2O[redacted]-08-21 16:00	同年*-08-24 16:00	16	SEVERE
		[redacted]	4[redacted]/F/BLACK	躁病*/MANIA WITH PSYCHOSIS	精神障害	2O[redacted]-12-29	翌年*-01-02	-5	MODERATE
				うつ病*/DEPRESSIVE EPISODE	精神障害	2O[redacted]-01-27	同年*-02-07	25	MODERATE
		[redacted]	4[redacted]/M/CAUC.	精神状態変化*/CHANGE IN MENTAL STATUS	精神障害	2O[redacted]-09-14 06:00	同年*-09-19 09:00	26	MODERATE
				反応性精神病*/BRIEF REACTIVE PSYCHOSIS	精神障害	2O[redacted]-09-14 06:00	同年*-09-19 09:00	26	MODERATE
		[redacted]	5[redacted]/F/BLACK	ブドウ球菌感染*/MSSA HIP INFECTION	感染症および寄生虫症	2O[redacted]-12-17	翌年*-02-08	29	SEVERE

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	6[redacted]/M/CAUC.	前立腺癌*/PROSTATE CANCER	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）	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	躁病*/MANIA WITH PSYCHOSIS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
				うつ病*/DEPRESSIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	精神状態変化*/CHANGE IN MENTAL STATUS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				反応性精神病*/BRIEF REACTIVE PSYCHOSIS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	ブドウ球菌感染*/MSSA HIP INFECTION	感染症および寄生虫症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-05-20 16:37	同年*-05-28 12:44	12	SEVERE
		[redacted]	5[redacted]/F/BLACK	うつ病*/INCREASED DEPRESSION	精神障害	20[redacted]-07-24 11:00	ONGOING	22	MILD
				不安*/INCREASED ANXIETY	精神障害	20[redacted]-07-24 11:00	ONGOING	22	MILD
				躁病*/INCREASED MANIA	精神障害	20[redacted]-07-24 11:00	ONGOING	22	MODERATE
	ARIP 6-12MG	[redacted]	6[redacted]/M/ASIAN	胃潰瘍*/GASTRIC ULCER	胃腸障害	20[redacted]-10-21	同年*-11-28 15:00	18	SEVERE
				双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-10-29 14:10	翌年*-03-03 11:10	26	SEVERE
		[redacted]	5[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-04-01 13:00	同年*-06-17 13:15	5	MODERATE

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PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	うつ病*/INCREASED DEPRESSION	精神障害	MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DOSE INCREASED	NOT RECOVERED/ NOT RESOLVED
				不安*/INCREASED ANXIETY	精神障害	MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DOSE INCREASED	NOT RECOVERED/ NOT RESOLVED
				躁病*/INCREASED MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DOSE INCREASED	NOT RECOVERED/ NOT RESOLVED
	ARIP 6-12MG	[redacted]	6[redacted]/M/ASIAN	胃潰瘍*/GASTRIC ULCER	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG INTERRUPTED	RECOVERED/ RESOLVED
				双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED

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PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/M/ASIAN	鎖骨骨折*/RIGHT CLAVICLE DISTAL FRACTURE	傷害、中毒および処置合併症	20[redacted]-03-21 14:10	同年*-04-22 15:00	31	SEVERE
				手骨折*/RIGHT THIRD AND FORTH METACARPAL BONE FRACTURE	傷害、中毒および処置合併症	20[redacted]-03-21 14:10	同年*-04-22 15:00	31	SEVERE
				前腕骨折*/RIGHT RADIUS ULNA DISTAL FRACTURE	傷害、中毒および処置合併症	20[redacted]-03-21 14:10	同年*-04-22 15:00	31	SEVERE
	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSION	精神障害	20[redacted]-01-03 09:00	ONGOING	52	SEVERE
		[redacted]	2[redacted]/M/CAUC.	各種物質毒性*/COCAINE AND FENTANYL INTOXICATION	傷害、中毒および処置合併症	20[redacted]-06-09	同年*-06-09	41	SEVERE
		[redacted]	6[redacted]/M/CAUC.	ブドウ球菌性蜂巣炎*/MRSA CELLULITIS	感染症および寄生虫症	20[redacted]-06-13 09:00	同年*-07-03 09:00	63	SEVERE
		[redacted]	3[redacted]/F/CAUC.	コントロール不良の糖尿病*/HIGH BLOOD GLUCOSE LEVEL UNCONTROLLED DIABETES	代謝および栄養障害	20[redacted]-11-08 12:45	同年*-12-05	46	MODERATE

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PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/M/ASIAN	鎖骨骨折*/RIGHT CLAVICLE DISTAL FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				手骨折*/RIGHT THIRD AND FORTH METACARPAL BONE FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				前腕骨折*/RIGHT RADIUS ULNA DISTAL FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSION	精神障害	LIFE-THREATENING CONDITION, HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	2[redacted]/M/CAUC.	各種物質毒性*/COCAINE AND FENTANYL INTOXICATION	傷害、中毒および処置合併症	DEATH	NOT LIKELY	DOSE NOT CHANGED	FATAL
		[redacted]	6[redacted]/M/CAUC.	ブドウ球菌性蜂巣炎*/MRSA CELLULITIS	感染症および寄生虫症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	コントロール不良の糖尿病*/HIGH BLOOD GLUCOSE LEVEL UNCONTROLLED DIABETES	代謝および栄養障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 15-30MG	[redacted]	5[redacted]/F/ASIAN	腎細胞癌*/RENAL CELL CARCINOMA	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）	2C[redacted]-07-25	同年*-08-26	44	SEVERE
		[redacted]	4[redacted]/F/BLACK	高プロラクチン血症*/HYPERPROLACTINEMIA	内分泌障害	2C[redacted]-11-22 12:00	同年*-12-19 13:15	43	MODERATE
		[redacted]	4[redacted]/F/BLACK	自殺企図*/SUICIDAL ATTEMPT	精神障害	2C[redacted]-11-30	同年*-11-30	75	MODERATE
		[redacted]	2[redacted]/F/CAUC.	熱傷*/3 PERCENT TBSA SUPERFICIAL BURNS TO RIGHT LATERAL LOWER LEG ANKLE FOOT 5TH TOE POSTERIOR LOWER LEG AND ANKLE	傷害、中毒および処置合併症	2C[redacted]-12-18 14:30	ONGOING	37	SEVERE
		[redacted]	4[redacted]/F/BLACK	意識消失*/LOSS OF CONSCIOUSNESS	神経系障害	2C[redacted]-08-29 09:00	同年*-08-29 10:10	17	MILD
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/BLACK	糖尿病*/NEW ONSET DIABETES	代謝および栄養障害	2C[redacted]-09-14	同年*-09-16	35	SEVERE

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FILE: ADAE1D.LIS, RUN: [redacted]2C[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]2C[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

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CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 15-30MG	[redacted]	5[redacted]/F/ASIAN	腎細胞癌*/RENAL CELL CARCINOMA	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）	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	高プロラクチン血症*/HYPERPROLACTINEMIA	内分泌障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	自殺企図*/SUICIDAL ATTEMPT	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	熱傷*/3 PERCENT TBSA SUPERFICIAL BURNS TO RIGHT LATERAL LOWER LEG ANKLE FOOT 5TH TOE POSTERIOR LOWER LEG AND ANKLE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/BLACK	意識消失*/LOSS OF CONSCIOUSNESS	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/BLACK	糖尿病*/NEW ONSET DIABETES	代謝および栄養障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DOSE NOT CHANGED	RECOVERED RESOLVED/ WITH SEQUELAE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

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CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/PSYCHIATRIC HOSPITALIZATION DUE TO SUICIDIAL THOUGTHS	精神障害	20[redacted]-02-08	同年*-03-18	97	MILD
		[redacted]	4[redacted]/M/CAUC.	躁病*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	20[redacted]-12-20 08:00	翌年*-01-29 11:07	126	SEVERE
		[redacted]	4[redacted]/M/CAUC.	社会逃避行動*/SOCIAL ISOLATION	精神障害	20[redacted]-08-07	同年*-08-07	245	SEVERE
		[redacted]	3[redacted]/M/CAUC.	躁病*/PSYCHOTIC MANIC EPISODE	精神障害	20[redacted]-12-02 20:00	翌年*-03-28 12:00	25	SEVERE
		[redacted]	3[redacted]/F/CAUC.	双極１型障害*/BIPOLAR I DISORDER.MIXED EPISODE	精神障害	20[redacted]-04-23 09:00	ONGOING	156	MODERATE
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	20[redacted]-04-04 17:00	ONGOING	131	SEVERE
		[redacted]	4[redacted]/F/ASIAN	双極性障害*/BIPOLAR AFFECTIVE DISORDER	精神障害	20[redacted]-03-01 22:00	同年*-04-01	186	MODERATE

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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/PSYCHIATRIC HOSPITALIZATION DUE TO SUICIDIAL THOUGTHS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	躁病*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	社会逃避行動*/SOCIAL ISOLATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	躁病*/PSYCHOTIC MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	双極１型障害*/BIPOLAR I DISORDER.MIXED EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/ASIAN	双極性障害*/BIPOLAR AFFECTIVE DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

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Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/ASIAN	攻撃性*/AGGRESIVE BEHAVIOUR	精神障害	20[redacted]-03-11 11:00	同年*-03-19 08:00	153	MODERATE
				攻撃性*/AGGRESIVE BEHAVIOR	精神障害	20[redacted]-09-04 16:00	同年*-09-11 09:20	330	MODERATE
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	20[redacted]-05-12	同年*-06-12 14:00	40	MODERATE
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-07-15 14:00	同年*-10-08 14:45	80	SEVERE
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/INCREASE IN DEPRESSIVE PHASE OF BIPOLAR DISORDER	精神障害	20[redacted]-10-11	同年*-10-22	340	SEVERE
		[redacted]	4[redacted]/F/CAUC.	躁病*/MANIC EPISODE WITH PSYCHOTIC FEATURES	精神障害	20[redacted]-11-03 15:00	同年*-11-19 10:00	110	SEVERE
		[redacted]	6[redacted]/M/CAUC.	胸痛*/ACUTE CHEST PAIN	一般・全身障害および投与部位の状態	20[redacted]-02-01 11:00	同年*-02-09 16:00	95	SEVERE
		[redacted]	3[redacted]/M/CAUC.	プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	20[redacted]-05-04 20:47	同年*-05-07 19:31	187	SEVERE

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/ASIAN	攻撃性*/AGGRESIVE BEHAVIOUR	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				攻撃性*/AGGRESIVE BEHAVIOR	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/INCREASE IN DEPRESSIVE PHASE OF BIPOLAR DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	躁病*/MANIC EPISODE WITH PSYCHOTIC FEATURES	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	胸痛*/ACUTE CHEST PAIN	一般・全身障害および投与部位の状態	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED

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Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	20[redacted]-05-21 18:20	同年*-05-23 13:34	204	SEVERE
				プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	20[redacted]-06-18 19:28	同年*-06-20 17:43	232	SEVERE
				自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-23	同年*-06-27	237	SEVERE
		[redacted]	3[redacted]/F/CAUC.	呼吸困難*/SHORTNESS OF BREATH	呼吸器、胸郭および縦隔障害	20[redacted]-10-20	ONGOING	376	SEVERE
				肥満*/MORBID OBESITY	代謝および栄養障害	20[redacted]-10-20	ONGOING	376	SEVERE
		[redacted]	4[redacted]/M/CAUC.	遅発性ジスキネジア*/TARDIVE DYSKINESIA	神経系障害	20[redacted]-05-23	ONGOING	169	SEVERE
		[redacted]	2[redacted]/F/CAUC.	腎感染*/RIGHT KIDNEY INFECTION	感染症および寄生虫症	20[redacted]-05-21 19:45	同年*-05-25 08:00	156	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	呼吸困難*/SHORTNESS OF BREATH	呼吸器、胸郭および縦隔障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	NOT APPLICABLE	NOT RECOVERED/ NOT RESOLVED
				肥満*/MORBID OBESITY	代謝および栄養障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	NOT APPLICABLE	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/M/CAUC.	遅発性ジスキネジア*/TARDIVE DYSKINESIA	神経系障害	PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY	DEFINITE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/F/CAUC.	腎感染*/RIGHT KIDNEY INFECTION	感染症および寄生虫症	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	同年* END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/CAUC.	胸痛*/CHEST PAIN	一般・全身障害および投与部位の状態	20[redacted]-06-28	同年*-07-10	265	SEVERE
		[redacted]	5[redacted]/M/OTHER	心筋梗塞*/MYOCARDIAL INFARCTION	心臓障害	20[redacted]-11-03 12:00	ONGOING	351	SEVERE
		[redacted]	3[redacted]/F/CAUC.	乳癌*/LEFT BREAST ADENOCARCINOMA	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）	20[redacted]-04-10	同年*-05-28	99	MODERATE
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-17 08:00	同年*-06-23 08:00	141	SEVERE
				自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-06-24 08:00	同年*-06-24 08:00	148	SEVERE
		[redacted]	3[redacted]/F/BLACK	急性胆嚢炎*/ACUTE CHOLECYSTITIS	肝胆道系障害	20[redacted]-09-28 18:00	同年*-09-29	257	SEVERE
		[redacted]	5[redacted]/M/BLACK	急性心筋梗塞*/ACUTE MYOCARDIAL INFARCTION NON ST ELEVATION	心臓障害	20[redacted]-02-09	同年*-02-11	49	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/CAUC.	胸痛*/CHEST PAIN	一般・全身障害および投与部位の状態	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/OTHER	心筋梗塞*/MYOCARDIAL INFARCTION	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERING/ RESOLVING
		[redacted]	3[redacted]/F/CAUC.	乳癌*/LEFT BREAST ADENOCARCINOMA	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）	MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	LIFE-THREATENING CONDITION, HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	LIFE-THREATENING CONDITION, HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	急性胆嚢炎*/ACUTE CHOLECYSTITIS	肝胆道系障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	急性心筋梗塞*/ACUTE MYOCARDIAL INFARCTION NON ST ELEVATION	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/BLACK	心停止*/CARDIAC ARREST	心臓障害	20[redacted]-09-25	同年*-09-25	277	SEVERE
		[redacted]	2[redacted]/M/BLACK	双極１型障害*/BIPOLAR I MIXED EPISODE WITH PSYCHOTIC FEATURES	精神障害	20[redacted]-03-31 09:00	同年*-04-04 13:20	244	SEVERE
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL THOUGHTS WITHOUT INTENT	精神障害	20[redacted]-06-07	同年*-06-07	257	MODERATE
		[redacted]	4[redacted]/M/BLACK	傾眠*/DROWSINESS	神経系障害	20[redacted]-10-16 09:00	同年*-10-20 14:00	7	MODERATE
		[redacted]	3[redacted]/M/CAUC.	節足動物咬傷*/TICK BITE	傷害、中毒および処置合併症	20[redacted]-05-17	同年*-05-20	153	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-77　　重篤な有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-9.2

Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/BLACK	心停止*/CARDIAC ARREST	心臓障害	DEATH	UNRELATED	DOSE NOT CHANGED	FATAL
		[redacted]	2[redacted]/M/BLACK	双極１型障害*/BIPOLAR I MIXED EPISODE WITH PSYCHOTIC FEATURES	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL THOUGHTS WITHOUT INTENT	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	傾眠*/DROWSINESS	神経系障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	節足動物咬傷*/TICK BITE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.2　FINAL

＜資料番号 5.3.5.2-01：CT-9.2 より作成＞

表 2.7.4.7-78　器官別大分類別投与中止に至った有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.6.1
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase D
by System Organ Class (Phase D Safety Sample)

SYSTEM ORGAN CLASS	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
精神障害	18	(13.6)	33	(24.8)	51	(19.2)
神経系障害	3	(2.3)	0	(0.0)	3	(1.1)
血管障害	0	(0.0)	1	(0.8)	1	(0.4)
呼吸器、胸郭および縦隔障害	1	(0.8)	0	(0.0)	1	(0.4)
臨床検査	1	(0.8)	0	(0.0)	1	(0.4)
TOTAL1)	23	(17.4)	34	(25.6)	57	(21.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AEA.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.1　FINAL

＜資料番号 5.3.5.1-01：CT-8.6.1 より作成＞

表 2.7.4.7-79　重症度別投与中止に至った有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase D
by System Organ Class, MedDRA Preferred Term and Severity (Phase D Safety Sample)

		ARIP IMD (N=132)				PLACEBO (N=133)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	不安	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)	2 (1.5)	4 (3.0)	2 (1.5)	8 (6.0)
	抑うつ気分	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	うつ病	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	1 (0.8)	2 (1.5)	0 (0.0)	3 (2.3)
	躁病	1 (0.8)	1 (0.8)	1 (0.8)	3 (2.3)	0 (0.0)	6 (4.5)	5 (3.8)	11 (8.3)
	自殺企図	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	感情不安定	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	4 (3.0)	1 (0.8)	5 (3.8)	0 (0.0)	1 (0.8)	3 (2.3)	4 (3.0)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)
神経系障害	アカシジア	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
呼吸器、胸郭および縦隔障害	呼吸不全	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
臨床検査	体重増加	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

表 2.7.4.7-79　重症度別投与中止に至った有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase D
by System Organ Class, MedDRA Preferred Term and Severity (Phase D Safety Sample)

		TOTAL (N=265)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
精神障害	感情障害	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
	攻撃性	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	不安	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	双極１型障害	2 (0.8)	5 (1.9)	3 (1.1)	10 (3.8)
	抑うつ気分	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	うつ病	4 (1.5)	3 (1.1)	0 (0.0)	7 (2.6)
	躁病	1 (0.4)	7 (2.6)	6 (2.3)	14 (5.3)
	自殺企図	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
	感情不安定	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	双極性障害	0 (0.0)	5 (1.9)	4 (1.5)	9 (3.4)
	大うつ病	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
神経系障害	アカシジア	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
	傾眠	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
血管障害	高血圧	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
呼吸器、胸郭および縦隔障害	呼吸不全	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
臨床検査	体重増加	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

＜資料番号 5.3.5.1-01：CT-8.6.3 より作成＞

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/CAUC.	不眠症*/WORSENING OF INSOMNIA	精神障害	20[redacted]-01-18 22:00	同年*-01-21 22:00	16	MODERATE
		[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-10-16 20:00	同年*-10-21 20:00	20	MILD
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-10-29 14:00	同年*-11-06 18:00	29	MILD
		[redacted]	5[redacted]/F/CAUC.	遅発性ジスキネジア*/TARDIVE DYSKINESIA	神経系障害	20[redacted]-04-02 11:00	同年*-04-14 11:00	36	MILD
		[redacted]	6[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-09-27 13:00	同年*-10-10 11:31	12	MODERATE
				アカシジア*/AKATHISIA	神経系障害	20[redacted]-09-29 12:05	同年*-10-10 10:30	14	MODERATE
		[redacted]	4[redacted]/F/BLACK	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-11-01 12:00	翌年*-03-20 22:00	10	MILD
		[redacted]	3[redacted]/F/BLACK	アカシジア*/AKATHESIA	神経系障害	20[redacted]-03-10	同年*-03-11	39	MODERATE
		[redacted]	5[redacted]/M/CAUC.	大うつ病*/SEVERE DEPRESSION WITH PSYCHOSIS	精神障害	20[redacted]-08-12	同年*-08-13	37	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/CAUC.	不眠症*/WORSENING OF INSOMNIA	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	遅発性ジスキネジア*/TARDIVE DYSKINESIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	アカシジア*/AKATHESIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	大うつ病*/SEVERE DEPRESSION WITH PSYCHOSIS	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-07-14 10:00	同年*-09-14 09:20	25	MODERATE
		[redacted]	3[redacted]/F/CAUC.	悪心*/NAUSEA	胃腸障害	20[redacted]-07-19	同年*-07-23	9	MODERATE
				傾眠*/SOMNOLENCE	神経系障害	20[redacted]-07-19	同年*-07-23	9	MODERATE
		[redacted]	5[redacted]/M/CAUC.	不安*/ANXIETY	精神障害	20[redacted]-04-20 02:00	ONGOING	11	MODERATE
		[redacted]	4[redacted]/M/OTHER	躁病*/MANIA	精神障害	20[redacted]-01-04	同年*-01-08	19	MODERATE
		[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-03-22	同年*-04-09	12	MODERATE
		[redacted]	4[redacted]/M/BLACK	双極性障害*/BIPOLAR AFFECTIVE DISORDER AGGRAVATED	精神障害	20[redacted]-01-03	同年*-01-14	14	SEVERE
		[redacted]	3[redacted]/F/BLACK	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-10-04	同年*-10-12	43	MODERATE

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	悪心*/NAUSEA	胃腸障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				傾眠*/SOMNOLENCE	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	不安*/ANXIETY	精神障害	NO	UNRELATED	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/M/OTHER	躁病*/MANIA	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	双極性障害*/BIPOLAR AFFECTIVE DISORDER AGGRAVATED	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-01-17	同年*-03-11	19	SEVERE
				振戦*/TREMOR	神経系障害	20[redacted]-01-17	同年*-04-21	19	MODERATE
		[redacted]	2[redacted]/M/CAUC.	不安*/INCREASED ANXIETY	精神障害	20[redacted]-02-28	同年*-03-06	16	MODERATE
		[redacted]	2[redacted]/M/BLACK	躁病*/MANIA AGGRAVATED	精神障害	20[redacted]-04-25 10:00	同年*-05-05 12:00	66	SEVERE
		[redacted]	5[redacted]/F/CAUC.	脳血管発作*/SMALL STROKE	神経系障害	20[redacted]-04-09 08:00	同年*-05-28 15:00	37	MODERATE
		[redacted]	3[redacted]/F/CAUC.	疲労*/FATIGUE	一般・全身障害および投与部位の状態	20[redacted]-04-11	同年*-05-06	2	MODERATE
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-16 15:25	同年*-06-21 10:15	25	MILD
				双極１型障害*/BIPOLAR AFFECTIVE DISORDER TYPE I, DEPRESSED EPISODE	精神障害	20[redacted]-06-16 15:25	同年*-06-21 10:15	25	SEVERE

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PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				振戦*/TREMOR	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED RESOLVED/ WITH SEQUELAE
		[redacted]	2[redacted]/M/CAUC.	不安*/INCREASED ANXIETY	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/BLACK	躁病*/MANIA AGGRAVATED	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	脳血管発作*/SMALL STROKE	神経系障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	疲労*/FATIGUE	一般・全身障害および投与部位の状態	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				双極１型障害*/BIPOLAR AFFECTIVE DISORDER TYPE I, DEPRESSED EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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PHASE A	ARIP 5-15MG	[redacted]	2[redacted]/F/CAUC.	傾眠*/DAYTIME DROWSINESS	神経系障害	20[redacted]-10-17	同年*-12-16	1	MILD
		[redacted]	5[redacted]/F/BLACK	自殺念慮*/ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	精神障害	20[redacted]-02-15	同年*-02-19	17	MODERATE
		[redacted]	5[redacted]/M/CAUC.	狭心症*/CARDIAC CHEST PAIN	心臓障害	20[redacted]-05-01	同年*-05-03	20	SEVERE
		[redacted]	5[redacted]/F/BLACK	肝機能検査値上昇*/ELEVATED LIVER FUNCTIONS	臨床検査	20[redacted]-12-21 10:15	翌年*-01-04 08:45	35	MODERATE
		[redacted]	2[redacted]/F/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-03-01 06:30	ONGOING	23	MODERATE
		[redacted]	2[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-01-23 08:00	ONGOING	36	MODERATE
		[redacted]	2[redacted]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-11-06 08:00	同年*-11-12	22	MODERATE
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-03-06 10:00	同年*-03-11 13:00	42	MODERATE

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PHASE A	ARIP 5-15MG	[redacted]	2[redacted]/F/CAUC.	傾眠*/DAYTIME DROWSINESS	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	自殺念慮*/ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	狭心症*/CARDIAC CHEST PAIN	心臓障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	肝機能検査値上昇*/ELEVATED LIVER FUNCTIONS	臨床検査	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	NO	DEFINITE	DRUG WITHDRAWN	UNKNOWN
		[redacted]	2[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-02-25 15:50	同年*-03-04	16	MODERATE
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-02-17 08:00	同年*-03-07	4	MODERATE
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-04-24 13:15	同年*-05-08	6	MODERATE
		[redacted]	2[redacted]/M/OTHER	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	20[redacted]-05-26 15:00	同年*-06-09	14	SEVERE
		[redacted]	2[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-06-12	同年*-06-25	30	MODERATE
		[redacted]	2[redacted]/M/BLACK	躁病*/MANIA	精神障害	20[redacted]-06-06 15:00	同年*-06-13	11	MODERATE
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-06-11	同年*-06-30	6	SEVERE
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-07-17 10:00	同年*-07-23	31	MODERATE
		[redacted]	5[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-07-08	同年*-07-14	21	SEVERE

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PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/OTHER	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/BLACK	躁病*/MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-05-14	ONGOING	9	MILD
		[redacted]	5[redacted]/M/CAUC.	鎮静*/SEDATION	神経系障害	20[redacted]-07-30 09:00	同年*-08-06 15:00	9	SEVERE
		[redacted]	6[redacted]/M/ASIAN	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	20[redacted]-01-10	同年*-02-07	9	MODERATE
		[redacted]	3[redacted]/M/ASIAN	アカシジア*/AGGRAVATION OF AKATHISIA	神経系障害	20[redacted]-09-24	同年*-12-09	2	SEVERE
		[redacted]	3[redacted]/M/ASIAN	双極１型障害*/WORSENING OF SYMPTOM OF BIPOLAR I	精神障害	20[redacted]-05-19 00:00	同年*-06-21 10:00	4	MILD
		[redacted]	2[redacted]/M/ASIAN	アカシジア*/AKATHISIA	神経系障害	20[redacted]-01-16 22:00	同年*-02-07 16:00	21	MODERATE
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME WORSENING	神経系障害	20[redacted]-01-16 22:00	同年*-02-07 16:00	21	MODERATE
				抑うつ気分*/DEPRESSIVE MOOD	精神障害	20[redacted]-01-16 22:00	同年*-02-07 16:00	21	MODERATE

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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	5[redacted]/M/CAUC.	鎮静*/SEDATION	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/ASIAN	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	アカシジア*/AGGRAVATION OF AKATHISIA	神経系障害	YES	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	双極１型障害*/WORSENING OF SYMPTOM OF BIPOLAR I	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/ASIAN	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED RESOLVED/ WITH SEQUELAE
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME WORSENING	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED RESOLVED/ WITH SEQUELAE
				抑うつ気分*/DEPRESSIVE MOOD	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED RESOLVED/ WITH SEQUELAE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/F/ASIAN	躁病*/MANIC EPISODE AGGRAVATED	精神障害	20[redacted]-01-22 18:49	同年*-02-06 13:00	17	SEVERE
PHASE B	ARIP 10-30MG	[redacted]	2[redacted]/M/CAUC.	傾眠*/SOMNOLENCE	神経系障害	20[redacted]-06-24 12:00	同年*-07-06 08:00	1	MODERATE
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-12-12 12:00	同年*-12-17 12:00	22	MODERATE
		[redacted]	3[redacted]/F/CAUC.	疲労*/TIREDNESS	一般・全身障害および投与部位の状態	20[redacted]-03-10 08:00	同年*-08-01 08:00	31	MILD
		[redacted]	5[redacted]/F/BLACK	精神的機能障害*/DECREASED MENTAL CLARITY	神経系障害	20[redacted]-11-14 07:00	翌年*-01-15 07:00	9	MILD
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-04-11 09:00	同年*-04-14 09:00	45	MODERATE
		[redacted]	4[redacted]/M/CAUC.	抑うつ症状*/INCREASED DEPRESSIVE SYMPTOMS	精神障害	20[redacted]-06-27 08:00	同年*-08-04 12:00	25	SEVERE
		[redacted]	6[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-05-18 12:00	同年*-05-31 12:00	17	MILD
		[redacted]	3[redacted]/F/CAUC.	鎮静*/INCREASED SEDATION	神経系障害	20[redacted]-04-13	同年*-05-13	2	MODERATE

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/F/ASIAN	躁病*/MANIC EPISODE AGGRAVATED	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE B	ARIP 10-30MG	[redacted]	2[redacted]/M/CAUC.	傾眠*/SOMNOLENCE	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	疲労*/TIREDNESS	一般・全身障害および投与部位の状態	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	精神的機能障害*/DECREASED MENTAL CLARITY	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	抑うつ症状*/INCREASED DEPRESSIVE SYMPTOMS	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	鎮静*/INCREASED SEDATION	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSION	精神障害	20[redacted]-12-20	ONGOING	9	MODERATE
		[redacted]	2[redacted]/F/CAUC.	傾眠*/DROWSINESS	神経系障害	20[redacted]-09-11 17:00	同年*-09-16 10:00	1	MODERATE
		[redacted]	5[redacted]/M/CAUC.	躁病*/MANIA	精神障害	20[redacted]-11-12	同年*-11-13	27	MODERATE
		[redacted]	3[redacted]/F/BLACK	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-02-21	同年*-03-29	15	MODERATE
		[redacted]	3[redacted]/M/CAUC.	うつ病*/WORSENING DEPRESSION	精神障害	20[redacted]-05-03	同年*-06-02	22	MODERATE
		[redacted]	2[redacted]/M/CAUC.	傾眠*/DROWSINESS	神経系障害	20[redacted]-12-11	同年*-12-13	16	MODERATE
		[redacted]	4[redacted]/F/BLACK	抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	20[redacted]-03-29	同年*-05-09	39	SEVERE
		[redacted]	5[redacted]/M/BLACK	抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	20[redacted]-03-08	同年*-04-03	25	MODERATE
		[redacted]	4[redacted]/F/BLACK	心拍数増加*/INCREASED HEART RATE	臨床検査	20[redacted]-04-07	同年*-05-20	25	MILD

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSION	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/F/CAUC.	傾眠*/DROWSINESS	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	躁病*/MANIA	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	体重増加*/WEIGHT GAIN	臨床検査	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	うつ病*/WORSENING DEPRESSION	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	傾眠*/DROWSINESS	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	心拍数増加*/INCREASED HEART RATE	臨床検査	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/F/BLACK	口内乾燥*/DRY MOUTH	胃腸障害	20[redacted]-04-08	同年* -05-08	26	MILD
				頭痛*/INTERMITTENT HEADACHES	神経系障害	20[redacted]-04-08	同年* -05-08	26	MILD
		[redacted]	3[redacted]/F/CAUC.	双極性障害*/BIPOLAR DEPRESSION	精神障害	20[redacted]-05-07	同年* -05-21	27	MODERATE
		[redacted]	5[redacted]/F/BLACK	アカシジア*/AKATHISIA	神経系障害	20[redacted]-07-31	同年*-08-31	35	MODERATE
		[redacted]	4[redacted]/F/BLACK	体重増加*/WEIGHT GAIN GREATER THAN 7 PERCENT	臨床検査	20[redacted]-02-01 09:00	同年*-11-01 08:00	12	MILD
		[redacted]	6[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIC SYMPTOMS	精神障害	20[redacted]-05-09 10:00	同年*-05-14 10:00	38	MODERATE
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	20[redacted]-08-09 20:00	同年*-08-19 09:00	11	MODERATE
		[redacted]	3[redacted]/F/CAUC.	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	20[redacted]-09-03 08:00	同年*-09-11 09:00	6	MODERATE
		[redacted]	2[redacted]/F/BLACK	傾眠*/DROWSINESS	神経系障害	20[redacted]-06-01	同年*-06-15	2	MODERATE

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PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/F/BLACK	口内乾燥*/DRY MOUTH	胃腸障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				頭痛*/INTERMITTENT HEADACHES	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	双極性障害*/BIPOLAR DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	アカシジア*/AKATHISIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	体重増加*/WEIGHT GAIN GREATER THAN 7 PERCENT	臨床検査	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIC SYMPTOMS	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/BLACK	傾眠*/DROWSINESS	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-02-01	同年*-02-28	3	MODERATE
		[redacted]	2[redacted]/F/ASIAN	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-02-13	同年*-04-03	2	MODERATE
		[redacted]	2[redacted]/M/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-03-29	同年*-04-25	2	MODERATE
		[redacted]	2[redacted]/M/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-04-28	同年*-06-02	4	MODERATE
		[redacted]	4[redacted]/M/BLACK	血圧上昇*/ELEVATED BLOOD PRESSURE	臨床検査	20[redacted]-03-20	ONGOING	29	MODERATE
		[redacted]	4[redacted]/F/BLACK	斑状丘疹状皮疹*/MACULOPOPULAR RASH	皮膚および皮下組織障害	20[redacted]-05-01	同年*-05-21	2	SEVERE
		[redacted]	2[redacted]/F/CAUC.	悪心*/NAUSEA	胃腸障害	20[redacted]-03-13	同年*-04-01	15	MILD
				構語障害*/SLURRED SPEECH	神経系障害	20[redacted]-03-13	同年*-04-22	15	SEVERE
				錯感覚*/TINGLING OF UPPER EXTREMITIES	神経系障害	20[redacted]-03-13	同年*-05-06	15	MILD

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/ASIAN	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	血圧上昇*/ELEVATED BLOOD PRESSURE	臨床検査	NO	NOT LIKELY	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/F/BLACK	斑状丘疹状皮疹*/MACULOPOPULAR RASH	皮膚および皮下組織障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	悪心*/NAUSEA	胃腸障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				構語障害*/SLURRED SPEECH	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				錯感覚*/TINGLING OF UPPER EXTREMITIES	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	2[redacted]/F/CAUC.	舌の運動障害*/TONGUE MOTOR WEAKNESS	胃腸障害	20[redacted]-03-13	同年*-04-01	15	SEVERE
				流涎過多*/INCREASED SALIVATION	胃腸障害	20[redacted]-03-13	同年*-04-22	15	MILD
		[redacted]	5[redacted]/M/CAUC.	甲状腺機能低下症*/HYPOTHYROIDISM	内分泌障害	20[redacted]-06-14	ONGOING	11	MILD
		[redacted]	2[redacted]/M/CAUC.	傾眠*/SOMNOLENCE	神経系障害	20[redacted]-08-09	同年*-08-13	3	MODERATE
		[redacted]	3[redacted]/F/CAUC.	感情の平板化*/FLAT AFFECT	精神障害	20[redacted]-05-02 08:00	同年*-06-26	2	MODERATE
				疲労*/FATIGUE	一般・全身障害および投与部位の状態	20[redacted]-05-02 08:00	同年*-05-29	2	MODERATE
				霧視*/BLURRED VISION	眼障害	20[redacted]-05-02 08:00	同年*-05-14	2	MODERATE
		[redacted]	4[redacted]/F/CAUC.	起立性低血圧*/ORTHOSTATIC HYPOTENSION	血管障害	20[redacted]-10-11	同年*-10-28 09:00	1	MODERATE
		[redacted]	4[redacted]/F/CAUC.	うつ病*/DEPRESSED EPISODE	精神障害	20[redacted]-11-09	同年*-11-12	34	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 10-30MG	[redacted]	2[redacted]/F/CAUC.	舌の運動障害*/TONGUE MOTOR WEAKNESS	胃腸障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				流涎過多*/INCREASED SALIVATION	胃腸障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	甲状腺機能低下症*/HYPOTHYROIDISM	内分泌障害	NO	UNRELATED	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/M/CAUC.	傾眠*/SOMNOLENCE	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	感情の平板化*/FLAT AFFECT	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				疲労*/FATIGUE	一般・全身障害および投与部位の状態	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				霧視*/BLURRED VISION	眼障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	起立性低血圧*/ORTHOSTATIC HYPOTENSION	血管障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	うつ病*/DEPRESSED EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-11-09	同年*-11-12	34	MODERATE
		[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-11-14	同年*-12-20	4	MILD
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/INCREASED RESTLESSNESS	精神障害	20[redacted]-03-13	同年*-03-15	3	MILD
		[redacted]	2[redacted]/F/ASIAN	鎮静*/OVER SEDATION	神経系障害	20[redacted]-07-02	同年*-07-16	15	MODERATE
		[redacted]	3[redacted]/F/CAUC.	偶発的過量投与*/ACCIDENTAL DRUG OVERDOSE	傷害、中毒および処置合併症	20[redacted]-04-29 01:57	同年*-04-29 08:07	6	SEVERE
		[redacted]	3[redacted]/F/BLACK	不眠症*/WORSENING OF INSOMNIA	精神障害	20[redacted]-09-14 21:00	同年*-09-23 08:00	12	MODERATE
		[redacted]	4[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-11-18 08:00	同年*-11-27	19	MODERATE
		[redacted]	5[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-02-27 08:00	同年*-03-04	11	MODERATE
		[redacted]	5[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-04-14	同年*-04-21	36	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/INCREASED RESTLESSNESS	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/ASIAN	鎮静*/OVER SEDATION	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	偶発的過量投与*/ACCIDENTAL DRUG OVERDOSE	傷害、中毒および処置合併症	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	不眠症*/WORSENING OF INSOMNIA	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	2[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-06-16	同年*-06-25	6	MODERATE
		[redacted]	3[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-07-16 11:15	同年*-07-21 12:00	8	MODERATE
		[redacted]	5[redacted]/M/CAUC.	双極１型障害*/WORSENING BIPOLAR 1	精神障害	20[redacted]-08-27	同年*-09-22	29	MILD
		[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSIVE EPISODE	精神障害	20[redacted]-03-24 07:58	同年*-05-30 12:00	15	MODERATE
		[redacted]	6[redacted]/F/CAUC.	うつ病*/RECURRENCE OF MOOD EPISODE DEPRESIVE EPISODE	精神障害	20[redacted]-05-26 09:26	同年*-06-13	46	MODERATE
		[redacted]	6[redacted]/M/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	20[redacted]-01-06 10:59	同年*-01-16 14:00	18	SEVERE
		[redacted]	6[redacted]/F/CAUC.	躁病*/MANIC EPISODE	精神障害	20[redacted]-02-07 08:00	同年*-03-12 09:45	5	SEVERE
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/MAJOR DEPRESSIVE EPISOD BIPOLAR I DISORDER	精神障害	20[redacted]-03-28 08:00	同年*-04-29 08:00	38	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
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FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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PHASE B	ARIP 10-30MG	[redacted]	2[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	双極１型障害*/WORSENING BIPOLAR 1	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSIVE EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	うつ病*/RECURRENCE OF MOOD EPISODE DEPRESIVE EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	躁病*/MANIC EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/MAJOR DEPRESSIVE EPISOD BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/F/ASIAN	抑うつ症状*/DEPRESSIVE SYMPTOM	精神障害	20[redacted]-11-13	ONGOING	3	MODERATE
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/ASIAN	疲労*/TIREDNESS	一般・全身障害および投与部位の状態	20[redacted]-01-23 08:00	同年*-04-24 12:00	44	MILD
		[redacted]	4[redacted]/F/CAUC.	血栓症*/BLOOD CLOT RIGHT CALF	血管障害	20[redacted]-06-23 08:00	同年*-07-10 11:30	124	MILD
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/INNER RESTLESSNESS	精神障害	20[redacted]-04-20 08:15	同年*-06-15 09:00	3	MILD
		[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-07-20 13:00	同年*-08-03 09:00	84	MODERATE
		[redacted]	2[redacted]/F/CAUC.	うつ病*/RECURRENCE OF MOOD EPISODE DEPRESSIVE	精神障害	20[redacted]-11-30 08:00	翌年*-01-05 08:00	140	MODERATE
				自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-11-30 08:00	同年*-12-03 09:00	140	MODERATE
		[redacted]	2[redacted]/M/CAUC.	自殺企図*/SUICIDE ATTEMPT	精神障害	20[redacted]-12-13 18:00	同年*-12-15	36	MODERATE
		[redacted]	2[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	20[redacted]-08-22	同年*-08-26	17	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 10-30MG	[redacted]	4[redacted]/F/ASIAN	抑うつ症状*/DEPRESSIVE SYMPTOM	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/ASIAN	疲労*/TIREDNESS	一般・全身障害および投与部位の状態	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	血栓症*/BLOOD CLOT RIGHT CALF	血管障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/INNER RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	うつ病*/RECURRENCE OF MOOD EPISODE DEPRESSIVE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	自殺企図*/SUICIDE ATTEMPT	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/CAUC.	リビドー減退*/LOW LIBIDO	精神障害	20[redacted]-08-15	ONGOING	159	MODERATE
		[redacted]	5[redacted]/F/CAUC.	乳癌*/BREAST CANCER	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）	20[redacted]-08-01	ONGOING	152	MODERATE
		[redacted]	4[redacted]/M/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-07-05	ONGOING	59	MODERATE
		[redacted]	4[redacted]/F/BLACK	ヘモグロビン減少*/DECREASE HEMOGLOBIN HGB	臨床検査	20[redacted]-02-07	同年*-03-03	22	MILD
		[redacted]	4[redacted]/F/CAUC.	うつ病*/INCREASED DEPRESSION WITH HOPELESSNESS	精神障害	20[redacted]-05-08	同年*-06-05	36	SEVERE
		[redacted]	3[redacted]/F/CAUC.	うつ病*/DEPRESSION	精神障害	20[redacted]-01-25	同年*-02-04	10	MODERATE
		[redacted]	5[redacted]/F/CAUC.	躁病*/RECURRENCE OF MANIC MOOD EPISODE	精神障害	20[redacted]-09-30 10:00	同年*-10-24 11:00	62	MODERATE
		[redacted]	2[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-03-30	同年*-05-01	16	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/CAUC.	リビドー減退*/LOW LIBIDO	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	5[redacted]/F/CAUC.	乳癌*/BREAST CANCER	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）	YES	UNRELATED	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/M/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	NO	PROBABLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/F/BLACK	ヘモグロビン減少*/DECREASE HEMOGLOBIN HGB	臨床検査	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	うつ病*/INCREASED DEPRESSION WITH HOPELESSNESS	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	うつ病*/DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	躁病*/RECURRENCE OF MANIC MOOD EPISODE	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	2[redacted]/M/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	20[redacted]-02-09	同年*-03-03	45	MODERATE
		[redacted]	4[redacted]/F/BLACK	うつ病*/WORSENING OF DEPRESSION	精神障害	20[redacted]-11-02	ONGOING	73	MODERATE
		[redacted]	4[redacted]/F/BLACK	躁病*/EXACERBATION OF MANIA	精神障害	20[redacted]-04-25	同年*-04-29	57	SEVERE
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-03-03	同年*-03-05	22	MODERATE
		[redacted]	2[redacted]/M/CAUC.	偶発的過量投与*/ACCIDENTAL OVERDOSE	傷害、中毒および処置合併症	20[redacted]-09-26	同年*-09-29	74	MODERATE
		[redacted]	3[redacted]/F/BLACK	疲労*/WORSENING OF FATIGUE	一般・全身障害および投与部位の状態	20[redacted]-07-13 09:00	ONGOING	13	MODERATE
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/BIPOLAR I DISORDER DEPRESSIVE EPISODE	精神障害	20[redacted]-10-27 14:00	同年*-11-20 11:30	173	MODERATE
		[redacted]	5[redacted]/M/CAUC.	双極性障害*/BIPOLAR I DISORDER DEPRESSIVE EPISODE	精神障害	20[redacted]-10-31 09:00	同年*-11-20 11:00	79	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	2[redacted]/M/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	うつ病*/WORSENING OF DEPRESSION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/F/BLACK	躁病*/EXACERBATION OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	偶発的過量投与*/ACCIDENTAL OVERDOSE	傷害、中毒および処置合併症	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	疲労*/WORSENING OF FATIGUE	一般・全身障害および投与部位の状態	NO	PROBABLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/BIPOLAR I DISORDER DEPRESSIVE EPISODE	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	双極性障害*/BIPOLAR I DISORDER DEPRESSIVE EPISODE	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
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FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	2[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	20[redacted]-06-25 08:00	同年*-07-25 10:00	113	SEVERE
		[redacted]	3[redacted]/F/CAUC.	躁病*/EXACERBATION OF MANIA WITH HOSPITALISATION	精神障害	20[redacted]-10-07 12:31	同年*-11-06 15:32	191	MODERATE
		[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSIVE EPISODE	精神障害	20[redacted]-05-05	ONGOING	32	SEVERE
		[redacted]	4[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR DISORDER,MANIC EPISODE	精神障害	20[redacted]-11-11 07:00	同年*-11-25 09:00	85	MODERATE
		[redacted]	3[redacted]/M/ASIAN	躁病*/MENTAL CONDITION MANIC EXACERBATED	精神障害	20[redacted]-06-10	同年*-08-14	15	SEVERE
		[redacted]	5[redacted]/M/ASIAN	躁病*/RELAPSE OF MANIA	精神障害	20[redacted]-05-26	同年*-09-02	83	SEVERE
		[redacted]	5[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR 1 DISORDER, MANIC WITH PSYCHOTIC FEATURES	精神障害	20[redacted]-10-31	同年*-12-31	4	SEVERE
		[redacted]	2[redacted]/M/ASIAN	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-05-20 09:00	同年*-06-17 09:30	85	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	2[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	躁病*/EXACERBATION OF MANIA WITH HOSPITALISATION	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSIVE EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR DISORDER,MANIC EPISODE	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	躁病*/MENTAL CONDITION MANIC EXACERBATED	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	躁病*/RELAPSE OF MANIA	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR 1 DISORDER, MANIC WITH PSYCHOTIC FEATURES	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/ASIAN	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/F/ASIAN	振戦*/WHOLE BODY TREMOR	神経系障害	20[redacted]-02-05 10:00	同年*-03-04 08:00	77	MODERATE
		[redacted]	3[redacted]/M/ASIAN	躁病*/MANIC EPISODE	精神障害	20[redacted]-03-28	同年*-04-28 15:05	65	SEVERE
		[redacted]	3[redacted]/F/ASIAN	うつ病*/INCREASED DEPRESSION EPISODE	精神障害	20[redacted]-03-19	同年*-05-30	71	MODERATE
		[redacted]	6[redacted]/F/ASIAN	うつ病*/INCREASED DEPRESSIVE EPISODE	精神障害	20[redacted]-09-03	同年*-10-08	8	MODERATE
PHASE D	ARIP IMD	[redacted]	2[redacted]/F/BLACK	うつ病*/WORSENING OF DEPRESSIVE EPISODE	精神障害	20[redacted]-09-08 12:00	同年*-09-27 12:00	6	MILD
		[redacted]	2[redacted]/F/BLACK	自殺企図*/SUICIDE ATTEMPT	精神障害	20[redacted]-02-28 17:00	同年*-02-28 17:00	171	SEVERE
		[redacted]	4[redacted]/M/BLACK	呼吸不全*/RESPIRATORY FAILURE	呼吸器、胸郭および縦隔障害	20[redacted]-05-19	同年*-07-15 01:31	258	SEVERE
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	20[redacted]-09-30	同年*-10-31	121	SEVERE
		[redacted]	4[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	20[redacted]-12-26	翌年*-01-24	109	MILD

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 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/F/ASIAN	振戦*/WHOLE BODY TREMOR	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	躁病*/MANIC EPISODE	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	うつ病*/INCREASED DEPRESSION EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/ASIAN	うつ病*/INCREASED DEPRESSIVE EPISODE	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE D	ARIP IMD	[redacted]	2[redacted]/F/BLACK	うつ病*/WORSENING OF DEPRESSIVE EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/BLACK	自殺企図*/SUICIDE ATTEMPT	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	呼吸不全*/RESPIRATORY FAILURE	呼吸器、胸郭および縦隔障害	YES	NOT LIKELY	DRUG WITHDRAWN	FATAL
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE D	ARIP IMD	[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-06-07	同年*-08-02	259	MODERATE
		[redacted]	5[redacted]/M/CAUC.	うつ病*/INCREASED DEPRESSION	精神障害	20[redacted]-04-01 10:00	同年*-05-14 14:00	70	MODERATE
		[redacted]	4[redacted]/M/CAUC.	双極性障害*/WORSENING OF BIPOLAR DEPRESSION	精神障害	20[redacted]-10-01	同年*-10-10	225	MODERATE
		[redacted]	5[redacted]/M/BLACK	傾眠*/DROWSINESS	神経系障害	20[redacted]-05-16	同年*-06-15	2	MODERATE
		[redacted]	5[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR DEPRESSION	精神障害	20[redacted]-07-28	同年*-07-31	21	MODERATE
		[redacted]	6[redacted]/F/CAUC.	躁病*/RELAPSE OF MANIC SYMPTOMS	精神障害	20[redacted]-02-24	同年*-03-02	72	SEVERE
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR DISORDER	精神障害	20[redacted]-11-29	翌年*-01-06	17	MODERATE
		[redacted]	3[redacted]/F/CAUC.	抑うつ気分*/RECURRENCE OF MOOD DEPRESSION	精神障害	20[redacted]-05-05	同年*-06-03	116	MILD
		[redacted]	6[redacted]/F/CAUC.	アカシジア*/ACUTE AKATHISIA	神経系障害	20[redacted]-01-07 07:00	同年*-01-21 07:00	57	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE D	ARIP IMD	[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	うつ病*/INCREASED DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	双極性障害*/WORSENING OF BIPOLAR DEPRESSION	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	傾眠*/DROWSINESS	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	躁病*/RELAPSE OF MANIC SYMPTOMS	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR DISORDER	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	抑うつ気分*/RECURRENCE OF MOOD DEPRESSION	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	アカシジア*/ACUTE AKATHISIA	神経系障害	YES	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE D	ARIP IMD	[redacted]	4[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	20[redacted]-07-10 08:00	同年*-08-12 10:20	86	SEVERE
		[redacted]	6[redacted]/M/CAUC.	双極性障害*/BYPOLAR I DISEASE, DEPRESIVE EPISODE	精神障害	20[redacted]-05-23	同年*-06-06	43	MODERATE
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE, BIPOLAR DISORDER	精神障害	20[redacted]-01-06	同年*-01-26 15:00	204	MODERATE
		[redacted]	3[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	20[redacted]-02-04 13:30	同年*-02-11 15:00	55	MILD
		[redacted]	3[redacted]/F/ASIAN	うつ病*/RECURRENCE OF DEPRESSIVE EPISODE	精神障害	20[redacted]-09-02 15:10	ONGOING	174	MILD
		[redacted]	2[redacted]/F/ASIAN	感情不安定*/EMOTIONAL INSTABILITY	精神障害	20[redacted]-09-19 11:40	同年*-10-06 15:20	200	MILD
		[redacted]	4[redacted]/M/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	20[redacted]-11-09	翌年*-07-03	157	MODERATE
		[redacted]	3[redacted]/F/ASIAN	うつ病*/DEPRESSIVE STATE	精神障害	20[redacted]-12-21	同年*-12-30	24	MILD
	PLACEBO	[redacted]	5[redacted]/M/BLACK	躁病*/MANIC EPISODE	精神障害	20[redacted]-05-19	同年*-05-21	76	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE D	ARIP IMD	[redacted]	4[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	双極性障害*/BYPOLAR I DISEASE, DEPRESIVE EPISODE	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE, BIPOLAR DISORDER	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	うつ病*/RECURRENCE OF DEPRESSIVE EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/F/ASIAN	感情不安定*/EMOTIONAL INSTABILITY	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	うつ病*/DEPRESSIVE STATE	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
	PLACEBO	[redacted]	5[redacted]/M/BLACK	躁病*/MANIC EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE D	PLACEBO	[redacted]	5[redacted]/F/CAUC.	感情障害*/RECURRENCE OF MOOD EPISODE	精神障害	20[redacted]-06-26 14:30	同年*-07-03 11:00	8	SEVERE
		[redacted]	4[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR ILLNESS REQUIRING HOSPITALIZATION	精神障害	20[redacted]-01-20	同年*-02-05	146	SEVERE
		[redacted]	4[redacted]/F/OTHER	うつ病*/DEPRESSION	精神障害	20[redacted]-05-20	同年*-06-03	225	MODERATE
		[redacted]	4[redacted]/F/CAUC.	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	20[redacted]-01-27 05:00	同年*-02-01 08:00	46	MODERATE
		[redacted]	2[redacted]/M/OTHER	躁病*/RECURRENCE OF MOOD EPISODE, MANIC	精神障害	20[redacted]-06-15	同年*-06-16	203	SEVERE
		[redacted]	4[redacted]/M/CAUC.	躁病*/RECURRENCE OF MOOD EPISODE, MANIC	精神障害	20[redacted]-03-17	ONGOING	36	MODERATE
		[redacted]	2[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-04-11	同年*-04-11	172	MODERATE
		[redacted]	3[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR DISORDER	精神障害	20[redacted]-05-27 10:15	ONGOING	338	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE D	PLACEBO	[redacted]	5[redacted]/F/CAUC.	感情障害*/RECURRENCE OF MOOD EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR ILLNESS REQUIRING HOSPITALIZATION	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/OTHER	うつ病*/DEPRESSION	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/OTHER	躁病*/RECURRENCE OF MOOD EPISODE, MANIC	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	躁病*/RECURRENCE OF MOOD EPISODE, MANIC	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	2[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR DISORDER	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE D	PLACEBO	[redacted]	1[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIA	精神障害	20[redacted]-05-22	同年*-05-29	46	MODERATE
		[redacted]	6[redacted]/M/CAUC.	うつ病*/WORSENING DEPRESSION	精神障害	20[redacted]-09-04	同年*-10-09	127	MODERATE
		[redacted]	4[redacted]/M/OTHER	うつ病*/RECURRENCE OF DEPRESSIVE EPISODE	精神障害	20[redacted]-01-30 08:00	ONGOING	115	MILD
		[redacted]	4[redacted]/F/BLACK	躁病*/MANIC MOOD EVENT	精神障害	20[redacted]-06-05	同年*-06-12	123	SEVERE
		[redacted]	4[redacted]/F/BLACK	高血圧*/MODERATE WORSENING OF HYPERTENSION	血管障害	20[redacted]-01-07 14:15	ONGOING	45	MODERATE
		[redacted]	5[redacted]/F/CAUC.	攻撃性*/AGRESSIVE BEHAVIOUR	精神障害	20[redacted]-03-16 18:50	ONGOING	85	MODERATE
		[redacted]	3[redacted]/M/CAUC.	双極１型障害*/BIPOLAR I DISEASE MANIC EPISODE	精神障害	20[redacted]-04-02 09:00	同年*-04-16 10:00	24	MODERATE
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/SEVERE MAJOR DEPRESSIVE EPISODE	精神障害	20[redacted]-04-28 13:44	同年*-05-24 15:10	7	MODERATE
		[redacted]	3[redacted]/F/CAUC.	感情障害*/RECURENCE OF MOOD EPISODE	精神障害	20[redacted]-07-07 12:00	同年*-08-04	70	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE D	PLACEBO	[redacted]	1[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIA	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	うつ病*/WORSENING DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/OTHER	うつ病*/RECURRENCE OF DEPRESSIVE EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/BLACK	躁病*/MANIC MOOD EVENT	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	高血圧*/MODERATE WORSENING OF HYPERTENSION	血管障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	5[redacted]/F/CAUC.	攻撃性*/AGRESSIVE BEHAVIOUR	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	3[redacted]/M/CAUC.	双極１型障害*/BIPOLAR I DISEASE MANIC EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/SEVERE MAJOR DEPRESSIVE EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	感情障害*/RECURENCE OF MOOD EPISODE	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE D	PLACEBO	[redacted]	4[redacted]/F/CAUC.	大うつ病*/SEVER MAJOR DEPRESIVE EPISOD	精神障害	20[redacted]-03-13 10:55	同年*-04-15	178	SEVERE
		[redacted]	6[redacted]/M/CAUC.	躁病*/MANIC EPISODE	精神障害	20[redacted]-09-21 08:00	同年*-11-16 08:00	315	SEVERE
		[redacted]	5[redacted]/M/CAUC.	双極１型障害*/BYPOLAR DISORDER, MANIC EPISODE	精神障害	20[redacted]-11-28 08:00	同年*-12-29 15:40	253	MODERATE
		[redacted]	4[redacted]/M/CAUC.	双極１型障害*/BYPOLAR DISORDER,MANIC EPISODE WITH PSYCHOTIC FEATURES	精神障害	20[redacted]-11-26	翌年*-01-20 12:00	148	SEVERE
		[redacted]	4[redacted]/M/CAUC.	双極１型障害*/BYPOLAR DISORDER, MIXED EPISODE	精神障害	20[redacted]-11-25 10:00	同年*-12-15 13:40	155	SEVERE
		[redacted]	3[redacted]/F/CAUC.	双極性障害*/BYPOLAR DISORDER, DEPRESSIVE EPISODE	精神障害	20[redacted]-11-06 13:25	同年*-11-26 18:00	44	SEVERE
		[redacted]	4[redacted]/F/CAUC.	双極１型障害*/BIPOLAR DISORDER, MANIC EPISODE	精神障害	20[redacted]-12-23	翌年*-01-06 15:00	125	MILD
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/BYPOLAR DISORDER,MIXED EPISODE	精神障害	20[redacted]-09-24 20:00	同年*-11-16	346	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE D	PLACEBO	[redacted]	4[redacted]/F/CAUC.	大うつ病*/SEVER MAJOR DEPRESIVE EPISOD	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	躁病*/MANIC EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	双極１型障害*/BYPOLAR DISORDER, MANIC EPISODE	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	双極１型障害*/BYPOLAR DISORDER,MANIC EPISODE WITH PSYCHOTIC FEATURES	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	双極１型障害*/BYPOLAR DISORDER, MIXED EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	双極性障害*/BYPOLAR DISORDER, DEPRESSIVE EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極１型障害*/BIPOLAR DISORDER, MANIC EPISODE	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/BYPOLAR DISORDER,MIXED EPISODE	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE D	PLACEBO	[redacted]	5[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR DISORDER MANIC EPISODE	精神障害	20[redacted]-05-07 08:00	同年*-06-04 10:00	57	MODERATE
		[redacted]	4[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR 1 DISORDER MANIC	精神障害	20[redacted]-01-27	同年*-02-17	50	MILD
		[redacted]	5[redacted]/M/ASIAN	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-09-16 13:00	同年*-11-29 11:00	99	SEVERE
		[redacted]	3[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	20[redacted]-04-01 16:00	同年*-04-24 09:00	308	MODERATE
		[redacted]	4[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	20[redacted]-11-21 23:06	同年*-12-13 08:00	16	MODERATE
		[redacted]	2[redacted]/M/ASIAN	躁病*/RECURRENCE OF MANIC STATE	精神障害	20[redacted]-03-26 01:13	同年*-06-30 15:00	359	MODERATE
		[redacted]	4[redacted]/F/ASIAN	抑うつ気分*/DEPRESSED MOOD	精神障害	20[redacted]-10-28 14:10	同年*-11-25 16:00	254	MODERATE
		[redacted]	3[redacted]/F/ASIAN	躁病*/MANIC EPISODE AGGRAVATED	精神障害	20[redacted]-09-07	同年*-12-15 13:04	322	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-80　投与中止に至った有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE D	PLACEBO	[redacted]	5[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR DISORDER MANIC EPISODE	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR 1 DISORDER MANIC	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	YES	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	YES	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/ASIAN	躁病*/RECURRENCE OF MANIC STATE	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/ASIAN	抑うつ気分*/DEPRESSED MOOD	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	躁病*/MANIC EPISODE AGGRAVATED	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＜資料番号 5.3.5.1-01：CT-9.3 より作成＞

表 2.7.4.7-81　投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.2

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
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）	乳癌	0	(0.0)	1	(0.2)
内分泌障害	甲状腺機能低下症	1	(0.2)	0	(0.0)
精神障害	双極１型障害	1	(0.2)	4	(0.9)
	うつ病	5	(0.8)	8	(1.9)
	感情の平板化	1	(0.2)	0	(0.0)
	不眠症	1	(0.2)	0	(0.0)
	リビドー減退	0	(0.0)	1	(0.2)
	躁病	10	(1.6)	6	(1.4)
	落ち着きのなさ	4	(0.7)	2	(0.5)
	自殺念慮	3	(0.5)	1	(0.2)
	自殺企図	0	(0.0)	1	(0.2)
	抑うつ症状	4	(0.7)	0	(0.0)
	双極性障害	2	(0.3)	3	(0.7)
	大うつ病	1	(0.2)	1	(0.2)
神経系障害	アカシジア	8	(1.3)	2	(0.5)
	構語障害	1	(0.2)	0	(0.0)
	頭痛	1	(0.2)	0	(0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BEB.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.2　FINAL

表 2.7.4.7-81　投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.2

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
神経系障害	精神的機能障害	1	(0.2)	0	(0.0)
	錯感覚	1	(0.2)	0	(0.0)
	鎮静	2	(0.3)	0	(0.0)
	傾眠	6	(1.0)	0	(0.0)
	遅発性ジスキネジア	1	(0.2)	0	(0.0)
	振戦	1	(0.2)	1	(0.2)
眼障害	霧視	1	(0.2)	0	(0.0)
血管障害	起立性低血圧	1	(0.2)	0	(0.0)
	血栓症	0	(0.0)	1	(0.2)
胃腸障害	口内乾燥	1	(0.2)	0	(0.0)
	悪心	1	(0.2)	0	(0.0)
	流涎過多	1	(0.2)	0	(0.0)
	舌の運動障害	1	(0.2)	0	(0.0)
皮膚および皮下組織障害	斑状丘疹状皮疹	1	(0.2)	0	(0.0)
一般・全身障害および投与部位の状態	疲労	1	(0.2)	3	(0.7)
臨床検査	血圧上昇	1	(0.2)	0	(0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BEB.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.2　FINAL

表 2.7.4.7-81　投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.2

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
臨床検査	ヘモグロビン減少	0	(0.0)	1	(0.2)
	心拍数増加	1	(0.2)	0	(0.0)
	体重増加	2	(0.3)	1	(0.2)
傷害、中毒および処置合併症	偶発的過量投与	1	(0.2)	1	(0.2)
TOTAL1)		58	(9.4)	37	(8.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BEB.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.2　FINAL

＜資料番号 5.3.5.1-01：CT-21.6.2 より作成＞

表 2.7.4.7-82　器官別大分類別投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class
(Phase B Safety Sample and Phase C Safety Sample)

SYSTEM ORGAN CLASS	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
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	(0.2)
内分泌障害	1	(0.2)	0	(0.0)
精神障害	31	(5.0)	26	(6.1)
神経系障害	20	(3.3)	3	(0.7)
眼障害	1	(0.2)	0	(0.0)
血管障害	1	(0.2)	1	(0.2)
胃腸障害	2	(0.3)	0	(0.0)
皮膚および皮下組織障害	1	(0.2)	0	(0.0)
一般・全身障害および投与部位の状態	1	(0.2)	3	(0.7)
臨床検査	4	(0.7)	2	(0.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BEA.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.1　FINAL

表 2.7.4.7-82　器官別大分類別投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class
(Phase B Safety Sample and Phase C Safety Sample)

	PHASE B (N=614)		PHASE C (N=425)	
SYSTEM ORGAN CLASS	n	(%)	n	(%)
傷害、中毒および処置合併症	1	(0.2)	1	(0.2)
TOTAL1)	58	(9.4)	37	(8.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BEA.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.1　FINAL

＜資料番号 5.3.5.1-01：CT-21.6.1 より作成＞

表 2.7.4.7-83　重症度別投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product
by System Organ Class, MedDRA Preferred Term and Severity (Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)				PHASE C (N=425)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
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）	乳癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
内分泌障害	甲状腺機能低下症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	双極１型障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	2 (0.5)	2 (0.5)	4 (0.9)
	うつ病	0 (0.0)	5 (0.8)	0 (0.0)	5 (0.8)	0 (0.0)	5 (1.2)	3 (0.7)	8 (1.9)
	感情の平板化	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	躁病	0 (0.0)	9 (1.5)	1 (0.2)	10 (1.6)	0 (0.0)	2 (0.5)	4 (0.9)	6 (1.4)
	落ち着きのなさ	1 (0.2)	3 (0.5)	0 (0.0)	4 (0.7)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	自殺念慮	0 (0.0)	3 (0.5)	0 (0.0)	3 (0.5)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	抑うつ症状	0 (0.0)	2 (0.3)	2 (0.3)	4 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.3)	0 (0.0)	3 (0.7)	0 (0.0)	3 (0.7)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
神経系障害	アカシジア	3 (0.5)	3 (0.5)	2 (0.3)	8 (1.3)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	構語障害	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2BEC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.3　FINAL

表 2.7.4.7-83　重症度別投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product
by System Organ Class, MedDRA Preferred Term and Severity (Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)				PHASE C (N=425)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
神経系障害	精神的機能障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	1 (0.2)	5 (0.8)	0 (0.0)	6 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
眼障害	霧視	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	起立性低血圧	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血栓症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
胃腸障害	口内乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌の運動障害	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	斑状丘疹状皮疹	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	疲労	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2BEC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.3　FINAL

表 2.7.4.7-83　重症度別投与中止に至った有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product
by System Organ Class, MedDRA Preferred Term and Severity (Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)				PHASE C (N=425)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
臨床検査	血圧上昇	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘモグロビン減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心拍数増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症	偶発的過量投与	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2BEC.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.3　FINAL

＜資料番号 5.3.5.1-01：CT-21.6.3 より作成＞

表 2.7.4.7-84　器官別大分類別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.1
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class (Phase C Safety Sample)

SYSTEM ORGAN CLASS	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	1	(0.3)	0	(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）	1	(0.3)	0	(0.0)	1	(0.2)
内分泌障害	1	(0.3)	0	(0.0)	1	(0.2)
代謝および栄養障害	3	(0.8)	1	(1.2)	4	(0.9)
精神障害	20	(5.3)	2	(2.4)	22	(4.7)
神経系障害	12	(3.2)	0	(0.0)	12	(2.6)
心臓障害	1	(0.3)	0	(0.0)	1	(0.2)
呼吸器、胸郭および縦隔障害	1	(0.3)	0	(0.0)	1	(0.2)
筋骨格系および結合組織障害	1	(0.3)	0	(0.0)	1	(0.2)
一般・全身障害および投与部位の状態	2	(0.5)	0	(0.0)	2	(0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AEA.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.1　FINAL

表 2.7.4.7-84　器官別大分類別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.1
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class (Phase C Safety Sample)

SYSTEM ORGAN CLASS	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
臨床検査	8	(2.1)	0	(0.0)	8	(1.7)
TOTAL1)	44	(11.6)	3	(3.5)	47	(10.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AEA.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.1　FINAL

＜資料番号 5.3.5.2-01：CT-8.6.1 より作成＞

表 2.7.4.7-85　重症度別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.3

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity (Phase C Safety Sample)

		DE NOVO (N=379)				ROLLOVER (N=85)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	ウイルス性胃腸炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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）	乳癌	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
内分泌障害	高プロラクチン血症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	糖尿病	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	食欲亢進	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	不安	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	4 (1.1)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	0 (0.0)	2 (0.5)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	0 (0.0)	2 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
	落ち着きのなさ	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.5)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

表 2.7.4.7-85　重症度別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.3

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C by System Organ Class, MedDRA Preferred Term and Severity (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	ウイルス性胃腸炎	0 (0.0)	1 (0.2)	0 (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）	乳癌	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
内分泌障害	高プロラクチン血症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
代謝および栄養障害	糖尿病	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	コントロール不良の糖尿病	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	食欲亢進	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
精神障害	不安	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	双極１型障害	0 (0.0)	4 (0.9)	0 (0.0)	4 (0.9)
	歯ぎしり	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	うつ病	0 (0.0)	2 (0.4)	1 (0.2)	3 (0.6)
	不眠症	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.4)
	躁病	0 (0.0)	0 (0.0)	3 (0.6)	3 (0.6)
	落ち着きのなさ	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	自殺念慮	1 (0.2)	1 (0.2)	1 (0.2)	3 (0.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

表 2.7.4.7-85　重症度別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity (Phase C Safety Sample)

		DE NOVO (N=379)				ROLLOVER (N=85)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
精神障害	双極性障害	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	咽頭反射亢進	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
筋骨格系および結合組織障害	筋萎縮	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	無力症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

表 2.7.4.7-85　重症度別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.3

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
精神障害	双極性障害	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
神経系障害	アカシジア	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	錐体外路障害	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	嗜眠	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	パーキンソニズム	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鎮静	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	傾眠	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	遅発性ジスキネジア	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	振戦	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
心臓障害	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
呼吸器、胸郭および縦隔障害	咽頭反射亢進	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
筋骨格系および結合組織障害	筋萎縮	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
一般・全身障害および投与部位の状態	無力症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

表 2.7.4.7-85　　重症度別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity (Phase C Safety Sample)

		DE NOVO (N=379)				ROLLOVER (N=85)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態	疲労	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
臨床検査	体重増加	2 (0.5)	4 (1.1)	1 (0.3)	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.6.3　FINAL

表 2.7.4.7-85　重症度別投与中止に至った有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.6.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態	疲労	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
臨床検査	体重増加	2 (0.4)	4 (0.9)	1 (0.2)	7 (1.5)
	肝機能検査値上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AEC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3　FINAL

＜資料番号 5.3.5.2-01：CT-8.6.3 より作成＞

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	6[redacted]/F/CAUC.	錐体外路障害*/EXTRA PYRAMIDAL SYNDROM	神経系障害	20[redacted]-10-28 22:00	同年*-11-30 12:00	15	MODERATE
		[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-11-24	翌年*-01-02	12	MODERATE
		[redacted]	5[redacted]/M/CAUC.	椎間板障害*/DISCOPATHY	筋骨格系および結合組織障害	20[redacted]-01-28 14:00	同年*-01-30	27	MILD
		[redacted]	5[redacted]/M/ASIAN	躁病*/WORSENING OF MANIA SYMPTOMS	精神障害	20[redacted]-11-16 21:00	同年*-12-05 18:00	27	SEVERE
		[redacted]	3[redacted]/F/ASIAN	不眠症*/INSOMNIA	精神障害	20[redacted]-11-20 22:00	同年*-12-19 22:00	1	SEVERE
		[redacted]	5[redacted]/F/CAUC.	鎮静*/SEDATION	神経系障害	20[redacted]-10-21	同年*-11-18	43	MILD
		[redacted]	6[redacted]/M/CAUC.	抑うつ気分*/INCREASED DEPRESSED MOOD	精神障害	20[redacted]-10-31 10:00	同年*-12-14	43	MODERATE
		[redacted]	5[redacted]/M/BLACK	血中クレアチンホスホキナーゼ増加*/WORSENING OF ELEVATED CK	臨床検査	20[redacted]-09-05 12:30	同年*-10-09 10:30	8	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	6[redacted]/F/CAUC.	錐体外路障害*/EXTRA PYRAMIDAL SYNDROM	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	椎間板障害*/DISCOPATHY	筋骨格系および結合組織障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	躁病*/WORSENING OF MANIA SYMPTOMS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	不眠症*/INSOMNIA	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	鎮静*/SEDATION	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	抑うつ気分*/INCREASED DEPRESSED MOOD	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	血中クレアチンホスホキナーゼ増加*/WORSENING OF ELEVATED CK	臨床検査	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-12-27 08:00	翌年*-01-02 08:00	15	MODERATE
		[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-07-23 06:00	同年*-08-27	29	SEVERE
		[redacted]	5[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-07-26	同年*-09-22	10	MILD
		[redacted]	2[redacted]/F/CAUC.	食欲亢進*/INCREASED APPETITE	代謝および栄養障害	20[redacted]-01-04 19:00	同年*-03-01 19:00	15	MODERATE
		[redacted]	2[redacted]/F/CAUC.	躁病*/MANIA AGGRAVATED	精神障害	20[redacted]-01-31 16:30	同年*-02-02 16:30	9	SEVERE
		[redacted]	4[redacted]/F/CAUC.	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	20[redacted]-12-09 11:50	翌年*-10-01 09:00	42	MILD
		[redacted]	5[redacted]/M/CAUC.	不眠症*/INSOMNIA	精神障害	20[redacted]-03-06	同年*-04-11	6	MODERATE
		[redacted]	3[redacted]/F/BLACK	嗜眠*/LETHARGIC	神経系障害	20[redacted]-09-20	同年*-10-09	1	MODERATE
		[redacted]	3[redacted]/M/CAUC.	不安*/ANXIETY	精神障害	20[redacted]-10-18	同年*-10-27	22	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHESIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	食欲亢進*/INCREASED APPETITE	代謝および栄養障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	躁病*/MANIA AGGRAVATED	精神障害	YES	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	不眠症*/INSOMNIA	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	嗜眠*/LETHARGIC	神経系障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	不安*/ANXIETY	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/BLACK	線維筋痛*/WORSENING OF FIBROMYALGIA PAIN	筋骨格系および結合組織障害	20[redacted]-11-29 18:00	同年*-12-05 09:00	31	SEVERE
		[redacted]	2[redacted]/F/CAUC.	食欲亢進*/INCREASED APPETITE	代謝および栄養障害	20[redacted]-11-25 08:00	同年*-12-04 08:00	19	MODERATE
		[redacted]	5[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-09-25	同年*-10-12	6	MODERATE
		[redacted]	2[redacted]/F/CAUC.	無力症*/LACK OF ENERGY	一般・全身障害および投与部位の状態	20[redacted]-11-08	同年*-11-20	22	MODERATE
		[redacted]	3[redacted]/F/BLACK	痙攣発作*/WORSENING OF SEIZURE DISORDER	神経系障害	20[redacted]-07-01	同年*-07-02	22	MILD
		[redacted]	4[redacted]/M/CAUC.	食欲亢進*/INCREASE APPETITE	代謝および栄養障害	20[redacted]-06-28	同年*-07-13	8	MILD
		[redacted]	5[redacted]/F/CAUC.	肺腺癌*/BRONCHOGENIC ADENOCARCINOMA	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）	20[redacted]-09-11	同年*-10-10	27	SEVERE
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL THOUGHTS	精神障害	20[redacted]-11-29	同年*-11-29	17	MODERATE

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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/BLACK	線維筋痛*/WORSENING OF FIBROMYALGIA PAIN	筋骨格系および結合組織障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	食欲亢進*/INCREASED APPETITE	代謝および栄養障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	無力症*/LACK OF ENERGY	一般・全身障害および投与部位の状態	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	痙攣発作*/WORSENING OF SEIZURE DISORDER	神経系障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	食欲亢進*/INCREASE APPETITE	代謝および栄養障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	肺腺癌*/BRONCHOGENIC ADENOCARCINOMA	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）	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL THOUGHTS	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/CAUC.	不安*/WORSENING OF ANXIETY	精神障害	20[redacted]-11-29	同年*-11-30	17	MILD
		[redacted]	1[redacted]/F/CAUC.	激越*/WORSENING OF AGITATION	精神障害	20[redacted]-01-11	同年*-01-16	37	MODERATE
		[redacted]	5[redacted]/F/BLACK	項部硬直*/NECK RIGDITY	筋骨格系および結合組織障害	20[redacted]-11-20 14:00	同年*-12-16 09:00	44	MILD
		[redacted]	2[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-02-28	同年*-03-19	7	MODERATE
		[redacted]	4[redacted]/F/CAUC.	疲労*/FATIGUE	一般・全身障害および投与部位の状態	20[redacted]-04-27 08:00	同年*-04-28 08:00	22	MILD
		[redacted]	5[redacted]/F/CAUC.	企図的過量投与*/INTENTIONAL OVERDOSE	傷害、中毒および処置合併症	20[redacted]-05-25 23:00	同年*-05-26 14:00	19	MODERATE
		[redacted]	4[redacted]/F/CAUC.	傾眠*/SOMNOLENCE	神経系障害	20[redacted]-06-07	同年*-06-12 07:00	23	MODERATE
		[redacted]	5[redacted]/M/CAUC.	傾眠*/SOMNOLENCE	神経系障害	20[redacted]-12-12 07:00	同年*-12-13 07:00	9	MODERATE
		[redacted]	3[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-11-29 05:00	翌年*-01-20 21:00	3	MILD

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/CAUC.	不安*/WORSENING OF ANXIETY	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	1[redacted]/F/CAUC.	激越*/WORSENING OF AGITATION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	項部硬直*/NECK RIGDITY	筋骨格系および結合組織障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	疲労*/FATIGUE	一般・全身障害および投与部位の状態	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	企図的過量投与*/INTENTIONAL OVERDOSE	傷害、中毒および処置合併症	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	傾眠*/SOMNOLENCE	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	傾眠*/SOMNOLENCE	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/BLACK	アカシジア*/AKATHISIA	神経系障害	20[redacted]-04-05 08:00	同年*-05-28 08:00	2	MODERATE
		[redacted]	5[redacted]/F/BLACK	血圧上昇*/ELEVATED BLOOD PRESSURE	臨床検査	20[redacted]-10-15 10:22	ONGOING	41	MILD
				心拍数増加*/ELEVATED PULSE	臨床検査	20[redacted]-10-15 10:22	ONGOING	41	MILD
				心電図異常*/ABNORMAL ECG	臨床検査	20[redacted]-10-16 10:22	ONGOING	42	MILD
		[redacted]	3[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-09-19	同年*-10-31	22	MODERATE
		[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-05-15 08:00	同年*-06-05 08:00	20	MODERATE
		[redacted]	6[redacted]/M/CAUC.	前立腺癌*/PROSTATE CANCER	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）	20[redacted]-10-16	同年*-11	35	MODERATE
		[redacted]	3[redacted]/F/CAUC.	パニック発作*/INTERMITTENT PANIC ATTACKS	精神障害	20[redacted]-04-27	同年*-05-09	18	MILD

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/BLACK	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	血圧上昇*/ELEVATED BLOOD PRESSURE	臨床検査	NO	NOT LIKELY	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
				心拍数増加*/ELEVATED PULSE	臨床検査	NO	NOT LIKELY	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
				心電図異常*/ABNORMAL ECG	臨床検査	NO	NOT LIKELY	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	3[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	前立腺癌*/PROSTATE CANCER	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）	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	パニック発作*/INTERMITTENT PANIC ATTACKS	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/CAUC.	不安*/INCREASED ANXIETY	精神障害	20[redacted]-04-27	同年*-05-09	18	MODERATE
		[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-09-27 20:00	同年*-10-20 11:00	9	MILD
		[redacted]	5[redacted]/F/CAUC.	筋攣縮*/FOOT TWITCHING	筋骨格系および結合組織障害	20[redacted]-05-30	同年*-06-18	36	MODERATE
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-08-21 16:00	同年*-08-24 16:00	16	SEVERE
		[redacted]	3[redacted]/F/BLACK	アレルギー性そう痒症*/ALLERGIC PRURITUS	皮膚および皮下組織障害	20[redacted]-08-30	同年*-09-06	1	MILD
		[redacted]	4[redacted]/M/CAUC.	傾眠*/SOMOLENCE	神経系障害	20[redacted]-04-05	同年*-04-19	23	MODERATE
				浮動性めまい*/DIZZINESS	神経系障害	20[redacted]-04-07	同年*-04-19	25	MILD
				失見当識*/DISORIENTATION	精神障害	20[redacted]-04-08	同年*-04-20	26	MODERATE
		[redacted]	3[redacted]/M/CAUC.	傾眠*/DROWSINESS	神経系障害	20[redacted]-11-25 08:00	ONGOING	10	MODERATE

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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	3[redacted]/F/CAUC.	不安*/INCREASED ANXIETY	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	筋攣縮*/FOOT TWITCHING	筋骨格系および結合組織障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	アレルギー性そう痒症*/ALLERGIC PRURITUS	皮膚および皮下組織障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	傾眠*/SOMOLENCE	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				浮動性めまい*/DIZZINESS	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				失見当識*/DISORIENTATION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	傾眠*/DROWSINESS	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/BLACK	うつ病*/DEPRESSIVE EPISODE	精神障害	20[redacted]-01-27	同年*-02-07	25	MODERATE
		[redacted]	5[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-06-06 14:00	ONGOING	30	MODERATE
		[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-10-19	翌年*-05-23	17	MILD
		[redacted]	5[redacted]/F/BLACK	ブドウ球菌感染*/MSSA HIP INFECTION	感染症および寄生虫症	20[redacted]-12-17	翌年*-02-08	29	SEVERE
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-05-20 16:37	同年*-05-28 12:44	12	SEVERE
	ARIP 6-12MG	[redacted]	4[redacted]/F/ASIAN	不眠症*/INSOMNIA AGGRAVATED	精神障害	20[redacted]-02-09 09:00	同年*-03-13 10:30	-4	MILD
				浮動性めまい*/DIZZINESS	神経系障害	20[redacted]-02-22 13:00	同年*-03-04 09:00	10	MILD
				嘔吐*/VOMITING	胃腸障害	20[redacted]-03-09 12:00	同年*-03-11 09:00	25	MILD
		[redacted]	6[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-10-29 14:10	翌年*-03-03 11:10	26	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/BLACK	うつ病*/DEPRESSIVE EPISODE	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	アカシジア*/AKATHESIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	ブドウ球菌感染*/MSSA HIP INFECTION	感染症および寄生虫症	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
	ARIP 6-12MG	[redacted]	4[redacted]/F/ASIAN	不眠症*/INSOMNIA AGGRAVATED	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				浮動性めまい*/DIZZINESS	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				嘔吐*/VOMITING	胃腸障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 6-12MG	[redacted]	5[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-07-07 09:00	同年*-09-11 09:15	40	MODERATE
PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/F/ASIAN	糖尿病*/DIABETES MELLITUS AGGRAVATED	代謝および栄養障害	20[redacted]-01-24 10:08	ONGOING	29	MILD
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-08-14	同年*-10-28	17	MODERATE
		[redacted]	5[redacted]/F/ASIAN	うつ病*/RELAPSE OF DEPRESSION	精神障害	20[redacted]-04-05	同年*-07-17	17	MODERATE
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	20[redacted]-04-05	同年*-05-09	17	MODERATE
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-11-27 18:00	翌年*-01-21	30	MODERATE
		[redacted]	3[redacted]/M/ASIAN	不眠症*/INSOMNIA AGGRAVATED	精神障害	20[redacted]-01-04	ONGOING	8	MODERATE
	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSION	精神障害	20[redacted]-01-03 09:00	ONGOING	52	SEVERE
		[redacted]	3[redacted]/F/CAUC.	抑うつ気分*/INCREASED DEPRESSED MOOD	精神障害	20[redacted]-01-06	同年*-05-14	27	MODERATE

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Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 6-12MG	[redacted]	5[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/F/ASIAN	糖尿病*/DIABETES MELLITUS AGGRAVATED	代謝および栄養障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/ASIAN	うつ病*/RELAPSE OF DEPRESSION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	不眠症*/INSOMNIA AGGRAVATED	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	3[redacted]/F/CAUC.	抑うつ気分*/INCREASED DEPRESSED MOOD	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 15-30MG	[redacted]	6[redacted]/F/CAUC.	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	20[redacted]-12-15 08:00	翌年*-01-08 14:00	47	MODERATE
		[redacted]	5[redacted]/F/CAUC.	嘔吐*/INCREASED VOMITING	胃腸障害	20[redacted]-09-24 20:00	同年*-09-27 20:00	1	MODERATE
				発疹*/UNSPECIFIED RASH TO ARMS LEGS BACK	皮膚および皮下組織障害	20[redacted]-09-28 20:00	同年*-11-01 08:00	5	MODERATE
		[redacted]	4[redacted]/F/BLACK	うつ病*/WOSENING OF DEPRESSION	精神障害	20[redacted]-04-05 14:00	同年*-04-17 20:00	46	MODERATE
		[redacted]	3[redacted]/F/BLACK	傾眠*/SOMOLENCE	神経系障害	20[redacted]-10-15 13:40	同年*-11-02 09:00	1	MODERATE
				激越*/AGITATION	精神障害	20[redacted]-10-15 13:40	同年*-11-02 09:00	1	MODERATE
		[redacted]	5[redacted]/M/OTHER	アカシジア*/AKATHESIA	神経系障害	20[redacted]-04-25	同年*-05-05	17	SEVERE
		[redacted]	2[redacted]/F/CAUC.	易刺激性*/IRRITABILITY	精神障害	20[redacted]-11-27 08:00	同年*-12-07	14	SEVERE
		[redacted]	3[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	20[redacted]-05-24	ONGOING	4	SEVERE

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PHASE B	ARIP 15-30MG	[redacted]	6[redacted]/F/CAUC.	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	嘔吐*/INCREASED VOMITING	胃腸障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				発疹*/UNSPECIFIED RASH TO ARMS LEGS BACK	皮膚および皮下組織障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	うつ病*/WOSENING OF DEPRESSION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	傾眠*/SOMOLENCE	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				激越*/AGITATION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/OTHER	アカシジア*/AKATHESIA	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	易刺激性*/IRRITABILITY	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	20[redacted]-07-20	同年*-07-31	3	MODERATE
		[redacted]	5[redacted]/F/BLACK	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-11-15	ONGOING	17	MILD
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-12-01	同年*-12-17	5	MILD
		[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-12-31	翌年*-01-25	4	MILD
		[redacted]	5[redacted]/F/CAUC.	悪心*/NAUSEA	胃腸障害	20[redacted]-01-25	同年*-01-27	1	MODERATE
				易刺激性*/IRRITABILITY	精神障害	20[redacted]-01-25	同年*-01-27	1	MODERATE
				胸痛*/CHEST PAIN	一般・全身障害および投与部位の状態	20[redacted]-01-25	同年*-01-25	1	SEVERE
				鎮静*/SEDATION	神経系障害	20[redacted]-01-25	同年*-01-27	1	MODERATE
				不眠症*/WORSENING OF INSOMNIA	精神障害	20[redacted]-01-25	同年*-01-27	1	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	体重増加*/WEIGHT GAIN	臨床検査	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	悪心*/NAUSEA	胃腸障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				易刺激性*/IRRITABILITY	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				胸痛*/CHEST PAIN	一般・全身障害および投与部位の状態	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				鎮静*/SEDATION	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				不眠症*/WORSENING OF INSOMNIA	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	激越*/INTOLERABLE AGITATION	精神障害	20[redacted]-06-22	同年* -06-27	2	MODERATE
		[redacted]	5[redacted]/F/CAUC.	自殺念慮*/FLEETING SUICIDAL IDEATION WITH PLAN TO JUMP OFF 2ND STORY BALCONY	精神障害	20[redacted]-11-13	同年* -11-13	36	MODERATE
		[redacted]	1[redacted]/M/CAUC.	幻視*/VISUAL HALLUCUNATIONS	精神障害	20[redacted]-12-20	翌年*-01-08	15	MODERATE
				幻聴*/AUDITORY HALLUCINATIONS	精神障害	20[redacted]-12-20	翌年*-01-08	15	MODERATE
		[redacted]	2[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	20[redacted]-05-31 19:00	同年*-06-20 11:00	22	MODERATE
		[redacted]	4[redacted]/F/CAUC.	不安*/WORSENING ANXIETY	精神障害	20[redacted]-08-22 15:00	ONGOING	4	MODERATE
		[redacted]	3[redacted]/F/CAUC.	コントロール不良の糖尿病*/HIGH BLOOD GLUCOSE LEVEL UNCONTROLLED DIABETES	代謝および栄養障害	20[redacted]-11-08 12:45	同年*-12-05	46	MODERATE
		[redacted]	2[redacted]/F/CAUC.	疲労*/MODERATE INTERMITTENT FATIGUE	一般・全身障害および投与部位の状態	20[redacted]-06-06 07:00	同年*-07-09	9	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 15-30MG	[redacted]	2[redacted]/F/CAUC.	激越*/INTOLERABLE AGITATION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	自殺念慮*/FLEETING SUICIDAL IDEATION WITH PLAN TO JUMP OFF 2ND STORY BALCONY	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	1[redacted]/M/CAUC.	幻視*/VISUAL HALLUCUNATIONS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				幻聴*/AUDITORY HALLUCINATIONS	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	不安*/ANXIETY	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	不安*/WORSENING ANXIETY	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	3[redacted]/F/CAUC.	コントロール不良の糖尿病*/ HIGH BLOOD GLUCOSE LEVEL UNCONTROLLED DIABETES	代謝および栄養障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	疲労*/MODERATE INTERMITTENT FATIGUE	一般・全身障害および投与部位の状態	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 15-30MG	[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-11-26 12:00	同年*-12-04 12:00	22	SEVERE
		[redacted]	5[redacted]/F/ASIAN	腎細胞癌*/RENAL CELL CARCINOMA	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）	20[redacted]-07-25	同年*-08-26	44	SEVERE
		[redacted]	4[redacted]/F/BLACK	高プロラクチン血症*/HYPERPROLACTINEMIA	内分泌障害	20[redacted]-11-22 12:00	同年*-12-19 13:15	43	MODERATE
		[redacted]	2[redacted]/F/CAUC.	蕁麻疹*/URTICARIA	皮膚および皮下組織障害	20[redacted]-01-08	同年*-01-15	36	MODERATE
		[redacted]	3[redacted]/F/BLACK	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-11-15 10:00	ONGOING	25	SEVERE
		[redacted]	2[redacted]/F/CAUC.	熱傷*/3 PERCENT TBSA SUPERFICIAL BURNS TO RIGHT LATERAL LOWER LEG ANKLE FOOT 5TH TOE POSTERIOR LOWER LEG AND ANKLE	傷害、中毒および処置合併症	20[redacted]-12-18 14:30	ONGOING	37	SEVERE
		[redacted]	5[redacted]/F/CAUC.	ジストニア*/ACUTE DYSTONIC REACTION OF ARMS	神経系障害	20[redacted]-10-11 07:00	同年*-10-13 10:00	60	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 15-30MG	[redacted]	4[redacted]/F/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/ASIAN	腎細胞癌*/RENAL CELL CARCINOMA	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）	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	高プロラクチン血症*/HYPER PROLACTINEMIA	内分泌障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	蕁麻疹*/URTICARIA	皮膚および皮下組織障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	体重増加*/WEIGHT GAIN	臨床検査	NO	DEFINITE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	2[redacted]/F/CAUC.	熱傷*/3 PERCENT TBSA SUPERFICIAL BURNS TO RIGHT LATERAL LOWER LEG ANKLE FOOT 5TH TOE POSTERIOR LOWER LEG AND ANKLE	傷害、中毒および処置合併症	YES	UNRELATED	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	5[redacted]/F/CAUC.	ジストニア*/ACUTE DYSTONIC REACTION OF ARMS	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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PHASE B	ARIP 15-30MG	[redacted]	6[redacted]/F/CAUC.	抑うつ気分*/DEPRESSED MOOD	精神障害	20[redacted]-02-25 09:00	同年*-06-05 11:00	27	MODERATE
		[redacted]	5[redacted]/M/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-11-13	翌年*-05-23	14	MILD
		[redacted]	6[redacted]/F/CAUC.	甲状腺機能亢進症*/EXOGENOUS HYPERTHYROIDISM	内分泌障害	20[redacted]-11-27	翌年*-02-04	15	MODERATE
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/BLACK	コントロール不良の糖尿病*/ONGOING DIABETES M. WITH POOR CONTROL	代謝および栄養障害	20[redacted]-09-17	ONGOING	38	MODERATE
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/PSYCHIATRIC HOSPITALIZATION DUE TO SUICIDIAL THOUGTHS	精神障害	20[redacted]-02-08	同年*-03-18	97	MILD
		[redacted]	4[redacted]/M/CAUC.	躁病*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	20[redacted]-12-20 08:00	翌年*-01-29 11:07	126	SEVERE
		[redacted]	4[redacted]/M/CAUC.	社会逃避行動*/SOCIAL ISOLATION	精神障害	20[redacted]-08-07	同年*-08-07	245	SEVERE
		[redacted]	3[redacted]/M/CAUC.	躁病*/PSYCHOTIC MANIC EPISODE	精神障害	20[redacted]-12-02 20:00	翌年*-03-28 12:00	25	SEVERE

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PHASE B	ARIP 15-30MG	[redacted]	6[redacted]/F/CAUC.	抑うつ気分*/DEPRESSED MOOD	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	甲状腺機能亢進症*/EXOGENOUS HYPERTHYROIDISM	内分泌障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/M/BLACK	コントロール不良の糖尿病*/ONGOING DIABETES M. WITH POOR CONTROL	代謝および栄養障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/PSYCHIATRIC HOSPITALIZATION DUE TO SUICIDIAL THOUGTHS	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	躁病*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	社会逃避行動*/SOCIAL ISOLATION	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	躁病*/PSYCHOTIC MANIC EPISODE	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	双極１型障害*/BIPOLAR I DISORDER.MIXED EPISODE	精神障害	20[redacted]-04-23 09:00	ONGOING	156	MODERATE
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	20[redacted]-04-04 17:00	ONGOING	131	SEVERE
		[redacted]	4[redacted]/F/ASIAN	双極性障害*/BIPOLAR AFFECTIVE DISORDER	精神障害	20[redacted]-03-01 22:00	同年*-04-01	186	MODERATE
		[redacted]	3[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-12-28	翌年*-02-17 10:00	52	MODERATE
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	20[redacted]-05-12	同年*-06-12 14:00	40	MODERATE
		[redacted]	5[redacted]/M/ASIAN	筋萎縮*/MUSCLE ATROPHY	筋骨格系および結合組織障害	20[redacted]-10-08 09:30	同年*-11-05 10:00	169	MODERATE
		[redacted]	5[redacted]/M/ASIAN	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-04-24 14:00	ONGOING	72	MODERATE
		[redacted]	3[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-09-02 09:55	同年*-10-28 15:56	224	MODERATE
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/ACTIVE SUICIDAL IDEATION	精神障害	20[redacted]-09	同年*-10-22	300	MODERATE

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 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	双極１型障害*/BIPOLAR I DISORDER.MIXED EPISODE	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/F/ASIAN	双極性障害*/BIPOLAR AFFECTIVE DISORDER	精神障害	YES	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	筋萎縮*/MUSCLE ATROPHY	筋骨格系および結合組織障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	体重増加*/WEIGHT GAIN	臨床検査	NO	UNRELATED	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	3[redacted]/F/ASIAN	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/ACTIVE SUICIDAL IDEATION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/F/BLACK	不安*/ANXIETY	精神障害	20[redacted]-02-06 08:00	同年*-08-30	98	MODERATE
		[redacted]	4[redacted]/F/CAUC.	躁病*/MANIC EPISODE WITH PSYCHOTIC FEATURES	精神障害	20[redacted]-11-03 15:00	同年*-11-19 10:00	110	SEVERE
		[redacted]	4[redacted]/M/CAUC.	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	20[redacted]-05-28	同年*-11-18	120	MODERATE
		[redacted]	4[redacted]/F/CAUC.	うつ病*/INCREASED DEPRESSION	精神障害	20[redacted]-08-20 08:00	同年*-11-15 08:00	145	MODERATE
		[redacted]	3[redacted]/M/CAUC.	プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	20[redacted]-05-21 18:20	同年*-05-23 13:34	204	SEVERE
		[redacted]	3[redacted]/M/CAUC.	鎮静*/EXCESSIVE POST IM SEDATION	神経系障害	20[redacted]-06-10	同年*-07-15	82	MODERATE
		[redacted]	4[redacted]/F/CAUC.	肝機能検査値上昇*/INCREASE OF LIVER FUNCTION TEST (LFT)	臨床検査	20[redacted]-10-04	ONGOING	1	MILD
		[redacted]	4[redacted]/M/CAUC.	遅発性ジスキネジア*/TARDIVE DYSKINESIA	神経系障害	20[redacted]-05-23	ONGOING	169	SEVERE

同年*

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/F/BLACK	不安*/ANXIETY	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	躁病*/MANIC EPISODE WITH PSYCHOTIC FEATURES	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	うつ病*/INCREASED DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	プリンツメタル狭心症*/PRINZMETALS ANGINA	心臓障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	鎮静*/EXCESSIVE POST IM SEDATION	神経系障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	肝機能検査値上昇*/INCREASE OF LIVER FUNCTION TEST (LFT)	臨床検査	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/M/CAUC.	遅発性ジスキネジア*/TARDIVE DYSKINESIA	神経系障害	YES	DEFINITE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	ウイルス性胃腸炎*/WORSENING OF VIRAL ENTERITIS	感染症および寄生虫症	20[redacted]-03-15	ONGOING	79	MODERATE
		[redacted]	4[redacted]/M/CAUC.	不眠症*/INSOMNIA	精神障害	20[redacted]-05-18 23:30	同年*-06-15 22:00	2	MODERATE
		[redacted]	3[redacted]/F/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-03-11 08:30	同年*-04-15 07:00	112	MODERATE
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR I DEPRESSION	精神障害	20[redacted]-07-18	同年*-09-01	22	MODERATE
		[redacted]	3[redacted]/F/CAUC.	乳癌*/LEFT BREAST ADENOCARCINOMA	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）	20[redacted]-04-10	同年*-05-28	99	MODERATE
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-17 08:00	同年*-06-23 08:00	141	SEVERE
		[redacted]	2[redacted]/M/ASIAN	嗜眠*/LETHARGY	神経系障害	20[redacted]-05-15 21:00	同年*-07-18 21:00	87	SEVERE
		[redacted]	2[redacted]/F/CAUC.	うつ病*/DEPRESSION	精神障害	20[redacted]-01-19 14:00	同年*-08-01	323	MODERATE

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2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	ウイルス性胃腸炎*/WORSENING OF VIRAL ENTERITIS	感染症および寄生虫症	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
		[redacted]	4[redacted]/M/CAUC.	不眠症*/INSOMNIA	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR I DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	乳癌*/LEFT BREAST ADENOCARCINOMA	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）	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/ASIAN	嗜眠*/LETHARGY	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	うつ病*/DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	パーキンソニズム*/PARKANSONIAN EXTRAPYRAMIDAL SYMPTOMS	神経系障害	20[redacted]-08-27	同年*-11-01	75	MODERATE
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-07-31	同年*-11-01	20	MILD
				振戦*/TREMOR	神経系障害	20[redacted]-08-21	同年*-11-01	41	MILD
		[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	20[redacted]-12-13 09:00	ONGOING	54	MILD
				遅発性ジスキネジア*/TARDIVE DYSKINESIA LIP SMACKING	神経系障害	20[redacted]-06-23 09:00	ONGOING	246	MILD
		[redacted]	4[redacted]/M/BLACK	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-03-01	同年*-06-19	62	MODERATE
		[redacted]	2[redacted]/M/BLACK	うつ病*/WORSENING DEPRESSION	精神障害	20[redacted]-03-21 09:00	同年*-04-04 09:00	234	SEVERE
				不眠症*/INSOMNIA	精神障害	20[redacted]-03-21 23:00	同年*-04-04 23:00	234	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	パーキンソニズム*/PARKANSONIAN EXTRAPYRAMIDAL SYMPTOMS	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				振戦*/TREMOR	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	アカシジア*/AKATHISIA	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
				遅発性ジスキネジア*/TARDIVE DYSKINESIA LIP SMACKING	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/M/BLACK	体重増加*/WEIGHT GAIN	臨床検査	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/BLACK	うつ病*/WORSENING DEPRESSION	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				不眠症*/INSOMNIA	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

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PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	6[redacted]/F/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-03-26 08:00	ONGOING	16	MODERATE
		[redacted]	5[redacted]/M/CAUC.	疲労*/FATIGUE	一般・全身障害および投与部位の状態	20[redacted]-01-22	同年*-05-23	58	MILD
				傾眠*/SOMNOLENCE	神経系障害	20[redacted]-02-11	同年*-05-23	78	MILD
				歯ぎしり*/TEETH GRINDING	精神障害	20[redacted]-03-10	同年*-05-23	105	MILD
		[redacted]	3[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	20[redacted]-02-13	同年*-05-22	16	MILD
				振戦*/L HAND AND L FOOT TREMOR	神経系障害	20[redacted]-03-23	同年*-05-22	54	MILD
				食欲亢進*/INCREASED APPETITE	代謝および栄養障害	20[redacted]-03-29	同年*-05-01	60	MILD
				咽頭反射亢進*/INCREASED GAG REFLEX	呼吸器、胸郭および縦隔障害	20[redacted]-04-01	同年*-11-15	63	MODERATE
		[redacted]	5[redacted]/F/BLACK	無力症*/LOSS OF ENERGY	一般・全身障害および投与部位の状態	20[redacted]-02-24 12:00	同年*-06-12 12:00	49	MILD

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	6[redacted]/F/CAUC.	体重増加*/WEIGHT GAIN	臨床検査	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	5[redacted]/M/CAUC.	疲労*/FATIGUE	一般・全身障害および投与部位の状態	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				傾眠*/SOMNOLENCE	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				歯ぎしり*/TEETH GRINDING	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	落ち着きのなさ*/RESTLESSNESS	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				振戦*/L HAND AND L FOOT TREMOR	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				食欲亢進*/INCREASED APPETITE	代謝および栄養障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				咽頭反射亢進*/INCREASED GAG REFLEX	呼吸器、胸郭および縦隔障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	無力症*/LOSS OF ENERGY	一般・全身障害および投与部位の状態	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/F/BLACK	傾眠*/INCREASED DROWSINESS	神経系障害	20[redacted]-02-18	同年*-03-04	9	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-86　投与中止に至った有害事象一覧表［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	4[redacted]/F/BLACK	傾眠*/INCREASED DROWSINESS	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]2C[redacted] 10:20; ANALYSIS DATASET CREATED: [redacted]2C[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＜資料番号 5.3.5.2-01：CT-9.3 より作成＞

表 2.7.4.7-87　DIEPSS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.2.1
Drug-induced Extrapyramidal Symptoms Scale (DIEPSS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample from Japanese Sites)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									_BASELINE__							
PHASE B	ARIP 10-30MG	BASELINE	19	0.95	0.00	1.39	0	4								
		WEEK 4	19	0.74	0.00	1.24	0	4	19	0.95	1.39	-0.21	0.00	0.98	-3	2
		WEEK 8	19	0.84	0.00	1.26	0	4	19	0.95	1.39	-0.11	0.00	1.10	-3	2
PHASE C	ARIP IMD 400/300MG	BASELINE	19	0.84	0.00	1.26	0	4								
		WEEK 4	19	0.79	0.00	1.03	0	3	19	0.84	1.26	-0.05	0.00	0.78	-2	2
		WEEK 8	19	0.37	0.00	0.83	0	3	19	0.84	1.26	-0.47	0.00	1.12	-4	1
		WEEK 12	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2
		WEEK 16	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2
		WEEK 20	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2
		WEEK 24	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2
		WEEK 28	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

FILE: EFF4DL1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:49
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\EFF4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.1　FINAL

表 2.7.4.7-87　DIEPSS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.2.1
Drug-induced Extrapyramidal Symptoms Scale (DIEPSS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample from Japanese Sites)

											CHANGE FROM BASELINE								
		TRIAL							BASELINE			LS MEAN					COMPARISON (VS PLACEBO)		
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1]	(95% CI)[1]	P-VALUE[1]
PHASE D ARIP IMD		BASELINE	9	0.56	0.00	1.13	0	3											0.6827
		WEEK 4	9	0.78	0.00	1.20	0	3	9	0.56	1.13	0.22	0.00	0.67	0	2	0.21(0.22)	0.39	(-0.24,1.03)	0.2092
		WEEK 8	9	0.56	0.00	1.13	0	3	9	0.56	1.13	0.00	0.00	0.00	0	0	-0.07(0.24)	0.47	(-0.23,1.16)	0.1748
		WEEK 12	9	0.56	0.00	1.13	0	3	9	0.56	1.13	0.00	0.00	0.00	0	0	-0.08(0.21)	0.65	(0.02,1.27)	0.0430
		WEEK 16	9	0.56	0.00	1.13	0	3	9	0.56	1.13	0.00	0.00	0.00	0	0	-0.08(0.21)	0.65	(0.02,1.27)	0.0430
		WEEK 20	9	0.56	0.00	1.13	0	3	9	0.56	1.13	0.00	0.00	0.00	0	0	-0.08(0.21)	0.65	(0.02,1.27)	0.0430
		WEEK 24	9	0.56	0.00	1.13	0	3	9	0.56	1.13	0.00	0.00	0.00	0	0	-0.08(0.21)	0.65	(0.02,1.27)	0.0430
		WEEK 28	9	0.22	0.00	0.67	0	2	9	0.56	1.13	-0.33	0.00	1.00	-3	0	-0.45(0.15)	0.25	(-0.19,0.69)	0.2519
		WEEK 32	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00	(NA, NA)	
		WEEK 36	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00	(NA, NA)	
		WEEK 40	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00	(NA, NA)	
		WEEK 44	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00	(NA, NA)	
		WEEK 48	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00	(NA, NA)	
		WEEK 52	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00	(NA, NA)	
	PLACEBO	BASELINE	10	0.80	0.00	1.40	0	4											
		WEEK 4	10	0.60	0.00	1.35	0	4	10	0.80	1.40	-0.20	0.00	0.63	-2	0	-0.19(0.21)			
		WEEK 8	10	0.20	0.00	0.63	0	2	10	0.80	1.40	-0.60	0.00	1.35	-4	0	-0.54(0.23)			
		WEEK 12	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.73(0.20)			
		WEEK 16	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.73(0.20)			
		WEEK 20	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.73(0.20)			
		WEEK 24	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.73(0.20)			
		WEEK 28	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.70(0.14)			
		WEEK 32	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)			

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

FILE: EFF4DL1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:49
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\EFF4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.1　FINAL

表 2.7.4.7-87　DIEPSS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.2.1
Drug-induced Extrapyramidal Symptoms Scale (DIEPSS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample from Japanese Sites)

												CHANGE FROM BASELINE							
		TRIAL							BASELINE							LS MEAN	COMPARISON (VS PLACEBO)		
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 36	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)		
		WEEK 40	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)		
		WEEK 44	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)		
		WEEK 48	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)		
		WEEK 52	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

FILE: EFF4DL1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:49
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\EFF4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-6.1.2.1＞

表 2.7.4.7-88　DIEPSS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.2.2
Drug-induced Extrapyramidal Symptoms Scale (DIEPSS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample from Japanese Sites)

										CHANGE FROM BASELINE					
		TRIAL							BASELINE						
PHASE	TREATMENT	WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	19	0.95	0.00	1.39	0	4								
		WEEK 4	11	0.55	0.00	0.93	0	2	11	0.91	1.30	-0.36	0.00	1.29	-3	2
		WEEK 8	5	1.20	2.00	1.10	0	2	5	1.20	1.64	0.00	0.00	2.12	-3	2
		LAST VISIT	19	0.84	0.00	1.26	0	4	19	0.95	1.39	-0.11	0.00	1.10	-3	2
PHASE C	ARIP IMD 400/300MG	BASELINE	19	0.84	0.00	1.26	0	4								
		WEEK 4	19	0.79	0.00	1.03	0	3	19	0.84	1.26	-0.05	0.00	0.78	-2	2
		WEEK 8	19	0.37	0.00	0.83	0	3	19	0.84	1.26	-0.47	0.00	1.12	-4	1
		WEEK 12	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2
		WEEK 16	1	2.00	2.00		2	2	1	1.00		1.00	1.00		1	1
		LAST VISIT	19	0.68	0.00	1.25	0	4	19	0.84	1.26	-0.16	0.00	1.17	-4	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

FILE: EFF4DO1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:49
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\EFF4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.2　FINAL

表 2.7.4.7-88　DIEPSS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.2.2
Drug-induced Extrapyramidal Symptoms Scale (DIEPSS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample from Japanese Sites)

										CHANGE FROM BASELINE								
		TRIAL							BASELINE							LS MEAN	COMPARISON (VS PLACEBO)	
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	ARIP IMD	BASELINE	9	0.56	0.00	1.13	0	3										0.6827
		WEEK 4	9	0.78	0.00	1.20	0	3	9	0.56	1.13	0.22	0.00	0.67	0	2	0.21(0.22)	0.39 (-0.24,1.03)	0.2092
		WEEK 8	7	0.71	0.00	1.25	0	3	7	0.71	1.25	0.00	0.00	0.00	0	0	-0.03(0.28)	0.55 (-0.24,1.34)	0.1573
		WEEK 12	7	0.71	0.00	1.25	0	3	7	0.71	1.25	0.00	0.00	0.00	0	0	-0.03(0.25)	0.74 (0.04,1.44)	0.0389
		WEEK 16	6	0.83	0.00	1.33	0	3	6	0.83	1.33	0.00	0.00	0.00	0	0	0.06(0.28)	0.77 (-0.02,1.57)	0.0547
		WEEK 20	6	0.83	0.00	1.33	0	3	6	0.83	1.33	0.00	0.00	0.00	0	0	0.06(0.28)	0.77 (-0.02,1.57)	0.0547
		WEEK 24	4	0.75	0.00	1.50	0	3	4	0.75	1.50	0.00	0.00	0.00	0	0	0.04(0.34)	0.73 (-0.20,1.65)	0.1105
		WEEK 28	4	0.00	0.00	0.00	0	0	4	0.75	1.50	-0.75	0.00	1.50	-3	0	-0.79(NA)	0.00 (NA, NA)	
		WEEK 32	4	0.00	0.00	0.00	0	0	4	0.50	1.00	-0.50	0.00	1.00	-2	0	-0.71(NA)	0.00 (NA, NA)	
		WEEK 36	4	0.00	0.00	0.00	0	0	4	0.50	1.00	-0.50	0.00	1.00	-2	0	-0.71(NA)	0.00 (NA, NA)	
		WEEK 40	4	0.00	0.00	0.00	0	0	4	0.50	1.00	-0.50	0.00	1.00	-2	0	-0.77(NA)	0.00 (NA, NA)	
		WEEK 44	4	0.00	0.00	0.00	0	0	4	0.50	1.00	-0.50	0.00	1.00	-2	0	-0.77(NA)	0.00 (NA, NA)	
		WEEK 48	4	0.00	0.00	0.00	0	0	4	0.50	1.00	-0.50	0.00	1.00	-2	0	-0.67(NA)	0.00 (NA, NA)	
		WEEK 52	4	0.00	0.00	0.00	0	0	4	0.50	1.00	-0.50	0.00	1.00	-2	0	-0.36(NA)	0.00 (NA, NA)	
		LAST VISIT	9	0.00	0.00	0.00	0	0	9	0.56	1.13	-0.56	0.00	1.13	-3	0	-0.68(NA)	0.00 (NA, NA)	
	PLACEBO	BASELINE	10	0.80	0.00	1.40	0	4											
		WEEK 4	10	0.60	0.00	1.35	0	4	10	0.80	1.40	-0.20	0.00	0.63	-2	0	-0.19(0.21)		
		WEEK 8	10	0.20	0.00	0.63	0	2	10	0.80	1.40	-0.60	0.00	1.35	-4	0	-0.58(0.24)		
		WEEK 12	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.78(0.21)		
		WEEK 16	9	0.00	0.00	0.00	0	0	9	0.67	1.41	-0.67	0.00	1.41	-4	0	-0.71(0.23)		
		WEEK 20	9	0.00	0.00	0.00	0	0	9	0.67	1.41	-0.67	0.00	1.41	-4	0	-0.71(0.23)		
		WEEK 24	9	0.00	0.00	0.00	0	0	9	0.67	1.41	-0.67	0.00	1.41	-4	0	-0.68(0.23)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.2　FINAL

表 2.7.4.7-88　DIEPSS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

OPC14597 3 OF 3
PROTOCOL 31-08-250

CT-6.1.2.2
Drug-induced Extrapyramidal Symptoms Scale (DIEPSS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample from Japanese Sites)

												CHANGE FROM BASELINE							
		TRIAL							BASELINE							LS MEAN	COMPARISON (VS PLACEBO)		
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 28	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.79(NA)		
		WEEK 32	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.71(NA)		
		WEEK 36	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.71(NA)		
		WEEK 40	9	0.00	0.00	0.00	0	0	9	0.89	1.45	-0.89	0.00	1.45	-4	0	-0.77(NA)		
		WEEK 44	9	0.00	0.00	0.00	0	0	9	0.89	1.45	-0.89	0.00	1.45	-4	0	-0.77(NA)		
		WEEK 48	8	0.00	0.00	0.00	0	0	8	0.75	1.49	-0.75	0.00	1.49	-4	0	-0.67(NA)		
		WEEK 52	7	0.00	0.00	0.00	0	0	7	0.29	0.76	-0.29	0.00	0.76	-2	0	-0.36(NA)		
		LAST VISIT	10	0.00	0.00	0.00	0	0	10	0.80	1.40	-0.80	0.00	1.40	-4	0	-0.68(NA)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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＜資料番号 5.3.5.1-01：CT-6.1.2.2＞

表 2.7.4.7-89　AIMS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.3.1
Abnormal Involuntary Movement Scale (AIMS) Movement Rating Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									BASELINE							
PHASE B	ARIP 10-30MG	BASELINE	265	0.13	0.00	0.68	0	7								
		WEEK 4	263	0.13	0.00	0.50	0	4	263	0.13	0.69	-0.00	0.00	0.73	-6	3
		WEEK 8	264	0.13	0.00	0.53	0	4	264	0.13	0.69	0.00	0.00	0.75	-6	4
PHASE C	ARIP IMD 400/300MG	BASELINE	264	0.13	0.00	0.53	0	4								
		WEEK 4	257	0.12	0.00	0.48	0	4	256	0.13	0.54	-0.01	0.00	0.42	-4	2
		WEEK 8	265	0.09	0.00	0.50	0	5	264	0.13	0.53	-0.04	0.00	0.50	-3	4
		WEEK 12	265	0.14	0.00	0.71	0	8	264	0.13	0.53	0.01	0.00	0.68	-4	6
		WEEK 16	265	0.11	0.00	0.50	0	4	264	0.13	0.53	-0.03	0.00	0.51	-4	3
		WEEK 20	265	0.10	0.00	0.48	0	4	264	0.13	0.53	-0.03	0.00	0.51	-4	3
		WEEK 24	265	0.09	0.00	0.42	0	4	264	0.13	0.53	-0.05	0.00	0.50	-4	3
		WEEK 28	265	0.09	0.00	0.42	0	4	264	0.13	0.53	-0.05	0.00	0.50	-4	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

表 2.7.4.7-89　AIMS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.3.1
Abnormal Involuntary Movement Scale (AIMS) Movement Rating Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE N	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: LS MEAN	LS MEAN MEDIAN	LS MEAN SD	LS MEAN MIN	LS MEAN MAX	LS MEAN (SE)[1]	COMPARISON (VS PLACEBO): DIFF[1] (95% CI)[1]	COMPARISON (VS PLACEBO): P-VALUE[1]
PHASE D ARIP IMD		BASELINE	132	0.09	0.00	0.45	0	4											0.8746
		WEEK 4	127	0.06	0.00	0.26	0	2	127	0.06	0.30	-0.01	0.00	0.37	-2	2	-0.01(0.02)	-0.01 (-0.07,0.06)	0.8502
		WEEK 8	129	0.16	0.00	0.69	0	6	129	0.06	0.30	0.10	0.00	0.69	-2	5	0.10(0.04)	0.12 (0.00,0.24)	0.0494
		WEEK 12	129	0.16	0.00	0.68	0	5	129	0.06	0.30	0.09	0.00	0.67	-2	4	0.09(0.04)	0.11 (-0.00,0.23)	0.0582
		WEEK 16	129	0.19	0.00	0.76	0	5	129	0.06	0.30	0.12	0.00	0.75	-2	4	0.12(0.05)	0.13 (-0.01,0.26)	0.0606
		WEEK 20	129	0.16	0.00	0.73	0	6	129	0.06	0.30	0.09	0.00	0.71	-2	5	0.09(0.05)	0.10 (-0.03,0.23)	0.1285
		WEEK 24	129	0.19	0.00	0.87	0	8	129	0.06	0.30	0.12	0.00	0.83	-2	7	0.12(0.05)	0.13 (-0.02,0.28)	0.0820
		WEEK 28	129	0.22	0.00	0.90	0	8	129	0.06	0.30	0.16	0.00	0.88	-2	7	0.15(0.06)	0.18 (0.02,0.33)	0.0252
		WEEK 32	129	0.21	0.00	0.89	0	8	129	0.06	0.30	0.15	0.00	0.87	-2	7	0.14(0.06)	0.18 (0.02,0.33)	0.0241
		WEEK 36	129	0.21	0.00	0.89	0	8	129	0.06	0.30	0.15	0.00	0.87	-2	7	0.14(0.06)	0.18 (0.02,0.33)	0.0241
		WEEK 40	129	0.22	0.00	0.88	0	8	129	0.06	0.30	0.16	0.00	0.86	-2	7	0.15(0.05)	0.18 (0.03,0.33)	0.0225
		WEEK 44	129	0.20	0.00	0.89	0	8	129	0.06	0.30	0.14	0.00	0.86	-2	7	0.14(0.05)	0.16 (0.01,0.31)	0.0377
		WEEK 48	129	0.23	0.00	0.92	0	8	129	0.06	0.30	0.17	0.00	0.90	-2	7	0.17(0.06)	0.19 (0.03,0.35)	0.0177
		WEEK 52	129	0.25	0.00	1.02	0	8	129	0.06	0.30	0.19	0.00	1.01	-2	7	0.18(0.06)	0.21 (0.03,0.38)	0.0209
	PLACEBO	BASELINE	133	0.08	0.00	0.39	0	3											
		WEEK 4	130	0.07	0.00	0.31	0	2	130	0.08	0.39	-0.02	0.00	0.30	-3	1	-0.01(0.02)		
		WEEK 8	131	0.05	0.00	0.29	0	2	131	0.08	0.39	-0.03	0.00	0.25	-2	1	-0.03(0.04)		
		WEEK 12	132	0.05	0.00	0.26	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.04)		
		WEEK 16	132	0.07	0.00	0.33	0	2	132	0.08	0.39	-0.02	0.00	0.33	-2	2	-0.01(0.05)		
		WEEK 20	132	0.07	0.00	0.33	0	2	132	0.08	0.39	-0.02	0.00	0.30	-2	1	-0.01(0.05)		
		WEEK 24	132	0.07	0.00	0.33	0	2	132	0.08	0.39	-0.02	0.00	0.30	-2	1	-0.01(0.05)		
		WEEK 28	132	0.05	0.00	0.28	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.06)		
		WEEK 32	132	0.05	0.00	0.27	0	2	132	0.08	0.39	-0.04	0.00	0.29	-2	1	-0.03(0.05)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.3.1　FINAL

表 2.7.4.7-89　AIMS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

OPC14597 3 OF 3
PROTOCOL 31-08-250

CT-6.3.1
Abnormal Involuntary Movement Scale (AIMS) Movement Rating Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample)

										CHANGE FROM BASELINE						
		TRIAL		BASELINE									LS MEAN	COMPARISON (VS PLACEBO)		
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 36	132	0.05	0.00	0.27	0	2	132	0.08	0.39	-0.04	0.00	0.29	-2	1	-0.03(0.05)		
		WEEK 40	132	0.05	0.00	0.28	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.05)		
		WEEK 44	132	0.05	0.00	0.28	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.05)		
		WEEK 48	132	0.05	0.00	0.28	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.06)		
		WEEK 52	132	0.05	0.00	0.28	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.06)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

FILE: EFF4ML1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:46
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.3.1　FINAL

＜資料番号 5.3.5.1-01：CT-6.3.1＞

表 2.7.4.7-90　AIMS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.3.2

Abnormal Involuntary Movement Scale (AIMS) Movement Rating Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									_BASELINE__							
PHASE B	ARIP 10-30MG	BASELINE	265	0.13	0.00	0.68	0	7								
		WEEK 4	191	0.08	0.00	0.34	0	3	191	0.08	0.53	-0.01	0.00	0.61	-6	3
		WEEK 8	74	0.09	0.00	0.53	0	4	74	0.15	0.81	-0.05	0.00	0.98	-6	4
		LAST VISIT	264	0.13	0.00	0.53	0	4	264	0.13	0.69	0.00	0.00	0.75	-6	4
PHASE C	ARIP IMD 400/300MG	BASELINE	264	0.13	0.00	0.53	0	4								
		WEEK 4	257	0.12	0.00	0.48	0	4	256	0.13	0.54	-0.01	0.00	0.42	-4	2
		WEEK 8	260	0.09	0.00	0.50	0	5	259	0.14	0.54	-0.04	0.00	0.50	-3	4
		WEEK 12	256	0.14	0.00	0.72	0	8	255	0.14	0.54	0.01	0.00	0.69	-4	6
		WEEK 16	64	0.20	0.00	0.78	0	4	64	0.14	0.59	0.06	0.00	0.35	-1	2
		WEEK 20	37	0.30	0.00	0.97	0	4	37	0.22	0.75	0.08	0.00	0.43	-1	2
		WEEK 24	19	0.26	0.00	0.93	0	4	19	0.37	1.01	-0.11	0.00	0.32	-1	0
		WEEK 28	6	0.00	0.00	0.00	0	0	6	0.00	0.00	0.00	0.00	0.00	0	0
		LAST VISIT	265	0.09	0.00	0.42	0	4	264	0.13	0.53	-0.05	0.00	0.50	-4	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.3.2　FINAL

表 2.7.4.7-90　AIMS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.3.2
Abnormal Involuntary Movement Scale (AIMS) Movement Rating Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample)

											CHANGE FROM BASELINE									
		TRIAL							BASELINE								LS MEAN	COMPARISON (VS PLACEBO)	
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	ARIP IMD	BASELINE	132	0.09	0.00	0.45	0	4											0.8746
		WEEK 4	124	0.04	0.00	0.20	0	1	124	0.06	0.31	-0.02	0.00	0.32	-2	1	-0.03(0.02)	-0.01 (-0.07,0.04)	0.5917
		WEEK 8	103	0.15	0.00	0.71	0	6	103	0.06	0.27	0.09	0.00	0.67	-2	5	0.08(0.05)	0.11 (-0.02,0.25)	0.1058
		WEEK 12	93	0.09	0.00	0.54	0	5	93	0.06	0.29	0.02	0.00	0.47	-1	4	0.02(0.04)	0.05 (-0.06,0.16)	0.4001
		WEEK 16	89	0.07	0.00	0.45	0	4	89	0.03	0.18	0.03	0.00	0.46	-1	4	0.03(0.04)	0.01 (-0.11,0.12)	0.9086
		WEEK 20	82	0.09	0.00	0.67	0	6	82	0.05	0.22	0.04	0.00	0.58	-1	5	0.02(0.05)	-0.02 (-0.15,0.11)	0.7755
		WEEK 24	77	0.14	0.00	0.93	0	8	77	0.05	0.22	0.09	0.00	0.81	-1	7	0.07(0.06)	0.01 (-0.18,0.20)	0.9249
		WEEK 28	79	0.19	0.00	0.96	0	8	79	0.05	0.22	0.14	0.00	0.89	-1	7	0.14(0.08)	0.17 (-0.07,0.42)	0.1551
		WEEK 32	76	0.08	0.00	0.32	0	2	76	0.03	0.16	0.05	0.00	0.36	-1	2	0.04(0.03)	0.08 (-0.01,0.16)	0.0683
		WEEK 36	72	0.07	0.00	0.31	0	2	72	0.01	0.12	0.06	0.00	0.33	-1	2	0.04(0.03)	0.07 (-0.02,0.15)	0.1106
		WEEK 40	70	0.09	0.00	0.28	0	1	70	0.01	0.12	0.07	0.00	0.31	-1	1	0.06(0.03)	0.07 (-0.01,0.16)	0.0929
		WEEK 44	69	0.06	0.00	0.29	0	2	69	0.01	0.12	0.04	0.00	0.32	-1	2	0.03(0.03)	0.06 (-0.03,0.14)	0.1859
		WEEK 48	68	0.12	0.00	0.47	0	3	68	0.01	0.12	0.10	0.00	0.49	-1	3	0.09(0.05)	0.12 (-0.03,0.26)	0.1120
		WEEK 52	64	0.16	0.00	0.80	0	5	64	0.02	0.13	0.14	0.00	0.81	-1	5	0.13(0.08)	0.16 (-0.10,0.41)	0.2341
		LAST VISIT	129	0.25	0.00	1.02	0	8	129	0.06	0.30	0.19	0.00	1.01	-2	7	0.18(0.06)	0.21 (0.03,0.38)	0.0209
	PLACEBO	BASELINE	133	0.08	0.00	0.39	0	3											
		WEEK 4	121	0.06	0.00	0.27	0	2	121	0.07	0.37	-0.02	0.00	0.32	-3	1	-0.01(0.02)		
		WEEK 8	100	0.05	0.00	0.26	0	2	100	0.09	0.40	-0.04	0.00	0.28	-2	1	-0.03(0.05)		
		WEEK 12	85	0.04	0.00	0.19	0	1	85	0.06	0.28	-0.02	0.00	0.27	-2	1	-0.02(0.04)		
		WEEK 16	79	0.06	0.00	0.33	0	2	79	0.04	0.19	0.03	0.00	0.28	-1	2	0.03(0.04)		
		WEEK 20	71	0.04	0.00	0.26	0	2	71	0.01	0.12	0.03	0.00	0.17	0	1	0.04(0.05)		
		WEEK 24	62	0.05	0.00	0.28	0	2	62	0.02	0.13	0.03	0.00	0.18	0	1	0.06(0.07)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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表 2.7.4.7-90　AIMS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.3.2
Abnormal Involuntary Movement Scale (AIMS) Movement Rating Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample)

												CHANGE FROM BASELINE								
		TRIAL		BASELINE												LS MEAN	COMPARISON (VS PLACEBO)		
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 28	57	0.02	0.00	0.13	0	1	57	0.05	0.29	-0.04	0.00	0.26	-2	0	-0.04(0.09)		
		WEEK 32	56	0.00	0.00	0.00	0	0	56	0.05	0.30	-0.05	0.00	0.30	-2	0	-0.04(0.03)		
		WEEK 36	52	0.00	0.00	0.00	0	0	52	0.06	0.31	-0.06	0.00	0.31	-2	0	-0.03(0.03)		
		WEEK 40	51	0.02	0.00	0.14	0	1	51	0.06	0.31	-0.04	0.00	0.28	-2	0	-0.02(0.03)		
		WEEK 44	46	0.00	0.00	0.00	0	0	46	0.04	0.29	-0.04	0.00	0.29	-2	0	-0.03(0.03)		
		WEEK 48	43	0.00	0.00	0.00	0	0	43	0.05	0.30	-0.05	0.00	0.30	-2	0	-0.03(0.06)		
		WEEK 52	39	0.00	0.00	0.00	0	0	39	0.05	0.32	-0.05	0.00	0.32	-2	0	-0.03(0.10)		
		LAST VISIT	132	0.05	0.00	0.28	0	2	132	0.08	0.39	-0.03	0.00	0.27	-2	1	-0.03(0.06)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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＜資料番号 5.3.5.1-01：CT-6.3.2＞

表 2.7.4.7-91　BAS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.2.1
Barnes Akathisia (BARS) Global Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									_BASELINE__							
PHASE B	ARIP 10-30MG	BASELINE	265	0.23	0.00	0.63	0	3								
		WEEK 4	263	0.29	0.00	0.68	0	3	263	0.24	0.63	0.05	0.00	0.72	-3	3
		WEEK 8	264	0.25	0.00	0.61	0	3	264	0.23	0.63	0.01	0.00	0.70	-3	3
PHASE C	ARIP IMD 400/300MG	BASELINE	264	0.25	0.00	0.61	0	3								
		WEEK 4	257	0.21	0.00	0.64	0	5	256	0.25	0.62	-0.04	0.00	0.60	-3	4
		WEEK 8	265	0.23	0.00	0.61	0	3	264	0.25	0.61	-0.02	0.00	0.63	-2	3
		WEEK 12	265	0.26	0.00	0.65	0	3	264	0.25	0.61	0.02	0.00	0.65	-3	3
		WEEK 16	265	0.24	0.00	0.63	0	3	264	0.25	0.61	-0.00	0.00	0.65	-3	3
		WEEK 20	265	0.23	0.00	0.60	0	3	264	0.25	0.61	-0.02	0.00	0.62	-3	3
		WEEK 24	265	0.23	0.00	0.61	0	3	264	0.25	0.61	-0.02	0.00	0.62	-2	3
		WEEK 28	265	0.23	0.00	0.62	0	3	264	0.25	0.61	-0.01	0.00	0.61	-2	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

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表 2.7.4.7-91　BAS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.2.1
Barnes Akathisia (BARS) Global Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample)

										CHANGE FROM BASELINE										
		TRIAL							BASELINE								LS MEAN	COMPARISON (VS PLACEBO)	
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	ARIP IMD	BASELINE	132	0.30	0.00	0.70	0	3											0.0708
		WEEK 4	127	0.23	0.00	0.63	0	4	127	0.28	0.67	-0.05	0.00	0.73	-3	4	-0.01(0.04)	0.07 (-0.05,0.19)	0.2323
		WEEK 8	129	0.27	0.00	0.82	0	5	129	0.29	0.69	-0.02	0.00	0.92	-3	5	0.03(0.05)	0.16 (0.01,0.30)	0.0410
		WEEK 12	129	0.30	0.00	0.83	0	5	129	0.29	0.69	0.02	0.00	0.92	-3	5	0.06(0.05)	0.16 (0.01,0.31)	0.0429
		WEEK 16	129	0.28	0.00	0.83	0	5	129	0.29	0.69	-0.01	0.00	0.92	-3	5	0.03(0.05)	0.14 (-0.01,0.29)	0.0613
		WEEK 20	129	0.33	0.00	0.85	0	5	129	0.29	0.69	0.04	0.00	0.89	-3	5	0.08(0.05)	0.19 (0.04,0.34)	0.0121
		WEEK 24	129	0.34	0.00	0.90	0	5	129	0.29	0.69	0.05	0.00	0.95	-3	5	0.10(0.06)	0.20 (0.04,0.37)	0.0146
		WEEK 28	129	0.30	0.00	0.84	0	5	129	0.29	0.69	0.02	0.00	0.89	-3	5	0.06(0.05)	0.16 (0.01,0.32)	0.0333
		WEEK 32	129	0.28	0.00	0.84	0	5	129	0.29	0.69	-0.01	0.00	0.88	-3	5	0.03(0.05)	0.15 (-0.00,0.30)	0.0527
		WEEK 36	129	0.33	0.00	0.88	0	5	129	0.29	0.69	0.05	0.00	0.92	-3	5	0.09(0.06)	0.20 (0.05,0.36)	0.0114
		WEEK 40	129	0.38	0.00	0.95	0	5	129	0.29	0.69	0.09	0.00	0.98	-3	5	0.13(0.06)	0.25 (0.08,0.41)	0.0042
		WEEK 44	129	0.37	0.00	0.95	0	5	129	0.29	0.69	0.09	0.00	0.94	-3	5	0.12(0.06)	0.23 (0.07,0.40)	0.0059
		WEEK 48	129	0.35	0.00	0.93	0	5	129	0.29	0.69	0.06	0.00	0.94	-3	5	0.10(0.06)	0.20 (0.03,0.36)	0.0194
		WEEK 52	129	0.34	0.00	0.91	0	5	129	0.29	0.69	0.05	0.00	0.91	-3	5	0.09(0.06)	0.18 (0.02,0.34)	0.0272
	PLACEBO	BASELINE	133	0.17	0.00	0.52	0	3											
		WEEK 4	130	0.12	0.00	0.39	0	2	130	0.15	0.51	-0.04	0.00	0.50	-2	2	-0.08(0.04)		
		WEEK 8	131	0.08	0.00	0.35	0	2	131	0.17	0.53	-0.08	0.00	0.54	-3	2	-0.13(0.05)		
		WEEK 12	132	0.11	0.00	0.40	0	2	132	0.17	0.53	-0.06	0.00	0.52	-3	2	-0.10(0.05)		
		WEEK 16	132	0.10	0.00	0.37	0	2	132	0.17	0.53	-0.07	0.00	0.50	-3	2	-0.11(0.05)		
		WEEK 20	132	0.09	0.00	0.36	0	2	132	0.17	0.53	-0.08	0.00	0.55	-3	2	-0.11(0.05)		
		WEEK 24	132	0.10	0.00	0.41	0	3	132	0.17	0.53	-0.07	0.00	0.58	-3	3	-0.11(0.06)		
		WEEK 28	132	0.10	0.00	0.37	0	2	132	0.17	0.53	-0.07	0.00	0.56	-3	2	-0.11(0.05)		
		WEEK 32	132	0.09	0.00	0.36	0	2	132	0.17	0.53	-0.08	0.00	0.55	-3	2	-0.12(0.05)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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表 2.7.4.7-91　BAS のベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.2.1
Barnes Akathisia (BARS) Global Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE N	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX	LS MEAN (SE)[1]	COMPARISON (VS PLACEBO): DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 36	132	0.09	0.00	0.36	0	2	132	0.17	0.53	-0.08	0.00	0.55	-3	2	-0.12(0.06)		
		WEEK 40	132	0.09	0.00	0.36	0	2	132	0.17	0.53	-0.08	0.00	0.55	-3	2	-0.11(0.06)		
		WEEK 44	132	0.09	0.00	0.36	0	2	132	0.17	0.53	-0.08	0.00	0.55	-3	2	-0.11(0.06)		
		WEEK 48	132	0.11	0.00	0.40	0	2	132	0.17	0.53	-0.06	0.00	0.58	-3	2	-0.10(0.06)		
		WEEK 52	132	0.11	0.00	0.40	0	2	132	0.17	0.53	-0.05	0.00	0.58	-3	2	-0.09(0.06)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-6.2.1＞

表 2.7.4.7-92　BAS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.2.2
Barnes Akathisia (BARS) Global Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									_BASELINE__							
PHASE B	ARIP 10-30MG	BASELINE	265	0.23	0.00	0.63	0	3								
		WEEK 4	191	0.31	0.00	0.70	0	3	191	0.24	0.66	0.07	0.00	0.78	-3	3
		WEEK 8	74	0.24	0.00	0.64	0	2	74	0.20	0.57	0.04	0.00	0.61	-2	2
		LAST VISIT	264	0.25	0.00	0.61	0	3	264	0.23	0.63	0.01	0.00	0.70	-3	3
PHASE C	ARIP IMD 400/300MG	BASELINE	264	0.25	0.00	0.61	0	3								
		WEEK 4	257	0.21	0.00	0.64	0	5	256	0.25	0.62	-0.04	0.00	0.60	-3	4
		WEEK 8	260	0.23	0.00	0.62	0	3	259	0.25	0.62	-0.02	0.00	0.63	-2	3
		WEEK 12	257	0.26	0.00	0.65	0	3	256	0.25	0.62	0.01	0.00	0.64	-3	3
		WEEK 16	64	0.33	0.00	0.74	0	3	64	0.31	0.69	0.02	0.00	0.79	-3	3
		WEEK 20	37	0.24	0.00	0.60	0	2	37	0.32	0.71	-0.08	0.00	0.80	-3	2
		WEEK 24	19	0.26	0.00	0.65	0	2	19	0.68	0.95	-0.42	0.00	0.61	-2	0
		WEEK 28	6	0.50	0.00	0.84	0	2	6	0.67	1.03	-0.17	0.00	0.41	-1	0
		LAST VISIT	265	0.23	0.00	0.62	0	3	264	0.25	0.61	-0.01	0.00	0.61	-2	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

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表 2.7.4.7-92　BAS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.2.2
Barnes Akathisia (BARS) Global Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample)

											CHANGE FROM BASELINE									
		TRIAL							BASELINE			LS MEAN					COMPARISON (VS PLACEBO)		
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1]	(95% CI)[1]	P-VALUE[1]
PHASE D	ARIP IMD	BASELINE	132	0.30	0.00	0.70	0	3												0.0708
		WEEK 4	124	0.20	0.00	0.54	0	3	124	0.28	0.68	-0.08	0.00	0.65	-3	3	-0.04(0.04)	0.06	(-0.04,0.17)	0.2357
		WEEK 8	103	0.23	0.00	0.73	0	5	103	0.25	0.62	-0.02	0.00	0.79	-2	5	0.01(0.05)	0.14	(-0.01,0.29)	0.0655
		WEEK 12	93	0.19	0.00	0.54	0	2	93	0.24	0.60	-0.04	0.00	0.62	-2	2	-0.01(0.04)	0.12	(-0.00,0.25)	0.0503
		WEEK 16	89	0.16	0.00	0.50	0	2	89	0.24	0.60	-0.08	0.00	0.57	-2	2	-0.05(0.04)	0.09	(-0.02,0.20)	0.1186
		WEEK 20	82	0.21	0.00	0.54	0	2	82	0.24	0.62	-0.04	0.00	0.53	-2	2	-0.00(0.04)	0.15	(0.02,0.27)	0.0219
		WEEK 24	77	0.25	0.00	0.67	0	3	77	0.23	0.60	0.01	0.00	0.66	-2	3	0.04(0.06)	0.18	(-0.01,0.36)	0.0567
		WEEK 28	79	0.20	0.00	0.56	0	2	79	0.23	0.60	-0.03	0.00	0.51	-2	2	0.00(0.05)	0.11	(-0.04,0.25)	0.1412
		WEEK 32	76	0.13	0.00	0.47	0	2	76	0.25	0.64	-0.12	0.00	0.46	-2	1	-0.08(0.04)	0.05	(-0.07,0.17)	0.4032
		WEEK 36	72	0.21	0.00	0.58	0	2	72	0.24	0.62	-0.03	0.00	0.60	-2	2	0.01(0.05)	0.11	(-0.05,0.26)	0.1880
		WEEK 40	70	0.30	0.00	0.79	0	3	70	0.21	0.59	0.09	0.00	0.74	-2	3	0.11(0.07)	0.19	(-0.02,0.40)	0.0788
		WEEK 44	69	0.29	0.00	0.79	0	3	69	0.22	0.59	0.07	0.00	0.65	-2	3	0.09(0.07)	0.14	(-0.07,0.35)	0.1840
		WEEK 48	68	0.21	0.00	0.66	0	3	68	0.22	0.59	-0.01	0.00	0.53	-2	2	0.01(0.06)	0.04	(-0.13,0.22)	0.6151
		WEEK 52	64	0.20	0.00	0.60	0	3	64	0.23	0.61	-0.03	0.00	0.44	-2	1	-0.01(0.04)	0.03	(-0.11,0.17)	0.6416
		LAST VISIT	129	0.34	0.00	0.91	0	5	129	0.29	0.69	0.05	0.00	0.91	-3	5	0.09(0.06)	0.18	(0.02,0.34)	0.0272
	PLACEBO	BASELINE	133	0.17	0.00	0.52	0	3												
		WEEK 4	121	0.10	0.00	0.35	0	2	121	0.17	0.52	-0.07	0.00	0.48	-2	2	-0.10(0.04)			
		WEEK 8	100	0.07	0.00	0.33	0	2	100	0.18	0.54	-0.11	0.00	0.53	-3	2	-0.14(0.05)			
		WEEK 12	85	0.05	0.00	0.30	0	2	85	0.15	0.50	-0.11	0.00	0.51	-3	2	-0.14(0.05)			
		WEEK 16	79	0.04	0.00	0.25	0	2	79	0.14	0.47	-0.10	0.00	0.44	-3	1	-0.14(0.04)			
		WEEK 20	71	0.03	0.00	0.24	0	2	71	0.14	0.49	-0.11	0.00	0.55	-3	2	-0.15(0.05)			
		WEEK 24	62	0.05	0.00	0.38	0	3	62	0.16	0.52	-0.11	0.00	0.66	-3	3	-0.14(0.07)			

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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表 2.7.4.7-92　BAS のベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.2.2
Barnes Akathisia (BARS) Global Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample)

											CHANGE FROM BASELINE							
		TRIAL							BASELINE							LS MEAN	COMPARISON (VS PLACEBO)	
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 28	57	0.05	0.00	0.29	0	2	57	0.12	0.47	-0.07	0.00	0.56	-3	2	-0.11(0.06)		
		WEEK 32	56	0.04	0.00	0.27	0	2	56	0.13	0.47	-0.09	0.00	0.55	-3	2	-0.14(0.05)		
		WEEK 36	52	0.04	0.00	0.28	0	2	52	0.08	0.27	-0.04	0.00	0.39	-1	2	-0.09(0.06)		
		WEEK 40	51	0.04	0.00	0.28	0	2	51	0.08	0.27	-0.04	0.00	0.40	-1	2	-0.08(0.08)		
		WEEK 44	46	0.04	0.00	0.29	0	2	46	0.07	0.25	-0.02	0.00	0.39	-1	2	-0.05(0.08)		
		WEEK 48	43	0.05	0.00	0.30	0	2	43	0.05	0.21	0.00	0.00	0.38	-1	2	-0.04(0.07)		
		WEEK 52	39	0.03	0.00	0.16	0	1	39	0.03	0.16	0.00	0.00	0.23	-1	1	-0.04(0.06)		
		LAST VISIT	132	0.11	0.00	0.40	0	2	132	0.17	0.53	-0.05	0.00	0.58	-3	2	-0.09(0.06)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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＜資料番号 5.3.5.1-01：CT-6.2.2＞

表 2.7.4.7-93　SAS 合計スコアのベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.1.1
Simpson-Angus Scale (SAS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample from non-Japanese Sites)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									_BASELINE__							
PHASE B	ARIP 10-30MG	BASELINE	246	10.46	10.00	1.10	10	19								
		WEEK 4	244	10.41	10.00	1.05	10	18	244	10.46	1.10	-0.05	0.00	1.09	-5	8
		WEEK 8	245	10.42	10.00	1.05	10	18	245	10.46	1.10	-0.03	0.00	1.04	-5	8
PHASE C	ARIP IMD 400/300MG	BASELINE	245	10.42	10.00	1.05	10	18								
		WEEK 4	238	10.39	10.00	1.07	10	18	237	10.43	1.05	-0.03	0.00	0.82	-3	5
		WEEK 8	246	10.41	10.00	1.10	10	18	245	10.42	1.05	-0.01	0.00	0.93	-3	5
		WEEK 12	246	10.43	10.00	1.09	10	18	245	10.42	1.05	0.00	0.00	1.02	-6	6
		WEEK 16	246	10.41	10.00	1.11	10	18	245	10.42	1.05	-0.02	0.00	0.99	-6	6
		WEEK 20	246	10.37	10.00	1.05	10	18	245	10.42	1.05	-0.05	0.00	0.96	-6	5
		WEEK 24	246	10.41	10.00	1.14	10	18	245	10.42	1.05	-0.02	0.00	1.08	-6	6
		WEEK 28	246	10.41	10.00	1.14	10	18	245	10.42	1.05	-0.01	0.00	1.08	-6	6

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

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表 2.7.4.7-93　SAS 合計スコアのベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.1.1
Simpson-Angus Scale (SAS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample from non-Japanese Sites)

				CHANGE FROM BASELINE														
		TRIAL							BASELINE							LS MEAN	COMPARISON (VS PLACEBO)	
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D ARIP IMD		BASELINE	123	10.50	10.00	1.34	10	18										0.1983
		WEEK 4	118	10.43	10.00	0.91	10	15	118	10.43	1.17	0.00	0.00	0.98	-6	3	0.04(0.07)	0.12 (-0.07,0.32)	0.2203
		WEEK 8	120	10.46	10.00	1.17	10	17	120	10.43	1.16	0.03	0.00	1.15	-4	5	0.06(0.09)	0.12 (-0.12,0.36)	0.3289
		WEEK 12	120	10.36	10.00	0.86	10	14	120	10.43	1.16	-0.08	0.00	1.01	-5	4	-0.04(0.06)	0.09 (-0.07,0.26)	0.2708
		WEEK 16	120	10.40	10.00	0.94	10	15	120	10.43	1.16	-0.03	0.00	1.04	-6	4	0.00(0.06)	0.18 (0.00,0.35)	0.0463
		WEEK 20	120	10.42	10.00	0.96	10	15	120	10.43	1.16	-0.02	0.00	1.04	-6	4	0.02(0.06)	0.19 (0.02,0.37)	0.0321
		WEEK 24	120	10.46	10.00	1.02	10	15	120	10.43	1.16	0.03	0.00	1.05	-6	4	0.06(0.07)	0.21 (0.02,0.40)	0.0324
		WEEK 28	120	10.43	10.00	0.98	10	15	120	10.43	1.16	-0.01	0.00	1.07	-6	4	0.03(0.06)	0.22 (0.04,0.40)	0.0175
		WEEK 32	120	10.44	10.00	1.03	10	15	120	10.43	1.16	0.01	0.00	1.06	-6	4	0.04(0.07)	0.18 (-0.01,0.38)	0.0655
		WEEK 36	120	10.50	10.00	1.02	10	15	120	10.43	1.16	0.07	0.00	1.03	-4	4	0.10(0.07)	0.25 (0.06,0.43)	0.0091
		WEEK 40	120	10.50	10.00	1.05	10	15	120	10.43	1.16	0.07	0.00	1.12	-6	4	0.10(0.07)	0.25 (0.06,0.45)	0.0109
		WEEK 44	120	10.55	10.00	1.09	10	15	120	10.43	1.16	0.12	0.00	0.96	-3	4	0.15(0.07)	0.31 (0.13,0.50)	0.0008
		WEEK 48	120	10.49	10.00	1.06	10	15	120	10.43	1.16	0.06	0.00	1.10	-6	4	0.09(0.07)	0.22 (0.01,0.42)	0.0387
		WEEK 52	120	10.48	10.00	1.05	10	15	120	10.43	1.16	0.05	0.00	0.99	-3	4	0.08(0.07)	0.22 (0.03,0.41)	0.0230
	PLACEBO	BASELINE	123	10.32	10.00	0.89	10	15										
		WEEK 4	120	10.26	10.00	0.85	10	16	120	10.31	0.89	-0.05	0.00	0.98	-5	6	-0.09(0.07)		
		WEEK 8	121	10.29	10.00	0.93	10	17	121	10.32	0.90	-0.03	0.00	1.09	-5	7	-0.06(0.09)		
		WEEK 12	122	10.22	10.00	0.66	10	14	122	10.32	0.89	-0.10	0.00	0.80	-5	2	-0.13(0.06)		
		WEEK 16	122	10.18	10.00	0.60	10	14	122	10.32	0.89	-0.14	0.00	0.83	-5	2	-0.17(0.06)		
		WEEK 20	122	10.18	10.00	0.60	10	14	122	10.32	0.89	-0.14	0.00	0.83	-5	2	-0.17(0.06)		
		WEEK 24	122	10.20	10.00	0.65	10	14	122	10.32	0.89	-0.11	0.00	0.88	-5	3	-0.15(0.07)		
		WEEK 28	122	10.16	10.00	0.58	10	14	122	10.32	0.89	-0.16	0.00	0.83	-5	2	-0.19(0.06)		
		WEEK 32	122	10.21	10.00	0.68	10	14	122	10.32	0.89	-0.11	0.00	0.92	-5	4	-0.14(0.07)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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表 2.7.4.7-93　SAS 合計スコアのベースラインからの変化量［LOCF，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.1.1
Simpson-Angus Scale (SAS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - LOCF
(Phase D Safety Sample from non-Japanese Sites)

				BASELINE						CHANGE FROM BASELINE							
PHASE	TREATMENT	TRIAL WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	LS MEAN (SE)[1]	COMPARISON (VS PLACEBO) DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D	PLACEBO	WEEK 36	122	10.20	10.00	0.63	10	14	122	10.32	0.89	-0.11	0.00	0.86	-5	2	-0.15(0.07)		
		WEEK 40	122	10.20	10.00	0.62	10	14	122	10.32	0.89	-0.11	0.00	0.85	-5	2	-0.15(0.07)		
		WEEK 44	122	10.18	10.00	0.59	10	14	122	10.32	0.89	-0.14	0.00	0.83	-5	2	-0.17(0.07)		
		WEEK 48	122	10.23	10.00	0.72	10	14	122	10.32	0.89	-0.09	0.00	0.93	-5	4	-0.12(0.07)		
		WEEK 52	122	10.21	10.00	0.66	10	14	122	10.32	0.89	-0.11	0.00	0.87	-5	2	-0.14(0.07)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

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＜資料番号 5.3.5.1-01：CT-6.1.1.1＞

表 2.7.4.7-94　SAS 合計スコアのベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.1.2
Simpson-Angus Scale (SAS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample from non-Japanese Sites)

PHASE	TREATMENT	TRIAL WEEK	N[1]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: N[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
									_BASELINE__							
PHASE B	ARIP 10-30MG	BASELINE	246	10.46	10.00	1.10	10	19								
		WEEK 4	180	10.32	10.00	0.97	10	18	180	10.41	0.96	-0.09	0.00	1.06	-5	8
		WEEK 8	69	10.36	10.00	1.14	10	18	69	10.35	0.84	0.01	0.00	1.13	-2	8
		LAST VISIT	245	10.42	10.00	1.05	10	18	245	10.46	1.10	-0.03	0.00	1.04	-5	8
PHASE C	ARIP IMD 400/300MG	BASELINE	245	10.42	10.00	1.05	10	18								
		WEEK 4	238	10.39	10.00	1.07	10	18	237	10.43	1.05	-0.03	0.00	0.82	-3	5
		WEEK 8	241	10.42	10.00	1.11	10	18	240	10.43	1.06	-0.01	0.00	0.94	-3	5
		WEEK 12	238	10.44	10.00	1.11	10	18	237	10.44	1.07	0.00	0.00	1.04	-6	6
		WEEK 16	63	10.59	10.00	1.61	10	18	63	10.65	1.55	-0.06	0.00	1.34	-6	6
		WEEK 20	37	10.57	10.00	1.77	10	18	37	10.70	1.70	-0.14	0.00	1.27	-5	5
		WEEK 24	19	10.95	10.00	2.27	10	18	19	11.00	2.21	-0.05	0.00	2.20	-6	6
		WEEK 28	6	10.33	10.00	0.52	10	11	6	10.33	0.52	0.00	0.00	0.00	0	0
		LAST VISIT	246	10.41	10.00	1.14	10	18	245	10.42	1.05	-0.01	0.00	1.08	-6	6

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]N = SUBJECTS WITH ASSESSMENT AT SPECIFIC WEEK.
[2]N = SUBJECTS WITH BASELINE AND ASSESSMENT AT SPECIFIC WEEK.

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表 2.7.4.7-94　SAS 合計スコアのベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.1.2
Simpson-Angus Scale (SAS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample from non-Japanese Sites)

											CHANGE FROM BASELINE									
		TRIAL							BASELINE							LS MEAN	COMPARISON (VS PLACEBO)	
PHASE	TREATMENT	WEEK	N	MEAN	MEDIAN	SD	MIN	MAX	N	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	(SE)[1]	DIFF[1] (95% CI)[1]	P-VALUE[1]
PHASE D ARIP IMD		BASELINE	123	10.50	10.00	1.34	10	18										0.1983
		WEEK 4	115	10.42	10.00	0.89	10	15	115	10.44	1.18	-0.03	0.00	0.95	-6	2	0.01(0.07)	0.12 (-0.07,0.32)	0.2131
		WEEK 8	96	10.49	10.00	1.26	10	17	96	10.49	1.26	0.00	0.00	1.23	-4	5	0.04(0.10)	0.15 (-0.15,0.44)	0.3258
		WEEK 12	86	10.27	10.00	0.71	10	14	86	10.49	1.30	-0.22	0.00	0.91	-5	1	-0.16(0.05)	0.07 (-0.08,0.22)	0.3399
		WEEK 16	83	10.28	10.00	0.75	10	15	83	10.40	1.07	-0.12	0.00	0.94	-6	2	-0.09(0.06)	0.19 (0.01,0.36)	0.0371
		WEEK 20	76	10.24	10.00	0.61	10	13	76	10.33	0.99	-0.09	0.00	0.90	-6	2	-0.06(0.05)	0.15 (-0.01,0.31)	0.0593
		WEEK 24	73	10.32	10.00	0.78	10	14	73	10.26	0.75	0.05	0.00	0.62	-2	2	0.05(0.07)	0.18 (-0.04,0.41)	0.1002
		WEEK 28	75	10.27	10.00	0.68	10	13	75	10.32	0.99	-0.05	0.00	0.96	-6	3	-0.01(0.06)	0.20 (0.00,0.39)	0.0452
		WEEK 32	72	10.25	10.00	0.73	10	14	72	10.35	1.01	-0.10	0.00	0.87	-6	2	-0.06(0.08)	0.03 (-0.21,0.27)	0.7943
		WEEK 36	68	10.31	10.00	0.72	10	13	68	10.32	1.01	-0.01	0.00	0.84	-4	3	0.03(0.07)	0.09 (-0.13,0.30)	0.4295
		WEEK 40	66	10.32	10.00	0.79	10	13	66	10.32	1.03	0.00	0.00	1.02	-6	2	0.07(0.08)	0.08 (-0.17,0.32)	0.5468
		WEEK 44	65	10.42	10.00	0.92	10	15	65	10.32	1.03	0.09	0.00	0.68	-2	3	0.12(0.06)	0.15 (-0.05,0.36)	0.1450
		WEEK 48	64	10.28	10.00	0.81	10	14	64	10.33	1.04	-0.05	0.00	0.97	-6	2	0.01(0.09)	-0.05 (-0.37,0.26)	0.7347
		WEEK 52	60	10.28	10.00	0.80	10	15	60	10.35	1.07	-0.07	0.00	0.71	-3	2	-0.02(0.06)	0.01 (-0.21,0.23)	0.9045
		LAST VISIT	120	10.48	10.00	1.05	10	15	120	10.43	1.16	0.05	0.00	0.99	-3	4	0.08(0.07)	0.22 (0.03,0.41)	0.0230
	PLACEBO	BASELINE	123	10.32	10.00	0.89	10	15										
		WEEK 4	111	10.24	10.00	0.84	10	16	111	10.32	0.92	-0.08	0.00	0.99	-5	6	-0.12(0.07)		
		WEEK 8	90	10.28	10.00	0.94	10	17	90	10.33	0.90	-0.06	0.00	1.18	-5	7	-0.10(0.11)		
		WEEK 12	75	10.13	10.00	0.47	10	12	75	10.31	0.90	-0.17	0.00	0.86	-5	2	-0.24(0.06)		
		WEEK 16	70	10.07	10.00	0.31	10	12	70	10.31	0.93	-0.24	0.00	0.92	-5	1	-0.28(0.06)		
		WEEK 20	62	10.06	10.00	0.31	10	12	62	10.23	0.73	-0.16	0.00	0.75	-4	1	-0.21(0.06)		
		WEEK 24	53	10.13	10.00	0.52	10	13	53	10.26	0.79	-0.13	0.00	0.94	-4	3	-0.13(0.08)		

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

FILE: EFF4SO1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 17:01
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\EFF4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.1.2　FINAL

表 2.7.4.7-94　SAS 合計スコアのベースラインからの変化量［OC，二重盲検試験の二重盲検期（Phase D）］

CT-6.1.1.2
Simpson-Angus Scale (SAS) Total Score - Mean Change from Baseline by Week in Phase B, C and D - OC
(Phase D Safety Sample from non-Japanese Sites)

PHASE	TREATMENT	TRIAL WEEK	BASELINE N	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE N	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX	LS MEAN (SE)[1]	COMPARISON (VS PLACEBO) DIFF[1] (95% CI)[1]	COMPARISON (VS PLACEBO) P-VALUE[1]
PHASE D	PLACEBO	WEEK 28	47	10.04	10.00	0.20	10	11	47	10.19	0.68	-0.15	0.00	0.72	-4	1	-0.21(0.08)	
		WEEK 32	46	10.17	10.00	0.64	10	14	46	10.20	0.69	-0.02	0.00	0.95	-4	4	-0.09(0.10)	
		WEEK 36	42	10.14	10.00	0.47	10	12	42	10.12	0.40	0.02	0.00	0.56	-2	2	-0.05(0.08)	
		WEEK 40	42	10.17	10.00	0.44	10	12	42	10.07	0.26	0.10	0.00	0.43	-1	2	-0.01(0.10)	
		WEEK 44	37	10.08	10.00	0.28	10	11	37	10.05	0.23	0.03	0.00	0.29	-1	1	-0.03(0.08)	
		WEEK 48	35	10.23	10.00	0.84	10	14	35	10.06	0.24	0.17	0.00	0.79	-1	4	0.07(0.13)	
		WEEK 52	32	10.09	10.00	0.39	10	12	32	10.03	0.18	0.06	0.00	0.44	-1	2	-0.03(0.09)	
		LAST VISIT	122	10.21	10.00	0.66	10	14	122	10.32	0.89	-0.11	0.00	0.87	-5	2	-0.14(0.07)	

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.
[1]DERIVED FROM ANOVA MODEL WITH TREATMENT AS A FACTOR FOR COMPARISON AT BASELINE, OR DERIVED FROM ANCOVA MODEL WITH TREATMENT AS A FACTOR AND BASELINE VALUE AS COVARIATE FOR THE COMPARISON AT OTHER VISITS.
LS MEAN(SE): LEAST SQUARE MEAN (STANDARD ERROR); DIFF: DIFFERENCE OF LEAST SQUARE MEANS; CI: CONFIDENCE INTERVAL OF DIFFERENCE OF LEAST SQUARE MEAN

FILE: EFF4SO1.LIS, RUN: [redacted]20[redacted] 17:21; ANALYSIS DATASET CREATED: [redacted]20[redacted] 17:01
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\EFF4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.1.2　FINAL

＜資料番号 5.3.5.1-01：CT-6.1.1.2＞

表 2.7.4.7-95　錐体外路系有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.1.1
Incidence of Treatment-emergent EPS and EPS-Related Adverse Events
(Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
DYSTONIC EVENT	TOTAL1)	8	(1.3)	2	(0.5)
	ジストニア	2	(0.3)	2	(0.5)
	筋固縮	1	(0.2)	0	(0.0)
	筋痙縮	3	(0.5)	0	(0.0)
	開口障害	2	(0.3)	0	(0.0)
PARKINSONISM EVENT	TOTAL1)	10	(1.6)	15	(3.5)
	錐体外路障害	4	(0.7)	6	(1.4)
	パーキンソニズム	0	(0.0)	3	(0.7)
	振戦	6	(1.0)	8	(1.9)
AKATHISIA EVENT	TOTAL1)	99	(16.1)	78	(18.4)
	アカシジア	95	(15.5)	74	(17.4)
	精神運動亢進	4	(0.7)	4	(0.9)
DYSKINETIC EVENT	TOTAL1)	4	(0.7)	5	(1.2)
	ジスキネジア	3	(0.5)	2	(0.5)
	遅発性ジスキネジア	1	(0.2)	3	(0.7)
RESIDUAL EVENT	TOTAL1)	2	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BA.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.1.1　FINAL

表 2.7.4.7-95　錐体外路系有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.1.1
Incidence of Treatment-emergent EPS and EPS-Related Adverse Events
(Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
RESIDUAL EVENT	筋攣縮	2	(0.3)	0	(0.0)
	ミオクローヌス	0	(0.0)	1	(0.2)
TOTAL2)		116	(18.9)	92	(21.6)
TOTAL EXCLUDING AKATHISIA2)		24	(3.9)	22	(5.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BA.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.5.1.1　FINAL

表 2.7.4.7-95　錐体外路系有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.1.1
Incidence of Treatment-emergent EPS and EPS-Related Adverse Events
(Phase B Safety Sample and Phase C Safety Sample)

EPS AND EPS-RELATED ADVERSE EVENTS: MEDDRA 19.0 PRIMARY TERMS

DYSTONIC EVENT: DYSTONIA, EMPROSTHOTONUS, MUSCLE CONTRACTIONS INVOLUNTARY, MUSCLE RIGIDITY, MUSCLE SPASMS, MUSCLE SPASTICITY, MYOTONIA, NUCHAL RIGIDITY, OCULOGYRIC CRISIS, OPISTHOTONUS, PLEUROTHOTONUS, RISUS SARDONICUS, TORTICOLLIS, TRISMUS

PARKINSONISM EVENT: AKINESIA, ASTERIXIS, ATHETOSIS, BRADYKINESIA, COGWHEEL RIGIDITY, ESSENTIAL TREMOR, EXTRAPYRAMIDAL DISORDER, FREEZING PHENOMENON, HYPERTONIA, HYPOKINESIA, HYPOKINESIA NEONATAL, INTENTION TREMOR, MASKED FACIES, PARKINSON'S DISEASE, PARKINSONIAN CRISIS, PARKINSONIAN GAIT, PARKINSONIAN REST TREMOR, PARKINSONISM, TREMOR

AKATHISIA EVENT: AKATHISIA, HYPERKINESIA, HYPERKINESIA NEONATAL, PSYCHOMOTOR HYPERACTIVITY

DYSKINETIC EVENT: BALLISMUS, BUCCOGLOSSAL SYNDROME, CHOREOATHETOSIS, CLUMSINESS, DYSKINESIA, DYSKINESIA NEONATAL, DYSKINESIA OESOPHAGEAL, FUMBLING, HEAD TITUBATION, ON-AND-OFF PHENOMENON, TARDIVE DYSKINESIA

RESIDUAL EVENT: CHOREA, CLONUS, HUNTINGTON'S DISEASE, MUSCLE TWITCHING, MYOCLONUS

FILE: ADAE3BA.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.1.1　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.5.1.1 より作成＞

表 2.7.4.7-96　抗コリン薬を服用していた被験者の錐体外路系有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.1.2
Proportion of Subjects Receiving Anticholinergics for Treatment-emergent EPS and EPS-Related Adverse Events
(Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B N=(614) NUMBER OF SUBJECTS Ne1)	(%)	PHASE B N=(614) ADVERSE EVENTS n2)	(%)	PHASE C N=(425) NUMBER OF SUBJECTS Ne1)	(%)	PHASE C N=(425) ADVERSE EVENTS n2)	(%)
DYSTONIC EVENT	TOTAL1)	86	(14.0)	4	(0.7)	76	(17.9)	1	(0.2)
	ジストニア	86	(14.0)	2	(0.3)	76	(17.9)	1	(0.2)
	筋固縮	86	(14.0)	1	(0.2)	76	(17.9)	0	(0.0)
	開口障害	86	(14.0)	1	(0.2)	76	(17.9)	0	(0.0)
PARKINSONISM EVENT	TOTAL1)	86	(14.0)	7	(1.1)	76	(17.9)	10	(2.4)
	錐体外路障害	86	(14.0)	4	(0.7)	76	(17.9)	4	(0.9)
	パーキンソニズム	86	(14.0)	0	(0.0)	76	(17.9)	1	(0.2)
	振戦	86	(14.0)	3	(0.5)	76	(17.9)	6	(1.4)
AKATHISIA EVENT	TOTAL1)	86	(14.0)	44	(7.2)	76	(17.9)	40	(9.4)
	アカシジア	86	(14.0)	42	(6.8)	76	(17.9)	39	(9.2)
	精神運動亢進	86	(14.0)	2	(0.3)	76	(17.9)	1	(0.2)
DYSKINETIC EVENT	TOTAL1)	86	(14.0)	2	(0.3)	76	(17.9)	3	(0.7)
	ジスキネジア	86	(14.0)	2	(0.3)	76	(17.9)	1	(0.2)
	遅発性ジスキネジア	86	(14.0)	0	(0.0)	76	(17.9)	2	(0.5)
RESIDUAL EVENT	TOTAL1)	86	(14.0)	1	(0.2)	76	(17.9)	0	(0.0)
	筋攣縮	86	(14.0)	1	(0.2)	76	(17.9)	0	(0.0)

1)Ne = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS.
2)n = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS AND HAVING SPECIFIED ADVERSE EVENT DURING CORRESPONDING PHASE B OR C.
3)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
4)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BB.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.1.2　FINAL

表 2.7.4.7-96　抗コリン薬を服用していた被験者の錐体外路系有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.1.2
Proportion of Subjects Receiving Anticholinergics for Treatment-emergent EPS and EPS-Related Adverse Events
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B N=(614)				PHASE C N=(425)			
		NUMBER OF SUBJECTS		ADVERSE EVENTS		NUMBER OF SUBJECTS		ADVERSE EVENTS	
CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	Ne1)	(%)	n2)	(%)	Ne1)	(%)	n2)	(%)
TOTAL4)		86	(14.0)	53	(8.6)	76	(17.9)	49	(11.5)

1)Ne = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS.
2)n = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS AND HAVING SPECIFIED ADVERSE EVENT DURING CORRESPONDING PHASE B OR C.
3)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
4)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BB.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.1.2　FINAL
＜資料番号 5.3.5.1-01：CT-21.2.5.1.2 より作成＞

表 2.7.4.7-97　DIEPSS のベースラインからの変化量［LOCF，二重盲検試験の IM デポ剤安定期（Phase C）］

CT-19.1.2.1
DIEPSS Scale Total Score - Mean Change from Baseline by Week - LOCF
(Phase B Safety Sample and Phase C Safety Sample)

									CHANGE FROM BASELINE					
				BASELINE										
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	32	1.25	0.00	2.05	0	8							
		WEEK 4	32	1.03	0.00	1.82	0	8	32	1.25	-0.22	0.00	0.91	-3	2
		WEEK 8	32	1.16	0.00	1.82	0	8	32	1.25	-0.09	0.00	1.06	-3	2
PHASE C	ARIP IMD 400/300MG	BASELINE	28	0.86	0.00	1.15	0	4							
		WEEK 4	27	0.89	0.00	1.15	0	4	27	0.85	0.04	0.00	0.76	-2	2
		WEEK 8	27	0.63	0.00	1.11	0	4	27	0.85	-0.22	0.00	1.09	-4	2
		WEEK 12	28	0.79	0.00	1.29	0	4	28	0.86	-0.07	0.00	1.09	-4	2
		WEEK 16	28	0.79	0.00	1.29	0	4	28	0.86	-0.07	0.00	1.09	-4	2
		WEEK 20	28	0.79	0.00	1.29	0	4	28	0.86	-0.07	0.00	1.09	-4	2
		WEEK 24	28	0.79	0.00	1.29	0	4	28	0.86	-0.07	0.00	1.09	-4	2
		WEEK 28	28	0.79	0.00	1.29	0	4	28	0.86	-0.07	0.00	1.09	-4	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BDPL.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:49
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.1.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-19.1.2.1＞

表 2.7.4.7-98　DIEPSS のベースラインからの変化量［OC，二重盲検試験の IM デポ剤安定期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-250

CT-19.1.2.2
DIEPSS Scale Total Score - Mean Change from Baseline by Week - OC
(Phase B Safety Sample and Phase C Safety Sample)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	32	1.25	0.00	2.05	0	8							
		WEEK 4	18	1.00	0.00	1.94	0	8	18	1.33	-0.33	0.00	1.08	-3	2
		WEEK 8	7	1.00	1.00	1.00	0	2	7	1.00	0.00	0.00	1.73	-3	2
		LAST VISIT	32	1.16	0.00	1.82	0	8	32	1.25	-0.09	0.00	1.06	-3	2
PHASE C	ARIP IMD 400/300MG	BASELINE	28	0.86	0.00	1.15	0	4							
		WEEK 4	26	0.85	0.00	1.16	0	4	26	0.81	0.04	0.00	0.77	-2	2
		WEEK 8	24	0.46	0.00	0.88	0	3	24	0.79	-0.33	0.00	1.05	-4	1
		WEEK 12	20	0.65	0.00	1.23	0	4	20	0.80	-0.15	0.00	1.14	-4	2
		WEEK 16	1	2.00	2.00		2	2	1	1.00	1.00	1.00		1	1
		LAST VISIT	28	0.79	0.00	1.29	0	4	28	0.86	-0.07	0.00	1.09	-4	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BDPO.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:49
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.1.2.2　FINAL

＜資料番号 5.3.5.1-01：CT-19.1.2.2＞

表 2.7.4.7-99　AIMS のベースラインからの変化量［LOCF，二重盲検試験の IM デポ剤安定期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-250

CT-19.3.1
AIMS Movement Rating Score - Mean Change from Baseline by Week - LOCF
(Phase B Safety Sample and Phase C Safety Sample)

										CHANGE FROM BASELINE					
									BASELINE						
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	614	0.09	0.00	0.54	0	7							
		WEEK 4	556	0.13	0.00	0.55	0	4	556	0.09	0.03	0.00	0.66	-6	4
		WEEK 8	567	0.13	0.00	0.55	0	4	567	0.10	0.03	0.00	0.66	-6	4
PHASE C	ARIP IMD 400/300MG	BASELINE	424	0.15	0.00	0.60	0	4							
		WEEK 4	395	0.16	0.00	0.82	0	10	394	0.15	0.02	0.00	0.70	-4	10
		WEEK 8	405	0.15	0.00	0.82	0	10	404	0.15	-0.00	0.00	0.71	-3	10
		WEEK 12	407	0.17	0.00	0.87	0	10	406	0.15	0.02	0.00	0.81	-4	10
		WEEK 16	407	0.15	0.00	0.80	0	10	406	0.15	0.00	0.00	0.73	-4	10
		WEEK 20	407	0.14	0.00	0.79	0	10	406	0.15	-0.00	0.00	0.73	-4	10
		WEEK 24	407	0.14	0.00	0.79	0	10	406	0.15	-0.01	0.00	0.73	-4	10
		WEEK 28	407	0.13	0.00	0.74	0	10	406	0.15	-0.02	0.00	0.73	-4	10

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BAML.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:46
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.3.1　FINAL
＜資料番号 5.3.5.1-01：CT-19.3.1＞

表 2.7.4.7-100　AIMS のベースラインからの変化量［OC，二重盲検試験の IM デポ剤安定期（Phase C）］

CT-19.3.2
AIMS Movement Rating Score - Mean Change from Baseline by Week - OC
(Phase B Safety Sample and Phase C Safety Sample)

PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	BASELINE n	BASELINE MEAN	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PHASE B	ARIP 10-30MG	BASELINE	614	0.09	0.00	0.54	0	7							
		WEEK 4	402	0.09	0.00	0.45	0	4	402	0.06	0.03	0.00	0.60	-6	4
		WEEK 8	139	0.13	0.00	0.59	0	4	139	0.12	0.01	0.00	0.92	-6	4
		LAST VISIT	568	0.13	0.00	0.55	0	4	568	0.10	0.03	0.00	0.66	-6	4
PHASE C	ARIP IMD 400/300MG	BASELINE	424	0.15	0.00	0.60	0	4							
		WEEK 4	379	0.17	0.00	0.83	0	10	378	0.15	0.02	0.00	0.71	-4	10
		WEEK 8	354	0.10	0.00	0.56	0	6	353	0.14	-0.03	0.00	0.48	-3	4
		WEEK 12	315	0.13	0.00	0.68	0	8	314	0.14	-0.01	0.00	0.67	-4	6
		WEEK 16	90	0.21	0.00	0.84	0	5	90	0.19	0.02	0.00	0.54	-4	2
		WEEK 20	56	0.32	0.00	1.03	0	5	56	0.23	0.09	0.00	0.39	-1	2
		WEEK 24	27	0.44	0.00	1.37	0	6	27	0.41	0.04	0.00	0.52	-1	2
		WEEK 28	8	0.38	0.00	1.06	0	3	8	0.50	-0.13	0.00	0.35	-1	0
		LAST VISIT	407	0.13	0.00	0.74	0	10	406	0.15	-0.02	0.00	0.73	-4	10

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BAMO.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:46
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.3.2　FINAL

＜資料番号 5.3.5.1-01：CT-19.3.2＞

表 2.7.4.7-101　BAS のベースラインからの変化量［LOCF，二重盲検試験の IM デポ剤安定期（Phase C）］

CT-19.2.1
Barnes Akathisia Global Score - Mean Change from Baseline by Week - LOCF
(Phase B Safety Sample and Phase C Safety Sample)

										CHANGE FROM BASELINE					
									BASELINE						
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	614	0.26	0.00	0.66	0	4							
		WEEK 4	556	0.29	0.00	0.71	0	4	556	0.26	0.03	0.00	0.78	-3	4
		WEEK 8	567	0.27	0.00	0.68	0	4	567	0.26	0.01	0.00	0.78	-3	4
PHASE C	ARIP IMD 400/300MG	BASELINE	424	0.23	0.00	0.58	0	3							
		WEEK 4	395	0.22	0.00	0.63	0	5	394	0.23	-0.01	0.00	0.56	-3	4
		WEEK 8	405	0.24	0.00	0.61	0	3	404	0.23	0.01	0.00	0.61	-2	3
		WEEK 12	407	0.28	0.00	0.68	0	4	406	0.22	0.05	0.00	0.68	-3	4
		WEEK 16	407	0.26	0.00	0.66	0	4	406	0.22	0.04	0.00	0.66	-3	4
		WEEK 20	407	0.25	0.00	0.64	0	4	406	0.22	0.02	0.00	0.64	-3	4
		WEEK 24	407	0.25	0.00	0.65	0	4	406	0.22	0.03	0.00	0.64	-2	4
		WEEK 28	407	0.26	0.00	0.66	0	4	406	0.22	0.03	0.00	0.63	-2	4

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BBAL.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:47
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.2.1　FINAL
＜資料番号 5.3.5.1-01：CT-19.2.1＞

表 2.7.4.7-102　BAS のベースラインからの変化量［OC，二重盲検試験の IM デポ剤安定期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-250

CT-19.2.2
Barnes Akathisia Global Score - Mean Change from Baseline by Week - OC
(Phase B Safety Sample and Phase C Safety Sample)

										CHANGE FROM BASELINE					
									BASELINE						
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	614	0.26	0.00	0.66	0	4							
		WEEK 4	402	0.29	0.00	0.70	0	3	402	0.24	0.05	0.00	0.80	-3	3
		WEEK 8	139	0.25	0.00	0.64	0	3	139	0.23	0.02	0.00	0.72	-2	3
		LAST VISIT	568	0.27	0.00	0.68	0	4	568	0.27	0.00	0.00	0.79	-3	4
PHASE C	ARIP IMD 400/300MG	BASELINE	424	0.23	0.00	0.58	0	3							
		WEEK 4	379	0.21	0.00	0.62	0	5	378	0.22	-0.01	0.00	0.55	-3	4
		WEEK 8	354	0.23	0.00	0.61	0	3	353	0.23	-0.00	0.00	0.61	-2	3
		WEEK 12	316	0.28	0.00	0.68	0	4	315	0.24	0.04	0.00	0.69	-3	4
		WEEK 16	90	0.34	0.00	0.77	0	3	90	0.29	0.06	0.00	0.74	-3	3
		WEEK 20	56	0.30	0.00	0.71	0	3	56	0.29	0.02	0.00	0.77	-3	2
		WEEK 24	27	0.22	0.00	0.58	0	2	27	0.48	-0.26	0.00	0.59	-2	1
		WEEK 28	8	0.38	0.00	0.74	0	2	8	0.50	-0.13	0.00	0.35	-1	0
		LAST VISIT	407	0.26	0.00	0.66	0	4	406	0.22	0.03	0.00	0.63	-2	4

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BBAO.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:47
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.2.2　FINAL
＜資料番号 5.3.5.1-01：CT-19.2.2＞

表 2.7.4.7-103　SAS 合計スコアのベースラインからの変化量［LOCF，二重盲検試験の IM デポ剤安定期（Phase C）］

CT-19.1.1.1
Simpson-Angus Scale Total Score - Mean Change from Baseline by Week - LOCF
(Phase B Safety Sample and Phase C Safety Sample)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	582	10.39	10.00	0.99	10	20							
		WEEK 4	523	10.34	10.00	0.87	10	18	523	10.39	-0.05	0.00	0.94	-5	8
		WEEK 8	535	10.35	10.00	0.89	10	18	535	10.39	-0.04	0.00	0.92	-5	8
PHASE C	ARIP IMD 400/300MG	BASELINE	396	10.37	10.00	0.94	10	18							
		WEEK 4	368	10.36	10.00	1.13	10	23	367	10.37	-0.01	0.00	1.03	-5	13
		WEEK 8	378	10.39	10.00	1.15	10	23	377	10.37	0.02	0.00	1.09	-5	13
		WEEK 12	379	10.42	10.00	1.17	10	23	378	10.37	0.05	0.00	1.18	-6	13
		WEEK 16	379	10.41	10.00	1.17	10	23	378	10.37	0.04	0.00	1.15	-6	13
		WEEK 20	379	10.39	10.00	1.14	10	23	378	10.37	0.02	0.00	1.12	-6	13
		WEEK 24	379	10.40	10.00	1.19	10	23	378	10.37	0.03	0.00	1.20	-6	13
		WEEK 28	379	10.41	10.00	1.19	10	23	378	10.37	0.04	0.00	1.20	-6	13

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BSTL.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 17:01
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.1.1.1　FINAL

＜資料番号 5.3.5.1-01：CT-19.1.1.1＞

表 2.7.4.7-104　SAS 合計スコアのベースラインからの変化量［OC，二重盲検試験の IM デポ剤安定期（Phase C）］

CT-19.1.1.2
Simpson-Angus Scale Total Score - Mean Change from Baseline by Week - OC
(Phase B Safety Sample and Phase C Safety Sample)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TREATMENT	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	ARIP 10-30MG	BASELINE	582	10.39	10.00	0.99	10	20							
		WEEK 4	383	10.28	10.00	0.81	10	18	383	10.35	-0.06	0.00	0.94	-5	8
		WEEK 8	131	10.34	10.00	0.95	10	18	131	10.28	0.05	0.00	0.96	-2	8
		LAST VISIT	536	10.35	10.00	0.88	10	18	536	10.39	-0.04	0.00	0.91	-5	8
PHASE C	ARIP IMD 400/300MG	BASELINE	396	10.37	10.00	0.94	10	18							
		WEEK 4	353	10.36	10.00	1.14	10	23	352	10.36	0.00	0.00	1.02	-3	13
		WEEK 8	330	10.38	10.00	0.99	10	18	329	10.39	-0.00	0.00	0.86	-3	5
		WEEK 12	296	10.44	10.00	1.07	10	18	295	10.40	0.03	0.00	1.02	-6	6
		WEEK 16	89	10.51	10.00	1.40	10	18	89	10.55	-0.04	0.00	1.18	-6	6
		WEEK 20	56	10.52	10.00	1.51	10	18	56	10.55	-0.04	0.00	1.06	-5	5
		WEEK 24	27	10.67	10.00	1.94	10	18	27	10.78	-0.11	0.00	1.87	-6	6
		WEEK 28	8	10.25	10.00	0.46	10	11	8	10.50	-0.25	0.00	0.71	-2	0
		LAST VISIT	379	10.41	10.00	1.19	10	23	378	10.37	0.04	0.00	1.20	-6	13

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: AEFF2BSTO.LIS, RUN: [redacted]20[redacted] 10:47; ANALYSIS DATASET CREATED: [redacted]20[redacted] 17:01
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\AEFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.1.1.2　FINAL

＜資料番号 5.3.5.1-01：CT-19.1.1.2＞

表 2.7.4.7-105　抗コリン薬を服用していた被験者の錐体外路系有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.5.1.2
Proportion of Subjects Receiving Anticholinergics for Treatment-emergent EPS and EPS-Related Adverse Events in Phase C
(Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO N=(379) NUMBER OF SUBJECTS Ne1)	(%)	DE NOVO N=(379) ADVERSE EVENTS n2)	(%)	ROLLOVER N=(85) NUMBER OF SUBJECTS Ne1)	(%)	ROLLOVER N=(85) ADVERSE EVENTS n2)	(%)	TOTAL N=(464) NUMBER OF SUBJECTS Ne1)	(%)	TOTAL N=(464) ADVERSE EVENTS n2)	(%)
DYSTONIC EVENT	TOTAL3)	67	(17.7)	5	(1.3)	9	(10.6)	0	(0.0)	76	(16.4)	5	(1.1)
	ジストニア	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
	筋痙縮	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
	開口障害	67	(17.7)	1	(0.3)	9	(10.6)	0	(0.0)	76	(16.4)	1	(0.2)
PARKINSONISM EVENT	TOTAL3)	67	(17.7)	23	(6.1)	9	(10.6)	0	(0.0)	76	(16.4)	23	(5.0)
	運動緩慢	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
	錐体外路障害	67	(17.7)	7	(1.8)	9	(10.6)	0	(0.0)	76	(16.4)	7	(1.5)
	パーキンソニズム	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
	振戦	67	(17.7)	12	(3.2)	9	(10.6)	0	(0.0)	76	(16.4)	12	(2.6)
AKATHISIA EVENT	TOTAL3)	67	(17.7)	27	(7.1)	9	(10.6)	1	(1.2)	76	(16.4)	28	(6.0)
	アカシジア	67	(17.7)	26	(6.9)	9	(10.6)	1	(1.2)	76	(16.4)	27	(5.8)
	運動過多	67	(17.7)	1	(0.3)	9	(10.6)	0	(0.0)	76	(16.4)	1	(0.2)
DYSKINETIC EVENT	TOTAL3)	67	(17.7)	4	(1.1)	9	(10.6)	0	(0.0)	76	(16.4)	4	(0.9)
	ジスキネジア	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
	遅発性ジスキネジア	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
RESIDUAL EVENT	TOTAL3)	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)
	筋攣縮	67	(17.7)	2	(0.5)	9	(10.6)	0	(0.0)	76	(16.4)	2	(0.4)

1)Ne = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS.
2)n = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS DURING PHASE D AND HAVING SPECIFIED ADVERSE EVENT.
3)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
4)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AB.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.1.2　FINAL

表 2.7.4.7-105　抗コリン薬を服用していた被験者の錐体外路系有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.5.1.2
Proportion of Subjects Receiving Anticholinergics for Treatment-emergent EPS and EPS-Related Adverse Events in Phase C
(Phase C Safety Sample)

		DE NOVO N=(379)				ROLLOVER N=(85)				TOTAL N=(464)			
		NUMBER OF SUBJECTS		ADVERSE EVENTS		NUMBER OF SUBJECTS		ADVERSE EVENTS		NUMBER OF SUBJECTS		ADVERSE EVENTS	
CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	Ne1)	(%)	n2)	(%)	Ne1)	(%)	n2)	(%)	Ne1)	(%)	n2)	(%)
TOTAL4)		67	(17.7)	48	(12.7)	9	(10.6)	1	(1.2)	76	(16.4)	49	(10.6)

1)Ne = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS.
2)n = NUMBER OF SUBJECTS RECEIVING ANTICHOLINERGICS DURING PHASE D AND HAVING SPECIFIED ADVERSE EVENT.
3)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
4)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AB.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.1.2　FINAL
＜資料番号 5.3.5.2-01：CT-8.2.5.1.2＞

表 2.7.4.7-106　DIEPSS のベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.2.1
Drug-induced Extrapyramidal Symptom Scale Total Score (Japanese Sites) - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

											CHANGE FROM BASELINE				
									BASELINE						
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	DE NOVO	BASELINE	65	0.63	0.00	1.38	0	6								
		WEEK 4	65	0.42	0.00	0.90	0	3	65	0.63	1.38	-0.22	0.00	0.98	-4	3
		WEEK 8	65	0.43	0.00	0.88	0	3	65	0.63	1.38	-0.20	0.00	0.83	-3	2
		WEEK 12	65	0.43	0.00	0.88	0	3	65	0.63	1.38	-0.20	0.00	0.83	-3	2
PHASE C	DE NOVO	BASELINE	65	0.43	0.00	0.88	0	3								
		WEEK 4	64	0.41	0.00	1.00	0	5	64	0.41	0.87	0.00	0.00	0.78	-2	3
		WEEK 8	65	0.40	0.00	1.04	0	5	65	0.43	0.88	-0.03	0.00	0.92	-3	5
		WEEK 12	65	0.40	0.00	1.06	0	5	65	0.43	0.88	-0.03	0.00	0.79	-2	4
		WEEK 16	65	0.38	0.00	0.98	0	5	65	0.43	0.88	-0.05	0.00	0.80	-3	2
		WEEK 20	65	0.43	0.00	0.98	0	5	65	0.43	0.88	0.00	0.00	0.75	-2	3
		WEEK 24	65	0.57	0.00	1.13	0	5	65	0.43	0.88	0.14	0.00	0.92	-2	3
		WEEK 28	65	0.77	0.00	1.62	0	9	65	0.43	0.88	0.34	0.00	1.36	-2	7
		WEEK 32	65	0.83	0.00	1.82	0	9	65	0.43	0.88	0.40	0.00	1.63	-3	7
		WEEK 36	65	0.86	0.00	1.94	0	10	65	0.43	0.88	0.43	0.00	1.59	-2	9
		WEEK 40	65	0.72	0.00	1.57	0	9	65	0.43	0.88	0.29	0.00	1.21	-2	7
		WEEK 44	65	0.65	0.00	1.50	0	9	65	0.43	0.88	0.22	0.00	1.18	-2	7
		WEEK 48	65	0.68	0.00	1.49	0	9	65	0.43	0.88	0.25	0.00	1.25	-3	7
		WEEK 52	65	0.65	0.00	1.51	0	9	65	0.43	0.88	0.22	0.00	1.17	-2	7
	ROLLOVER	BASELINE	10	0.00	0.00	0.00	0	0								
		WEEK 4	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 8	10	0.00	0.00	0.00	0	0	10	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 12	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 16	10	0.00	0.00	0.00	0	0	10	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 20	10	0.00	0.00	0.00	0	0	10	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 24	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ADPL.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.1　FINAL

表 2.7.4.7-106　DIEPSS のベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.2.1
Drug-induced Extrapyramidal Symptom Scale Total Score (Japanese Sites) - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

											CHANGE FROM BASELINE				
									BASELINE						
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ROLLOVER	WEEK 28	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 32	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 36	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 40	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 44	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 48	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 52	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
	TOTAL	BASELINE	75	0.37	0.00	0.83	0	3							
		WEEK 4	74	0.38	0.00	0.96	0	5	74	0.35	0.82	0.03	0.00	0.76	-2	3
		WEEK 8	75	0.35	0.00	0.98	0	5	75	0.37	0.83	-0.03	0.00	0.85	-3	5
		WEEK 12	75	0.37	0.00	1.01	0	5	75	0.37	0.83	0.00	0.00	0.77	-2	4
		WEEK 16	75	0.33	0.00	0.92	0	5	75	0.37	0.83	-0.04	0.00	0.74	-3	2
		WEEK 20	75	0.37	0.00	0.93	0	5	75	0.37	0.83	0.00	0.00	0.70	-2	3
		WEEK 24	75	0.52	0.00	1.08	0	5	75	0.37	0.83	0.15	0.00	0.88	-2	3
		WEEK 28	75	0.69	0.00	1.53	0	9	75	0.37	0.83	0.32	0.00	1.29	-2	7
		WEEK 32	75	0.75	0.00	1.72	0	9	75	0.37	0.83	0.37	0.00	1.53	-3	7
		WEEK 36	75	0.77	0.00	1.83	0	10	75	0.37	0.83	0.40	0.00	1.50	-2	9
		WEEK 40	75	0.65	0.00	1.48	0	9	75	0.37	0.83	0.28	0.00	1.15	-2	7
		WEEK 44	75	0.59	0.00	1.42	0	9	75	0.37	0.83	0.21	0.00	1.12	-2	7
		WEEK 48	75	0.61	0.00	1.41	0	9	75	0.37	0.83	0.24	0.00	1.18	-3	7
		WEEK 52	75	0.59	0.00	1.43	0	9	75	0.37	0.83	0.21	0.00	1.11	-2	7

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ADPL.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.1　FINAL

＜資料番号 5.3.5.2-01：CT-6.1.2.1＞

表 2.7.4.7-107　DIEPSS のベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.2.2
Drug-induced Extrapyramidal Symptom Scale Total Score (Japanese Sites) - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

										CHANGE FROM BASELINE						
	ENROLLMENT									BASELINE						
PHASE	SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	DE NOVO	BASELINE	65	0.63	0.00	1.38	0	6								
		WEEK 4	65	0.42	0.00	0.90	0	3	65	0.63	1.38	-0.22	0.00	0.98	-4	3
		WEEK 8	3	0.00	0.00	0.00	0	0	3	0.00	0.00	0.00	0.00	0.00	0	0
		LAST VISIT	65	0.43	0.00	0.88	0	3	65	0.63	1.38	-0.20	0.00	0.83	-3	2
PHASE C	DE NOVO	BASELINE	65	0.43	0.00	0.88	0	3								
		WEEK 4	63	0.41	0.00	1.01	0	5	63	0.41	0.87	0.00	0.00	0.78	-2	3
		WEEK 8	60	0.32	0.00	0.87	0	5	60	0.38	0.83	-0.07	0.00	0.92	-3	5
		WEEK 12	57	0.33	0.00	0.91	0	4	57	0.40	0.84	-0.07	0.00	0.80	-2	4
		WEEK 16	56	0.27	0.00	0.73	0	3	56	0.38	0.82	-0.11	0.00	0.80	-3	2
		WEEK 20	56	0.32	0.00	0.74	0	3	56	0.38	0.82	-0.05	0.00	0.75	-2	3
		WEEK 24	54	0.46	0.00	0.97	0	4	54	0.39	0.83	0.07	0.00	0.93	-2	3
		WEEK 28	53	0.72	0.00	1.62	0	9	53	0.40	0.84	0.32	0.00	1.46	-2	7
		WEEK 32	51	0.65	0.00	1.51	0	6	51	0.37	0.82	0.27	0.00	1.54	-3	6
		WEEK 36	51	0.69	0.00	1.69	0	10	51	0.37	0.82	0.31	0.00	1.49	-2	9
		WEEK 40	49	0.49	0.00	1.04	0	4	49	0.39	0.84	0.10	0.00	0.87	-2	3
		WEEK 44	48	0.40	0.00	0.89	0	4	48	0.40	0.84	0.00	0.00	0.80	-2	2
		WEEK 48	48	0.44	0.00	0.87	0	3	48	0.40	0.84	0.04	0.00	0.94	-3	3
		WEEK 52	48	0.40	0.00	0.92	0	4	48	0.40	0.84	0.00	0.00	0.77	-2	2
		LAST VISIT	65	0.65	0.00	1.51	0	9	65	0.43	0.88	0.22	0.00	1.17	-2	7
	ROLLOVER	BASELINE	10	0.00	0.00	0.00	0	0								
		WEEK 4	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 8	10	0.00	0.00	0.00	0	0	10	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 12	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 16	10	0.00	0.00	0.00	0	0	10	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 20	10	0.00	0.00	0.00	0	0	10	0.00	0.00	0.00	0.00	0.00	0	0

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ADPO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.2　FINAL

表 2.7.4.7-107　DIEPSS のベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 2 OF 2
PROTOCOL 31-08-252

CT-6.1.2.2
Drug-induced Extrapyramidal Symptom Scale Total Score (Japanese Sites) - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ROLLOVER	WEEK 24	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 28	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
		WEEK 32	1	0.00	0.00		0	0	1	0.00		0.00	0.00		0	0
		WEEK 36	1	0.00	0.00		0	0	1	0.00		0.00	0.00		0	0
		WEEK 40	1	0.00	0.00		0	0	1	0.00		0.00	0.00		0	0
		WEEK 44	1	0.00	0.00		0	0	1	0.00		0.00	0.00		0	0
		LAST VISIT	10	0.20	0.00	0.63	0	2	10	0.00	0.00	0.20	0.00	0.63	0	2
	TOTAL	BASELINE	75	0.37	0.00	0.83	0	3								
		WEEK 4	73	0.38	0.00	0.97	0	5	73	0.36	0.82	0.03	0.00	0.76	-2	3
		WEEK 8	70	0.27	0.00	0.82	0	5	70	0.33	0.77	-0.06	0.00	0.85	-3	5
		WEEK 12	67	0.31	0.00	0.87	0	4	67	0.34	0.79	-0.03	0.00	0.78	-2	4
		WEEK 16	66	0.23	0.00	0.67	0	3	66	0.32	0.77	-0.09	0.00	0.74	-3	2
		WEEK 20	66	0.27	0.00	0.69	0	3	66	0.32	0.77	-0.05	0.00	0.69	-2	3
		WEEK 24	64	0.42	0.00	0.92	0	4	64	0.33	0.78	0.09	0.00	0.89	-2	3
		WEEK 28	63	0.63	0.00	1.52	0	9	63	0.33	0.78	0.30	0.00	1.36	-2	7
		WEEK 32	52	0.63	0.00	1.50	0	6	52	0.37	0.82	0.27	0.00	1.52	-3	6
		WEEK 36	52	0.67	0.00	1.68	0	10	52	0.37	0.82	0.31	0.00	1.48	-2	9
		WEEK 40	50	0.48	0.00	1.03	0	4	50	0.38	0.83	0.10	0.00	0.86	-2	3
		WEEK 44	49	0.39	0.00	0.89	0	4	49	0.39	0.84	0.00	0.00	0.79	-2	2
		WEEK 48	48	0.44	0.00	0.87	0	3	48	0.40	0.84	0.04	0.00	0.94	-3	3
		WEEK 52	48	0.40	0.00	0.92	0	4	48	0.40	0.84	0.00	0.00	0.77	-2	2
		LAST VISIT	75	0.59	0.00	1.43	0	9	75	0.37	0.83	0.21	0.00	1.11	-2	7

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ADPO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.2.2　FINAL
＜資料番号 5.3.5.2-01：CT-6.1.2.2＞

表 2.7.4.7-108　AIMS のベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.4.1
AIMS Movement Rating Score - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

											CHANGE FROM BASELINE				
				BASELINE											
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	DE NOVO	BASELINE	379	0.07	0.00	0.37	0	3								
		WEEK 4	378	0.09	0.00	0.49	0	5	378	0.07	0.37	0.02	0.00	0.56	-3	5
		WEEK 8	379	0.10	0.00	0.59	0	7	379	0.07	0.37	0.03	0.00	0.67	-3	7
		WEEK 12	379	0.09	0.00	0.49	0	5	379	0.07	0.37	0.02	0.00	0.57	-3	5
PHASE C	DE NOVO	BASELINE	379	0.09	0.00	0.49	0	5								
		WEEK 4	367	0.08	0.00	0.50	0	7	367	0.09	0.48	-0.01	0.00	0.52	-3	7
		WEEK 8	373	0.10	0.00	0.70	0	11	373	0.09	0.48	0.01	0.00	0.73	-4	11
		WEEK 12	373	0.09	0.00	0.54	0	7	373	0.09	0.48	0.00	0.00	0.58	-4	7
		WEEK 16	373	0.12	0.00	0.68	0	7	373	0.09	0.48	0.03	0.00	0.73	-4	7
		WEEK 20	373	0.13	0.00	0.66	0	7	373	0.09	0.48	0.03	0.00	0.72	-4	7
		WEEK 24	373	0.19	0.00	1.11	0	17	373	0.09	0.48	0.10	0.00	1.14	-4	17
		WEEK 28	373	0.17	0.00	1.06	0	17	373	0.09	0.48	0.08	0.00	1.10	-4	17
		WEEK 32	373	0.20	0.00	1.10	0	17	373	0.09	0.48	0.11	0.00	1.11	-4	17
		WEEK 36	373	0.21	0.00	1.28	0	17	373	0.09	0.48	0.12	0.00	1.31	-4	17
		WEEK 40	373	0.15	0.00	1.03	0	17	373	0.09	0.48	0.06	0.00	1.07	-4	17
		WEEK 44	373	0.14	0.00	1.02	0	17	373	0.09	0.48	0.05	0.00	1.07	-4	17
		WEEK 48	373	0.16	0.00	1.04	0	17	373	0.09	0.48	0.07	0.00	1.06	-4	17
		WEEK 52	373	0.16	0.00	1.04	0	17	373	0.09	0.48	0.06	0.00	1.07	-4	17
	ROLLOVER	BASELINE	85	0.01	0.00	0.11	0	1								
		WEEK 4	81	0.00	0.00	0.00	0	0	81	0.01	0.11	-0.01	0.00	0.11	-1	0
		WEEK 8	84	0.00	0.00	0.00	0	0	84	0.01	0.11	-0.01	0.00	0.11	-1	0
		WEEK 12	84	0.07	0.00	0.40	0	3	84	0.01	0.11	0.06	0.00	0.42	-1	3
		WEEK 16	84	0.04	0.00	0.24	0	2	84	0.01	0.11	0.02	0.00	0.27	-1	2
		WEEK 20	84	0.01	0.00	0.11	0	1	84	0.01	0.11	0.00	0.00	0.16	-1	1
		WEEK 24	84	0.02	0.00	0.15	0	1	84	0.01	0.11	0.01	0.00	0.19	-1	1

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2AAML.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:30
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.4.1　FINAL

表 2.7.4.7-108　AIMS のベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.4.1
AIMS Movement Rating Score - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

												CHANGE FROM BASELINE				
									BASELINE							
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ROLLOVER	WEEK 28	84	0.02	0.00	0.15	0	1	84	0.01	0.11	0.01	0.00	0.19	-1	1
		WEEK 32	84	0.02	0.00	0.15	0	1	84	0.01	0.11	0.01	0.00	0.19	-1	1
		WEEK 36	84	0.02	0.00	0.15	0	1	84	0.01	0.11	0.01	0.00	0.19	-1	1
		WEEK 40	84	0.01	0.00	0.11	0	1	84	0.01	0.11	0.00	0.00	0.16	-1	1
		WEEK 44	84	0.01	0.00	0.11	0	1	84	0.01	0.11	0.00	0.00	0.16	-1	1
		WEEK 48	84	0.01	0.00	0.11	0	1	84	0.01	0.11	0.00	0.00	0.16	-1	1
		WEEK 52	84	0.02	0.00	0.15	0	1	84	0.01	0.11	0.01	0.00	0.19	-1	1
	TOTAL	BASELINE	464	0.08	0.00	0.45	0	5								
		WEEK 4	448	0.07	0.00	0.45	0	7	448	0.08	0.44	-0.01	0.00	0.48	-3	7
		WEEK 8	457	0.08	0.00	0.64	0	11	457	0.08	0.44	0.01	0.00	0.66	-4	11
		WEEK 12	457	0.09	0.00	0.52	0	7	457	0.08	0.44	0.01	0.00	0.55	-4	7
		WEEK 16	457	0.11	0.00	0.62	0	7	457	0.08	0.44	0.03	0.00	0.67	-4	7
		WEEK 20	457	0.11	0.00	0.60	0	7	457	0.08	0.44	0.03	0.00	0.65	-4	7
		WEEK 24	457	0.16	0.00	1.01	0	17	457	0.08	0.44	0.08	0.00	1.04	-4	17
		WEEK 28	457	0.14	0.00	0.96	0	17	457	0.08	0.44	0.07	0.00	1.00	-4	17
		WEEK 32	457	0.17	0.00	1.00	0	17	457	0.08	0.44	0.09	0.00	1.00	-4	17
		WEEK 36	457	0.18	0.00	1.16	0	17	457	0.08	0.44	0.10	0.00	1.19	-4	17
		WEEK 40	457	0.12	0.00	0.93	0	17	457	0.08	0.44	0.05	0.00	0.97	-4	17
		WEEK 44	457	0.12	0.00	0.93	0	17	457	0.08	0.44	0.04	0.00	0.97	-4	17
		WEEK 48	457	0.14	0.00	0.94	0	17	457	0.08	0.44	0.06	0.00	0.96	-4	17
		WEEK 52	457	0.13	0.00	0.95	0	17	457	0.08	0.44	0.05	0.00	0.97	-4	17

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2AAML.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:30
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.4.1　FINAL

＜資料番号 5.3.5.2-01：CT-6.1.4.1＞

表 2.7.4.7-109　AIMS のベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.4.2
AIMS Movement Rating Score - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
				BASELINE												
PHASE B	DE NOVO	BASELINE	379	0.07	0.00	0.37	0	3								
		WEEK 4	378	0.09	0.00	0.49	0	5	378	0.07	0.37	0.02	0.00	0.56	-3	5
		WEEK 8	95	0.09	0.00	0.73	0	7	95	0.09	0.44	0.00	0.00	0.84	-3	7
		WEEK 12	27	0.11	0.00	0.42	0	2	27	0.04	0.19	0.07	0.00	0.38	0	2
		LAST VISIT	379	0.09	0.00	0.49	0	5	379	0.07	0.37	0.02	0.00	0.57	-3	5
PHASE C	DE NOVO	BASELINE	379	0.09	0.00	0.49	0	5								
		WEEK 4	355	0.07	0.00	0.46	0	7	355	0.08	0.42	-0.01	0.00	0.53	-3	7
		WEEK 8	337	0.10	0.00	0.71	0	11	337	0.08	0.43	0.01	0.00	0.76	-4	11
		WEEK 12	330	0.09	0.00	0.53	0	7	330	0.08	0.43	0.01	0.00	0.60	-4	7
		WEEK 16	321	0.10	0.00	0.58	0	6	321	0.08	0.43	0.02	0.00	0.66	-4	6
		WEEK 20	308	0.11	0.00	0.55	0	5	308	0.08	0.43	0.02	0.00	0.65	-4	4
		WEEK 24	288	0.18	0.00	1.14	0	17	288	0.08	0.44	0.09	0.00	1.19	-4	17
		WEEK 28	278	0.10	0.00	0.48	0	5	278	0.09	0.45	0.02	0.00	0.60	-4	5
		WEEK 32	261	0.15	0.00	0.60	0	5	261	0.09	0.46	0.05	0.00	0.61	-4	5
		WEEK 36	249	0.16	0.00	1.00	0	11	249	0.09	0.46	0.07	0.00	1.07	-4	11
		WEEK 40	238	0.06	0.00	0.32	0	3	238	0.09	0.47	-0.03	0.00	0.52	-4	3
		WEEK 44	232	0.06	0.00	0.27	0	2	232	0.09	0.46	-0.03	0.00	0.50	-4	2
		WEEK 48	229	0.09	0.00	0.36	0	3	229	0.09	0.46	0.00	0.00	0.48	-4	2
		WEEK 52	224	0.08	0.00	0.39	0	4	224	0.09	0.46	-0.01	0.00	0.51	-4	2
		LAST VISIT	373	0.16	0.00	1.04	0	17	373	0.09	0.48	0.06	0.00	1.07	-4	17
	ROLLOVER	BASELINE	85	0.01	0.00	0.11	0	1								
		WEEK 4	78	0.00	0.00	0.00	0	0	78	0.01	0.11	-0.01	0.00	0.11	-1	0
		WEEK 8	76	0.00	0.00	0.00	0	0	76	0.01	0.11	-0.01	0.00	0.11	-1	0
		WEEK 12	76	0.08	0.00	0.42	0	3	76	0.01	0.11	0.07	0.00	0.44	-1	3
		WEEK 16	75	0.04	0.00	0.26	0	2	75	0.01	0.12	0.03	0.00	0.28	-1	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2AAMO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:30
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.4.2　FINAL

表 2.7.4.7-109　AIMS のベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.4.2
AIMS Movement Rating Score - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

												CHANGE FROM BASELINE				
									BASELINE							
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ROLLOVER	WEEK 20	74	0.01	0.00	0.12	0	1	74	0.01	0.12	0.00	0.00	0.17	-1	1
		WEEK 24	72	0.03	0.00	0.17	0	1	72	0.01	0.12	0.01	0.00	0.21	-1	1
		WEEK 28	71	0.03	0.00	0.17	0	1	71	0.01	0.12	0.01	0.00	0.21	-1	1
		WEEK 32	27	0.04	0.00	0.19	0	1	27	0.04	0.19	0.00	0.00	0.28	-1	1
		WEEK 36	24	0.04	0.00	0.20	0	1	24	0.00	0.00	0.04	0.00	0.20	0	1
		WEEK 40	18	0.00	0.00	0.00	0	0	18	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 44	18	0.00	0.00	0.00	0	0	18	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 48	15	0.00	0.00	0.00	0	0	15	0.00	0.00	0.00	0.00	0.00	0	0
		WEEK 52	14	0.07	0.00	0.27	0	1	14	0.00	0.00	0.07	0.00	0.27	0	1
		LAST VISIT	84	0.02	0.00	0.15	0	1	84	0.01	0.11	0.01	0.00	0.19	-1	1
	TOTAL	BASELINE	464	0.08	0.00	0.45	0	5								
		WEEK 4	433	0.06	0.00	0.42	0	7	433	0.07	0.38	-0.01	0.00	0.48	-3	7
		WEEK 8	413	0.08	0.00	0.64	0	11	413	0.07	0.39	0.01	0.00	0.69	-4	11
		WEEK 12	406	0.09	0.00	0.51	0	7	406	0.07	0.39	0.02	0.00	0.57	-4	7
		WEEK 16	396	0.09	0.00	0.53	0	6	396	0.07	0.39	0.02	0.00	0.61	-4	6
		WEEK 20	382	0.09	0.00	0.50	0	5	382	0.07	0.39	0.02	0.00	0.59	-4	4
		WEEK 24	360	0.15	0.00	1.02	0	17	360	0.07	0.40	0.08	0.00	1.07	-4	17
		WEEK 28	349	0.09	0.00	0.44	0	5	349	0.07	0.41	0.02	0.00	0.54	-4	5
		WEEK 32	288	0.14	0.00	0.58	0	5	288	0.09	0.44	0.05	0.00	0.59	-4	5
		WEEK 36	273	0.15	0.00	0.96	0	11	273	0.08	0.44	0.07	0.00	1.02	-4	11
		WEEK 40	256	0.06	0.00	0.31	0	3	256	0.09	0.45	-0.03	0.00	0.50	-4	3
		WEEK 44	250	0.05	0.00	0.26	0	2	250	0.08	0.44	-0.03	0.00	0.49	-4	2
		WEEK 48	244	0.08	0.00	0.35	0	3	244	0.08	0.45	0.00	0.00	0.46	-4	2
		WEEK 52	238	0.08	0.00	0.38	0	4	238	0.08	0.45	-0.01	0.00	0.50	-4	2
		LAST VISIT	457	0.13	0.00	0.95	0	17	457	0.08	0.44	0.05	0.00	0.97	-4	17

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2AAMO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:30
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.4.2　FINAL

＜資料番号 5.3.5.2-01：CT-6.1.4.2＞

表 2.7.4.7-110　BAS のベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.3.1
Barnes Akathisia Global Score - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

									CHANGE FROM BASELINE						
	ENROLLMENT			BASELINE											
PHASE	SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	DE NOVO	BASELINE	379	0.15	0.00	0.48	0	3								
		WEEK 4	378	0.14	0.00	0.42	0	3	378	0.15	0.48	-0.01	0.00	0.52	-2	3
		WEEK 8	379	0.12	0.00	0.42	0	3	379	0.15	0.48	-0.02	0.00	0.53	-3	3
		WEEK 12	379	0.14	0.00	0.45	0	3	379	0.15	0.48	-0.01	0.00	0.53	-2	3
PHASE C	DE NOVO	BASELINE	379	0.14	0.00	0.45	0	3								
		WEEK 4	367	0.14	0.00	0.45	0	2	367	0.14	0.46	0.00	0.00	0.46	-2	2
		WEEK 8	373	0.18	0.00	0.54	0	3	373	0.14	0.46	0.03	0.00	0.55	-2	3
		WEEK 12	373	0.18	0.00	0.56	0	3	373	0.14	0.46	0.04	0.00	0.58	-2	3
		WEEK 16	373	0.19	0.00	0.57	0	3	373	0.14	0.46	0.05	0.00	0.57	-2	3
		WEEK 20	373	0.18	0.00	0.59	0	3	373	0.14	0.46	0.04	0.00	0.60	-2	3
		WEEK 24	373	0.23	0.00	0.63	0	3	373	0.14	0.46	0.08	0.00	0.64	-2	3
		WEEK 28	373	0.21	0.00	0.62	0	3	373	0.14	0.46	0.06	0.00	0.64	-2	3
		WEEK 32	373	0.23	0.00	0.66	0	3	373	0.14	0.46	0.09	0.00	0.67	-2	3
		WEEK 36	373	0.24	0.00	0.69	0	4	373	0.14	0.46	0.10	0.00	0.69	-2	4
		WEEK 40	373	0.22	0.00	0.63	0	3	373	0.14	0.46	0.08	0.00	0.66	-2	3
		WEEK 44	373	0.21	0.00	0.64	0	4	373	0.14	0.46	0.07	0.00	0.65	-2	3
		WEEK 48	373	0.20	0.00	0.62	0	4	373	0.14	0.46	0.06	0.00	0.65	-2	3
		WEEK 52	373	0.18	0.00	0.59	0	3	373	0.14	0.46	0.04	0.00	0.62	-2	3
	ROLLOVER	BASELINE	85	0.14	0.00	0.52	0	3								
		WEEK 4	81	0.20	0.00	0.58	0	2	81	0.15	0.53	0.05	0.00	0.38	-1	2
		WEEK 8	84	0.13	0.00	0.53	0	3	84	0.14	0.52	-0.01	0.00	0.36	-2	2
		WEEK 12	84	0.17	0.00	0.58	0	3	84	0.14	0.52	0.02	0.00	0.35	-1	2
		WEEK 16	84	0.17	0.00	0.53	0	2	84	0.14	0.52	0.02	0.00	0.41	-2	2
		WEEK 20	84	0.15	0.00	0.55	0	3	84	0.14	0.52	0.01	0.00	0.48	-2	3
		WEEK 24	84	0.17	0.00	0.58	0	3	84	0.14	0.52	0.02	0.00	0.54	-2	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ABAL.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:33
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.3.1　FINAL

表 2.7.4.7-110　BAS のベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.3.1
Barnes Akathisia Global Score - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

										CHANGE FROM BASELINE					
									BASELINE						
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ROLLOVER	WEEK 28	84	0.14	0.00	0.54	0	3	84	0.14	0.52	0.00	0.00	0.41	-1	3
		WEEK 32	84	0.18	0.00	0.58	0	3	84	0.14	0.52	0.04	0.00	0.45	-1	3
		WEEK 36	84	0.23	0.00	0.65	0	3	84	0.14	0.52	0.08	0.00	0.52	-1	3
		WEEK 40	84	0.17	0.00	0.56	0	3	84	0.14	0.52	0.02	0.00	0.44	-1	3
		WEEK 44	84	0.18	0.00	0.58	0	3	84	0.14	0.52	0.04	0.00	0.50	-2	3
		WEEK 48	84	0.17	0.00	0.58	0	3	84	0.14	0.52	0.02	0.00	0.51	-2	3
		WEEK 52	84	0.17	0.00	0.58	0	3	84	0.14	0.52	0.02	0.00	0.51	-2	3
	TOTAL	BASELINE	464	0.14	0.00	0.46	0	3								
		WEEK 4	448	0.15	0.00	0.48	0	2	448	0.14	0.47	0.01	0.00	0.45	-2	2
		WEEK 8	457	0.17	0.00	0.54	0	3	457	0.14	0.47	0.03	0.00	0.52	-2	3
		WEEK 12	457	0.18	0.00	0.57	0	3	457	0.14	0.47	0.04	0.00	0.54	-2	3
		WEEK 16	457	0.18	0.00	0.57	0	3	457	0.14	0.47	0.04	0.00	0.55	-2	3
		WEEK 20	457	0.18	0.00	0.59	0	3	457	0.14	0.47	0.04	0.00	0.58	-2	3
		WEEK 24	457	0.21	0.00	0.62	0	3	457	0.14	0.47	0.07	0.00	0.62	-2	3
		WEEK 28	457	0.19	0.00	0.60	0	3	457	0.14	0.47	0.05	0.00	0.61	-2	3
		WEEK 32	457	0.22	0.00	0.65	0	3	457	0.14	0.47	0.08	0.00	0.63	-2	3
		WEEK 36	457	0.24	0.00	0.68	0	4	457	0.14	0.47	0.10	0.00	0.67	-2	4
		WEEK 40	457	0.21	0.00	0.61	0	3	457	0.14	0.47	0.07	0.00	0.62	-2	3
		WEEK 44	457	0.20	0.00	0.63	0	4	457	0.14	0.47	0.06	0.00	0.62	-2	3
		WEEK 48	457	0.20	0.00	0.61	0	4	457	0.14	0.47	0.05	0.00	0.63	-2	3
		WEEK 52	457	0.18	0.00	0.59	0	3	457	0.14	0.47	0.04	0.00	0.60	-2	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ABAL.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:33
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.3.1　FINAL
＜資料番号 5.3.5.2-01：CT-6.1.3.1＞

表 2.7.4.7-111　BAS のベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.3.2
Barnes Akathisia Global Score - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PHASE B	DE NOVO	BASELINE	379	0.15	0.00	0.48	0	3								
		WEEK 4	378	0.14	0.00	0.42	0	3	378	0.15	0.48	-0.01	0.00	0.52	-2	3
		WEEK 8	95	0.09	0.00	0.36	0	2	95	0.16	0.49	-0.06	0.00	0.62	-3	2
		WEEK 12	27	0.33	0.00	0.73	0	2	27	0.30	0.67	0.04	0.00	0.94	-2	2
		LAST VISIT	379	0.14	0.00	0.45	0	3	379	0.15	0.48	-0.01	0.00	0.53	-2	3
PHASE C	DE NOVO	BASELINE	379	0.14	0.00	0.45	0	3								
		WEEK 4	355	0.13	0.00	0.43	0	2	355	0.13	0.45	0.00	0.00	0.47	-2	2
		WEEK 8	337	0.17	0.00	0.52	0	3	337	0.14	0.46	0.03	0.00	0.56	-2	3
		WEEK 12	330	0.17	0.00	0.54	0	3	330	0.13	0.45	0.04	0.00	0.58	-2	3
		WEEK 16	321	0.16	0.00	0.51	0	3	321	0.13	0.44	0.03	0.00	0.54	-2	3
		WEEK 20	308	0.15	0.00	0.53	0	3	308	0.13	0.45	0.01	0.00	0.56	-2	3
		WEEK 24	288	0.18	0.00	0.56	0	3	288	0.11	0.39	0.07	0.00	0.63	-2	3
		WEEK 28	278	0.15	0.00	0.51	0	3	278	0.12	0.40	0.03	0.00	0.61	-2	3
		WEEK 32	261	0.16	0.00	0.55	0	3	261	0.12	0.41	0.04	0.00	0.61	-2	3
		WEEK 36	249	0.20	0.00	0.62	0	4	249	0.13	0.42	0.07	0.00	0.68	-2	4
		WEEK 40	238	0.14	0.00	0.44	0	3	238	0.13	0.42	0.01	0.00	0.56	-2	3
		WEEK 44	232	0.13	0.00	0.48	0	4	232	0.12	0.40	0.01	0.00	0.52	-2	3
		WEEK 48	229	0.12	0.00	0.44	0	4	229	0.12	0.40	0.00	0.00	0.53	-2	3
		WEEK 52	224	0.08	0.00	0.35	0	2	224	0.11	0.39	-0.03	0.00	0.44	-2	2
		LAST VISIT	373	0.18	0.00	0.59	0	3	373	0.14	0.46	0.04	0.00	0.62	-2	3
	ROLLOVER	BASELINE	85	0.14	0.00	0.52	0	3								
		WEEK 4	78	0.18	0.00	0.55	0	2	78	0.12	0.43	0.06	0.00	0.37	-1	2
		WEEK 8	76	0.09	0.00	0.47	0	3	76	0.09	0.37	0.00	0.00	0.37	-2	2
		WEEK 12	76	0.16	0.00	0.57	0	3	76	0.12	0.43	0.04	0.00	0.34	-1	2
		WEEK 16	75	0.16	0.00	0.52	0	2	75	0.12	0.43	0.04	0.00	0.42	-2	2

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ABAO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:33
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.3.2　FINAL

表 2.7.4.7-111　BAS のベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-6.1.3.2
Barnes Akathisia Global Score - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE C	ROLLOVER	WEEK 20	74	0.15	0.00	0.54	0	3	74	0.12	0.44	0.03	0.00	0.50	-2	3
		WEEK 24	72	0.17	0.00	0.58	0	3	72	0.13	0.44	0.04	0.00	0.57	-2	3
		WEEK 28	71	0.14	0.00	0.54	0	3	71	0.13	0.44	0.01	0.00	0.43	-1	3
		WEEK 32	27	0.19	0.00	0.56	0	2	27	0.19	0.48	0.00	0.00	0.48	-1	2
		WEEK 36	24	0.38	0.00	0.77	0	2	24	0.17	0.48	0.21	0.00	0.66	-1	2
		WEEK 40	18	0.11	0.00	0.32	0	1	18	0.17	0.51	-0.06	0.00	0.42	-1	1
		WEEK 44	18	0.17	0.00	0.51	0	2	18	0.17	0.51	0.00	0.00	0.69	-2	2
		WEEK 48	15	0.00	0.00	0.00	0	0	15	0.20	0.56	-0.20	0.00	0.56	-2	0
		WEEK 52	14	0.00	0.00	0.00	0	0	14	0.21	0.58	-0.21	0.00	0.58	-2	0
		LAST VISIT	84	0.17	0.00	0.58	0	3	84	0.14	0.52	0.02	0.00	0.51	-2	3
	TOTAL	BASELINE	464	0.14	0.00	0.46	0	3								
		WEEK 4	433	0.14	0.00	0.46	0	2	433	0.13	0.44	0.01	0.00	0.45	-2	2
		WEEK 8	413	0.15	0.00	0.51	0	3	413	0.13	0.44	0.03	0.00	0.53	-2	3
		WEEK 12	406	0.17	0.00	0.55	0	3	406	0.13	0.44	0.04	0.00	0.54	-2	3
		WEEK 16	396	0.16	0.00	0.51	0	3	396	0.13	0.44	0.03	0.00	0.52	-2	3
		WEEK 20	382	0.15	0.00	0.53	0	3	382	0.13	0.45	0.02	0.00	0.55	-2	3
		WEEK 24	360	0.18	0.00	0.57	0	3	360	0.11	0.40	0.07	0.00	0.62	-2	3
		WEEK 28	349	0.15	0.00	0.51	0	3	349	0.12	0.41	0.03	0.00	0.58	-2	3
		WEEK 32	288	0.17	0.00	0.55	0	3	288	0.13	0.42	0.04	0.00	0.60	-2	3
		WEEK 36	273	0.21	0.00	0.64	0	4	273	0.13	0.43	0.08	0.00	0.68	-2	4
		WEEK 40	256	0.14	0.00	0.43	0	3	256	0.13	0.43	0.01	0.00	0.55	-2	3
		WEEK 44	250	0.13	0.00	0.48	0	4	250	0.12	0.41	0.01	0.00	0.53	-2	3
		WEEK 48	244	0.11	0.00	0.43	0	4	244	0.13	0.41	-0.01	0.00	0.53	-2	3
		WEEK 52	238	0.08	0.00	0.34	0	2	238	0.12	0.40	-0.04	0.00	0.45	-2	2
		LAST VISIT	457	0.18	0.00	0.59	0	3	457	0.14	0.47	0.04	0.00	0.60	-2	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ABAO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:33
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.3.2　FINAL

＜資料番号 5.3.5.2-01：CT-6.1.3.2＞

表 2.7.4.7-112　SAS 合計スコアのベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 1 OF 2
PROTOCOL 31-08-252

CT-6.1.1.1
Simpson-Angus Scale Total Score (Non-Japanese Sites) - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

										CHANGE FROM BASELINE						
										BASELINE						
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	DE NOVO	BASELINE	314	10.29	10.00	1.05	10	21								
		WEEK 4	313	10.28	10.00	0.89	10	20	313	10.28	1.05	0.00	0.00	0.74	-7	5
		WEEK 8	314	10.30	10.00	0.96	10	20	314	10.29	1.05	0.01	0.00	0.83	-7	6
		WEEK 12	314	10.30	10.00	0.99	10	20	314	10.29	1.05	0.02	0.00	0.85	-7	6
PHASE C	DE NOVO	BASELINE	314	10.30	10.00	0.99	10	20								
		WEEK 4	303	10.30	10.00	0.95	10	19	303	10.30	0.99	0.00	0.00	0.63	-4	3
		WEEK 8	308	10.35	10.00	0.99	10	17	308	10.30	0.98	0.05	0.00	0.74	-4	5
		WEEK 12	308	10.42	10.00	1.24	10	20	308	10.30	0.98	0.12	0.00	0.89	-3	6
		WEEK 16	308	10.43	10.00	1.22	10	19	308	10.30	0.98	0.13	0.00	0.99	-3	6
		WEEK 20	308	10.46	10.00	1.31	10	21	308	10.30	0.98	0.16	0.00	1.16	-4	7
		WEEK 24	308	10.54	10.00	1.69	10	29	308	10.30	0.98	0.24	0.00	1.47	-3	19
		WEEK 28	308	10.53	10.00	1.77	10	29	308	10.30	0.98	0.23	0.00	1.68	-5	19
		WEEK 32	308	10.57	10.00	1.86	10	29	308	10.30	0.98	0.27	0.00	1.71	-4	19
		WEEK 36	308	10.58	10.00	1.96	10	29	308	10.30	0.98	0.29	0.00	1.75	-4	19
		WEEK 40	308	10.59	10.00	1.93	10	29	308	10.30	0.98	0.30	0.00	1.75	-4	19
		WEEK 44	308	10.56	10.00	1.96	10	29	308	10.30	0.98	0.26	0.00	1.76	-4	19
		WEEK 48	308	10.53	10.00	1.82	10	29	308	10.30	0.98	0.23	0.00	1.62	-4	19
		WEEK 52	308	10.51	10.00	1.81	10	29	308	10.30	0.98	0.21	0.00	1.65	-4	19
	ROLLOVER	BASELINE	70	10.20	10.00	0.71	10	15								
		WEEK 4	71	10.27	10.00	0.79	10	14	66	10.21	0.73	0.03	0.00	0.88	-4	4
		WEEK 8	74	10.19	10.00	0.66	10	14	69	10.20	0.72	-0.04	0.00	0.44	-2	2
		WEEK 12	74	10.23	10.00	0.75	10	14	69	10.20	0.72	-0.01	0.00	0.53	-2	2
		WEEK 16	74	10.24	10.00	0.72	10	14	69	10.20	0.72	0.03	0.00	0.92	-5	3
		WEEK 20	74	10.35	10.00	1.13	10	16	69	10.20	0.72	0.14	0.00	0.99	-2	6
		WEEK 24	74	10.32	10.00	1.21	10	18	69	10.20	0.72	0.12	0.00	1.28	-3	8

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ASTL.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:20
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.1.1　FINAL

表 2.7.4.7-112　SAS 合計スコアのベースラインからの変化量［LOCF，長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 2 OF 2
PROTOCOL 31-08-252

CT-6.1.1.1
Simpson-Angus Scale Total Score (Non-Japanese Sites) - Mean Change from Baseline by Week - LOCF
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE C	ROLLOVER	WEEK 28	74	10.34	10.00	1.13	10	18	69	10.20	0.72	0.13	0.00	1.14	-3	8
		WEEK 32	74	10.36	10.00	1.14	10	18	69	10.20	0.72	0.16	0.00	1.20	-3	8
		WEEK 36	74	10.43	10.00	1.22	10	18	69	10.20	0.72	0.22	0.00	1.27	-3	8
		WEEK 40	74	10.36	10.00	1.14	10	18	69	10.20	0.72	0.14	0.00	1.18	-3	8
		WEEK 44	74	10.41	10.00	1.19	10	18	69	10.20	0.72	0.19	0.00	1.25	-3	8
		WEEK 48	74	10.39	10.00	1.19	10	18	69	10.20	0.72	0.17	0.00	1.25	-3	8
		WEEK 52	74	10.36	10.00	1.19	10	18	69	10.20	0.72	0.17	0.00	1.25	-3	8
	TOTAL	BASELINE	384	10.28	10.00	0.94	10	20								
		WEEK 4	374	10.30	10.00	0.92	10	19	369	10.29	0.95	0.01	0.00	0.68	-4	4
		WEEK 8	382	10.32	10.00	0.94	10	17	377	10.28	0.94	0.03	0.00	0.70	-4	5
		WEEK 12	382	10.38	10.00	1.16	10	20	377	10.28	0.94	0.09	0.00	0.84	-3	6
		WEEK 16	382	10.40	10.00	1.14	10	19	377	10.28	0.94	0.11	0.00	0.98	-5	6
		WEEK 20	382	10.44	10.00	1.27	10	21	377	10.28	0.94	0.16	0.00	1.13	-4	7
		WEEK 24	382	10.49	10.00	1.61	10	29	377	10.28	0.94	0.21	0.00	1.44	-3	19
		WEEK 28	382	10.49	10.00	1.67	10	29	377	10.28	0.94	0.21	0.00	1.59	-5	19
		WEEK 32	382	10.53	10.00	1.74	10	29	377	10.28	0.94	0.25	0.00	1.63	-4	19
		WEEK 36	382	10.55	10.00	1.84	10	29	377	10.28	0.94	0.27	0.00	1.67	-4	19
		WEEK 40	382	10.55	10.00	1.81	10	29	377	10.28	0.94	0.27	0.00	1.66	-4	19
		WEEK 44	382	10.53	10.00	1.84	10	29	377	10.28	0.94	0.25	0.00	1.68	-4	19
		WEEK 48	382	10.50	10.00	1.72	10	29	377	10.28	0.94	0.22	0.00	1.56	-4	19
		WEEK 52	382	10.48	10.00	1.71	10	29	377	10.28	0.94	0.20	0.00	1.58	-4	19

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ASTL.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:20
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.1.1　FINAL

＜資料番号 5.3.5.2-01：CT-6.1.1.1＞

表 2.7.4.7-113　SAS 合計スコアのベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 1 OF 2
PROTOCOL 31-08-252

CT-6.1.1.2
Simpson-Angus Scale Total Score (Non-Japanese Sites) - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

										CHANGE FROM BASELINE						
										BASELINE						
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	DE NOVO	BASELINE	314	10.29	10.00	1.05	10	21								
		WEEK 4	313	10.28	10.00	0.89	10	20	313	10.28	1.05	0.00	0.00	0.74	-7	5
		WEEK 8	92	10.24	10.00	0.82	10	16	92	10.25	0.66	-0.01	0.00	0.88	-2	6
		WEEK 12	27	10.44	10.00	1.09	10	15	27	10.44	0.97	0.00	0.00	1.07	-2	3
		LAST VISIT	314	10.30	10.00	0.99	10	20	314	10.29	1.05	0.02	0.00	0.85	-7	6
PHASE C	DE NOVO	BASELINE	314	10.30	10.00	0.99	10	20								
		WEEK 4	292	10.29	10.00	0.95	10	19	292	10.28	0.95	0.02	0.00	0.61	-4	3
		WEEK 8	277	10.36	10.00	1.03	10	17	277	10.29	0.98	0.08	0.00	0.76	-4	5
		WEEK 12	273	10.44	10.00	1.30	10	20	273	10.29	0.98	0.15	0.00	0.92	-3	6
		WEEK 16	265	10.43	10.00	1.24	10	19	265	10.29	0.99	0.14	0.00	1.00	-3	6
		WEEK 20	251	10.44	10.00	1.31	10	21	251	10.29	1.01	0.15	0.00	1.14	-4	7
		WEEK 24	234	10.56	10.00	1.85	10	29	234	10.29	1.03	0.27	0.00	1.59	-3	19
		WEEK 28	225	10.48	10.00	1.55	10	26	225	10.30	1.05	0.18	0.00	1.39	-5	12
		WEEK 32	210	10.47	10.00	1.36	10	18	210	10.28	1.04	0.19	0.00	1.23	-4	8
		WEEK 36	198	10.48	10.00	1.53	10	21	198	10.26	1.00	0.23	0.00	1.34	-4	9
		WEEK 40	189	10.44	10.00	1.35	10	19	189	10.25	0.99	0.19	0.00	1.14	-4	9
		WEEK 44	184	10.38	10.00	1.42	10	23	184	10.27	1.04	0.11	0.00	1.21	-4	11
		WEEK 48	181	10.33	10.00	1.06	10	19	181	10.28	1.04	0.05	0.00	0.83	-4	5
		WEEK 52	176	10.30	10.00	1.03	10	18	176	10.25	1.01	0.05	0.00	0.86	-4	7
		LAST VISIT	308	10.51	10.00	1.81	10	29	308	10.30	0.98	0.21	0.00	1.65	-4	19
	ROLLOVER	BASELINE	70	10.20	10.00	0.71	10	15								
		WEEK 4	68	10.26	10.00	0.80	10	14	65	10.22	0.74	0.03	0.00	0.88	-4	4
		WEEK 8	66	10.18	10.00	0.68	10	14	63	10.21	0.74	-0.05	0.00	0.46	-2	2
		WEEK 12	66	10.24	10.00	0.79	10	14	63	10.22	0.75	-0.02	0.00	0.55	-2	2
		WEEK 16	65	10.26	10.00	0.76	10	14	62	10.23	0.76	0.03	0.00	0.97	-5	3

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ASTO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:20
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.1.2　FINAL

表 2.7.4.7-113　SAS 合計スコアのベースラインからの変化量［OC，長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 2 OF 2
PROTOCOL 31-08-252

CT-6.1.1.2
Simpson-Angus Scale Total Score (Non-Japanese Sites) - Mean Change from Baseline by Week - OC
(Phase C Safety Sample)

										CHANGE FROM BASELINE						
										BASELINE						
PHASE	ENROLLMENT SOURCE	TRIAL WEEK	n	MEAN	MEDIAN	SD	MIN	MAX	n	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ROLLOVER	WEEK 20	64	10.39	10.00	1.20	10	16	61	10.23	0.76	0.16	0.00	1.05	-2	6
		WEEK 24	62	10.37	10.00	1.31	10	18	59	10.24	0.77	0.14	0.00	1.38	-3	8
		WEEK 28	61	10.39	10.00	1.23	10	18	58	10.24	0.78	0.16	0.00	1.24	-3	8
		WEEK 32	26	10.23	10.00	0.59	10	12	23	10.17	0.49	0.04	0.00	0.77	-2	2
		WEEK 36	23	10.43	10.00	0.99	10	14	20	10.15	0.49	0.25	0.00	1.16	-2	4
		WEEK 40	17	10.29	10.00	0.69	10	12	14	10.21	0.58	0.00	0.00	0.88	-2	2
		WEEK 44	17	10.47	10.00	1.01	10	14	14	10.07	0.27	0.36	0.00	1.15	-1	4
		WEEK 48	15	10.20	10.00	0.41	10	11	12	10.08	0.29	0.00	0.00	0.43	-1	1
		WEEK 52	14	10.07	10.00	0.27	10	11	11	10.00	0.00	0.09	0.00	0.30	0	1
		LAST VISIT	74	10.36	10.00	1.19	10	18	69	10.20	0.72	0.17	0.00	1.25	-3	8
	TOTAL	BASELINE	384	10.28	10.00	0.94	10	20								
		WEEK 4	360	10.29	10.00	0.92	10	19	357	10.27	0.92	0.02	0.00	0.66	-4	4
		WEEK 8	343	10.33	10.00	0.97	10	17	340	10.27	0.94	0.05	0.00	0.71	-4	5
		WEEK 12	339	10.40	10.00	1.22	10	20	336	10.27	0.94	0.12	0.00	0.87	-3	6
		WEEK 16	330	10.40	10.00	1.17	10	19	327	10.28	0.95	0.12	0.00	1.00	-5	6
		WEEK 20	315	10.43	10.00	1.29	10	21	312	10.28	0.96	0.15	0.00	1.12	-4	7
		WEEK 24	296	10.52	10.00	1.75	10	29	293	10.28	0.98	0.25	0.00	1.55	-3	19
		WEEK 28	286	10.46	10.00	1.48	10	26	283	10.29	1.00	0.17	0.00	1.36	-5	12
		WEEK 32	236	10.44	10.00	1.30	10	18	233	10.27	1.00	0.18	0.00	1.19	-4	8
		WEEK 36	221	10.48	10.00	1.49	10	21	218	10.25	0.97	0.23	0.00	1.32	-4	9
		WEEK 40	206	10.43	10.00	1.30	10	19	203	10.25	0.97	0.17	0.00	1.12	-4	9
		WEEK 44	201	10.39	10.00	1.39	10	23	198	10.26	1.00	0.13	0.00	1.21	-4	11
		WEEK 48	196	10.32	10.00	1.02	10	19	193	10.26	1.01	0.05	0.00	0.81	-4	5
		WEEK 52	190	10.28	10.00	0.99	10	18	187	10.24	0.98	0.05	0.00	0.83	-4	7
		LAST VISIT	382	10.48	10.00	1.71	10	29	377	10.28	0.94	0.20	0.00	1.58	-4	19

NOTE: SUBJECTS WITH BASELINE OR AT LEAST ONE POST-BASELINE ASSESSMENT ARE INCLUDED.

FILE: EFF2ASTO.LIS, RUN: [redacted]20[redacted] 11:25; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:20
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\EFF2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.1.1.2　FINAL
＜資料番号 5.3.5.2-01：CT-6.1.1.2＞

表 2.7.4.7-114　体重の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.2
Mean Change from Baseline in Weight(kg) in Phase D
(Phase D Safety Sample)

TRIAL WEEK[1]	PHASE D TREATMENT	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX	P-VALUE[3] (VS PLACEBO)
BASELINE	ARIP IMD	132	89.5	89.1	24.1	40.9	197.1									
	PLACEBO	133	89.2	87.7	22.6	49.0	155.6									
WEEK 8	ARIP IMD	105	89.4	85.6	25.3	41.4	195.9	105	88.8	25.2	0.5	0.5	2.3	-7.3	9.6	0.6137
	PLACEBO	101	90.5	87.5	23.4	50.0	157.9	101	90.1	23.1	0.4	0.5	2.6	-8.4	9.6	
WEEK 16	ARIP IMD	88	91.1	88.1	25.4	45.1	192.6	88	90.3	25.6	0.8	1.0	3.6	-11.0	13.6	0.7598
	PLACEBO	79	92.3	89.9	23.9	49.3	159.2	79	91.7	23.1	0.6	0.6	3.3	-9.5	9.6	
WEEK 24	ARIP IMD	79	91.4	87.3	25.6	46.7	192.6	79	90.0	26.0	1.4	1.5	4.7	-17.0	15.9	0.3111
	PLACEBO	65	90.9	86.8	23.8	47.5	160.6	65	90.3	23.4	0.6	0.0	4.8	-11.2	12.3	
WEEK 32	ARIP IMD	75	90.0	86.8	24.2	46.4	186.6	75	88.9	25.0	1.1	0.7	5.8	-15.4	17.7	0.8312
	PLACEBO	56	90.3	83.7	25.4	46.1	167.1	56	89.0	24.0	1.3	1.3	5.7	-15.4	17.8	
WEEK 40	ARIP IMD	69	89.8	86.9	24.7	45.8	187.5	69	88.5	25.6	1.3	0.7	6.1	-17.6	17.2	0.4334
	PLACEBO	51	88.1	84.7	21.7	55.6	138.9	51	87.7	21.4	0.4	0.3	6.9	-25.2	22.6	
WEEK 48	ARIP IMD	67	90.5	87.0	24.7	45.9	185.2	67	89.2	25.6	1.2	0.5	6.3	-15.4	17.2	0.6873
	PLACEBO	47	88.3	85.2	22.9	54.4	135.9	47	87.5	21.9	0.8	-0.6	7.2	-24.6	24.3	
WEEK 52	ARIP IMD	64	90.3	86.8	25.6	46.2	183.6	64	88.9	25.9	1.3	0.8	5.9	-15.0	18.2	0.8824
	PLACEBO	41	89.3	85.1	22.8	54.1	138.5	41	87.7	21.4	1.5	0.5	6.1	-7.0	22.8	
LAST VISIT	ARIP IMD	128	89.6	86.9	24.0	42.5	183.6	128	88.7	24.0	0.9	0.2	5.3	-15.4	18.2	0.2159

[1]BASELINE = BASELINE IS DEFINED AS VALUE AT THE END OF PHASE C VISIT.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]P-VALUES ARE DERIVED FROM ANALYSIS OF COVARIATE MODEL WITH TREATMENT AS TERM AND BASELINE AS COVARIATE.

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表 2.7.4.7-114　体重の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.2
Mean Change from Baseline in Weight(kg) in Phase D
(Phase D Safety Sample)

TRIAL WEEK[1]	PHASE D TREATMENT	n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX	P-VALUE[3] (VS PLACEBO)
LAST VISIT	PLACEBO	132	89.4	86.6	23.1	45.1	167.1	132	89.4	22.6	0.0	0.0	5.9	-24.3	22.8	

[1]BASELINE = BASELINE IS DEFINED AS VALUE AT THE END OF PHASE C VISIT.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]P-VALUES ARE DERIVED FROM ANALYSIS OF COVARIATE MODEL WITH TREATMENT AS TERM AND BASELINE AS COVARIATE.

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＜資料番号 5.3.5.1-01：CT-14.3.2＞

表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=WEIGHT (kg)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE ___BASELINE___ n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	132	89.5	89.1	24.1	40.9	197.1								
	WEEK 8	105	89.4	85.6	25.3	41.4	195.9	105	88.8	25.2	0.5	0.5	2.3	-7.3	9.6
	WEEK 16	88	91.1	88.1	25.4	45.1	192.6	88	90.3	25.6	0.8	1.0	3.6	-11.0	13.6
	WEEK 24	79	91.4	87.3	25.6	46.7	192.6	79	90.0	26.0	1.4	1.5	4.7	-17.0	15.9
	WEEK 32	75	90.0	86.8	24.2	46.4	186.6	75	88.9	25.0	1.1	0.7	5.8	-15.4	17.7
	WEEK 40	69	89.8	86.9	24.7	45.8	187.5	69	88.5	25.6	1.3	0.7	6.1	-17.6	17.2
	WEEK 48	67	90.5	87.0	24.7	45.9	185.2	67	89.2	25.6	1.2	0.5	6.3	-15.4	17.2
	WEEK 52	64	90.3	86.8	25.6	46.2	183.6	64	88.9	25.9	1.3	0.8	5.9	-15.0	18.2
	LAST VISIT	128	89.6	86.9	24.0	42.5	183.6	128	88.7	24.0	0.9	0.2	5.3	-15.4	18.2
PLACEBO	BASELINE	133	89.2	87.7	22.6	49.0	155.6								
	WEEK 8	101	90.5	87.5	23.4	50.0	157.9	101	90.1	23.1	0.4	0.5	2.6	-8.4	9.6
	WEEK 16	79	92.3	89.9	23.9	49.3	159.2	79	91.7	23.1	0.6	0.6	3.3	-9.5	9.6
	WEEK 24	65	90.9	86.8	23.8	47.5	160.6	65	90.3	23.4	0.6	0.0	4.8	-11.2	12.3
	WEEK 32	56	90.3	83.7	25.4	46.1	167.1	56	89.0	24.0	1.3	1.3	5.7	-15.4	17.8
	WEEK 40	51	88.1	84.7	21.7	55.6	138.9	51	87.7	21.4	0.4	0.3	6.9	-25.2	22.6
	WEEK 48	47	88.3	85.2	22.9	54.4	135.9	47	87.5	21.9	0.8	-0.6	7.2	-24.6	24.3
	WEEK 52	41	89.3	85.1	22.8	54.1	138.5	41	87.7	21.4	1.5	0.5	6.1	-7.0	22.8
	LAST VISIT	132	89.4	86.6	23.1	45.1	167.1	132	89.4	22.6	0.0	0.0	5.9	-24.3	22.8

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115 バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=BODY MASS INDEX (kg/m²)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	132	31.4	30.5	7.7	17.5	72.4								
	WEEK 8	105	31.3	30.4	8.2	17.7	72.0	105	31.0	8.2	0.2	0.2	0.8	-2.3	3.7
	WEEK 16	88	31.7	30.2	8.2	20.3	70.7	88	31.4	8.3	0.3	0.3	1.3	-4.6	5.3
	WEEK 24	79	32.1	30.8	8.4	20.2	70.7	79	31.5	8.6	0.5	0.5	1.7	-7.0	6.2
	WEEK 32	75	31.7	29.9	8.1	19.2	68.5	75	31.3	8.3	0.4	0.2	2.1	-6.4	6.1
	WEEK 40	69	31.8	29.8	8.3	19.6	68.9	69	31.3	8.6	0.5	0.2	2.2	-7.3	5.8
	WEEK 48	67	32.0	30.5	8.3	20.2	68.0	67	31.5	8.7	0.5	0.2	2.3	-6.4	5.9
	WEEK 52	64	31.7	29.6	8.6	19.9	67.4	64	31.2	8.6	0.5	0.3	2.1	-5.0	5.4
	LAST VISIT	128	31.5	30.5	7.7	18.2	67.4	128	31.2	7.7	0.3	0.1	1.9	-6.4	6.3
PLACEBO	BASELINE	133	30.5	29.3	7.0	18.7	55.1								
	WEEK 8	101	30.8	29.5	7.0	18.4	55.9	101	30.7	6.9	0.1	0.1	0.9	-3.3	3.1
	WEEK 16	79	31.5	30.1	7.1	18.4	56.4	79	31.3	6.9	0.2	0.2	1.2	-3.5	3.1
	WEEK 24	65	31.0	29.1	6.9	18.5	56.9	65	30.9	6.9	0.2	0.0	1.7	-4.3	4.6
	WEEK 32	56	30.7	29.1	7.4	18.2	59.2	56	30.2	7.0	0.4	0.4	2.0	-4.7	6.7
	WEEK 40	51	29.7	29.1	5.7	19.3	45.5	51	29.6	5.9	0.1	0.1	2.3	-7.7	8.5
	WEEK 48	47	29.6	29.0	5.8	19.4	45.7	47	29.4	5.6	0.2	-0.2	2.4	-7.5	9.1
	WEEK 52	41	30.0	29.7	5.8	19.2	45.4	41	29.5	5.5	0.5	0.2	2.1	-2.4	8.6
	LAST VISIT	132	30.6	29.6	7.1	18.8	59.2	132	30.6	7.0	-0.0	0.0	2.0	-7.5	8.6

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=WAIST CIRCUMFERENCE (cm)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	132	100.8	98.5	18.6	59.0	183.0								
	WEEK 52	64	100.9	98.5	19.9	67.0	174.0	64	99.3	20.4	1.6	1.5	5.8	-15.0	22.0
	LAST VISIT	119	101.3	101.0	18.0	64.0	174.0	119	99.9	18.7	1.5	1.0	5.9	-18.0	22.0
PLACEBO	BASELINE	132	99.1	99.0	17.4	68.0	150.0								
	WEEK 52	41	98.7	98.0	17.5	68.0	138.0	41	97.1	16.6	1.7	0.0	8.3	-19.0	25.0
	LAST VISIT	123	99.6	99.0	17.5	67.0	160.0	122	99.6	17.7	-0.3	0.0	8.0	-40.0	25.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE ___BASELINE___ n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	132	36.6	36.7	0.4	35.4	37.7								
	WEEK 2	123	36.6	36.6	0.3	35.6	37.5	123	36.6	0.4	-0.0	0.0	0.4	-1.1	1.0
	WEEK 4	125	36.6	36.6	0.3	35.5	37.6	125	36.6	0.4	-0.0	0.0	0.4	-1.4	1.3
	WEEK 6	118	36.6	36.6	0.3	35.3	37.5	118	36.6	0.4	-0.0	0.0	0.4	-1.6	1.4
	WEEK 8	106	36.6	36.6	0.3	35.8	37.6	106	36.6	0.4	-0.0	0.0	0.4	-1.4	1.0
	WEEK 10	105	36.6	36.6	0.3	35.6	37.5	105	36.6	0.4	0.0	0.0	0.4	-1.1	1.8
	WEEK 12	98	36.6	36.6	0.3	35.8	37.4	98	36.6	0.4	-0.0	0.0	0.4	-1.6	1.3
	WEEK 14	100	36.6	36.6	0.4	35.3	37.9	100	36.6	0.4	-0.0	0.0	0.4	-1.7	1.3
	WEEK 16	90	36.6	36.7	0.3	35.0	37.3	90	36.6	0.4	-0.0	0.0	0.4	-1.5	1.1
	WEEK 18	88	36.6	36.6	0.3	35.5	37.7	88	36.6	0.4	0.0	0.0	0.4	-1.3	1.3
	WEEK 20	82	36.6	36.6	0.3	35.9	37.5	82	36.6	0.4	0.0	0.0	0.4	-1.0	1.3
	WEEK 22	85	36.6	36.6	0.3	35.3	37.6	85	36.6	0.4	-0.0	0.0	0.4	-1.5	1.0
	WEEK 24	80	36.6	36.6	0.4	35.3	37.9	80	36.6	0.4	-0.0	0.0	0.4	-1.5	1.5
	WEEK 26	77	36.6	36.6	0.3	36.0	37.2	77	36.6	0.3	-0.0	0.0	0.4	-1.6	0.7
	WEEK 28	81	36.6	36.6	0.4	35.8	37.9	81	36.6	0.4	-0.0	0.0	0.4	-0.9	1.0
	WEEK 32	77	36.6	36.6	0.4	35.9	38.3	77	36.7	0.3	-0.0	-0.1	0.4	-0.9	1.2
	WEEK 36	73	36.6	36.6	0.3	36.0	37.3	73	36.7	0.3	-0.0	0.0	0.3	-1.2	0.7
	WEEK 40	70	36.6	36.6	0.3	35.7	37.6	70	36.7	0.3	-0.0	0.0	0.3	-0.8	0.9
	WEEK 44	69	36.6	36.6	0.3	35.7	37.4	69	36.7	0.3	-0.1	0.0	0.4	-1.0	1.0
	WEEK 48	68	36.6	36.7	0.3	35.4	37.3	68	36.7	0.3	-0.0	0.0	0.4	-1.6	0.8
	WEEK 52	64	36.6	36.6	0.3	35.8	37.7	64	36.7	0.3	-0.1	0.0	0.4	-1.0	0.9
	WEEK > 52	1	35.8	35.8		35.8	35.8	1	36.6		-0.8	-0.8		-0.8	-0.8
	LAST VISIT	131	36.6	36.6	0.4	35.3	37.7	131	36.6	0.4	-0.0	0.0	0.4	-1.3	1.2
PLACEBO	BASELINE	133	36.7	36.6	0.3	35.7	37.8								
	WEEK 2	126	36.7	36.7	0.3	35.5	37.4	126	36.7	0.3	0.0	0.0	0.4	-1.1	1.3

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PLACEBO	WEEK 4	122	36.7	36.7	0.3	36.0	37.6	122	36.6	0.3	0.0	0.0	0.4	-1.0	1.0
	WEEK 6	107	36.6	36.6	0.3	35.5	37.9	107	36.6	0.3	-0.0	0.0	0.4	-1.2	1.0
	WEEK 8	101	36.6	36.6	0.4	34.3	37.8	101	36.7	0.3	-0.1	0.0	0.5	-2.8	1.2
	WEEK 10	96	36.6	36.6	0.3	35.5	38.0	96	36.7	0.3	-0.0	0.0	0.4	-1.3	1.1
	WEEK 12	88	36.6	36.6	0.3	35.9	37.3	88	36.7	0.3	-0.1	0.0	0.3	-1.0	0.7
	WEEK 14	84	36.6	36.6	0.4	35.5	37.9	84	36.6	0.3	-0.0	0.0	0.4	-1.1	1.3
	WEEK 16	82	36.6	36.6	0.3	35.2	37.4	82	36.7	0.3	-0.0	-0.1	0.4	-1.1	0.9
	WEEK 18	81	36.6	36.6	0.4	35.6	37.8	81	36.7	0.3	-0.1	-0.1	0.4	-1.4	0.9
	WEEK 20	75	36.6	36.6	0.3	35.9	37.2	75	36.7	0.3	-0.1	-0.1	0.3	-1.1	0.7
	WEEK 22	71	36.6	36.6	0.4	35.1	38.4	71	36.7	0.3	-0.1	0.0	0.4	-1.5	1.2
	WEEK 24	69	36.6	36.6	0.3	35.2	37.1	69	36.7	0.3	-0.1	-0.1	0.4	-1.1	0.7
	WEEK 26	63	36.6	36.6	0.3	35.7	37.5	63	36.7	0.3	-0.0	-0.1	0.4	-1.3	0.9
	WEEK 28	58	36.6	36.7	0.3	35.7	37.3	58	36.7	0.3	-0.0	-0.1	0.4	-1.1	1.3
	WEEK 32	57	36.6	36.6	0.3	35.9	37.6	57	36.7	0.3	-0.1	-0.1	0.4	-1.0	0.8
	WEEK 36	52	36.6	36.6	0.4	35.5	37.3	52	36.6	0.3	-0.1	-0.1	0.4	-1.0	1.0
	WEEK 40	51	36.6	36.6	0.4	35.5	37.1	51	36.6	0.3	-0.1	-0.1	0.5	-1.3	1.2
	WEEK 44	46	36.5	36.6	0.4	35.5	37.2	46	36.6	0.3	-0.1	-0.1	0.4	-1.3	0.7
	WEEK 48	47	36.5	36.5	0.3	35.7	37.2	47	36.6	0.3	-0.2	-0.2	0.4	-1.3	0.6
	WEEK 52	41	36.5	36.5	0.3	35.8	36.9	41	36.6	0.3	-0.1	-0.1	0.4	-1.0	1.1
	WEEK > 52	1	36.5	36.5		36.5	36.5	1	36.9		-0.4	-0.4		-0.4	-0.4
	LAST VISIT	133	36.6	36.6	0.3	35.5	37.2	133	36.7	0.3	-0.1	0.0	0.4	-1.2	1.1

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ARIP IMD	BASELINE	132	73.6	73.5	10.7	49.0	104.0								
	WEEK 2	123	74.1	74.0	10.4	48.0	104.0	123	73.1	10.5	1.0	1.0	8.8	-28.0	28.0
	WEEK 4	125	75.2	76.0	11.7	50.0	108.0	125	73.6	10.8	1.6	2.0	9.3	-38.0	28.0
	WEEK 6	118	74.8	76.0	10.5	47.0	97.0	118	74.1	10.7	0.7	1.0	9.2	-32.0	22.0
	WEEK 8	106	74.7	74.0	10.1	53.0	102.0	106	73.9	10.6	0.8	0.0	10.0	-32.0	26.0
	WEEK 10	105	75.4	74.0	11.0	50.0	102.0	105	73.6	10.5	1.9	1.0	9.9	-24.0	29.0
	WEEK 12	98	74.3	73.5	10.5	46.0	106.0	98	74.1	10.7	0.2	0.0	9.4	-26.0	23.0
	WEEK 14	100	75.0	74.0	9.8	53.0	102.0	100	73.7	10.9	1.3	0.0	8.7	-15.0	27.0
	WEEK 16	90	75.5	74.0	10.5	47.0	106.0	90	74.3	10.5	1.2	-1.0	10.2	-22.0	30.0
	WEEK 18	88	75.5	76.0	10.8	46.0	105.0	88	73.9	10.9	1.6	0.5	10.7	-28.0	29.0
	WEEK 20	82	75.4	76.0	10.2	51.0	102.0	82	74.2	10.9	1.2	0.0	7.9	-21.0	18.0
	WEEK 22	85	74.8	75.0	10.5	44.0	97.0	85	74.0	10.8	0.8	0.0	9.9	-26.0	30.0
	WEEK 24	80	75.1	75.5	11.5	48.0	104.0	80	74.0	10.9	1.0	0.0	10.5	-30.0	28.0
	WEEK 26	77	74.5	73.0	10.9	49.0	102.0	77	73.6	10.3	0.9	0.0	9.4	-18.0	28.0
	WEEK 28	81	73.4	72.0	10.6	47.0	100.0	81	73.6	10.4	-0.2	-1.0	9.9	-23.0	26.0
	WEEK 32	77	75.1	75.0	12.0	46.0	104.0	77	73.8	10.2	1.4	2.0	10.1	-22.0	28.0
	WEEK 36	73	75.2	74.0	10.0	57.0	101.0	73	73.9	10.1	1.3	0.0	9.1	-20.0	23.0
	WEEK 40	70	73.9	72.0	10.2	52.0	97.0	70	73.7	10.2	0.2	-1.5	8.4	-21.0	28.0
	WEEK 44	69	74.4	72.0	11.9	52.0	107.0	69	73.4	10.1	1.0	0.0	9.1	-19.0	25.0
	WEEK 48	68	75.6	75.0	11.2	54.0	100.0	68	73.4	10.1	2.2	2.0	9.6	-18.0	24.0
	WEEK 52	64	73.8	72.5	12.5	40.0	103.0	64	73.6	10.3	0.2	-0.5	9.7	-23.0	25.0
	WEEK > 52	1	88.0	88.0		88.0	88.0	1	72.0		16.0	16.0		16.0	16.0
	LAST VISIT	131	74.4	74.0	11.8	40.0	103.0	131	73.6	10.7	0.7	-1.0	10.1	-23.0	28.0
PLACEBO	BASELINE	133	72.0	71.0	10.4	40.0	99.0								
	WEEK 2	126	73.3	72.0	10.3	45.0	100.0	126	71.9	10.4	1.3	2.0	9.5	-27.0	34.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PLACEBO	WEEK 4	122	74.1	74.5	11.0	47.0	99.0	122	72.2	10.6	1.9	2.0	9.6	-23.0	32.0
	WEEK 6	107	72.6	72.0	10.9	44.0	98.0	107	71.7	10.3	0.9	2.0	9.5	-30.0	26.0
	WEEK 8	102	71.7	72.0	10.6	42.0	102.0	102	71.0	10.0	0.7	1.0	8.9	-32.0	20.0
	WEEK 10	97	73.9	72.0	10.9	46.0	103.0	97	71.7	10.5	2.2	1.0	9.7	-20.0	33.0
	WEEK 12	88	71.3	72.0	9.5	46.0	89.0	88	71.6	10.5	-0.3	0.0	9.7	-28.0	24.0
	WEEK 14	84	72.5	72.0	10.3	44.0	96.0	84	72.5	10.8	-0.0	0.0	10.0	-33.0	24.0
	WEEK 16	82	73.2	70.0	11.4	38.0	105.0	82	72.0	10.6	1.2	1.0	10.5	-25.0	39.0
	WEEK 18	81	72.0	72.0	10.2	37.0	93.0	81	72.0	10.5	-0.0	0.0	8.9	-19.0	23.0
	WEEK 20	75	72.2	72.0	11.3	37.0	102.0	75	71.7	10.6	0.5	0.0	10.0	-24.0	30.0
	WEEK 22	71	73.6	74.0	10.4	37.0	99.0	71	72.3	10.4	1.3	1.0	9.2	-16.0	24.0
	WEEK 24	69	72.9	72.0	10.3	41.0	96.0	69	71.5	10.3	1.4	2.0	10.0	-22.0	24.0
	WEEK 26	63	74.1	75.0	10.8	39.0	102.0	63	71.7	10.3	2.3	0.0	9.5	-19.0	28.0
	WEEK 28	58	72.3	72.0	11.3	37.0	95.0	58	71.9	10.5	0.4	1.0	9.5	-24.0	22.0
	WEEK 32	57	73.3	71.0	10.1	49.0	102.0	57	71.7	10.5	1.6	2.0	7.2	-14.0	18.0
	WEEK 36	52	71.7	70.5	11.1	49.0	107.0	52	70.9	10.5	0.8	0.0	8.4	-21.0	25.0
	WEEK 40	51	74.8	75.0	11.8	48.0	119.0	51	71.3	10.5	3.5	2.0	10.7	-19.0	44.0
	WEEK 44	46	74.7	74.5	9.8	51.0	96.0	46	71.8	10.6	2.9	1.0	8.8	-12.0	23.0
	WEEK 48	47	73.3	72.0	9.3	52.0	92.0	47	71.1	10.7	2.1	0.0	9.4	-20.0	18.0
	WEEK 52	41	73.9	72.0	10.6	55.0	101.0	41	71.3	10.8	2.5	4.0	9.9	-20.0	29.0
	WEEK > 52	1	74.0	74.0		74.0	74.0	1	62.0		12.0	12.0		12.0	12.0
	LAST VISIT	133	73.5	72.0	10.3	52.0	101.0	133	72.0	10.4	1.5	2.0	10.0	-25.0	29.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]						CHANGE FROM BASELINE							
							BASELINE							
		n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	132	119.3	120.0	13.5	90.0	160.0								
	WEEK 2	123	118.7	118.0	13.2	76.0	152.0	123	118.8	13.6	-0.0	0.0	9.1	-24.0	24.0
	WEEK 4	125	120.2	120.0	12.3	94.0	153.0	125	119.3	13.5	0.8	1.0	12.2	-42.0	28.0
	WEEK 6	118	119.9	120.0	12.1	98.0	150.0	118	119.8	13.6	0.1	0.0	11.7	-33.0	24.0
	WEEK 8	106	119.5	118.5	12.5	94.0	162.0	106	119.4	14.0	0.1	0.0	11.5	-29.0	23.0
	WEEK 10	105	119.8	119.0	13.4	95.0	170.0	105	119.5	14.1	0.3	0.0	13.0	-38.0	48.0
	WEEK 12	98	119.7	119.0	14.0	88.0	162.0	98	118.8	13.6	1.0	0.0	11.5	-36.0	30.0
	WEEK 14	100	119.0	119.5	13.2	92.0	158.0	100	119.3	14.4	-0.3	0.0	12.0	-31.0	24.0
	WEEK 16	90	118.7	120.0	12.7	83.0	150.0	90	118.6	13.9	0.0	0.0	13.6	-39.0	41.0
	WEEK 18	88	118.4	118.5	12.7	90.0	163.0	88	119.0	14.8	-0.6	2.0	11.1	-28.0	24.0
	WEEK 20	82	119.0	118.5	13.0	88.0	154.0	82	118.5	15.0	0.5	0.5	12.7	-28.0	43.0
	WEEK 22	85	118.3	119.0	13.2	91.0	145.0	85	119.0	15.0	-0.6	0.0	11.8	-32.0	37.0
	WEEK 24	80	119.4	119.0	13.7	96.0	150.0	80	119.3	14.9	0.1	0.0	12.7	-39.0	34.0
	WEEK 26	77	121.2	121.0	13.9	91.0	155.0	77	119.5	15.1	1.6	0.0	11.6	-36.0	29.0
	WEEK 28	81	120.5	122.0	13.5	95.0	159.0	81	119.2	14.9	1.3	2.0	11.7	-37.0	27.0
	WEEK 32	77	121.3	120.0	13.3	93.0	152.0	77	119.8	15.0	1.5	2.0	11.7	-29.0	23.0
	WEEK 36	73	118.5	118.0	12.3	94.0	147.0	73	118.6	13.6	-0.1	1.0	10.7	-32.0	26.0
	WEEK 40	70	118.8	119.5	11.5	86.0	143.0	70	118.4	13.8	0.4	2.0	11.3	-33.0	27.0
	WEEK 44	69	120.2	121.0	13.2	83.0	147.0	69	118.1	13.7	2.1	1.0	10.6	-28.0	26.0
	WEEK 48	68	120.6	120.0	12.5	91.0	154.0	68	118.4	13.6	2.1	0.5	10.5	-15.0	31.0
	WEEK 52	64	120.7	120.0	11.9	91.0	148.0	64	118.7	13.9	2.0	1.5	11.8	-33.0	27.0
	WEEK > 52	1	129.0	129.0		129.0	129.0	1	110.0		19.0	19.0		19.0	19.0
	LAST VISIT	131	120.9	120.0	11.8	91.0	158.0	131	119.2	13.4	1.7	2.0	11.6	-33.0	27.0
PLACEBO	BASELINE	133	119.5	119.0	12.1	93.0	177.0								
	WEEK 2	126	119.8	120.0	13.0	87.0	153.0	126	119.5	12.2	0.3	0.0	9.7	-26.0	33.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PLACEBO	WEEK 4	122	119.6	119.0	13.5	90.0	175.0	122	119.7	12.2	-0.0	0.0	9.3	-28.0	30.0
	WEEK 6	107	120.6	120.0	12.8	91.0	160.0	107	119.8	12.6	0.8	0.0	10.2	-22.0	31.0
	WEEK 8	102	120.7	120.0	13.1	93.0	157.0	102	119.8	12.8	0.9	0.0	11.1	-37.0	37.0
	WEEK 10	97	121.0	121.0	12.8	98.0	165.0	97	120.1	12.9	1.0	0.0	9.9	-27.0	22.0
	WEEK 12	88	119.0	120.0	13.1	95.0	156.0	88	119.9	13.0	-1.0	0.0	11.6	-46.0	29.0
	WEEK 14	84	120.5	120.5	14.0	89.0	173.0	84	119.0	12.7	1.5	0.0	13.7	-46.0	60.0
	WEEK 16	82	118.7	118.0	14.1	88.0	156.0	82	119.6	12.7	-0.9	0.0	13.5	-43.0	29.0
	WEEK 18	81	118.5	118.0	13.5	89.0	160.0	81	119.5	12.7	-0.9	-2.0	11.2	-34.0	29.0
	WEEK 20	75	120.5	119.0	14.7	87.0	178.0	75	118.6	11.2	2.0	0.0	12.8	-35.0	47.0
	WEEK 22	71	120.9	121.0	13.5	91.0	153.0	71	119.1	11.1	1.8	0.0	13.1	-26.0	40.0
	WEEK 24	69	119.4	120.0	11.8	97.0	144.0	69	119.3	11.1	0.1	0.0	10.6	-22.0	28.0
	WEEK 26	63	122.4	122.0	12.7	89.0	161.0	63	119.8	11.0	2.6	2.0	11.6	-21.0	38.0
	WEEK 28	58	121.4	121.5	11.8	95.0	150.0	58	119.5	11.6	1.9	0.0	12.4	-34.0	32.0
	WEEK 32	57	120.5	120.0	12.5	93.0	148.0	57	119.5	11.7	1.0	0.0	13.1	-41.0	29.0
	WEEK 36	52	121.8	120.0	11.8	90.0	140.0	52	118.9	11.6	2.9	4.0	11.8	-41.0	28.0
	WEEK 40	51	119.2	120.0	11.4	91.0	150.0	51	119.2	11.6	-0.1	0.0	13.3	-40.0	28.0
	WEEK 44	46	122.5	124.5	12.1	100.0	144.0	46	119.6	10.7	2.9	4.0	11.2	-20.0	24.0
	WEEK 48	47	121.2	122.0	11.6	94.0	144.0	47	119.4	11.2	1.8	3.0	13.7	-37.0	31.0
	WEEK 52	41	123.5	124.0	12.6	93.0	145.0	41	120.4	11.3	3.1	4.0	13.8	-33.0	35.0
	WEEK > 52	1	135.0	135.0		135.0	135.0	1	110.0		25.0	25.0		25.0	25.0
	LAST VISIT	133	121.8	120.0	13.6	89.0	165.0	133	119.5	12.1	2.3	2.0	13.0	-34.0	60.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	132	75.6	75.0	9.5	56.0	100.0								
	WEEK 2	123	74.4	75.0	9.4	52.0	95.0	123	75.1	9.2	-0.7	-1.0	7.7	-36.0	16.0
	WEEK 4	125	76.6	77.0	9.5	54.0	106.0	125	75.6	9.4	1.0	0.0	9.2	-19.0	28.0
	WEEK 6	118	75.5	76.0	9.6	52.0	104.0	118	75.4	9.6	0.0	0.0	8.3	-28.0	20.0
	WEEK 8	106	75.0	73.0	8.3	60.0	95.0	106	75.2	9.7	-0.2	0.0	8.5	-20.0	25.0
	WEEK 10	105	75.2	74.0	9.5	55.0	100.0	105	75.0	9.6	0.2	0.0	8.2	-19.0	30.0
	WEEK 12	98	74.8	75.0	8.7	53.0	105.0	98	74.5	9.5	0.3	0.0	8.0	-23.0	21.0
	WEEK 14	100	75.0	76.0	8.5	57.0	108.0	100	74.9	9.8	0.1	0.0	8.1	-22.0	18.0
	WEEK 16	90	74.0	73.0	9.4	52.0	93.0	90	74.9	9.5	-0.8	0.0	9.5	-26.0	24.0
	WEEK 18	88	75.2	74.0	9.5	58.0	99.0	88	75.1	9.7	0.1	0.0	8.2	-22.0	18.0
	WEEK 20	82	74.8	72.5	8.9	50.0	97.0	82	74.8	9.8	0.0	0.0	9.4	-24.0	32.0
	WEEK 22	85	74.2	74.0	9.5	52.0	99.0	85	75.1	9.8	-0.9	0.0	8.7	-20.0	31.0
	WEEK 24	80	74.8	75.5	9.5	57.0	98.0	80	75.4	9.7	-0.6	-0.5	9.3	-29.0	26.0
	WEEK 26	77	75.5	75.0	10.1	46.0	96.0	77	75.2	10.1	0.3	0.0	8.8	-20.0	21.0
	WEEK 28	81	75.1	75.0	10.0	53.0	96.0	81	75.2	9.8	-0.1	0.0	7.4	-22.0	16.0
	WEEK 32	77	76.5	77.0	9.8	54.0	99.0	77	75.5	9.8	1.1	0.0	8.5	-18.0	23.0
	WEEK 36	73	74.7	75.0	8.6	58.0	97.0	73	74.8	9.4	-0.1	0.0	6.7	-19.0	15.0
	WEEK 40	70	75.1	75.5	9.0	50.0	92.0	70	74.7	9.6	0.4	0.5	8.7	-22.0	21.0
	WEEK 44	69	74.9	74.0	8.6	48.0	95.0	69	74.7	9.6	0.2	0.0	7.5	-19.0	20.0
	WEEK 48	68	75.6	76.0	9.0	59.0	101.0	68	74.9	9.5	0.6	0.0	8.8	-21.0	22.0
	WEEK 52	64	76.5	76.0	9.2	56.0	103.0	64	74.6	9.7	1.9	2.0	9.4	-22.0	31.0
	WEEK > 52	1	83.0	83.0		83.0	83.0	1	74.0		9.0	9.0		9.0	9.0
	LAST VISIT	131	76.8	78.0	8.7	56.0	103.0	131	75.5	9.4	1.3	2.0	8.5	-22.0	31.0
PLACEBO	BASELINE	133	76.5	77.0	8.9	58.0	107.0								
	WEEK 2	126	76.1	78.0	9.0	55.0	99.0	126	76.3	8.9	-0.3	0.0	7.6	-24.0	20.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PLACEBO	WEEK 4	122	75.7	76.0	10.0	53.0	104.0	122	76.6	9.0	-0.9	0.0	7.0	-23.0	17.0
	WEEK 6	107	75.5	76.0	10.4	52.0	108.0	107	76.9	9.0	-1.4	-1.0	7.8	-22.0	14.0
	WEEK 8	102	75.3	75.5	9.9	56.0	102.0	102	76.6	9.2	-1.3	-1.0	7.2	-22.0	16.0
	WEEK 10	97	75.9	75.0	9.1	58.0	108.0	97	77.1	9.1	-1.2	-1.0	7.0	-16.0	14.0
	WEEK 12	88	75.3	76.0	9.2	60.0	92.0	88	77.3	9.1	-2.0	-2.0	7.9	-26.0	14.0
	WEEK 14	84	76.0	75.0	10.7	53.0	109.0	84	77.1	9.1	-1.1	0.0	10.0	-34.0	40.0
	WEEK 16	82	74.6	75.0	9.6	56.0	101.0	82	77.2	8.9	-2.6	-3.0	8.5	-35.0	16.0
	WEEK 18	81	74.9	75.0	9.2	56.0	107.0	81	77.4	8.9	-2.6	-2.0	8.0	-27.0	22.0
	WEEK 20	75	75.3	76.0	9.8	52.0	105.0	75	76.9	8.5	-1.6	0.0	8.6	-34.0	20.0
	WEEK 22	71	76.3	78.0	9.3	50.0	94.0	71	77.2	8.6	-0.9	0.0	8.5	-21.0	19.0
	WEEK 24	69	75.6	75.0	8.8	57.0	101.0	69	77.2	8.4	-1.6	-2.0	8.4	-19.0	28.0
	WEEK 26	63	76.8	79.0	9.7	57.0	99.0	63	77.4	8.7	-0.6	0.0	9.1	-20.0	26.0
	WEEK 28	58	77.2	78.0	9.3	58.0	96.0	58	77.3	8.8	-0.1	0.0	9.9	-27.0	32.0
	WEEK 32	57	76.4	76.0	8.8	58.0	104.0	57	77.1	8.8	-0.7	-1.0	8.6	-24.0	32.0
	WEEK 36	52	76.4	78.0	7.6	61.0	90.0	52	76.4	8.5	-0.0	1.5	8.6	-26.0	15.0
	WEEK 40	51	75.6	75.0	8.5	60.0	92.0	51	76.8	8.8	-1.3	-1.0	8.0	-24.0	18.0
	WEEK 44	46	76.0	76.0	9.9	57.0	94.0	46	77.2	8.4	-1.3	-1.0	8.5	-27.0	15.0
	WEEK 48	47	77.0	78.0	9.2	60.0	95.0	47	76.9	8.4	0.0	0.0	8.9	-19.0	21.0
	WEEK 52	41	78.7	81.0	9.4	59.0	99.0	41	77.7	7.9	1.0	2.0	8.6	-19.0	22.0
	WEEK > 52	1	76.0	76.0		76.0	76.0	1	86.0		-10.0	-10.0		-10.0	-10.0
	LAST VISIT	133	77.1	78.0	9.7	53.0	108.0	133	76.5	8.9	0.6	0.0	9.0	-27.0	40.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ARIP IMD	BASELINE	132	77.2	77.0	10.6	49.0	106.0								
	WEEK 2	123	78.3	78.0	10.6	51.0	114.0	123	77.0	10.6	1.3	0.0	8.7	-26.0	29.0
	WEEK 4	125	78.8	79.0	11.0	51.0	111.0	125	77.1	10.6	1.7	2.0	9.5	-24.0	30.0
	WEEK 6	118	78.8	78.0	10.2	52.0	103.0	118	77.5	10.5	1.3	2.0	9.3	-20.0	26.0
	WEEK 8	106	79.3	79.5	11.0	49.0	102.0	106	77.1	10.5	2.2	2.0	10.3	-31.0	24.0
	WEEK 10	105	80.0	80.0	11.3	53.0	104.0	105	76.8	10.4	3.1	2.0	10.4	-26.0	30.0
	WEEK 12	98	77.8	76.5	10.8	51.0	107.0	98	77.4	10.6	0.3	-1.0	10.6	-29.0	26.0
	WEEK 14	100	77.8	77.0	10.0	52.0	101.0	100	77.1	10.8	0.8	0.0	9.4	-31.0	27.0
	WEEK 16	90	78.4	79.0	10.4	50.0	100.0	90	77.5	10.6	0.9	0.0	10.8	-27.0	31.0
	WEEK 18	88	78.8	78.5	10.9	51.0	104.0	88	77.1	10.8	1.7	1.0	11.5	-32.0	34.0
	WEEK 20	82	79.0	78.5	10.5	53.0	108.0	82	77.3	10.9	1.7	1.0	9.8	-30.0	22.0
	WEEK 22	85	79.1	79.0	10.8	54.0	106.0	85	77.2	10.7	1.9	1.0	11.3	-24.0	40.0
	WEEK 24	80	78.2	78.0	11.5	50.0	105.0	80	77.2	10.8	1.0	1.0	11.3	-30.0	32.0
	WEEK 26	77	78.0	78.0	10.3	48.0	108.0	77	76.5	10.1	1.5	0.0	9.7	-19.0	28.0
	WEEK 28	81	76.9	77.0	10.5	49.0	100.0	81	76.9	10.5	0.0	0.0	11.3	-32.0	28.0
	WEEK 32	77	78.5	78.0	11.3	48.0	103.0	77	76.7	9.8	1.8	2.0	10.1	-23.0	33.0
	WEEK 36	73	77.2	76.0	9.8	60.0	98.0	73	76.9	9.4	0.2	0.0	10.2	-21.0	22.0
	WEEK 40	70	77.0	75.0	10.2	56.0	103.0	70	76.7	9.5	0.3	-2.0	9.2	-24.0	24.0
	WEEK 44	69	77.1	76.0	11.7	59.0	106.0	69	76.6	9.6	0.5	0.0	9.7	-18.0	24.0
	WEEK 48	68	77.7	75.5	11.3	58.0	99.0	68	76.5	9.6	1.1	1.5	10.0	-19.0	22.0
	WEEK 52	64	75.8	73.5	12.5	37.0	101.0	64	76.5	9.8	-0.7	0.0	10.7	-26.0	30.0
	WEEK > 52	1	98.0	98.0		98.0	98.0	1	80.0		18.0	18.0		18.0	18.0
	LAST VISIT	131	77.0	77.0	12.3	37.0	103.0	131	77.3	10.6	-0.2	0.0	11.0	-32.0	30.0
PLACEBO	BASELINE	133	76.1	75.0	10.8	44.0	102.0								
	WEEK 2	126	77.4	77.0	10.7	54.0	107.0	126	76.2	11.0	1.2	1.5	10.4	-27.0	36.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PLACEBO	WEEK 4	122	77.9	79.0	11.5	52.0	103.0	122	76.4	11.1	1.5	1.0	9.6	-25.0	31.0
	WEEK 6	107	75.7	75.0	11.4	48.0	104.0	107	76.0	10.5	-0.3	1.0	10.5	-40.0	27.0
	WEEK 8	101	75.7	76.0	10.3	51.0	101.0	101	75.7	10.6	-0.1	0.0	8.9	-24.0	24.0
	WEEK 10	96	76.7	76.0	10.7	47.0	107.0	96	76.1	10.5	0.6	0.5	10.4	-33.0	30.0
	WEEK 12	88	75.8	76.0	9.8	47.0	102.0	88	76.2	10.8	-0.4	-1.0	9.9	-26.0	22.0
	WEEK 14	84	76.6	77.0	10.4	50.0	101.0	84	76.9	10.6	-0.4	0.0	9.5	-28.0	24.0
	WEEK 16	82	76.6	76.5	11.5	44.0	111.0	82	76.7	10.8	-0.1	0.0	11.1	-30.0	34.0
	WEEK 18	81	76.8	76.0	11.6	43.0	113.0	81	76.6	10.7	0.2	0.0	10.5	-25.0	36.0
	WEEK 20	75	76.7	76.0	10.9	44.0	101.0	75	76.6	11.0	0.2	0.0	10.1	-30.0	32.0
	WEEK 22	71	76.6	77.0	11.1	44.0	109.0	71	77.2	11.0	-0.5	0.0	10.9	-28.0	32.0
	WEEK 24	69	75.7	76.0	9.9	48.0	96.0	69	76.4	10.9	-0.8	-1.0	10.6	-25.0	26.0
	WEEK 26	63	77.3	77.0	11.1	45.0	102.0	63	76.6	10.8	0.7	1.0	11.0	-25.0	30.0
	WEEK 28	58	75.2	74.0	10.8	47.0	99.0	58	76.8	10.8	-1.6	-0.5	9.4	-26.0	22.0
	WEEK 32	57	76.7	76.0	10.8	56.0	110.0	57	76.6	10.8	0.1	0.0	8.7	-20.0	26.0
	WEEK 36	52	75.3	75.0	10.7	48.0	107.0	52	75.9	10.8	-0.7	-1.0	9.7	-24.0	30.0
	WEEK 40	51	78.5	77.0	13.6	52.0	127.0	51	76.6	11.1	1.9	0.0	12.6	-19.0	50.0
	WEEK 44	46	77.9	78.5	10.2	56.0	97.0	46	77.1	11.2	0.8	0.5	8.6	-16.0	21.0
	WEEK 48	47	76.0	76.0	10.3	53.0	96.0	47	76.4	11.5	-0.4	-1.0	10.1	-22.0	18.0
	WEEK 52	41	76.8	78.0	10.1	59.0	110.0	41	76.4	11.5	0.4	3.0	9.9	-19.0	25.0
	WEEK > 52	1	82.0	82.0		82.0	82.0	1	79.0		3.0	3.0		3.0	3.0
	LAST VISIT	133	76.8	76.0	10.5	58.0	110.0	133	76.1	10.8	0.7	2.0	10.4	-30.0	30.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]						CHANGE FROM BASELINE							
							BASELINE							
		n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	132	119.9	120.0	13.3	86.0	159.0								
	WEEK 2	123	120.3	120.0	13.8	90.0	160.0	123	119.9	13.4	0.5	1.0	10.4	-29.0	22.0
	WEEK 4	125	120.8	120.0	12.5	92.0	160.0	125	119.8	13.0	1.0	1.0	10.9	-35.0	28.0
	WEEK 6	118	120.6	121.5	12.7	90.0	150.0	118	120.6	13.1	0.0	0.0	10.2	-22.0	25.0
	WEEK 8	106	120.5	119.5	13.6	90.0	162.0	106	119.9	13.3	0.6	0.0	10.7	-24.0	32.0
	WEEK 10	105	119.9	118.0	12.7	93.0	162.0	105	120.3	13.3	-0.4	1.0	11.9	-34.0	29.0
	WEEK 12	98	119.6	120.0	14.1	90.0	165.0	98	119.6	13.1	0.0	0.0	11.9	-27.0	27.0
	WEEK 14	100	119.1	118.0	12.8	94.0	151.0	100	120.2	13.6	-1.1	0.0	12.2	-30.0	31.0
	WEEK 16	90	118.5	120.0	12.9	89.0	150.0	90	119.5	13.3	-1.1	-2.0	13.3	-50.0	38.0
	WEEK 18	88	118.2	118.0	13.3	91.0	170.0	88	119.9	13.9	-1.7	0.0	11.3	-31.0	24.0
	WEEK 20	82	119.8	119.0	12.9	92.0	150.0	82	119.4	14.0	0.4	2.0	11.8	-24.0	38.0
	WEEK 22	85	118.0	118.0	13.0	90.0	146.0	85	119.9	14.0	-1.9	0.0	12.0	-33.0	33.0
	WEEK 24	80	119.3	119.0	13.6	87.0	161.0	80	120.1	13.9	-0.8	0.0	11.9	-27.0	29.0
	WEEK 26	77	121.3	122.0	13.2	90.0	150.0	77	120.7	14.2	0.6	0.0	11.5	-36.0	28.0
	WEEK 28	81	119.6	120.0	13.4	94.0	165.0	81	120.1	14.1	-0.5	0.0	12.8	-42.0	35.0
	WEEK 32	77	121.3	120.0	12.2	100.0	146.0	77	120.4	14.3	0.9	1.0	10.6	-27.0	26.0
	WEEK 36	73	118.8	120.0	12.1	90.0	144.0	73	119.3	13.0	-0.5	0.0	9.5	-28.0	21.0
	WEEK 40	70	119.1	120.0	10.2	96.0	142.0	70	118.8	13.0	0.3	0.0	11.6	-39.0	28.0
	WEEK 44	69	118.7	120.0	14.5	91.0	156.0	69	119.0	13.0	-0.3	0.0	11.3	-31.0	22.0
	WEEK 48	68	120.7	120.0	12.7	82.0	148.0	68	119.3	12.9	1.4	2.0	11.6	-26.0	28.0
	WEEK 52	64	121.3	120.0	13.0	95.0	161.0	64	119.8	13.0	1.5	2.0	11.3	-30.0	29.0
	WEEK > 52	1	125.0	125.0		125.0	125.0	1	108.0		17.0	17.0		17.0	17.0
	LAST VISIT	131	121.4	120.0	12.6	93.0	161.0	131	119.8	13.2	1.7	2.0	11.7	-30.0	35.0
PLACEBO	BASELINE	133	119.5	118.0	12.9	86.0	158.0								
	WEEK 2	126	119.3	119.0	12.2	96.0	149.0	126	119.4	13.0	-0.1	0.0	9.9	-26.0	57.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PLACEBO	WEEK 4	122	120.0	118.5	13.4	91.0	177.0	122	119.5	13.1	0.6	0.0	10.1	-18.0	39.0
	WEEK 6	107	119.5	120.0	12.8	91.0	162.0	107	119.2	13.4	0.3	0.0	10.0	-26.0	30.0
	WEEK 8	101	120.5	121.0	13.6	92.0	178.0	101	119.0	13.3	1.5	0.0	13.3	-26.0	76.0
	WEEK 10	96	119.0	118.5	13.2	92.0	152.0	96	119.1	13.5	-0.1	0.5	10.5	-25.0	39.0
	WEEK 12	88	119.8	120.0	12.5	98.0	144.0	88	119.1	13.8	0.7	0.0	11.0	-25.0	23.0
	WEEK 14	84	118.9	120.0	12.8	90.0	165.0	84	118.5	13.7	0.4	0.0	12.4	-35.0	50.0
	WEEK 16	82	119.9	120.0	13.7	94.0	155.0	82	118.7	13.4	1.2	0.5	10.8	-28.0	25.0
	WEEK 18	81	119.1	118.0	12.8	93.0	157.0	81	118.7	13.6	0.3	-2.0	11.0	-27.0	25.0
	WEEK 20	75	120.8	120.0	14.4	90.0	175.0	75	117.9	13.1	2.9	2.0	10.6	-16.0	41.0
	WEEK 22	71	121.6	122.0	13.2	96.0	162.0	71	118.5	13.3	3.1	2.0	12.8	-22.0	46.0
	WEEK 24	69	119.5	120.0	13.4	96.0	145.0	69	118.6	13.3	0.9	0.0	12.0	-26.0	36.0
	WEEK 26	63	121.6	122.0	11.8	89.0	148.0	63	118.7	13.1	2.8	3.0	10.1	-17.0	24.0
	WEEK 28	58	122.4	120.5	11.2	94.0	148.0	58	119.1	13.3	3.2	2.0	10.7	-24.0	32.0
	WEEK 32	57	121.6	122.0	12.6	94.0	150.0	57	119.0	13.4	2.6	2.0	12.7	-22.0	53.0
	WEEK 36	52	120.8	120.0	13.1	91.0	145.0	52	118.9	13.0	1.9	2.5	11.2	-35.0	21.0
	WEEK 40	51	120.9	122.0	12.2	98.0	141.0	51	118.9	12.8	2.0	4.0	12.7	-37.0	33.0
	WEEK 44	46	123.2	125.5	12.4	98.0	148.0	46	119.2	12.3	4.0	4.0	9.3	-13.0	20.0
	WEEK 48	47	123.6	126.0	12.3	98.0	146.0	47	119.9	12.5	3.7	5.0	10.9	-35.0	28.0
	WEEK 52	41	123.0	124.0	12.6	93.0	142.0	41	120.3	12.4	2.6	2.0	10.9	-33.0	25.0
	WEEK > 52	1	134.0	134.0		134.0	134.0	1	132.0		2.0	2.0		2.0	2.0
	LAST VISIT	133	121.6	122.0	13.1	89.0	157.0	133	119.5	12.9	2.1	2.0	11.6	-33.0	50.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ARIP IMD	BASELINE	132	77.6	77.0	8.9	55.0	104.0								
	WEEK 2	123	77.8	78.0	9.4	58.0	100.0	123	77.2	8.5	0.6	0.0	7.2	-26.0	19.0
	WEEK 4	125	78.8	80.0	9.0	50.0	103.0	125	77.5	8.6	1.3	0.0	7.5	-21.0	20.0
	WEEK 6	118	77.6	78.0	9.5	50.0	110.0	118	77.4	8.8	0.2	0.0	7.3	-29.0	16.0
	WEEK 8	106	77.2	77.5	8.6	58.0	95.0	106	77.0	8.8	0.2	0.0	7.0	-17.0	20.0
	WEEK 10	105	78.0	77.0	8.8	60.0	99.0	105	77.0	8.8	1.0	0.0	7.0	-12.0	24.0
	WEEK 12	98	77.6	78.0	9.0	57.0	116.0	98	76.5	8.7	1.1	1.0	6.7	-12.0	20.0
	WEEK 14	100	77.7	78.0	9.0	61.0	105.0	100	77.0	8.9	0.7	1.5	8.4	-17.0	24.0
	WEEK 16	90	77.0	76.0	9.0	55.0	95.0	90	76.7	8.9	0.3	0.0	8.2	-20.0	25.0
	WEEK 18	88	76.4	76.0	9.4	57.0	103.0	88	77.1	8.9	-0.8	-1.0	7.6	-20.0	14.0
	WEEK 20	82	75.9	76.0	9.2	58.0	97.0	82	76.9	9.0	-0.9	-2.0	8.5	-20.0	32.0
	WEEK 22	85	76.8	77.0	9.4	60.0	99.0	85	77.2	9.0	-0.4	0.0	8.6	-20.0	30.0
	WEEK 24	80	76.4	75.0	9.5	57.0	105.0	80	77.3	9.0	-0.8	-0.5	8.0	-24.0	24.0
	WEEK 26	77	77.5	78.0	10.0	56.0	102.0	77	77.3	8.9	0.2	0.0	7.3	-20.0	16.0
	WEEK 28	81	77.4	77.0	8.9	58.0	97.0	81	77.2	8.9	0.2	0.0	7.6	-16.0	18.0
	WEEK 32	77	77.5	78.0	9.6	59.0	101.0	77	77.0	8.9	0.5	0.0	7.5	-13.0	21.0
	WEEK 36	73	76.3	77.0	8.9	60.0	102.0	73	76.5	8.5	-0.2	0.0	7.3	-25.0	14.0
	WEEK 40	70	77.2	77.0	8.6	56.0	96.0	70	76.3	8.6	0.9	2.0	8.1	-20.0	23.0
	WEEK 44	69	76.9	75.0	8.8	58.0	102.0	69	76.4	8.6	0.5	0.0	6.2	-11.0	22.0
	WEEK 48	68	77.5	77.0	9.5	59.0	107.0	68	76.5	8.6	1.0	0.5	7.2	-15.0	20.0
	WEEK 52	64	77.6	77.0	10.1	58.0	113.0	64	76.7	8.8	0.9	1.0	8.8	-16.0	33.0
	WEEK > 52	1	88.0	88.0		88.0	88.0	1	79.0		9.0	9.0		9.0	9.0
	LAST VISIT	131	78.3	78.0	9.3	58.0	113.0	131	77.4	8.8	0.9	0.0	8.2	-16.0	33.0
PLACEBO	BASELINE	133	78.6	80.0	9.9	58.0	101.0								
	WEEK 2	126	78.3	80.0	8.6	60.0	96.0	126	78.4	10.0	-0.1	0.0	8.1	-19.0	26.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-115　バイタルサインの記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase D
(Phase D Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

PHASE D TREATMENT	TRIAL WEEK[1]	BASELINE n[2]	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
PLACEBO	WEEK 4	122	78.3	80.0	10.0	58.0	119.0	122	78.8	10.0	-0.4	0.0	7.4	-26.0	20.0
	WEEK 6	107	77.1	78.0	10.2	56.0	108.0	107	79.0	9.5	-1.9	-2.0	8.9	-36.0	25.0
	WEEK 8	101	77.5	78.0	9.5	58.0	100.0	101	78.5	9.8	-1.0	-1.0	7.5	-15.0	28.0
	WEEK 10	96	77.4	78.0	9.8	58.0	105.0	96	79.1	9.5	-1.7	-1.0	8.2	-25.0	20.0
	WEEK 12	88	78.0	80.0	9.1	58.0	93.0	88	79.5	9.4	-1.6	-1.0	8.0	-20.0	21.0
	WEEK 14	84	78.0	78.0	10.3	56.0	100.0	84	79.5	9.3	-1.5	0.0	9.7	-28.0	40.0
	WEEK 16	82	77.8	79.5	10.3	49.0	99.0	82	79.6	9.1	-1.8	-1.5	8.7	-27.0	22.0
	WEEK 18	81	78.3	80.0	9.2	58.0	101.0	81	80.1	8.9	-1.8	-1.0	8.4	-22.0	25.0
	WEEK 20	75	78.8	80.0	10.2	53.0	105.0	75	79.5	8.8	-0.7	0.0	8.8	-31.0	24.0
	WEEK 22	71	79.9	80.0	9.3	60.0	98.0	71	79.9	9.0	-0.1	0.0	8.8	-26.0	26.0
	WEEK 24	69	78.6	78.0	9.1	60.0	100.0	69	79.8	8.8	-1.1	-2.0	8.9	-22.0	22.0
	WEEK 26	63	78.2	80.0	9.9	58.0	103.0	63	79.7	9.1	-1.5	-1.0	9.3	-23.0	31.0
	WEEK 28	58	79.6	81.0	8.4	60.0	94.0	58	80.3	8.9	-0.7	0.0	9.3	-24.0	30.0
	WEEK 32	57	79.3	81.0	9.3	60.0	100.0	57	80.1	8.8	-0.7	-1.0	9.3	-22.0	28.0
	WEEK 36	52	78.5	80.0	10.1	60.0	100.0	52	80.3	8.6	-1.8	0.0	9.7	-27.0	28.0
	WEEK 40	51	77.5	78.0	9.5	60.0	97.0	51	80.1	8.6	-2.5	-2.0	9.4	-29.0	20.0
	WEEK 44	46	78.8	78.0	9.5	60.0	96.0	46	79.9	8.5	-1.1	-0.5	8.7	-27.0	24.0
	WEEK 48	47	80.2	82.0	8.8	60.0	99.0	47	79.9	8.4	0.3	0.0	8.0	-20.0	21.0
	WEEK 52	41	80.4	80.0	9.8	56.0	100.0	41	80.5	8.2	-0.1	-1.0	10.4	-23.0	22.0
	WEEK > 52	1	84.0	84.0		84.0	84.0	1	72.0		12.0	12.0		12.0	12.0
	LAST VISIT	133	78.9	80.0	9.7	56.0	105.0	133	78.6	9.9	0.4	0.0	9.7	-27.0	40.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.1-01：CT-14.2＞

表 2.7.4.7-116　ベースライン BMI 別体重の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.3
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase D
(Phase D Safety Sample)

BASELINE BMI (kg/m²)	PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
										BASELINE						
< 23 kg/m²	ARIP IMD	BASELINE	12	55.8	56.2	8.9	40.9	71.4								
		WEEK 8	10	57.1	59.1	9.4	41.4	69.6	10	56.4	9.7	0.7	0.7	1.9	-1.8	5.2
		WEEK 16	8	58.3	60.0	7.0	45.1	66.7	8	56.5	7.4	1.9	1.1	1.7	0.0	5.2
		WEEK 24	8	59.4	61.3	7.2	46.7	67.5	8	56.5	7.4	2.9	1.3	3.0	0.9	9.2
		WEEK 32	8	58.6	61.0	7.6	46.4	67.0	8	56.5	7.4	2.1	1.0	3.4	-1.8	8.7
		WEEK 40	8	59.1	61.5	8.0	45.8	66.7	8	56.5	7.4	2.7	1.7	3.5	-0.9	8.2
		WEEK 48	8	60.5	63.0	8.4	45.9	70.0	8	56.5	7.4	4.1	2.1	4.8	0.5	12.8
		WEEK 52	8	59.8	62.1	7.9	46.2	67.2	8	56.5	7.4	3.4	1.3	4.6	-0.1	11.2
		LAST VISIT	12	57.9	59.6	10.4	42.5	75.7	12	55.8	8.9	2.1	1.3	4.8	-7.0	11.2
	PLACEBO	BASELINE	17	59.0	58.1	5.7	49.0	68.4								
		WEEK 8	10	59.2	59.0	5.8	50.0	69.0	10	58.7	5.8	0.5	0.5	1.9	-2.5	3.0
		WEEK 16	7	59.5	59.7	5.9	49.3	69.0	7	59.6	5.5	-0.1	0.0	2.0	-2.5	3.0
		WEEK 24	6	58.0	58.5	6.2	47.5	67.0	6	59.8	6.0	-1.7	-1.8	2.0	-5.0	1.0
		WEEK 32	6	57.1	58.7	5.6	46.1	62.0	6	59.8	6.0	-2.6	-3.1	1.9	-5.0	0.0
		WEEK 40	5	60.2	60.0	3.0	56.1	64.0	5	61.9	3.1	-1.7	-2.0	2.1	-5.0	0.3
		WEEK 48	5	59.7	59.0	3.6	54.4	64.0	5	61.9	3.1	-2.2	-2.0	2.2	-5.0	0.5
		WEEK 52	4	60.1	60.7	2.2	57.0	62.0	4	62.9	2.7	-2.8	-2.1	3.4	-7.0	0.0
		LAST VISIT	16	57.7	57.0	6.7	45.1	74.3	16	58.5	5.5	-0.8	-0.4	3.0	-7.0	5.9

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-116　ベースライン BMI 別体重の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.3
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase D
(Phase D Safety Sample)

BASELINE BMI (kg/m²)	PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
										BASELINE						
23 - 27 kg/m²	ARIP IMD	BASELINE	25	70.8	67.2	9.4	54.1	89.1								
		WEEK 8	23	71.5	69.0	9.1	59.4	92.1	23	71.4	9.1	0.1	0.0	1.8	-3.4	3.0
		WEEK 16	19	73.0	72.1	9.3	59.4	94.2	19	72.8	9.4	0.2	-0.5	3.2	-7.0	5.2
		WEEK 24	16	73.8	73.0	9.7	59.4	96.6	16	73.4	9.6	0.4	-0.5	3.6	-6.2	7.5
		WEEK 32	16	73.7	72.8	9.6	59.4	97.5	16	72.6	9.6	1.1	0.4	4.8	-6.0	8.4
		WEEK 40	16	74.1	73.1	9.2	59.4	94.2	16	72.6	9.6	1.5	0.2	4.9	-5.2	9.2
		WEEK 48	14	73.7	73.0	10.5	59.4	96.8	14	73.8	9.6	-0.1	-1.6	4.8	-6.4	7.8
		WEEK 52	14	72.7	73.8	11.4	57.8	96.2	14	73.5	9.9	-0.8	-1.6	4.1	-6.6	7.1
		LAST VISIT	25	71.3	72.8	9.5	56.5	96.2	25	70.8	9.4	0.5	-0.7	4.4	-6.6	9.2
	PLACEBO	BASELINE	33	73.9	75.0	9.3	57.0	90.2								
		WEEK 8	25	73.5	75.0	9.9	57.0	92.2	25	73.1	9.6	0.4	0.4	1.5	-3.0	3.0
		WEEK 16	17	75.8	79.8	10.2	58.1	92.2	17	74.5	10.4	1.3	1.6	2.3	-3.1	5.3
		WEEK 24	14	77.3	79.6	9.8	57.0	95.4	14	74.5	9.7	2.8	2.4	3.9	-2.1	12.3
		WEEK 32	14	77.6	81.0	9.9	56.4	92.3	14	74.6	9.8	3.1	1.8	4.6	-0.7	17.8
		WEEK 40	13	78.6	83.5	11.7	55.6	96.0	13	74.5	10.2	4.0	3.2	6.2	-1.5	22.6
		WEEK 48	11	78.5	83.6	13.9	54.6	99.8	11	73.9	10.8	4.7	2.6	7.9	-2.5	24.3
		WEEK 52	10	77.6	83.4	14.4	54.1	98.4	10	73.1	11.1	4.5	2.7	8.1	-5.6	22.8
		LAST VISIT	33	75.5	76.7	10.9	54.1	98.4	33	73.9	9.3	1.7	0.7	5.6	-10.0	22.8

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-116　ベースライン BMI 別体重の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.3
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase D
(Phase D Safety Sample)

BASELINE BMI (kg/m²)	PHASE D TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
> 27 kg/m²	ARIP IMD	BASELINE	95	98.6	95.3	21.3	66.4	197.1								
		WEEK 8	72	99.5	96.5	23.3	63.6	195.9	72	98.9	23.4	0.6	0.6	2.5	-7.3	9.6
		WEEK 16	61	101.0	97.8	23.6	62.5	192.6	61	100.2	23.8	0.9	0.9	3.9	-11.0	13.6
		WEEK 24	55	101.2	96.6	23.9	64.2	192.6	55	99.7	24.5	1.5	2.0	5.1	-17.0	15.9
		WEEK 32	51	100.1	95.1	22.1	62.0	186.6	51	99.2	23.1	0.9	0.4	6.4	-15.4	17.7
		WEEK 40	45	100.8	96.2	22.8	64.5	187.5	45	99.8	23.7	1.0	0.5	6.9	-17.6	17.2
		WEEK 48	45	101.0	96.0	22.4	65.7	185.2	45	99.8	23.7	1.1	0.1	6.9	-15.4	17.2
		WEEK 52	42	102.0	97.8	23.0	66.2	183.6	42	100.3	24.0	1.7	1.9	6.4	-15.0	18.2
		LAST VISIT	91	98.8	95.1	21.5	66.2	183.6	91	97.9	21.4	0.9	0.1	5.6	-15.4	18.2
	PLACEBO	BASELINE	83	101.5	99.6	18.5	68.4	155.6								
		WEEK 8	66	101.7	101.1	20.4	68.6	157.9	66	101.3	19.8	0.3	0.3	3.0	-8.4	9.6
		WEEK 16	55	101.6	98.8	21.8	66.4	159.2	55	101.1	20.5	0.5	0.2	3.7	-9.5	9.6
		WEEK 24	45	99.5	95.0	22.6	68.9	160.6	45	99.2	21.9	0.2	0.0	5.2	-11.2	11.7
		WEEK 32	36	100.8	98.3	24.7	68.5	167.1	36	99.5	22.9	1.3	1.9	6.3	-15.4	15.8
		WEEK 40	33	96.1	94.0	21.4	66.6	138.9	33	96.8	20.5	-0.7	-0.1	7.2	-25.2	12.8
		WEEK 48	31	96.4	95.0	22.3	65.3	135.9	31	96.5	20.8	-0.1	-1.5	7.1	-24.6	14.0
		WEEK 52	27	97.9	98.0	21.6	65.5	138.5	27	96.8	20.0	1.1	0.5	5.1	-5.3	15.0
		LAST VISIT	83	101.1	100.0	19.7	65.5	167.1	83	101.5	18.5	-0.4	-0.1	6.3	-24.3	15.8

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.1-01：CT-14.3.3＞

表 2.7.4.7-117　ベースライン BMI 別の 7%以上の体重の増加又は減少が認められた被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.4
Incidence of Potentially Clinically Relevant Weight Gain or Loss by Week and Baseline BMI in Phase D
(Phase D Safety Sample)

BASELINE BMI (kg/m²)		TRIAL WEEK	ARIP IMD (N=12) Ne[1]	n[2]	(%)	PLACEBO (N=17) Ne[1]	n[2]	(%)	TOTAL (N=29) Ne[1]	n[2]	(%)
< 23 kg/m²	INCREASE >= 7%	WEEK 8	10	1	(10.0)	10	0	(0.0)	20	1	(5.0)
		WEEK 16	8	1	(12.5)	7	0	(0.0)	15	1	(6.7)
		WEEK 24	8	3	(37.5)	6	0	(0.0)	14	3	(21.4)
		WEEK 32	8	3	(37.5)	6	0	(0.0)	14	3	(21.4)
		WEEK 40	8	2	(25.0)	5	0	(0.0)	13	2	(15.4)
		WEEK 48	8	2	(25.0)	5	0	(0.0)	13	2	(15.4)
		WEEK 52	8	3	(37.5)	4	0	(0.0)	12	3	(25.0)
		LAST VISIT	12	3	(25.0)	16	1	(6.3)	28	4	(14.3)
	DECREASE >= 7%	WEEK 8	10	0	(0.0)	10	0	(0.0)	20	0	(0.0)
		WEEK 16	8	0	(0.0)	7	0	(0.0)	15	0	(0.0)
		WEEK 24	8	0	(0.0)	6	1	(16.7)	14	1	(7.1)
		WEEK 32	8	0	(0.0)	6	1	(16.7)	14	1	(7.1)
		WEEK 40	8	0	(0.0)	5	1	(20.0)	13	1	(7.7)
		WEEK 48	8	0	(0.0)	5	1	(20.0)	13	1	(7.7)
		WEEK 52	8	0	(0.0)	4	1	(25.0)	12	1	(8.3)
		LAST VISIT	12	1	(8.3)	16	2	(12.5)	28	3	(10.7)

NOTE: A POTENTIALLY CLINICALLY RELEVANT WEIGHT GAIN (LOSS) IS DEFINED AS WEIGHT GAIN (LOSS) OF 7% OR MORE OVER BASELINE.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH A POST-BASELINE WEIGHT RESULT AT THE VISIT.
[2]n IS THE NUMBER OF SUBJECTS MEETING THE CRITERIA FOR POTENTIAL CLINICAL SIGNIFICANCE.

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表 2.7.4.7-117　ベースライン BMI 別の 7%以上の体重の増加又は減少が認められた被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.4
Incidence of Potentially Clinically Relevant Weight Gain or Loss by Week and Baseline BMI in Phase D
(Phase D Safety Sample)

BASELINE BMI (kg/m²)		TRIAL WEEK	ARIP IMD (N=25) Ne[1]	n[2]	(%)	PLACEBO (N=33) Ne[1]	n[2]	(%)	TOTAL (N=58) Ne[1]	n[2]	(%)
23 - 27 kg/m²	INCREASE >= 7%	WEEK 8	23	0	(0.0)	25	0	(0.0)	48	0	(0.0)
		WEEK 16	19	2	(10.5)	17	1	(5.9)	36	3	(8.3)
		WEEK 24	16	2	(12.5)	14	3	(21.4)	30	5	(16.7)
		WEEK 32	16	5	(31.3)	14	2	(14.3)	30	7	(23.3)
		WEEK 40	16	4	(25.0)	13	3	(23.1)	29	7	(24.1)
		WEEK 48	14	3	(21.4)	11	4	(36.4)	25	7	(28.0)
		WEEK 52	14	1	(7.1)	10	4	(40.0)	24	5	(20.8)
		LAST VISIT	25	4	(16.0)	33	6	(18.2)	58	10	(17.2)
	DECREASE >= 7%	WEEK 8	23	0	(0.0)	25	0	(0.0)	48	0	(0.0)
		WEEK 16	19	1	(5.3)	17	0	(0.0)	36	1	(2.8)
		WEEK 24	16	1	(6.3)	14	0	(0.0)	30	1	(3.3)
		WEEK 32	16	1	(6.3)	14	0	(0.0)	30	1	(3.3)
		WEEK 40	16	0	(0.0)	13	0	(0.0)	29	0	(0.0)
		WEEK 48	14	2	(14.3)	11	0	(0.0)	25	2	(8.0)
		WEEK 52	14	2	(14.3)	10	1	(10.0)	24	3	(12.5)
		LAST VISIT	25	2	(8.0)	33	2	(6.1)	58	4	(6.9)

NOTE: A POTENTIALLY CLINICALLY RELEVANT WEIGHT GAIN (LOSS) IS DEFINED AS WEIGHT GAIN (LOSS) OF 7% OR MORE OVER BASELINE.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH A POST-BASELINE WEIGHT RESULT AT THE VISIT.
[2]n IS THE NUMBER OF SUBJECTS MEETING THE CRITERIA FOR POTENTIAL CLINICAL SIGNIFICANCE.

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表 2.7.4.7-117　ベースライン BMI 別の 7%以上の体重の増加又は減少が認められた被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-14.3.4
Incidence of Potentially Clinically Relevant Weight Gain or Loss by Week and Baseline BMI in Phase D
(Phase D Safety Sample)

BASELINE BMI (kg/m²)		TRIAL WEEK	ARIP IMD (N=95) Ne¹	n²	(%)	PLACEBO (N=83) Ne¹	n²	(%)	TOTAL (N=178) Ne¹	n²	(%)
> 27 kg/m²	INCREASE >= 7%	WEEK 8	72	2	(2.8)	66	1	(1.5)	138	3	(2.2)
		WEEK 16	61	2	(3.3)	55	3	(5.5)	116	5	(4.3)
		WEEK 24	55	8	(14.5)	45	4	(8.9)	100	12	(12.0)
		WEEK 32	51	10	(19.6)	36	6	(16.7)	87	16	(18.4)
		WEEK 40	45	8	(17.8)	33	3	(9.1)	78	11	(14.1)
		WEEK 48	45	8	(17.8)	31	4	(12.9)	76	12	(15.8)
		WEEK 52	42	7	(16.7)	27	4	(14.8)	69	11	(15.9)
		LAST VISIT	91	10	(11.0)	83	9	(10.8)	174	19	(10.9)
	DECREASE >= 7%	WEEK 8	72	1	(1.4)	66	2	(3.0)	138	3	(2.2)
		WEEK 16	61	3	(4.9)	55	3	(5.5)	116	6	(5.2)
		WEEK 24	55	3	(5.5)	45	4	(8.9)	100	7	(7.0)
		WEEK 32	51	4	(7.8)	36	2	(5.6)	87	6	(6.9)
		WEEK 40	45	3	(6.7)	33	5	(15.2)	78	8	(10.3)
		WEEK 48	45	4	(8.9)	31	3	(9.7)	76	7	(9.2)
		WEEK 52	42	1	(2.4)	27	0	(0.0)	69	1	(1.4)
		LAST VISIT	91	4	(4.4)	83	10	(12.0)	174	14	(8.0)

NOTE: A POTENTIALLY CLINICALLY RELEVANT WEIGHT GAIN (LOSS) IS DEFINED AS WEIGHT GAIN (LOSS) OF 7% OR MORE OVER BASELINE.
¹Ne IS THE TOTAL NUMBER OF SUBJECTS WITH A POST-BASELINE WEIGHT RESULT AT THE VISIT.
²n IS THE NUMBER OF SUBJECTS MEETING THE CRITERIA FOR POTENTIAL CLINICAL SIGNIFICANCE.

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＜資料番号 5.3.5.1-01：CT-14.3.4＞

表 2.7.4.7-118　体重関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.10
Incidence of Treatment-emergent Adverse Events Related to Weight in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
臨床検査	TOTAL1)	31	(23.5)	30	(22.6)	61	(23.0)
	体重減少	0	(0.0)	6	(4.5)	6	(2.3)
	体重増加	31	(23.5)	24	(18.0)	55	(20.8)
TOTAL2)		31	(23.5)	30	(22.6)	61	(23.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

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表 2.7.4.7-118　体重関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.10
Incidence of Treatment-emergent Adverse Events Related to Weight in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO WEIGHT: MEDDRA 19.0 PRIMARY TERMS

UNDERWEIGHT, WEIGHT DECREASED, WEIGHT INCREASED, OVERWEIGHT, WEIGHT ABNORMAL, WEIGHT FLUCTUATION, WEIGHT GAIN POOR, WEIGHT LOSS DIET, WEIGHT NORMAL, WEIGHT CONTROL, FEAR OF WEIGHT GAIN, ABNORMAL WEIGHT GAIN, ABNORMAL LOSS OF WEIGHT, BONE DENSITY DECREASED, OEDEMA, DRY WEIGHT EVALUATION

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＜資料番号 5.3.5.1-01：CT-8.2.5.10 より作成＞

表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=WEIGHT (kg)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	613	87.6	84.8	22.7	37.3	187.0								
	WEEK 2	166	88.9	86.9	23.9	39.8	192.6	165	89.0	23.9	-0.1	0.0	2.0	-14.6	5.6
	WEEK 4	146	87.6	84.0	21.4	38.8	160.9	146	87.3	21.1	0.4	0.4	2.3	-9.5	10.9
	WEEK 6	108	87.3	83.4	22.8	42.1	188.4	108	87.2	23.1	0.1	0.0	2.9	-7.9	10.7
	WEEK 8	141	87.4	86.0	21.8	43.1	160.0	141	86.8	22.0	0.6	0.6	3.2	-14.5	9.0
	WEEK > 8	12	94.8	80.1	35.7	58.5	161.4	12	94.5	34.3	0.3	1.4	3.1	-4.9	4.1
	LAST VISIT	550	87.8	85.0	22.4	38.8	188.4	549	87.5	22.4	0.3	0.2	2.6	-14.6	10.9
PHASE C	BASELINE	425	87.7	85.7	22.4	38.8	188.4								
	WEEK 8	356	88.1	86.1	22.5	39.4	197.0	356	87.3	22.3	0.9	0.5	3.0	-7.6	15.0
	WEEK 12	225	89.7	88.3	23.7	40.9	197.1	225	88.6	23.7	1.1	1.0	3.6	-10.5	13.0
	WEEK 16	93	88.4	87.8	21.7	51.9	158.3	93	87.7	21.6	0.7	0.2	4.5	-8.2	17.7
	WEEK 28	8	98.9	105.3	15.4	76.0	117.0	8	97.9	13.7	1.0	1.4	5.7	-9.5	9.0
	LAST VISIT	403	88.6	86.6	22.9	40.9	197.1	403	87.6	22.7	1.0	0.7	4.0	-14.1	17.7

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY MASS INDEX (kg/m²)

								CHANGE FROM BASELINE						
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	613	30.5	29.4	7.2	16.1	68.7								
	WEEK 2	166	30.9	30.1	7.5	18.1	70.7	165	30.9	7.5	-0.0	0.0	0.7	-4.5	2.0
	WEEK 4	146	30.3	30.0	6.3	16.6	51.9	146	30.2	6.2	0.1	0.1	0.8	-3.7	4.2
	WEEK 6	108	30.4	29.3	7.8	17.7	69.2	108	30.4	7.9	0.0	0.0	1.0	-2.4	3.7
	WEEK 8	141	30.9	30.1	7.7	18.7	54.7	141	30.7	7.7	0.2	0.2	1.1	-4.7	3.1
	WEEK > 8	12	31.6	27.8	10.3	23.6	55.8	12	31.6	9.8	0.1	0.3	1.1	-1.8	1.4
	LAST VISIT	550	30.6	29.7	7.2	16.6	69.2	549	30.5	7.2	0.1	0.1	0.9	-4.7	4.2
PHASE C	BASELINE	425	30.6	29.8	7.2	16.6	69.2								
	WEEK 8	356	30.8	29.9	7.2	16.8	72.4	356	30.5	7.1	0.3	0.2	1.1	-3.1	5.6
	WEEK 12	225	31.2	30.1	7.5	17.5	72.4	225	30.8	7.5	0.4	0.4	1.3	-4.1	5.3
	WEEK 16	93	30.9	29.8	7.2	18.6	54.1	93	30.7	7.1	0.3	0.1	1.6	-3.0	5.4
	WEEK 28	8	36.1	35.7	7.1	27.6	49.3	8	35.7	6.0	0.5	0.5	2.1	-3.4	3.3
	LAST VISIT	403	30.9	30.0	7.4	17.5	72.4	403	30.6	7.3	0.4	0.3	1.4	-5.1	5.6

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	36.6	36.6	0.3	35.4	38.7								
	WEEK 2	552	36.6	36.6	0.3	35.1	37.8	552	36.6	0.3	-0.0	0.0	0.4	-2.2	1.2
	WEEK 4	406	36.6	36.6	0.3	35.0	37.7	406	36.6	0.3	0.0	0.0	0.4	-1.3	1.6
	WEEK 6	254	36.6	36.6	0.3	35.3	37.6	254	36.6	0.4	-0.0	0.0	0.4	-1.3	1.1
	WEEK 8	141	36.6	36.7	0.3	35.7	37.3	141	36.7	0.3	-0.0	0.0	0.4	-1.5	1.1
	WEEK > 8	12	36.7	36.7	0.2	36.1	37.0	12	36.7	0.4	-0.0	0.0	0.3	-0.7	0.5
	LAST VISIT	590	36.6	36.6	0.3	35.3	37.5	590	36.6	0.3	-0.0	0.0	0.4	-2.2	1.6
PHASE C	BASELINE	425	36.6	36.6	0.3	35.3	37.5								
	WEEK 1	405	36.6	36.6	0.4	34.7	37.8	405	36.6	0.3	0.0	0.0	0.4	-2.3	1.3
	WEEK 2	400	36.6	36.6	0.4	35.3	38.6	400	36.6	0.3	0.0	0.0	0.4	-1.9	1.9
	WEEK 3	382	36.6	36.6	0.3	35.4	38.2	382	36.6	0.3	0.0	0.0	0.4	-1.8	1.4
	WEEK 4	381	36.6	36.6	0.3	35.6	39.6	381	36.6	0.3	0.1	0.0	0.4	-1.1	2.9
	WEEK 6	372	36.6	36.7	0.3	34.8	37.9	372	36.6	0.3	0.0	0.0	0.4	-2.0	1.1
	WEEK 8	356	36.7	36.7	0.4	35.2	39.8	356	36.6	0.3	0.0	0.0	0.4	-1.2	3.1
	WEEK 10	344	36.7	36.7	0.3	35.5	38.2	344	36.6	0.3	0.1	0.0	0.4	-1.1	1.5
	WEEK 12	321	36.6	36.6	0.3	35.4	38.3	321	36.6	0.3	0.0	0.0	0.4	-1.3	1.6
	WEEK 14	108	36.7	36.7	0.3	35.7	38.0	108	36.6	0.3	0.1	0.1	0.3	-1.0	1.2
	WEEK 16	97	36.7	36.7	0.3	35.9	38.1	97	36.6	0.3	0.0	0.1	0.4	-1.0	1.3
	WEEK 18	69	36.6	36.6	0.4	35.2	37.9	69	36.6	0.3	-0.0	0.0	0.4	-1.4	0.7
	WEEK 20	62	36.7	36.7	0.3	35.7	37.5	62	36.6	0.3	0.0	0.0	0.3	-0.7	0.9
	WEEK 22	42	36.7	36.8	0.3	36.0	37.5	42	36.6	0.3	0.1	0.0	0.3	-0.8	0.9
	WEEK 24	28	36.6	36.7	0.3	36.2	37.5	28	36.6	0.3	0.1	0.1	0.3	-0.4	0.7
	WEEK 26	11	36.5	36.5	0.2	36.3	37.1	11	36.6	0.3	-0.1	0.0	0.3	-0.6	0.5
	WEEK 28	8	36.6	36.7	0.3	36.1	37.0	8	36.6	0.2	0.1	0.1	0.3	-0.4	0.5
	WEEK > 28	2	36.5	36.5	0.7	36.0	37.0	2	36.3	0.4	0.2	0.2	1.1	-0.6	1.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

									CHANGE FROM BASELINE						
									BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	36.6	36.6	0.3	35.4	38.3	421	36.6	0.3	0.0	0.0	0.4	-1.3	1.6

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-23.2.3　FINAL

表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

								CHANGE FROM BASELINE						
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	72.5	72.0	10.7	44.0	108.0								
	WEEK 2	552	73.9	73.0	11.1	38.0	121.0	552	72.2	10.7	1.7	2.0	10.7	-36.0	43.0
	WEEK 4	406	73.0	72.0	11.1	45.0	113.0	406	72.4	10.9	0.7	0.0	10.3	-36.0	38.0
	WEEK 6	254	73.1	72.0	10.8	48.0	106.0	254	72.8	10.5	0.3	0.0	9.6	-34.0	29.0
	WEEK 8	141	73.6	72.0	9.5	50.0	99.0	141	73.1	9.7	0.5	0.0	9.4	-30.0	37.0
	WEEK > 8	12	73.8	73.5	10.8	57.0	96.0	12	70.8	9.0	3.0	3.0	7.8	-12.0	18.0
	LAST VISIT	590	72.7	72.0	10.5	45.0	102.0	590	72.3	10.8	0.4	0.0	10.1	-36.0	37.0
PHASE C	BASELINE	425	72.8	72.0	10.4	45.0	102.0								
	WEEK 1	405	75.4	75.0	10.9	45.0	111.0	405	72.9	10.5	2.5	1.0	9.2	-21.0	48.0
	WEEK 2	400	75.3	74.0	10.8	49.0	108.0	400	72.7	10.4	2.6	2.0	9.8	-25.0	40.0
	WEEK 3	382	75.5	76.0	10.6	45.0	102.0	382	72.8	10.5	2.7	2.0	9.8	-36.0	32.0
	WEEK 4	381	74.4	74.0	10.2	45.0	106.0	381	72.7	10.4	1.7	0.0	9.8	-27.0	48.0
	WEEK 6	372	74.7	75.0	10.7	47.0	114.0	372	72.7	10.4	2.1	2.0	10.3	-27.0	45.0
	WEEK 8	356	74.2	74.0	10.9	48.0	107.0	356	72.8	10.6	1.4	0.0	9.8	-29.0	49.0
	WEEK 10	344	74.6	74.0	10.4	44.0	104.0	344	72.7	10.5	1.9	1.0	10.6	-32.0	43.0
	WEEK 12	321	73.0	72.0	10.5	40.0	104.0	321	72.9	10.7	0.1	0.0	9.9	-36.0	30.0
	WEEK 14	108	73.2	72.0	10.7	49.0	107.0	108	72.2	9.9	0.9	0.0	11.0	-32.0	41.0
	WEEK 16	97	75.3	76.0	11.6	47.0	109.0	97	72.5	10.3	2.8	2.0	10.3	-24.0	31.0
	WEEK 18	69	74.5	74.0	10.2	51.0	99.0	69	73.3	11.0	1.3	0.0	12.7	-32.0	32.0
	WEEK 20	62	74.0	73.0	8.5	51.0	90.0	62	72.5	10.6	1.4	1.0	10.2	-18.0	27.0
	WEEK 22	42	74.9	73.5	11.2	49.0	100.0	42	72.8	11.9	2.2	4.5	11.1	-28.0	21.0
	WEEK 24	28	73.3	73.0	10.0	51.0	90.0	28	71.5	10.3	1.9	3.5	11.3	-24.0	28.0
	WEEK 26	11	74.4	74.0	6.3	65.0	88.0	11	74.5	10.1	-0.1	1.0	11.6	-22.0	20.0
	WEEK 28	8	76.1	75.0	10.5	60.0	96.0	8	72.4	9.7	3.8	3.0	13.9	-20.0	27.0
	WEEK > 28	2	75.0	75.0	5.7	71.0	79.0	2	76.5	10.6	-1.5	-1.5	4.9	-5.0	2.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

									CHANGE FROM BASELINE						
								BASELINE							
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	73.1	72.0	10.7	40.0	104.0	421	72.9	10.4	0.3	0.0	10.0	-36.0	43.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-23.2.3　FINAL

表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	120.2	120.0	13.2	84.0	166.0								
	WEEK 2	552	120.4	120.0	12.5	89.0	155.0	552	120.0	13.1	0.4	0.0	10.5	-50.0	40.0
	WEEK 4	406	119.9	120.0	12.6	89.0	160.0	406	120.4	12.8	-0.5	0.0	9.8	-37.0	33.0
	WEEK 6	254	121.2	120.0	12.8	91.0	178.0	254	120.2	12.7	1.0	1.0	10.2	-33.0	32.0
	WEEK 8	141	119.9	120.0	12.4	88.0	150.0	141	120.7	12.9	-0.8	0.0	11.3	-43.0	28.0
	WEEK > 8	12	118.0	116.0	13.2	98.0	140.0	12	119.0	18.4	-1.0	-0.5	11.3	-22.0	18.0
	LAST VISIT	590	119.8	120.0	12.8	88.0	178.0	590	120.1	13.2	-0.3	0.0	10.9	-50.0	32.0
PHASE C	BASELINE	425	119.7	119.0	12.6	88.0	178.0								
	WEEK 1	405	120.5	120.0	13.6	90.0	168.0	405	119.6	12.6	0.8	0.0	9.7	-27.0	41.0
	WEEK 2	400	120.0	120.0	12.9	86.0	165.0	400	119.7	12.5	0.3	0.0	10.2	-40.0	33.0
	WEEK 3	382	119.1	119.0	12.1	84.0	165.0	382	119.3	12.3	-0.2	0.0	10.5	-51.0	28.0
	WEEK 4	381	118.9	120.0	12.2	90.0	163.0	381	119.3	11.9	-0.4	0.0	9.7	-34.0	32.0
	WEEK 6	372	119.0	120.0	12.2	90.0	156.0	372	119.4	12.3	-0.4	0.0	10.1	-47.0	37.0
	WEEK 8	356	119.0	120.0	12.8	89.0	159.0	356	119.3	12.4	-0.3	0.0	10.7	-31.0	37.0
	WEEK 10	344	119.6	120.0	13.3	90.0	164.0	344	119.3	12.4	0.3	0.0	11.6	-42.0	47.0
	WEEK 12	321	119.3	120.0	12.4	90.0	177.0	321	119.8	12.5	-0.4	0.0	11.4	-35.0	44.0
	WEEK 14	108	119.5	120.0	11.7	92.0	146.0	108	119.6	11.5	-0.1	0.0	10.9	-35.0	31.0
	WEEK 16	97	121.4	120.0	11.9	97.0	162.0	97	120.4	11.5	1.1	0.0	10.9	-23.0	33.0
	WEEK 18	69	118.4	118.0	12.8	98.0	158.0	69	119.2	11.2	-0.8	0.0	10.2	-25.0	32.0
	WEEK 20	62	120.7	119.0	11.8	90.0	155.0	62	118.3	11.1	2.4	2.0	11.8	-33.0	35.0
	WEEK 22	42	119.6	121.0	13.3	94.0	156.0	42	119.0	10.7	0.6	0.0	7.6	-14.0	15.0
	WEEK 24	28	122.0	122.0	15.4	94.0	158.0	28	118.5	10.9	3.5	2.5	12.3	-18.0	30.0
	WEEK 26	11	119.5	120.0	14.4	98.0	146.0	11	122.1	12.3	-2.6	0.0	11.2	-23.0	12.0
	WEEK 28	8	120.3	120.5	8.8	108.0	130.0	8	122.5	9.9	-2.3	-1.0	10.2	-20.0	13.0
	WEEK > 28	2	110.5	110.5	19.1	97.0	124.0	2	107.0	14.1	3.5	3.5	4.9	0.0	7.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

			BASELINE					CHANGE FROM BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	120.0	120.0	13.0	90.0	177.0	421	119.6	12.6	0.4	0.0	11.4	-33.0	44.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	75.5	76.0	9.6	45.0	116.0								
	WEEK 2	552	76.0	76.0	9.6	48.0	105.0	552	75.4	9.6	0.6	0.0	8.3	-34.0	29.0
	WEEK 4	406	75.8	76.0	10.0	50.0	109.0	406	75.4	9.6	0.4	0.0	8.3	-32.0	27.0
	WEEK 6	254	75.7	76.0	8.5	53.0	98.0	254	75.5	9.7	0.2	0.0	8.7	-36.0	25.0
	WEEK 8	141	76.5	77.0	9.4	49.0	100.0	141	75.9	9.4	0.6	0.0	9.5	-42.0	30.0
	WEEK > 8	12	75.0	76.0	7.7	62.0	86.0	12	75.8	9.5	-0.8	0.0	9.6	-20.0	14.0
	LAST VISIT	590	75.9	76.0	9.6	49.0	109.0	590	75.5	9.6	0.4	0.0	8.4	-42.0	30.0
PHASE C	BASELINE	425	75.7	76.0	9.4	49.0	100.0								
	WEEK 1	405	75.8	76.0	9.5	51.0	98.0	405	75.6	9.4	0.3	0.0	7.7	-25.0	26.0
	WEEK 2	400	75.9	76.0	9.6	52.0	103.0	400	75.9	9.2	0.1	0.0	8.3	-26.0	27.0
	WEEK 3	382	75.7	76.0	8.9	50.0	113.0	382	75.5	9.3	0.2	0.0	8.2	-26.0	35.0
	WEEK 4	381	75.0	74.0	9.3	49.0	104.0	381	75.6	9.2	-0.6	0.0	7.6	-27.0	21.0
	WEEK 6	372	75.2	75.0	9.3	50.0	102.0	372	75.6	9.2	-0.4	0.0	8.3	-27.0	20.0
	WEEK 8	356	75.0	75.5	9.6	44.0	98.0	356	75.4	9.2	-0.4	0.0	9.0	-32.0	19.0
	WEEK 10	344	75.3	76.0	9.5	48.0	105.0	344	75.6	9.1	-0.4	0.0	9.0	-31.0	29.0
	WEEK 12	321	76.2	76.0	9.1	54.0	107.0	321	75.9	9.1	0.3	0.0	8.2	-30.0	25.0
	WEEK 14	108	76.2	77.5	9.3	49.0	103.0	108	77.1	8.4	-0.9	0.0	9.8	-38.0	20.0
	WEEK 16	97	76.8	76.0	8.8	58.0	98.0	97	77.7	8.3	-0.9	-2.0	9.7	-26.0	26.0
	WEEK 18	69	75.1	78.0	9.5	59.0	113.0	69	76.8	8.5	-1.8	-2.0	9.9	-28.0	31.0
	WEEK 20	62	76.4	75.5	9.6	57.0	98.0	62	76.3	8.6	0.1	1.0	9.9	-24.0	20.0
	WEEK 22	42	77.0	77.5	9.7	60.0	99.0	42	76.5	9.1	0.5	1.5	8.7	-20.0	16.0
	WEEK 24	28	75.4	74.5	10.6	60.0	99.0	28	75.1	10.0	0.3	2.5	11.9	-24.0	24.0
	WEEK 26	11	77.2	78.0	11.0	58.0	93.0	11	78.5	11.2	-1.3	-2.0	9.0	-16.0	15.0
	WEEK 28	8	75.4	74.5	7.2	68.0	86.0	8	79.0	9.9	-3.6	-2.0	7.7	-18.0	4.0
	WEEK > 28	2	76.5	76.5	21.9	61.0	92.0	2	75.0	15.6	1.5	1.5	6.4	-3.0	6.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

									CHANGE FROM BASELINE						
									BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	76.3	77.0	9.5	54.0	107.0	421	75.7	9.4	0.6	1.0	8.5	-32.0	29.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

								CHANGE FROM BASELINE						
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	76.4	76.0	10.9	52.0	115.0								
	WEEK 2	552	77.7	77.0	10.8	50.0	114.0	552	76.2	10.9	1.4	1.0	10.4	-28.0	39.0
	WEEK 4	406	76.7	76.0	10.7	43.0	108.0	406	75.9	10.8	0.7	0.0	9.9	-27.0	40.0
	WEEK 6	254	77.0	77.0	10.6	48.0	103.0	254	76.3	10.6	0.6	1.0	9.9	-36.0	26.0
	WEEK 8	141	77.3	77.0	9.9	53.0	106.0	141	77.5	9.9	-0.2	1.0	9.5	-31.0	21.0
	WEEK > 8	12	77.0	76.0	12.5	55.0	104.0	12	75.6	9.6	1.4	0.0	9.5	-13.0	20.0
	LAST VISIT	590	76.4	76.0	10.7	43.0	108.0	590	76.3	10.9	0.1	0.0	10.2	-36.0	29.0
PHASE C	BASELINE	425	76.5	76.0	10.7	43.0	108.0								
	WEEK 1	405	79.3	79.0	11.1	50.0	115.0	405	76.5	10.7	2.7	2.0	9.5	-22.0	38.0
	WEEK 2	400	79.0	79.0	11.3	49.0	117.0	400	76.3	10.7	2.7	1.0	10.0	-26.0	53.0
	WEEK 3	382	79.0	78.5	11.1	51.0	120.0	382	76.4	10.7	2.6	1.0	10.3	-27.0	42.0
	WEEK 4	381	78.5	78.0	10.9	50.0	119.0	381	76.3	10.7	2.2	1.0	10.4	-39.0	55.0
	WEEK 6	372	78.8	79.5	11.4	47.0	115.0	372	76.2	10.7	2.6	2.0	10.5	-29.0	51.0
	WEEK 8	356	78.2	78.0	10.8	46.0	123.0	356	76.3	10.7	1.9	1.0	9.8	-30.0	53.0
	WEEK 10	344	78.7	78.0	11.2	48.0	116.0	344	76.1	10.8	2.6	2.0	10.9	-26.0	42.0
	WEEK 12	321	76.7	76.0	10.5	44.0	106.0	321	76.0	10.8	0.7	1.0	10.4	-36.0	30.0
	WEEK 14	108	77.2	76.5	10.6	51.0	107.0	108	75.2	9.1	2.0	1.0	10.3	-30.0	37.0
	WEEK 16	97	78.7	78.0	11.0	54.0	112.0	97	75.2	9.6	3.6	3.0	10.7	-21.0	32.0
	WEEK 18	69	77.7	78.0	10.5	47.0	101.0	69	75.9	10.0	1.8	1.0	12.4	-32.0	26.0
	WEEK 20	62	77.4	78.0	9.0	51.0	96.0	62	75.3	9.9	2.1	2.0	10.4	-21.0	28.0
	WEEK 22	42	77.9	78.0	10.5	52.0	99.0	42	75.9	10.7	2.0	4.0	9.8	-24.0	20.0
	WEEK 24	28	75.8	76.0	9.9	53.0	92.0	28	75.7	10.5	0.1	2.5	11.7	-30.0	26.0
	WEEK 26	11	79.2	80.0	7.0	69.0	92.0	11	77.1	9.4	2.1	0.0	13.7	-14.0	32.0
	WEEK 28	8	77.0	74.5	10.4	62.0	96.0	8	74.3	9.4	2.8	5.0	14.3	-22.0	22.0
	WEEK > 28	2	82.0	82.0	1.4	81.0	83.0	2	83.0	15.6	-1.0	-1.0	14.1	-11.0	9.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

			CHANGE FROM BASELINE											
			BASELINE											
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	77.3	78.0	10.8	44.0	113.0	421	76.6	10.7	0.7	0.0	10.5	-36.0	35.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	121.0	120.0	13.3	82.0	170.0								
	WEEK 2	552	121.5	121.0	13.1	82.0	172.0	552	120.7	13.0	0.8	0.0	10.3	-36.0	39.0
	WEEK 4	406	120.7	120.0	13.1	90.0	159.0	406	121.4	12.8	-0.7	0.0	10.6	-40.0	37.0
	WEEK 6	254	121.2	121.5	13.1	91.0	181.0	254	121.3	12.4	-0.1	0.0	10.7	-32.0	45.0
	WEEK 8	141	121.1	121.0	13.3	79.0	150.0	141	121.8	12.7	-0.6	0.0	10.8	-39.0	36.0
	WEEK > 8	12	122.5	121.0	12.3	100.0	140.0	12	123.5	19.4	-1.0	-0.5	15.4	-34.0	22.0
	LAST VISIT	590	120.4	120.0	13.7	79.0	181.0	590	120.9	13.3	-0.5	0.0	11.1	-40.0	45.0
PHASE C	BASELINE	425	120.2	120.0	13.5	79.0	181.0								
	WEEK 1	405	120.2	120.0	13.6	69.0	164.0	405	120.2	13.5	0.1	0.0	10.2	-42.0	32.0
	WEEK 2	400	119.9	120.0	13.4	85.0	176.0	400	120.2	13.4	-0.3	0.0	11.2	-47.0	31.0
	WEEK 3	382	119.2	120.0	12.4	87.0	170.0	382	119.8	13.3	-0.6	0.0	10.6	-52.0	30.0
	WEEK 4	381	119.2	119.0	12.5	89.0	155.0	381	119.9	13.0	-0.7	0.0	10.5	-29.0	38.0
	WEEK 6	372	119.2	119.0	12.5	90.0	156.0	372	120.0	13.3	-0.8	0.0	11.1	-49.0	34.0
	WEEK 8	356	119.8	120.0	12.7	88.0	158.0	356	119.8	13.4	0.0	0.0	11.6	-44.0	34.0
	WEEK 10	344	119.6	120.0	12.9	84.0	162.0	344	119.9	13.4	-0.3	0.0	11.8	-51.0	49.0
	WEEK 12	321	119.5	120.0	12.8	86.0	158.0	321	120.1	13.6	-0.6	0.0	12.0	-42.0	47.0
	WEEK 14	108	120.0	120.0	12.4	72.0	147.0	108	120.2	11.9	-0.1	0.0	12.1	-39.0	32.0
	WEEK 16	97	121.7	120.0	12.5	88.0	165.0	97	120.7	12.3	1.0	0.0	12.7	-30.0	57.0
	WEEK 18	69	118.5	119.0	14.7	91.0	155.0	69	119.6	11.6	-1.1	-1.0	10.8	-22.0	30.0
	WEEK 20	62	119.6	120.0	12.9	94.0	156.0	62	118.8	11.7	0.8	0.0	10.6	-25.0	30.0
	WEEK 22	42	120.7	121.0	13.1	96.0	159.0	42	119.8	12.0	0.9	0.5	11.0	-18.0	29.0
	WEEK 24	28	122.2	121.0	14.2	100.0	155.0	28	119.8	12.3	2.4	1.5	12.8	-18.0	22.0
	WEEK 26	11	118.5	115.0	13.2	100.0	144.0	11	120.7	13.7	-2.3	0.0	10.0	-20.0	15.0
	WEEK 28	8	117.5	117.0	9.0	106.0	130.0	8	121.1	12.1	-3.6	-6.0	14.5	-20.0	20.0
	WEEK > 28	2	113.5	113.5	26.2	95.0	132.0	2	112.5	20.5	1.0	1.0	5.7	-3.0	5.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

			BASELINE					CHANGE FROM BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	120.2	120.0	13.1	86.0	162.0	421	120.2	13.5	0.0	0.0	12.1	-42.0	47.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

								CHANGE FROM BASELINE						
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	614	78.4	79.0	9.6	52.0	113.0								
	WEEK 2	552	78.8	79.0	9.7	53.0	111.0	552	78.3	9.7	0.5	0.0	8.4	-36.0	31.0
	WEEK 4	406	78.4	78.5	10.1	48.0	113.0	406	78.4	9.5	0.0	0.0	8.4	-41.0	41.0
	WEEK 6	254	78.2	80.0	9.3	54.0	108.0	254	78.2	9.5	-0.0	0.0	8.5	-26.0	27.0
	WEEK 8	141	78.5	80.0	9.7	44.0	100.0	141	78.6	9.3	-0.2	0.0	9.9	-30.0	31.0
	WEEK > 8	12	77.8	76.0	7.6	64.0	89.0	12	79.4	6.6	-1.7	-0.5	8.4	-16.0	8.0
	LAST VISIT	590	78.4	79.0	9.7	44.0	112.0	590	78.4	9.6	-0.0	0.0	8.5	-30.0	31.0
PHASE C	BASELINE	425	78.4	79.0	9.8	44.0	108.0								
	WEEK 1	405	78.3	78.0	9.8	52.0	107.0	405	78.2	9.7	0.1	0.0	8.0	-28.0	27.0
	WEEK 2	400	78.6	79.0	9.6	41.0	106.0	400	78.4	9.7	0.1	0.0	8.2	-37.0	28.0
	WEEK 3	382	77.9	78.0	9.0	55.0	101.0	382	78.1	9.6	-0.2	0.0	8.5	-32.0	26.0
	WEEK 4	381	78.0	79.0	9.2	55.0	105.0	381	78.3	9.6	-0.3	0.0	8.1	-24.0	28.0
	WEEK 6	372	78.2	78.0	9.2	58.0	106.0	372	78.3	9.6	-0.0	0.0	8.4	-26.0	31.0
	WEEK 8	356	78.0	80.0	9.5	46.0	103.0	356	78.0	9.6	0.0	0.0	9.0	-38.0	35.0
	WEEK 10	344	78.4	79.0	9.9	51.0	110.0	344	78.1	9.6	0.3	0.0	8.8	-22.0	30.0
	WEEK 12	321	78.2	79.0	9.5	52.0	104.0	321	78.2	9.6	0.1	0.0	8.9	-25.0	31.0
	WEEK 14	108	78.6	78.0	9.1	51.0	107.0	108	78.9	8.8	-0.3	0.0	9.7	-22.0	28.0
	WEEK 16	97	79.3	80.0	8.6	60.0	100.0	97	79.3	8.9	0.0	0.0	10.5	-27.0	28.0
	WEEK 18	69	77.0	77.0	9.2	60.0	106.0	69	78.8	8.9	-1.8	-2.0	9.6	-24.0	22.0
	WEEK 20	62	78.0	78.0	8.7	58.0	100.0	62	78.4	8.8	-0.4	-1.0	9.9	-30.0	31.0
	WEEK 22	42	79.1	79.5	9.1	56.0	97.0	42	78.7	9.4	0.5	0.0	10.7	-26.0	27.0
	WEEK 24	28	76.5	76.0	9.4	60.0	92.0	28	78.4	9.4	-1.8	-2.0	10.4	-20.0	24.0
	WEEK 26	11	78.7	80.0	10.6	64.0	102.0	11	80.9	9.3	-2.2	-3.0	7.7	-16.0	9.0
	WEEK 28	8	77.0	78.5	6.6	66.0	84.0	8	81.0	8.6	-4.0	-3.0	7.9	-16.0	5.0
	WEEK > 28	2	80.0	80.0	12.7	71.0	89.0	2	82.0	15.6	-2.0	-2.0	2.8	-4.0	0.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-119　体重，バイタルサインの記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.3
Mean Change From Baseline in Vital Signs Parameters
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

			BASELINE					CHANGE FROM BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	LAST VISIT	421	78.5	79.0	9.6	55.0	110.0	421	78.3	9.8	0.1	0.0	9.2	-32.0	31.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.1-01：CT-23.2.3 より作成＞

表 2.7.4.7-120　体重関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.10
Incidence of Treatment-emergent Adverse Events Related to Weight
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
一般・全身障害および投与部位の状態	TOTAL1)	1	(0.2)	0	(0.0)
	浮腫	1	(0.2)	0	(0.0)
臨床検査	TOTAL1)	23	(3.7)	54	(12.7)
	体重減少	1	(0.2)	8	(1.9)
	体重増加	22	(3.6)	47	(11.1)
TOTAL2)		24	(3.9)	54	(12.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BK.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
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表 2.7.4.7-120　体重関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.10
Incidence of Treatment-emergent Adverse Events Related to Weight
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO WEIGHT: MEDDRA 19.0 PRIMARY TERMS

UNDERWEIGHT, WEIGHT DECREASED, WEIGHT INCREASED, OVERWEIGHT, WEIGHT ABNORMAL, WEIGHT FLUCTUATION, WEIGHT GAIN POOR, WEIGHT LOSS DIET, WEIGHT NORMAL, WEIGHT CONTROL, FEAR OF WEIGHT GAIN, ABNORMAL WEIGHT GAIN, ABNORMAL LOSS OF WEIGHT, BONE DENSITY DECREASED, OEDEMA, DRY WEIGHT EVALUATION

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＜資料番号 5.3.5.1-01：CT-21.2.5.10 より作成＞

表 2.7.4.7-121　ベースライン BMI 別体重の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.3.2
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	BASELINE BMI (kg/m²)	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: MEDIAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MIN	CHANGE FROM BASELINE: MAX
DE NOVO	< 23 kg/m²	BASELINE	57	57.3	55.0	9.0	43.4	83.9								
		WEEK 8	51	58.1	57.1	9.6	43.4	85.4	51	57.3	9.2	0.7	0.4	2.7	-3.4	13.1
		WEEK 16	49	58.1	56.4	9.4	43.9	86.0	49	57.4	9.1	0.7	0.1	3.3	-6.8	11.3
		WEEK 24	44	58.2	56.5	9.4	43.0	87.0	44	57.3	8.9	1.0	0.4	3.5	-6.8	10.0
		WEEK 28	2	60.7	60.7	1.9	59.3	62.0	2	55.8	9.4	4.9	4.9	7.5	-0.4	10.2
		WEEK 32	39	58.3	57.0	9.5	43.9	88.6	39	57.0	9.1	1.3	0.2	4.0	-4.4	11.6
		WEEK 40	35	57.9	56.8	10.0	41.8	89.0	35	57.0	9.3	1.0	0.3	4.1	-5.0	12.0
		WEEK 48	30	57.4	56.7	10.4	43.8	90.1	30	56.8	9.0	0.7	0.0	4.0	-7.6	12.4
		WEEK 52	33	58.0	57.5	10.3	43.0	92.3	33	57.0	9.2	1.0	0.0	4.2	-8.2	14.5
		LAST VISIT	57	58.1	57.0	9.3	43.0	92.3	57	57.3	9.0	0.8	-0.1	3.8	-8.2	13.5
	23 - 27 kg/m²	BASELINE	92	71.5	70.8	9.2	52.7	93.5								
		WEEK 8	81	71.6	70.8	9.8	51.7	97.5	81	71.3	9.3	0.2	0.1	2.3	-5.8	7.0
		WEEK 16	79	71.9	71.5	10.3	50.8	98.8	79	71.1	9.1	0.8	0.5	3.3	-6.9	9.6
		WEEK 24	73	71.2	70.0	10.5	51.2	102.5	73	70.7	9.2	0.5	0.0	3.9	-8.0	13.2
		WEEK 28	4	85.2	87.6	16.0	63.5	102.2	4	80.6	10.6	4.6	7.0	6.3	-4.5	9.0
		WEEK 32	68	70.8	70.1	10.0	51.5	94.7	68	70.7	9.0	0.0	0.0	4.7	-9.0	16.7
		WEEK 40	64	70.8	69.8	10.4	49.5	97.5	64	70.4	8.8	0.5	0.3	5.3	-12.0	18.7
		WEEK 48	63	70.8	69.5	10.3	49.5	99.5	63	70.5	8.6	0.3	0.7	5.6	-13.0	20.0
		WEEK 52	63	70.8	70.0	10.6	48.5	101.4	63	70.6	8.7	0.2	0.7	5.8	-13.0	21.9
		LAST VISIT	89	71.9	70.6	11.0	48.5	102.2	89	71.5	9.3	0.4	0.9	5.5	-13.0	21.9
	> 27 kg/m²	BASELINE	230	98.7	96.1	22.3	59.9	187.3								
		WEEK 8	205	99.3	96.1	22.5	61.8	186.6	205	99.0	22.6	0.3	0.1	2.9	-11.7	8.8
		WEEK 16	191	100.6	97.2	23.1	60.7	186.8	191	100.3	23.3	0.3	0.0	4.5	-15.7	11.9
		WEEK 24	168	100.0	96.4	23.3	61.0	194.2	168	99.3	22.1	0.7	0.0	6.5	-17.4	40.1

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.3.2 FINAL

表 2.7.4.7-121　ベースライン BMI 別体重の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.3.2
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	BASELINE BMI (kg/m²)	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: MEDIAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MIN	CHANGE FROM BASELINE: MAX
									__BASELINE___							
DE NOVO	> 27 kg/m²	WEEK 28	18	103.2	95.0	28.9	70.3	183.0	18	104.5	30.1	-1.4	-1.8	5.8	-11.7	8.1
		WEEK 32	150	100.2	96.7	22.5	59.6	180.0	150	99.5	21.9	0.7	0.5	6.7	-25.2	20.4
		WEEK 40	130	100.1	97.0	23.0	58.0	180.1	130	99.0	21.3	1.1	0.6	8.0	-29.2	22.0
		WEEK 48	128	99.9	97.2	23.0	54.0	180.1	128	98.8	21.0	1.1	0.8	8.8	-33.3	26.4
		WEEK 52	128	100.2	97.8	22.2	50.7	181.0	128	98.8	20.3	1.5	0.4	8.9	-35.6	29.3
		LAST VISIT	224	99.1	96.5	23.2	50.7	183.0	224	98.7	22.5	0.5	-0.0	8.1	-35.6	29.3
	TOTAL	BASELINE	379	85.9	83.5	24.7	43.4	187.3								
		WEEK 8	337	86.4	83.5	24.9	43.4	186.6	337	86.0	24.9	0.3	0.2	2.7	-11.7	13.1
		WEEK 16	319	87.0	84.4	25.6	43.9	186.8	319	86.5	25.7	0.5	0.0	4.1	-15.7	11.9
		WEEK 24	285	86.2	82.5	25.5	43.0	194.2	285	85.5	24.8	0.7	0.1	5.5	-17.4	40.1
		WEEK 28	24	96.6	91.2	28.6	59.3	183.0	24	96.5	30.5	0.1	0.2	6.3	-11.7	10.2
		WEEK 32	257	86.1	82.1	25.1	43.9	180.0	257	85.5	24.7	0.6	0.3	5.9	-25.2	20.4
		WEEK 40	229	85.5	81.6	25.4	41.8	180.1	229	84.5	24.1	0.9	0.4	6.8	-29.2	22.0
		WEEK 48	221	85.9	82.0	25.3	43.8	180.1	221	85.0	23.8	0.8	0.6	7.5	-33.3	26.4
		WEEK 52	224	85.7	82.7	25.0	43.0	181.0	224	84.7	23.5	1.0	0.4	7.6	-35.6	29.3
		LAST VISIT	370	86.2	83.0	25.3	43.0	183.0	370	85.8	24.8	0.5	0.1	7.0	-35.6	29.3

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-121　ベースライン BMI 別体重の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.3.2
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	BASELINE BMI (kg/m²)	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: MEDIAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MIN	CHANGE FROM BASELINE: MAX
									BASELINE							
ROLLOVER	< 23 kg/m²	BASELINE	11	58.8	60.0	5.9	46.2	66.3								
		WEEK 8	11	59.5	60.0	6.6	47.1	67.2	11	58.8	5.9	0.7	0.9	1.6	-1.0	4.6
		WEEK 16	11	59.6	60.0	6.4	46.9	67.7	11	58.8	5.9	0.8	0.7	1.5	-1.0	4.6
		WEEK 24	10	59.1	59.8	6.4	46.9	67.8	10	58.3	5.9	0.8	0.5	1.8	-1.9	4.5
		WEEK 28	7	60.4	60.6	6.8	47.2	67.8	7	58.8	6.2	1.5	1.5	2.4	-2.3	5.3
		WEEK 32	3	63.0	62.0	5.6	58.0	69.1	3	61.8	2.5	1.3	0.0	3.3	-1.2	5.0
		WEEK 40	2	63.5	63.5	9.2	57.0	70.0	2	61.7	3.5	1.9	1.9	5.7	-2.2	5.9
		WEEK 48	2	61.9	61.9	9.0	55.5	68.2	2	61.7	3.5	0.2	0.2	5.5	-3.7	4.1
		WEEK 52	2	62.4	62.4	8.3	56.5	68.2	2	61.7	3.5	0.7	0.7	4.8	-2.7	4.1
		LAST VISIT	11	60.0	60.6	6.7	47.2	68.2	11	58.8	5.9	1.2	1.2	2.4	-2.7	5.3
	23 - 27 kg/m²	BASELINE	18	70.9	67.4	9.9	54.1	85.1								
		WEEK 8	13	72.9	67.3	12.2	55.5	90.3	13	71.6	11.2	1.3	1.0	2.4	-2.5	5.7
		WEEK 16	13	72.1	67.3	12.2	56.1	92.1	13	70.8	10.6	1.3	0.2	3.4	-4.6	7.3
		WEEK 24	11	72.9	67.2	13.0	54.8	96.1	11	71.0	10.6	1.9	1.5	4.6	-7.2	11.3
		WEEK 28	8	75.8	77.1	15.2	55.6	99.4	8	73.4	11.6	2.3	1.8	5.8	-6.4	14.6
		WEEK 32	4	75.9	68.2	15.5	67.9	99.1	4	69.6	10.4	6.3	5.3	5.9	0.3	14.3
		WEEK 40	1	71.6	71.6		71.6	71.6	1	63.8		7.8	7.8		7.8	7.8
		LAST VISIT	17	72.5	69.1	12.0	55.6	99.1	17	70.6	10.1	1.9	1.4	4.5	-6.4	14.3
	> 27 kg/m²	BASELINE	56	101.5	96.6	22.5	67.8	183.6								
		WEEK 8	53	99.7	95.9	21.9	68.6	182.7	53	100.3	22.2	-0.6	0.5	3.7	-13.6	7.0
		WEEK 16	50	99.5	95.6	22.4	67.4	184.8	50	100.2	22.6	-0.7	0.1	4.7	-10.6	9.7
		WEEK 24	50	99.1	94.6	22.4	68.3	186.5	50	99.7	22.6	-0.6	0.6	5.1	-12.5	8.7
		WEEK 28	28	100.2	95.2	21.0	68.4	164.3	28	100.2	22.5	0.0	0.3	4.7	-10.0	10.2
		WEEK 32	23	99.6	92.9	24.3	70.5	186.6	23	99.6	23.1	-0.1	2.7	6.5	-16.4	7.7

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-121　ベースライン BMI 別体重の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.3.2
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	BASELINE BMI (kg/m²)	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: BASELINE MEAN	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: MEDIAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MIN	CHANGE FROM BASELINE: MAX
ROLLOVER	> 27 kg/m²	WEEK 40	15	100.0	90.0	27.2	76.0	187.0	15	100.0	26.4	0.1	0.0	5.5	-10.2	8.8
		WEEK 48	13	100.8	95.7	29.8	75.0	188.2	13	101.0	28.4	-0.2	1.1	6.5	-11.6	10.9
		WEEK 52	12	100.6	91.1	31.7	75.0	190.5	12	100.3	29.6	0.3	1.3	6.7	-12.5	10.9
		LAST VISIT	56	101.6	95.8	22.4	68.4	190.5	56	101.5	22.5	0.0	0.3	5.2	-13.9	10.9
	TOTAL	BASELINE	85	89.5	85.1	25.5	46.2	183.6								
		WEEK 8	77	89.4	86.2	24.7	47.1	182.7	77	89.5	25.2	-0.1	0.7	3.3	-13.6	7.0
		WEEK 16	74	88.8	86.1	25.0	46.9	184.8	74	88.9	25.5	-0.1	0.4	4.2	-10.6	9.7
		WEEK 24	71	89.4	87.0	25.0	46.9	186.5	71	89.4	25.4	0.0	1.0	4.8	-12.5	11.3
		WEEK 28	43	89.2	87.0	24.1	47.2	164.3	43	88.5	25.2	0.7	0.6	4.7	-10.0	14.6
		WEEK 32	30	92.7	89.1	25.4	58.0	186.6	30	91.8	25.0	0.9	2.9	6.4	-16.4	14.3
		WEEK 40	18	94.4	89.2	28.0	57.0	187.0	18	93.7	28.0	0.7	0.4	5.5	-10.2	8.8
		WEEK 48	15	95.6	89.3	30.9	55.5	188.2	15	95.8	29.8	-0.2	1.1	6.2	-11.6	10.9
		WEEK 52	14	95.1	87.4	32.4	56.5	190.5	14	94.8	30.6	0.3	1.3	6.3	-12.5	10.9
		LAST VISIT	84	90.2	87.4	25.2	47.2	190.5	84	89.7	25.6	0.6	0.5	4.8	-13.9	14.3

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-121　ベースライン BMI 別体重の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.3.2
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	BASELINE BMI (kg/m²)	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
										BASELINE						
TOTAL	< 23 kg/m²	BASELINE	68	57.5	57.9	8.5	43.4	83.9								
		WEEK 8	62	58.3	58.2	9.1	43.4	85.4	62	57.6	8.6	0.7	0.4	2.6	-3.4	13.1
		WEEK 16	60	58.3	57.3	8.9	43.9	86.0	60	57.7	8.6	0.7	0.1	3.1	-6.8	11.3
		WEEK 24	54	58.4	58.3	8.8	43.0	87.0	54	57.5	8.4	0.9	0.4	3.3	-6.8	10.0
		WEEK 28	9	60.4	60.6	6.0	47.2	67.8	9	58.1	6.4	2.3	1.5	3.7	-2.3	10.2
		WEEK 32	42	58.6	57.2	9.3	43.9	88.6	42	57.4	8.8	1.3	0.2	3.9	-4.4	11.6
		WEEK 40	37	58.2	57.0	9.9	41.8	89.0	37	57.2	9.1	1.0	0.3	4.1	-5.0	12.0
		WEEK 48	32	57.7	56.7	10.2	43.8	90.1	32	57.1	8.8	0.7	0.0	4.0	-7.6	12.4
		WEEK 52	35	58.3	57.5	10.2	43.0	92.3	35	57.3	9.0	0.9	0.0	4.1	-8.2	14.5
		LAST VISIT	68	58.4	57.9	8.9	43.0	92.3	68	57.5	8.5	0.9	0.0	3.6	-8.2	13.5
	23 - 27 kg/m²	BASELINE	110	71.4	70.5	9.3	52.7	93.5								
		WEEK 8	94	71.8	70.5	10.1	51.7	97.5	94	71.4	9.5	0.4	0.4	2.4	-5.8	7.0
		WEEK 16	92	72.0	71.3	10.5	50.8	98.8	92	71.1	9.3	0.9	0.5	3.3	-6.9	9.6
		WEEK 24	84	71.4	70.0	10.7	51.2	102.5	84	70.8	9.3	0.7	0.3	4.0	-8.0	13.2
		WEEK 28	12	78.9	81.6	15.5	55.6	102.2	12	75.8	11.3	3.1	2.3	5.8	-6.4	14.6
		WEEK 32	72	71.0	70.0	10.3	51.5	99.1	72	70.7	9.0	0.4	0.3	4.9	-9.0	16.7
		WEEK 40	65	70.8	69.8	10.4	49.5	97.5	65	70.2	8.7	0.6	0.3	5.3	-12.0	18.7
		WEEK 48	63	70.8	69.5	10.3	49.5	99.5	63	70.5	8.6	0.3	0.7	5.6	-13.0	20.0
		WEEK 52	63	70.8	70.0	10.6	48.5	101.4	63	70.6	8.7	0.2	0.7	5.8	-13.0	21.9
		LAST VISIT	106	72.0	70.6	11.1	48.5	102.2	106	71.4	9.4	0.6	0.9	5.4	-13.0	21.9
	> 27 kg/m²	BASELINE	286	99.3	96.2	22.4	59.9	187.3								
		WEEK 8	258	99.4	96.0	22.4	61.8	186.6	258	99.3	22.4	0.1	0.1	3.1	-13.6	8.8
		WEEK 16	241	100.4	97.0	22.9	60.7	186.8	241	100.3	23.1	0.1	0.0	4.5	-15.7	11.9
		WEEK 24	218	99.8	95.7	23.0	61.0	194.2	218	99.4	22.2	0.4	0.1	6.2	-17.4	40.1

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-121　ベースライン BMI 別体重の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.3.2
Mean Change from Baseline in Weight by Week and Baseline BMI in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	BASELINE BMI (kg/m²)	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
TOTAL	> 27 kg/m²	WEEK 28	46	101.4	95.2	24.1	68.4	183.0	46	101.9	25.5	-0.5	0.1	5.1	-11.7	10.2
		WEEK 32	173	100.1	96.0	22.7	59.6	186.6	173	99.6	22.0	0.6	0.6	6.7	-25.2	20.4
		WEEK 40	145	100.1	97.0	23.4	58.0	187.0	145	99.1	21.8	1.0	0.6	7.7	-29.2	22.0
		WEEK 48	141	100.0	97.1	23.6	54.0	188.2	141	99.0	21.6	1.0	0.9	8.6	-33.3	26.4
		WEEK 52	140	100.3	97.7	23.0	50.7	190.5	140	98.9	21.2	1.4	0.6	8.7	-35.6	29.3
		LAST VISIT	280	99.6	96.4	23.0	50.7	190.5	280	99.2	22.5	0.4	0.0	7.6	-35.6	29.3
	TOTAL	BASELINE	464	86.6	83.9	24.8	43.4	187.3								
		WEEK 8	414	86.9	84.4	24.9	43.4	186.6	414	86.7	25.0	0.3	0.3	2.9	-13.6	13.1
		WEEK 16	393	87.3	85.0	25.4	43.9	186.8	393	86.9	25.6	0.3	0.1	4.1	-15.7	11.9
		WEEK 24	356	86.8	84.2	25.4	43.0	194.2	356	86.3	24.9	0.6	0.3	5.4	-17.4	40.1
		WEEK 28	67	91.8	87.6	25.8	47.2	183.0	67	91.4	27.3	0.5	0.6	5.3	-11.7	14.6
		WEEK 32	287	86.8	83.9	25.2	43.9	186.6	287	86.1	24.7	0.6	0.4	5.9	-25.2	20.4
		WEEK 40	247	86.1	82.5	25.6	41.8	187.0	247	85.2	24.5	0.9	0.4	6.7	-29.2	22.0
		WEEK 48	236	86.5	83.6	25.7	43.8	188.2	236	85.7	24.3	0.8	0.6	7.4	-33.3	26.4
		WEEK 52	238	86.3	83.7	25.5	43.0	190.5	238	85.3	24.0	1.0	0.6	7.5	-35.6	29.3
		LAST VISIT	454	87.0	84.7	25.3	43.0	190.5	454	86.5	25.0	0.5	0.1	6.7	-35.6	29.3

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.2-01：CT-14.3.2＞

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=WEIGHT (kg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE BASELINE MEAN	CHANGE FROM BASELINE BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
DE NOVO	BASELINE	379	85.9	83.5	24.7	43.4	187.3								
	WEEK 8	337	86.4	83.5	24.9	43.4	186.6	337	86.0	24.9	0.3	0.2	2.7	-11.7	13.1
	WEEK 16	319	87.0	84.4	25.6	43.9	186.8	319	86.5	25.7	0.5	0.0	4.1	-15.7	11.9
	WEEK 24	285	86.2	82.5	25.5	43.0	194.2	285	85.5	24.8	0.7	0.1	5.5	-17.4	40.1
	WEEK 28	24	96.6	91.2	28.6	59.3	183.0	24	96.5	30.5	0.1	0.2	6.3	-11.7	10.2
	WEEK 32	257	86.1	82.1	25.1	43.9	180.0	257	85.5	24.7	0.6	0.3	5.9	-25.2	20.4
	WEEK 40	229	85.5	81.6	25.4	41.8	180.1	229	84.5	24.1	0.9	0.4	6.8	-29.2	22.0
	WEEK 48	221	85.9	82.0	25.3	43.8	180.1	221	85.0	23.8	0.8	0.6	7.5	-33.3	26.4
	WEEK 52	224	85.7	82.7	25.0	43.0	181.0	224	84.7	23.5	1.0	0.4	7.6	-35.6	29.3
	LAST VISIT	370	86.2	83.0	25.3	43.0	183.0	370	85.8	24.8	0.5	0.1	7.0	-35.6	29.3
ROLLOVER	BASELINE	85	89.5	85.1	25.5	46.2	183.6								
	WEEK 8	77	89.4	86.2	24.7	47.1	182.7	77	89.5	25.2	-0.1	0.7	3.3	-13.6	7.0
	WEEK 16	74	88.8	86.1	25.0	46.9	184.8	74	88.9	25.5	-0.1	0.4	4.2	-10.6	9.7
	WEEK 24	71	89.4	87.0	25.0	46.9	186.5	71	89.4	25.4	0.0	1.0	4.8	-12.5	11.3
	WEEK 28	43	89.2	87.0	24.1	47.2	164.3	43	88.5	25.2	0.7	0.6	4.7	-10.0	14.6
	WEEK 32	30	92.7	89.1	25.4	58.0	186.6	30	91.8	25.0	0.9	2.9	6.4	-16.4	14.3
	WEEK 40	18	94.4	89.2	28.0	57.0	187.0	18	93.7	28.0	0.7	0.4	5.5	-10.2	8.8
	WEEK 48	15	95.6	89.3	30.9	55.5	188.2	15	95.8	29.8	-0.2	1.1	6.2	-11.6	10.9
	WEEK 52	14	95.1	87.4	32.4	56.5	190.5	14	94.8	30.6	0.3	1.3	6.3	-12.5	10.9
	LAST VISIT	84	90.2	87.4	25.2	47.2	190.5	84	89.7	25.6	0.6	0.5	4.8	-13.9	14.3
TOTAL	BASELINE	464	86.6	83.9	24.8	43.4	187.3								
	WEEK 8	414	86.9	84.4	24.9	43.4	186.6	414	86.7	25.0	0.3	0.3	2.9	-13.6	13.1
	WEEK 16	393	87.3	85.0	25.4	43.9	186.8	393	86.9	25.6	0.3	0.1	4.1	-15.7	11.9
	WEEK 24	356	86.8	84.2	25.4	43.0	194.2	356	86.3	24.9	0.6	0.3	5.4	-17.4	40.1

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=WEIGHT (kg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
TOTAL	WEEK 28	67	91.8	87.6	25.8	47.2	183.0	67	91.4	27.3	0.5	0.6	5.3	-11.7	14.6
	WEEK 32	287	86.8	83.9	25.2	43.9	186.6	287	86.1	24.7	0.6	0.4	5.9	-25.2	20.4
	WEEK 40	247	86.1	82.5	25.6	41.8	187.0	247	85.2	24.5	0.9	0.4	6.7	-29.2	22.0
	WEEK 48	236	86.5	83.6	25.7	43.8	188.2	236	85.7	24.3	0.8	0.6	7.4	-33.3	26.4
	WEEK 52	238	86.3	83.7	25.5	43.0	190.5	238	85.3	24.0	1.0	0.6	7.5	-35.6	29.3
	LAST VISIT	454	87.0	84.7	25.3	43.0	190.5	454	86.5	25.0	0.5	0.1	6.7	-35.6	29.3

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY MASS INDEX (kg/m²)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
								___BASELINE___							
DE NOVO	BASELINE	379	30.0	28.5	7.7	16.9	62.6								
	WEEK 8	337	30.1	28.3	7.6	17.0	62.6	337	29.9	7.6	0.1	0.1	0.9	-3.8	4.8
	WEEK 16	319	30.2	28.5	7.8	17.1	62.4	319	30.0	7.9	0.2	0.0	1.4	-5.4	4.9
	WEEK 24	285	30.1	28.6	8.1	16.8	68.8	285	29.9	7.8	0.2	0.0	1.9	-6.4	14.2
	WEEK 28	24	32.2	29.6	8.3	20.7	50.5	24	32.2	9.0	0.1	0.0	2.2	-4.1	4.1
	WEEK 32	257	30.1	28.7	7.8	17.1	62.3	257	29.9	7.7	0.2	0.1	2.0	-9.2	6.2
	WEEK 40	229	29.8	28.2	7.7	16.7	62.3	229	29.5	7.4	0.3	0.1	2.3	-10.7	6.8
	WEEK 48	221	30.0	28.3	7.7	17.1	62.3	221	29.7	7.3	0.2	0.2	2.6	-12.2	7.6
	WEEK 52	224	29.9	28.5	7.8	17.7	62.6	224	29.6	7.4	0.3	0.2	2.6	-13.0	8.9
	LAST VISIT	370	30.1	28.8	7.8	17.5	62.6	370	30.0	7.7	0.2	0.0	2.4	-13.0	8.9
ROLLOVER	BASELINE	85	30.9	29.4	8.1	19.2	67.4								
	WEEK 8	77	30.9	29.8	7.7	19.5	67.1	77	30.9	8.0	-0.0	0.2	1.1	-4.0	2.1
	WEEK 16	74	30.8	29.3	7.9	19.7	67.9	74	30.9	8.1	-0.1	0.1	1.5	-4.2	2.9
	WEEK 24	71	31.1	29.7	7.9	19.4	68.5	71	31.1	8.1	-0.0	0.3	1.7	-5.3	3.7
	WEEK 28	43	30.8	28.8	7.0	20.8	46.6	43	30.6	7.6	0.2	0.2	1.7	-4.2	4.5
	WEEK 32	30	32.4	31.0	8.8	19.6	68.5	30	32.1	8.7	0.3	1.0	2.2	-5.1	4.4
	WEEK 40	18	32.3	31.4	9.9	19.3	68.7	18	32.1	9.9	0.2	0.1	2.0	-3.7	3.2
	WEEK 48	15	32.6	31.2	11.0	18.8	69.1	15	32.7	10.7	-0.1	0.4	2.1	-4.2	3.4
	WEEK 52	14	32.7	31.0	11.6	19.1	70.0	14	32.6	11.1	0.1	0.5	2.2	-4.5	3.4
	LAST VISIT	84	31.2	30.3	8.0	19.1	70.0	84	31.0	8.1	0.2	0.2	1.7	-4.5	4.4
TOTAL	BASELINE	464	30.2	28.7	7.7	16.9	67.4								
	WEEK 8	414	30.2	28.7	7.6	17.0	67.1	414	30.1	7.7	0.1	0.1	1.0	-4.0	4.8
	WEEK 16	393	30.3	28.7	7.8	17.1	67.9	393	30.2	7.9	0.1	0.0	1.4	-5.4	4.9
	WEEK 24	356	30.3	28.8	8.1	16.8	68.8	356	30.1	7.9	0.2	0.1	1.9	-6.4	14.2

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY MASS INDEX (kg/m²)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
TOTAL	WEEK 28	67	31.3	29.5	7.5	20.7	50.5	67	31.2	8.1	0.2	0.2	1.9	-4.2	4.5
	WEEK 32	287	30.3	29.0	8.0	17.1	68.5	287	30.1	7.8	0.2	0.1	2.0	-9.2	6.2
	WEEK 40	247	30.0	28.7	7.9	16.7	68.7	247	29.7	7.6	0.3	0.1	2.3	-10.7	6.8
	WEEK 48	236	30.1	28.9	8.0	17.1	69.1	236	29.9	7.6	0.2	0.2	2.6	-12.2	7.6
	WEEK 52	238	30.1	28.7	8.0	17.7	70.0	238	29.8	7.7	0.3	0.2	2.6	-13.0	8.9
	LAST VISIT	454	30.3	29.0	7.9	17.5	70.0	454	30.2	7.8	0.2	0.1	2.3	-13.0	8.9

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=WAIST CIRCUMFERENCE (cm)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE BASELINE MEAN	CHANGE FROM BASELINE BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
DE NOVO	BASELINE	379	98.3	97.0	18.1	60.0	178.0								
	WEEK 28	11	106.2	97.0	23.4	78.0	151.0	11	107.1	23.4	-0.9	-2.0	5.1	-8.0	7.0
	WEEK 52	222	98.9	98.0	17.8	64.0	154.0	222	97.9	17.8	1.0	1.0	9.2	-73.0	44.0
	LAST VISIT	326	99.2	98.0	18.1	60.0	154.0	326	98.5	18.3	0.6	0.0	8.4	-73.0	44.0
ROLLOVER	BASELINE	85	99.8	98.0	19.4	67.0	174.0								
	WEEK 28	43	99.9	100.0	18.4	65.0	145.0	43	98.3	17.8	1.6	1.0	4.9	-11.0	18.0
	WEEK 52	14	104.4	99.5	24.5	75.0	179.0	14	105.6	24.1	-1.3	0.0	7.4	-18.0	8.0
	LAST VISIT	81	101.3	98.0	19.4	65.0	179.0	81	100.8	19.3	0.5	1.0	5.4	-18.0	18.0
TOTAL	BASELINE	464	98.6	97.0	18.3	60.0	178.0								
	WEEK 28	54	101.2	98.0	19.4	65.0	151.0	54	100.1	19.1	1.1	1.0	5.0	-11.0	18.0
	WEEK 52	236	99.2	98.0	18.2	64.0	179.0	236	98.3	18.3	0.9	1.0	9.1	-73.0	44.0
	LAST VISIT	407	99.6	98.0	18.3	60.0	179.0	407	99.0	18.5	0.6	0.0	7.9	-73.0	44.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE BASELINE MEAN	CHANGE FROM BASELINE BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
DE NOVO	BASELINE	379	36.6	36.6	0.4	35.0	38.7								
	WEEK 1	364	36.6	36.6	0.4	35.5	38.9	364	36.6	0.4	0.0	0.0	0.4	-1.8	1.4
	WEEK 2	356	36.6	36.6	0.4	35.0	38.0	356	36.6	0.4	0.0	0.0	0.4	-1.9	1.3
	WEEK 3	356	36.6	36.6	0.4	34.6	37.7	356	36.6	0.4	0.0	0.0	0.3	-1.7	1.0
	WEEK 4	357	36.6	36.6	0.4	35.2	37.8	357	36.6	0.4	0.0	0.0	0.4	-1.6	1.4
	WEEK 6	350	36.6	36.6	0.4	35.3	37.8	350	36.6	0.4	-0.0	0.0	0.4	-1.9	1.8
	WEEK 8	344	36.6	36.6	0.4	35.1	37.8	344	36.6	0.4	-0.0	0.0	0.4	-1.9	1.6
	WEEK 10	338	36.6	36.6	0.4	35.0	37.6	338	36.6	0.4	0.0	0.0	0.4	-1.9	1.7
	WEEK 12	333	36.6	36.6	0.4	35.5	37.9	333	36.6	0.4	0.0	0.0	0.4	-2.1	1.8
	WEEK 16	322	36.6	36.6	0.4	35.4	37.8	322	36.6	0.4	-0.0	0.0	0.4	-1.6	1.7
	WEEK 20	308	36.6	36.6	0.4	35.1	38.8	308	36.6	0.4	0.0	0.0	0.4	-1.5	2.1
	WEEK 24	289	36.6	36.6	0.4	35.2	37.8	289	36.6	0.4	-0.0	0.0	0.4	-1.3	1.0
	WEEK 28	277	36.6	36.6	0.4	35.3	37.8	277	36.6	0.4	0.0	0.0	0.3	-1.7	1.6
	WEEK 32	261	36.6	36.6	0.4	35.3	38.0	261	36.6	0.4	0.0	0.0	0.3	-1.3	1.2
	WEEK 36	249	36.6	36.6	0.4	34.9	37.8	249	36.6	0.4	0.0	0.0	0.4	-2.3	1.5
	WEEK 40	238	36.6	36.6	0.4	34.7	38.5	238	36.6	0.4	-0.0	0.0	0.4	-1.7	1.5
	WEEK 44	232	36.6	36.6	0.4	35.6	37.8	232	36.6	0.4	-0.0	0.0	0.4	-1.5	1.7
	WEEK 48	229	36.6	36.6	0.4	35.3	37.8	229	36.6	0.4	-0.0	0.0	0.4	-1.6	1.1
	WEEK 52	224	36.6	36.6	0.4	35.1	37.7	224	36.6	0.4	-0.0	0.0	0.4	-1.0	1.3
	LAST VISIT	378	36.6	36.6	0.4	35.1	38.9	378	36.6	0.4	0.0	0.0	0.4	-1.0	1.4
ROLLOVER	BASELINE	85	36.5	36.6	0.3	35.8	37.7								
	WEEK 1	78	36.6	36.6	0.3	35.4	37.2	78	36.5	0.3	0.0	0.0	0.3	-0.7	0.8
	WEEK 2	78	36.5	36.6	0.3	35.9	37.3	78	36.5	0.3	-0.0	0.0	0.4	-1.7	1.0
	WEEK 3	81	36.6	36.6	0.3	35.7	37.2	81	36.5	0.3	0.0	0.0	0.4	-1.2	0.8
	WEEK 4	78	36.5	36.6	0.3	35.7	37.2	78	36.5	0.3	-0.0	0.0	0.3	-1.2	0.8

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
								___BASELINE___							
ROLLOVER	WEEK 6	82	36.5	36.6	0.3	35.9	37.3	82	36.5	0.3	0.0	0.0	0.3	-1.2	0.7
	WEEK 8	77	36.5	36.5	0.4	35.5	37.8	77	36.5	0.3	-0.0	0.0	0.4	-1.3	1.3
	WEEK 10	76	36.6	36.6	0.4	35.7	37.6	76	36.5	0.3	0.0	0.0	0.4	-0.7	1.1
	WEEK 12	76	36.6	36.6	0.3	35.6	37.2	76	36.5	0.3	0.1	0.0	0.3	-1.6	1.2
	WEEK 16	75	36.6	36.6	0.3	35.7	37.2	75	36.5	0.3	0.0	0.0	0.4	-1.7	0.8
	WEEK 20	74	36.5	36.6	0.3	35.7	37.2	74	36.5	0.3	0.0	0.0	0.4	-1.5	1.1
	WEEK 24	72	36.6	36.6	0.3	35.6	37.2	72	36.5	0.3	0.0	0.0	0.4	-1.5	0.8
	WEEK 28	71	36.5	36.6	0.3	35.7	37.2	71	36.5	0.3	0.0	0.0	0.3	-1.5	0.7
	WEEK 32	30	36.6	36.7	0.3	36.0	37.2	30	36.6	0.4	0.0	0.1	0.5	-1.3	1.2
	WEEK 36	24	36.6	36.7	0.4	35.8	37.4	24	36.6	0.4	0.0	0.0	0.5	-1.5	0.8
	WEEK 40	18	36.7	36.7	0.3	36.2	37.2	18	36.6	0.5	0.1	0.2	0.5	-1.3	0.8
	WEEK 44	18	36.6	36.6	0.4	35.7	37.2	18	36.6	0.5	-0.0	0.0	0.6	-1.6	1.1
	WEEK 48	15	36.7	36.7	0.5	36.2	38.1	15	36.6	0.5	0.2	0.1	0.4	-0.5	0.9
	WEEK 52	14	36.6	36.7	0.8	34.7	38.1	14	36.6	0.5	0.0	0.3	0.7	-1.7	0.6
	LAST VISIT	85	36.6	36.6	0.4	34.7	38.1	85	36.5	0.3	0.0	0.0	0.4	-1.7	1.2
TOTAL	BASELINE	464	36.6	36.6	0.4	35.0	38.7								
	WEEK 1	442	36.6	36.6	0.4	35.4	38.9	442	36.6	0.4	0.0	0.0	0.3	-1.8	1.4
	WEEK 2	434	36.6	36.6	0.4	35.0	38.0	434	36.6	0.4	0.0	0.0	0.4	-1.9	1.3
	WEEK 3	437	36.6	36.6	0.4	34.6	37.7	437	36.6	0.4	0.0	0.0	0.3	-1.7	1.0
	WEEK 4	435	36.6	36.6	0.4	35.2	37.8	435	36.6	0.4	0.0	0.0	0.4	-1.6	1.4
	WEEK 6	432	36.6	36.6	0.4	35.3	37.8	432	36.6	0.4	-0.0	0.0	0.4	-1.9	1.8
	WEEK 8	421	36.6	36.6	0.4	35.1	37.8	421	36.6	0.4	-0.0	0.0	0.4	-1.9	1.6
	WEEK 10	414	36.6	36.6	0.4	35.0	37.6	414	36.6	0.4	0.0	0.0	0.4	-1.9	1.7
	WEEK 12	409	36.6	36.6	0.4	35.5	37.9	409	36.6	0.4	0.0	0.0	0.4	-2.1	1.8
	WEEK 16	397	36.6	36.6	0.4	35.4	37.8	397	36.6	0.4	0.0	0.0	0.4	-1.7	1.7

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=BODY TEMPERATURE (°C)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE BASELINE MEAN	CHANGE FROM BASELINE BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
TOTAL	WEEK 20	382	36.6	36.6	0.4	35.1	38.8	382	36.6	0.4	0.0	0.0	0.4	-1.5	2.1
	WEEK 24	361	36.6	36.6	0.4	35.2	37.8	361	36.6	0.4	-0.0	0.0	0.4	-1.5	1.0
	WEEK 28	348	36.6	36.6	0.4	35.3	37.8	348	36.6	0.4	0.0	0.0	0.3	-1.7	1.6
	WEEK 32	291	36.6	36.6	0.4	35.3	38.0	291	36.6	0.4	0.0	0.0	0.4	-1.3	1.2
	WEEK 36	273	36.6	36.6	0.4	34.9	37.8	273	36.6	0.4	0.0	0.0	0.4	-2.3	1.5
	WEEK 40	256	36.6	36.6	0.4	34.7	38.5	256	36.6	0.4	-0.0	0.0	0.4	-1.7	1.5
	WEEK 44	250	36.6	36.6	0.4	35.6	37.8	250	36.6	0.4	-0.0	0.0	0.4	-1.6	1.7
	WEEK 48	244	36.6	36.6	0.4	35.3	38.1	244	36.6	0.4	-0.0	0.0	0.4	-1.6	1.1
	WEEK 52	238	36.6	36.6	0.4	34.7	38.1	238	36.6	0.4	-0.0	0.0	0.4	-1.7	1.3
	LAST VISIT	463	36.6	36.6	0.4	34.7	38.9	463	36.6	0.4	0.0	0.0	0.4	-1.7	1.4

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	379	71.7	72.0	10.5	47.0	110.0								
	WEEK 1	364	75.6	75.0	10.5	46.0	110.0	364	71.4	10.4	4.1	4.0	9.7	-43.0	29.0
	WEEK 2	356	75.2	75.0	10.3	48.0	106.0	356	71.6	10.4	3.5	3.0	10.2	-36.0	35.0
	WEEK 3	356	75.6	76.0	11.3	48.0	112.0	356	71.4	10.3	4.2	3.0	10.9	-39.0	49.0
	WEEK 4	357	74.6	74.0	11.1	50.0	119.0	357	71.5	10.4	3.1	3.0	10.1	-34.0	40.0
	WEEK 6	349	75.6	76.0	10.4	49.0	120.0	349	71.7	10.3	3.9	4.0	10.5	-40.0	48.0
	WEEK 8	344	74.8	74.0	10.2	51.0	110.0	344	71.6	10.4	3.2	3.0	9.7	-33.0	34.0
	WEEK 10	338	75.0	75.0	10.0	50.0	102.0	338	71.6	10.4	3.3	4.0	10.0	-38.0	35.0
	WEEK 12	334	74.1	74.0	10.4	48.0	109.0	334	71.6	10.5	2.5	2.0	10.7	-46.0	37.0
	WEEK 16	323	73.9	74.0	10.9	46.0	116.0	323	71.3	10.3	2.6	2.0	10.2	-42.0	46.0
	WEEK 20	308	75.0	75.0	10.5	50.0	114.0	308	71.2	10.5	3.8	4.0	10.7	-36.0	37.0
	WEEK 24	288	74.1	74.0	10.2	43.0	103.0	288	71.5	10.5	2.6	2.0	11.1	-46.0	45.0
	WEEK 28	278	74.0	74.0	11.1	46.0	115.0	278	71.4	10.6	2.6	2.0	11.2	-46.0	45.0
	WEEK 32	261	74.6	74.0	10.9	48.0	114.0	261	71.4	10.7	3.2	2.0	11.0	-46.0	32.0
	WEEK 36	249	73.4	73.0	11.6	45.0	111.0	249	71.6	10.7	1.8	1.0	11.0	-48.0	39.0
	WEEK 40	238	74.4	74.0	10.5	45.0	100.0	238	71.5	10.7	2.9	2.0	11.4	-45.0	36.0
	WEEK 44	232	74.8	74.0	11.2	46.0	130.0	232	71.5	10.6	3.4	2.0	12.0	-47.0	63.0
	WEEK 48	229	74.0	73.0	10.8	43.0	102.0	229	71.4	10.6	2.6	4.0	11.2	-47.0	38.0
	WEEK 52	224	72.3	71.0	11.4	46.0	108.0	224	71.3	10.7	1.0	1.0	12.3	-41.0	36.0
	LAST VISIT	378	73.1	72.0	11.2	46.0	108.0	378	71.6	10.4	1.5	2.0	12.3	-41.0	46.0
ROLLOVER	BASELINE	85	73.5	72.0	11.7	40.0	103.0								
	WEEK 1	78	75.1	72.5	10.9	55.0	112.0	78	73.8	12.0	1.3	0.5	7.9	-22.0	21.0
	WEEK 2	78	76.0	74.5	10.5	58.0	105.0	78	73.9	11.5	2.1	1.0	8.9	-25.0	31.0
	WEEK 3	81	76.7	75.0	11.5	51.0	104.0	81	73.7	11.4	3.0	1.0	10.0	-16.0	32.0
	WEEK 4	78	75.9	74.0	12.5	51.0	115.0	78	73.3	11.6	2.6	2.0	10.0	-23.0	32.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ROLLOVER	WEEK 6	82	75.4	73.0	10.9	56.0	103.0	82	73.4	11.4	2.0	1.5	9.5	-24.0	27.0
	WEEK 8	77	74.7	72.0	10.9	53.0	101.0	77	72.9	11.3	1.9	2.0	9.0	-20.0	37.0
	WEEK 10	76	74.9	73.5	11.2	56.0	107.0	76	73.0	11.4	1.9	2.0	10.3	-30.0	46.0
	WEEK 12	76	75.4	74.0	11.4	57.0	108.0	76	72.8	11.3	2.7	2.0	8.9	-18.0	27.0
	WEEK 16	75	74.6	74.0	12.0	51.0	108.0	75	72.9	11.3	1.8	1.0	7.7	-13.0	23.0
	WEEK 20	74	75.4	72.5	11.1	57.0	108.0	74	72.8	11.4	2.6	2.5	8.2	-24.0	30.0
	WEEK 24	72	73.3	71.0	11.8	51.0	115.0	72	72.6	11.3	0.6	0.0	9.8	-22.0	43.0
	WEEK 28	71	73.6	73.0	10.8	53.0	99.0	71	72.5	11.3	1.1	0.0	9.8	-22.0	28.0
	WEEK 32	30	71.6	71.0	9.4	56.0	96.0	30	72.1	9.2	-0.4	0.5	9.1	-21.0	18.0
	WEEK 36	24	69.8	70.0	7.3	51.0	88.0	24	71.9	9.1	-2.1	-1.5	7.1	-19.0	13.0
	WEEK 40	18	71.1	70.5	9.9	55.0	102.0	18	72.0	9.6	-0.9	-1.5	10.3	-22.0	22.0
	WEEK 44	18	69.9	69.5	12.7	54.0	106.0	18	73.2	9.7	-3.2	-3.0	12.3	-18.0	29.0
	WEEK 48	15	70.3	66.0	12.8	52.0	109.0	15	74.2	10.4	-3.9	-7.0	10.9	-20.0	20.0
	WEEK 52	14	71.4	69.5	9.9	52.0	95.0	14	75.1	10.1	-3.8	-4.5	8.5	-16.0	14.0
	LAST VISIT	85	74.9	73.0	11.3	52.0	103.0	85	73.5	11.7	1.4	1.0	9.8	-22.0	28.0
TOTAL	BASELINE	464	72.0	72.0	10.7	40.0	110.0								
	WEEK 1	442	75.5	75.0	10.6	46.0	112.0	442	71.9	10.7	3.6	3.0	9.4	-43.0	29.0
	WEEK 2	434	75.3	75.0	10.3	48.0	106.0	434	72.0	10.6	3.3	2.0	10.0	-36.0	35.0
	WEEK 3	437	75.8	76.0	11.3	48.0	112.0	437	71.9	10.5	3.9	2.0	10.7	-39.0	49.0
	WEEK 4	435	74.8	74.0	11.4	50.0	119.0	435	71.8	10.6	3.0	2.0	10.1	-34.0	40.0
	WEEK 6	431	75.6	76.0	10.5	49.0	120.0	431	72.0	10.5	3.6	4.0	10.3	-40.0	48.0
	WEEK 8	421	74.8	74.0	10.3	51.0	110.0	421	71.8	10.6	3.0	2.0	9.6	-33.0	37.0
	WEEK 10	414	75.0	74.0	10.2	50.0	107.0	414	71.9	10.6	3.1	3.0	10.1	-38.0	46.0
	WEEK 12	410	74.3	74.0	10.6	48.0	109.0	410	71.8	10.6	2.5	2.0	10.4	-46.0	37.0
	WEEK 16	398	74.0	74.0	11.1	46.0	116.0	398	71.6	10.5	2.4	2.0	9.8	-42.0	46.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SUPINE (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE BASELINE MEAN	CHANGE FROM BASELINE BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
TOTAL	WEEK 20	382	75.1	75.0	10.6	50.0	114.0	382	71.5	10.7	3.6	3.0	10.3	-36.0	37.0
	WEEK 24	360	73.9	73.0	10.5	43.0	115.0	360	71.7	10.7	2.2	2.0	10.8	-46.0	45.0
	WEEK 28	349	73.9	74.0	11.0	46.0	115.0	349	71.6	10.8	2.3	1.0	11.0	-46.0	45.0
	WEEK 32	291	74.3	74.0	10.8	48.0	114.0	291	71.5	10.5	2.8	2.0	10.9	-46.0	32.0
	WEEK 36	273	73.0	72.0	11.4	45.0	111.0	273	71.6	10.5	1.5	1.0	10.7	-48.0	39.0
	WEEK 40	256	74.2	73.0	10.5	45.0	102.0	256	71.5	10.6	2.7	2.0	11.4	-45.0	36.0
	WEEK 44	250	74.5	73.5	11.4	46.0	130.0	250	71.6	10.5	2.9	2.0	12.1	-47.0	63.0
	WEEK 48	244	73.8	72.0	10.9	43.0	109.0	244	71.5	10.6	2.2	3.0	11.3	-47.0	38.0
	WEEK 52	238	72.2	71.0	11.3	46.0	108.0	238	71.5	10.7	0.7	1.0	12.2	-41.0	36.0
	LAST VISIT	463	73.4	73.0	11.2	46.0	108.0	463	72.0	10.7	1.5	2.0	11.9	-41.0	46.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-14.2　FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	379	119.7	120.0	13.4	81.0	192.0								
	WEEK 1	364	120.5	120.0	13.6	87.0	164.0	364	119.6	13.3	0.9	1.0	10.6	-57.0	38.0
	WEEK 2	356	120.7	121.0	13.1	89.0	165.0	356	119.8	13.4	0.9	1.0	10.4	-61.0	30.0
	WEEK 3	356	120.5	120.0	13.1	85.0	174.0	356	119.7	13.4	0.8	1.0	10.9	-40.0	34.0
	WEEK 4	357	120.1	120.0	12.6	85.0	178.0	357	119.6	13.5	0.5	0.0	11.3	-78.0	29.0
	WEEK 6	349	120.0	120.0	13.2	86.0	174.0	349	119.5	13.5	0.5	1.0	11.3	-54.0	35.0
	WEEK 8	344	119.4	120.0	13.0	86.0	164.0	344	119.5	13.4	-0.1	0.0	11.2	-50.0	35.0
	WEEK 10	338	120.8	120.5	13.4	82.0	176.0	338	119.4	13.3	1.4	1.0	11.1	-43.0	46.0
	WEEK 12	334	121.1	120.0	13.5	86.0	169.0	334	119.6	13.4	1.5	1.0	11.9	-83.0	40.0
	WEEK 16	323	119.8	120.0	12.3	84.0	159.0	323	119.2	13.3	0.6	1.0	10.7	-52.0	44.0
	WEEK 20	308	120.2	120.0	13.4	87.0	184.0	308	119.5	13.4	0.7	1.0	11.1	-52.0	51.0
	WEEK 24	288	119.2	119.0	13.1	76.0	160.0	288	119.5	13.5	-0.3	0.0	11.4	-46.0	41.0
	WEEK 28	278	119.3	120.0	13.3	88.0	158.0	278	119.5	13.7	-0.2	0.0	11.4	-44.0	46.0
	WEEK 32	261	120.0	120.0	12.7	91.0	158.0	261	119.6	13.6	0.4	0.0	11.5	-44.0	44.0
	WEEK 36	249	119.8	120.0	13.5	92.0	165.0	249	119.7	13.8	0.1	0.0	11.8	-40.0	35.0
	WEEK 40	238	120.2	120.0	14.4	80.0	172.0	238	119.4	14.0	0.8	0.5	11.6	-36.0	38.0
	WEEK 44	232	120.1	120.0	13.4	89.0	181.0	232	119.8	14.0	0.3	1.0	11.6	-43.0	30.0
	WEEK 48	229	119.5	120.0	13.0	90.0	160.0	229	119.5	13.6	0.0	0.0	12.3	-43.0	38.0
	WEEK 52	224	119.5	120.0	13.7	90.0	164.0	224	119.6	14.0	-0.1	0.0	12.2	-44.0	39.0
	LAST VISIT	378	119.7	120.0	13.7	87.0	170.0	378	119.8	13.4	-0.0	0.0	12.4	-44.0	51.0
ROLLOVER	BASELINE	85	121.2	122.0	12.4	91.0	145.0								
	WEEK 1	78	121.2	122.0	12.7	91.0	148.0	78	121.0	12.4	0.2	0.0	8.3	-20.0	24.0
	WEEK 2	78	123.2	122.5	12.0	95.0	153.0	78	121.7	12.2	1.4	0.0	9.8	-15.0	48.0
	WEEK 3	81	122.3	122.0	12.3	93.0	147.0	81	121.1	12.5	1.2	2.0	10.5	-26.0	41.0
	WEEK 4	78	122.3	123.0	13.4	91.0	152.0	78	121.7	12.6	0.6	0.0	9.9	-34.0	28.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE BASELINE MEAN	CHANGE FROM BASELINE BASELINE SD	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE MEDIAN	CHANGE FROM BASELINE SD	CHANGE FROM BASELINE MIN	CHANGE FROM BASELINE MAX
ROLLOVER	WEEK 6	82	119.5	119.5	12.3	91.0	152.0	82	121.5	12.5	-2.0	-1.5	10.9	-33.0	22.0
	WEEK 8	77	121.6	121.0	13.4	96.0	154.0	77	122.2	12.5	-0.6	0.0	11.1	-30.0	30.0
	WEEK 10	76	121.1	120.0	11.6	99.0	148.0	76	121.6	12.5	-0.4	1.0	10.9	-34.0	36.0
	WEEK 12	76	120.5	120.0	12.4	98.0	147.0	76	121.7	12.7	-1.2	-1.0	9.3	-19.0	22.0
	WEEK 16	75	120.0	120.0	14.3	81.0	164.0	75	121.5	12.6	-1.5	0.0	10.8	-33.0	19.0
	WEEK 20	74	121.9	121.5	13.6	91.0	159.0	74	121.5	12.7	0.4	0.0	10.5	-20.0	35.0
	WEEK 24	72	120.7	120.0	11.9	98.0	150.0	72	121.4	12.6	-0.8	-2.0	10.6	-28.0	19.0
	WEEK 28	71	121.3	124.0	12.9	93.0	158.0	71	121.6	12.7	-0.3	-2.0	10.4	-20.0	32.0
	WEEK 32	30	118.1	118.0	12.8	98.0	155.0	30	119.3	11.7	-1.3	-1.5	9.1	-18.0	21.0
	WEEK 36	24	117.8	118.0	14.1	94.0	149.0	24	120.8	11.8	-3.0	-4.0	11.5	-21.0	18.0
	WEEK 40	18	121.7	119.0	11.9	102.0	151.0	18	124.1	10.4	-2.4	-1.5	8.1	-16.0	14.0
	WEEK 44	18	120.7	119.0	13.3	100.0	159.0	18	122.8	9.6	-2.1	-2.5	9.7	-18.0	22.0
	WEEK 48	15	118.6	119.0	10.3	100.0	134.0	15	122.3	9.7	-3.7	-2.0	12.0	-23.0	17.0
	WEEK 52	14	118.8	116.5	10.2	100.0	132.0	14	121.7	9.8	-2.9	-3.0	12.2	-30.0	17.0
	LAST VISIT	85	120.7	123.0	13.1	91.0	159.0	85	121.2	12.4	-0.5	-1.0	11.1	-30.0	32.0
TOTAL	BASELINE	464	120.0	120.0	13.2	81.0	192.0								
	WEEK 1	442	120.6	121.0	13.4	87.0	164.0	442	119.8	13.1	0.8	1.0	10.2	-57.0	38.0
	WEEK 2	434	121.1	122.0	13.0	89.0	165.0	434	120.1	13.2	1.0	1.0	10.3	-61.0	48.0
	WEEK 3	437	120.8	120.0	13.0	85.0	174.0	437	120.0	13.3	0.9	1.0	10.8	-40.0	41.0
	WEEK 4	435	120.5	120.0	12.8	85.0	178.0	435	120.0	13.3	0.5	0.0	11.1	-78.0	29.0
	WEEK 6	431	119.9	120.0	13.0	86.0	174.0	431	119.9	13.4	0.0	1.0	11.3	-54.0	35.0
	WEEK 8	421	119.8	120.0	13.1	86.0	164.0	421	120.0	13.3	-0.2	0.0	11.2	-50.0	35.0
	WEEK 10	414	120.9	120.0	13.1	82.0	176.0	414	119.8	13.2	1.0	1.0	11.0	-43.0	46.0
	WEEK 12	410	121.0	120.0	13.3	86.0	169.0	410	120.0	13.3	1.0	0.0	11.5	-83.0	40.0
	WEEK 16	398	119.8	120.0	12.7	81.0	164.0	398	119.6	13.2	0.2	0.0	10.7	-52.0	44.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SUPINE BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
TOTAL	WEEK 20	382	120.5	120.0	13.4	87.0	184.0	382	119.9	13.2	0.6	0.0	11.0	-52.0	51.0
	WEEK 24	360	119.5	120.0	12.9	76.0	160.0	360	119.9	13.4	-0.4	0.0	11.2	-46.0	41.0
	WEEK 28	349	119.7	120.0	13.2	88.0	158.0	349	119.9	13.5	-0.2	0.0	11.2	-44.0	46.0
	WEEK 32	291	119.8	120.0	12.7	91.0	158.0	291	119.6	13.4	0.3	0.0	11.3	-44.0	44.0
	WEEK 36	273	119.6	120.0	13.6	92.0	165.0	273	119.8	13.6	-0.2	0.0	11.8	-40.0	35.0
	WEEK 40	256	120.3	120.0	14.2	80.0	172.0	256	119.7	13.8	0.6	0.0	11.4	-36.0	38.0
	WEEK 44	250	120.1	120.0	13.4	89.0	181.0	250	120.0	13.7	0.1	0.5	11.5	-43.0	30.0
	WEEK 48	244	119.4	120.0	12.8	90.0	160.0	244	119.6	13.4	-0.2	0.0	12.3	-43.0	38.0
	WEEK 52	238	119.5	120.0	13.5	90.0	164.0	238	119.7	13.8	-0.2	0.0	12.2	-44.0	39.0
	LAST VISIT	463	119.9	120.0	13.6	87.0	170.0	463	120.0	13.2	-0.1	0.0	12.2	-44.0	51.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	379	75.7	75.0	9.7	51.0	105.0								
	WEEK 1	364	75.6	75.0	9.3	54.0	100.0	364	75.6	9.7	-0.0	0.0	8.0	-33.0	27.0
	WEEK 2	356	75.7	76.5	9.7	52.0	107.0	356	75.8	9.6	-0.1	0.0	7.8	-28.0	22.0
	WEEK 3	356	75.9	76.5	9.8	50.0	137.0	356	75.5	9.6	0.4	0.0	8.6	-25.0	58.0
	WEEK 4	357	75.4	76.0	9.6	45.0	104.0	357	75.7	9.7	-0.2	0.0	8.1	-28.0	25.0
	WEEK 6	349	75.2	75.0	9.8	48.0	105.0	349	75.4	9.7	-0.3	0.0	8.6	-33.0	28.0
	WEEK 8	344	75.1	75.0	8.8	50.0	98.0	344	75.5	9.6	-0.4	0.0	8.1	-24.0	22.0
	WEEK 10	338	75.8	76.0	10.2	40.0	104.0	338	75.4	9.7	0.3	0.0	8.5	-32.0	26.0
	WEEK 12	334	75.7	76.0	9.8	47.0	110.0	334	75.6	9.6	0.1	0.0	8.7	-31.0	24.0
	WEEK 16	323	75.2	76.0	9.3	46.0	107.0	323	75.3	9.6	-0.1	0.0	8.8	-31.0	30.0
	WEEK 20	308	75.7	76.0	9.6	47.0	113.0	308	75.4	9.6	0.3	0.0	9.1	-42.0	42.0
	WEEK 24	288	75.2	75.0	9.8	35.0	109.0	288	75.6	9.8	-0.4	0.0	9.0	-46.0	25.0
	WEEK 28	278	74.9	74.5	9.8	31.0	108.0	278	75.5	9.8	-0.6	0.0	9.0	-41.0	30.0
	WEEK 32	261	75.1	75.0	9.5	50.0	104.0	261	75.6	9.8	-0.5	0.0	8.9	-37.0	34.0
	WEEK 36	249	75.3	75.0	9.4	52.0	105.0	249	75.6	9.8	-0.3	0.0	9.2	-28.0	28.0
	WEEK 40	238	75.0	76.0	9.4	45.0	101.0	238	75.4	9.9	-0.4	0.0	8.7	-38.0	26.0
	WEEK 44	232	75.8	76.0	10.2	48.0	108.0	232	75.4	9.7	0.4	0.5	9.2	-32.0	36.0
	WEEK 48	229	75.4	75.0	9.7	54.0	105.0	229	75.4	9.9	0.1	0.0	10.0	-34.0	35.0
	WEEK 52	224	75.4	76.0	10.1	50.0	104.0	224	75.3	9.9	0.1	0.0	9.7	-39.0	36.0
	LAST VISIT	378	75.8	76.0	10.5	45.0	137.0	378	75.7	9.7	0.1	0.0	10.2	-39.0	58.0
ROLLOVER	BASELINE	85	76.7	76.0	9.1	56.0	99.0								
	WEEK 1	78	75.8	74.5	9.1	59.0	97.0	78	76.7	9.3	-0.9	0.0	6.1	-20.0	16.0
	WEEK 2	78	77.5	77.0	9.2	61.0	103.0	78	77.1	9.2	0.4	0.0	9.1	-22.0	29.0
	WEEK 3	81	75.8	76.0	9.5	56.0	96.0	81	76.9	9.1	-1.1	0.0	7.6	-20.0	20.0
	WEEK 4	78	76.0	76.0	8.9	58.0	99.0	78	77.0	9.2	-1.0	-1.0	7.3	-22.0	15.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ROLLOVER	WEEK 6	82	75.0	75.0	9.4	58.0	99.0	82	77.0	9.0	-2.0	-2.0	8.6	-24.0	24.0
	WEEK 8	77	76.7	76.0	7.9	60.0	94.0	77	77.4	8.9	-0.7	-1.0	6.4	-16.0	15.0
	WEEK 10	76	75.2	75.0	8.8	56.0	98.0	76	77.1	9.0	-1.9	-2.0	9.6	-30.0	24.0
	WEEK 12	76	76.5	76.0	8.5	58.0	101.0	76	77.1	9.1	-0.6	0.0	7.5	-16.0	22.0
	WEEK 16	75	75.1	73.0	8.3	57.0	101.0	75	76.8	8.8	-1.8	-2.0	8.0	-20.0	16.0
	WEEK 20	74	77.0	75.0	8.6	57.0	99.0	74	76.7	8.8	0.3	0.0	7.9	-20.0	22.0
	WEEK 24	72	75.3	75.0	8.9	57.0	96.0	72	76.9	8.8	-1.6	-2.5	8.0	-19.0	16.0
	WEEK 28	71	76.0	75.0	9.2	58.0	102.0	71	76.9	8.8	-0.8	0.0	8.7	-23.0	18.0
	WEEK 32	30	72.9	70.5	9.9	58.0	108.0	30	75.1	8.4	-2.2	-0.5	9.6	-22.0	18.0
	WEEK 36	24	72.6	71.0	9.7	58.0	106.0	24	75.5	9.0	-2.9	-2.0	9.1	-22.0	16.0
	WEEK 40	18	72.2	70.0	10.0	60.0	103.0	18	77.6	7.4	-5.4	-6.5	8.9	-22.0	12.0
	WEEK 44	18	73.7	72.0	11.3	60.0	110.0	18	78.3	7.8	-4.6	-6.0	9.6	-21.0	19.0
	WEEK 48	15	71.9	72.0	7.9	60.0	86.0	15	78.4	7.4	-6.5	-6.0	8.3	-22.0	6.0
	WEEK 52	14	72.1	69.5	8.9	58.0	92.0	14	78.3	7.7	-6.1	-6.5	9.4	-24.0	12.0
	LAST VISIT	85	76.3	76.0	9.8	58.0	110.0	85	76.7	9.1	-0.4	0.0	8.9	-24.0	22.0
TOTAL	BASELINE	464	75.9	75.5	9.6	51.0	105.0								
	WEEK 1	442	75.6	75.0	9.3	54.0	100.0	442	75.8	9.7	-0.2	0.0	7.7	-33.0	27.0
	WEEK 2	434	76.0	76.5	9.6	52.0	107.0	434	76.0	9.6	-0.0	0.0	8.1	-28.0	29.0
	WEEK 3	437	75.9	76.0	9.8	50.0	137.0	437	75.7	9.5	0.2	0.0	8.4	-25.0	58.0
	WEEK 4	435	75.5	76.0	9.5	45.0	104.0	435	75.9	9.6	-0.4	0.0	8.0	-28.0	25.0
	WEEK 6	431	75.1	75.0	9.7	48.0	105.0	431	75.7	9.6	-0.6	0.0	8.6	-33.0	28.0
	WEEK 8	421	75.4	76.0	8.6	50.0	98.0	421	75.8	9.5	-0.4	0.0	7.8	-24.0	22.0
	WEEK 10	414	75.7	76.0	9.9	40.0	104.0	414	75.7	9.6	-0.1	0.0	8.7	-32.0	26.0
	WEEK 12	410	75.8	76.0	9.5	47.0	110.0	410	75.9	9.5	-0.1	0.0	8.5	-31.0	24.0
	WEEK 16	398	75.2	76.0	9.1	46.0	107.0	398	75.6	9.4	-0.4	0.0	8.7	-31.0	30.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SUPINE BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
TOTAL	WEEK 20	382	76.0	76.0	9.5	47.0	113.0	382	75.7	9.5	0.3	0.0	8.8	-42.0	42.0
	WEEK 24	360	75.2	75.0	9.6	35.0	109.0	360	75.9	9.6	-0.7	-1.0	8.8	-46.0	25.0
	WEEK 28	349	75.1	75.0	9.7	31.0	108.0	349	75.8	9.6	-0.6	0.0	8.9	-41.0	30.0
	WEEK 32	291	74.9	75.0	9.5	50.0	108.0	291	75.6	9.6	-0.7	0.0	8.9	-37.0	34.0
	WEEK 36	273	75.1	75.0	9.4	52.0	106.0	273	75.6	9.7	-0.5	0.0	9.2	-28.0	28.0
	WEEK 40	256	74.8	75.0	9.5	45.0	103.0	256	75.5	9.8	-0.7	0.0	8.8	-38.0	26.0
	WEEK 44	250	75.7	75.0	10.3	48.0	110.0	250	75.7	9.6	0.0	0.0	9.3	-32.0	36.0
	WEEK 48	244	75.2	75.0	9.6	54.0	105.0	244	75.6	9.8	-0.3	0.0	10.0	-34.0	35.0
	WEEK 52	238	75.2	76.0	10.1	50.0	104.0	238	75.5	9.8	-0.3	0.0	9.8	-39.0	36.0
	LAST VISIT	463	75.9	76.0	10.4	45.0	137.0	463	75.9	9.6	0.0	0.0	10.0	-39.0	58.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	379	75.6	76.0	10.4	50.0	108.0								
	WEEK 1	364	79.2	79.0	10.4	51.0	112.0	364	75.4	10.3	3.8	3.0	9.8	-27.0	41.0
	WEEK 2	356	78.9	79.0	9.7	53.0	111.0	356	75.6	10.1	3.4	3.0	9.6	-26.0	34.0
	WEEK 3	356	79.6	80.0	10.9	52.0	117.0	356	75.4	10.2	4.3	4.0	10.8	-27.0	34.0
	WEEK 4	357	78.7	78.0	10.8	52.0	118.0	357	75.4	10.2	3.2	3.0	10.5	-26.0	49.0
	WEEK 6	350	79.4	80.0	9.9	53.0	112.0	350	75.5	10.2	3.9	4.0	10.5	-34.0	36.0
	WEEK 8	344	78.7	78.0	9.9	55.0	114.0	344	75.4	10.2	3.3	3.0	10.1	-25.0	33.0
	WEEK 10	337	78.9	79.0	9.7	50.0	107.0	337	75.4	10.3	3.5	3.0	10.6	-27.0	42.0
	WEEK 12	334	78.1	78.0	10.2	51.0	109.0	334	75.3	10.3	2.7	2.0	10.7	-26.0	35.0
	WEEK 16	323	77.6	78.0	10.8	51.0	112.0	323	75.2	10.3	2.4	2.0	10.4	-23.0	40.0
	WEEK 20	308	79.3	79.0	10.3	50.0	116.0	308	75.0	10.3	4.2	4.0	10.8	-30.0	37.0
	WEEK 24	289	78.3	78.0	10.2	52.0	117.0	289	75.3	10.4	3.0	2.0	11.1	-34.0	35.0
	WEEK 28	278	77.8	77.0	11.0	51.0	113.0	278	75.2	10.5	2.6	2.0	11.2	-31.0	38.0
	WEEK 32	261	77.8	77.0	10.7	53.0	120.0	261	75.2	10.7	2.6	2.0	10.3	-28.0	33.0
	WEEK 36	249	77.1	76.0	10.9	49.0	111.0	249	75.2	10.5	2.0	0.0	11.0	-27.0	38.0
	WEEK 40	238	77.8	78.0	10.4	51.0	105.0	238	75.2	10.6	2.6	2.0	11.7	-31.0	37.0
	WEEK 44	232	78.3	78.0	10.3	54.0	106.0	232	75.3	10.5	3.0	3.0	11.4	-34.0	38.0
	WEEK 48	229	77.8	77.0	10.7	48.0	106.0	229	75.3	10.5	2.5	3.0	11.0	-26.0	41.0
	WEEK 52	224	75.7	76.0	11.2	47.0	110.0	224	75.2	10.4	0.5	0.0	11.6	-35.0	39.0
	LAST VISIT	378	76.8	76.0	11.3	47.0	117.0	378	75.5	10.3	1.3	0.0	11.8	-35.0	40.0
ROLLOVER	BASELINE	85	75.9	76.0	11.4	37.0	101.0								
	WEEK 1	78	77.1	76.5	11.0	52.0	106.0	78	76.1	11.7	1.0	0.0	7.6	-20.0	23.0
	WEEK 2	78	78.7	76.5	11.2	57.0	106.0	78	76.2	11.6	2.5	2.0	8.7	-29.0	25.0
	WEEK 3	81	78.2	78.0	11.1	54.0	110.0	81	76.0	11.5	2.2	1.0	8.7	-19.0	25.0
	WEEK 4	78	78.1	76.5	11.8	51.0	106.0	78	75.8	11.7	2.3	2.0	9.1	-18.0	20.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ROLLOVER	WEEK 6	82	78.1	78.5	10.7	55.0	104.0	82	75.8	11.5	2.3	2.0	8.9	-16.0	25.0
	WEEK 8	77	77.2	75.0	10.3	56.0	103.0	77	75.2	11.1	2.1	0.0	8.1	-15.0	31.0
	WEEK 10	76	77.0	76.0	10.7	60.0	98.0	76	75.5	11.4	1.5	0.0	9.7	-21.0	31.0
	WEEK 12	76	78.3	76.5	10.9	60.0	103.0	76	75.3	11.4	3.0	2.0	8.7	-14.0	30.0
	WEEK 16	75	77.4	76.0	11.4	54.0	104.0	75	75.3	11.5	2.1	2.0	9.4	-15.0	26.0
	WEEK 20	74	78.1	76.0	11.0	58.0	106.0	74	75.3	11.5	2.9	3.5	10.2	-20.0	49.0
	WEEK 24	72	76.3	74.5	12.5	55.0	122.0	72	75.1	11.4	1.2	1.0	10.7	-25.0	37.0
	WEEK 28	71	75.7	76.0	10.5	55.0	101.0	71	75.0	11.5	0.7	0.0	10.1	-28.0	30.0
	WEEK 32	30	72.8	72.0	8.7	56.0	96.0	30	75.5	8.6	-2.7	-1.5	8.9	-24.0	16.0
	WEEK 36	24	70.8	69.5	8.0	53.0	91.0	24	74.5	8.8	-3.6	-4.0	7.5	-15.0	12.0
	WEEK 40	18	73.9	72.0	9.4	65.0	101.0	18	74.0	9.2	-0.1	-1.5	7.2	-11.0	16.0
	WEEK 44	18	73.8	71.0	11.6	58.0	108.0	18	74.9	9.4	-1.1	-1.5	9.5	-14.0	16.0
	WEEK 48	15	73.0	70.0	11.7	57.0	109.0	15	75.8	10.1	-2.8	-4.0	10.3	-20.0	11.0
	WEEK 52	14	74.9	72.5	9.2	64.0	100.0	14	76.6	10.0	-1.7	-2.5	7.0	-12.0	13.0
	LAST VISIT	85	76.8	76.0	10.3	55.0	100.0	85	75.9	11.4	0.9	0.0	9.0	-28.0	29.0
TOTAL	BASELINE	464	75.6	76.0	10.5	37.0	108.0								
	WEEK 1	442	78.9	78.5	10.5	51.0	112.0	442	75.5	10.6	3.3	2.0	9.5	-27.0	41.0
	WEEK 2	434	78.9	79.0	10.0	53.0	111.0	434	75.7	10.4	3.2	3.0	9.4	-29.0	34.0
	WEEK 3	437	79.4	79.0	11.0	52.0	117.0	437	75.5	10.5	3.9	3.0	10.4	-27.0	34.0
	WEEK 4	435	78.6	78.0	11.0	51.0	118.0	435	75.5	10.4	3.1	3.0	10.3	-26.0	49.0
	WEEK 6	432	79.2	80.0	10.0	53.0	112.0	432	75.5	10.4	3.6	3.0	10.2	-34.0	36.0
	WEEK 8	421	78.4	78.0	10.0	55.0	114.0	421	75.3	10.4	3.1	2.0	9.8	-25.0	33.0
	WEEK 10	413	78.5	79.0	9.9	50.0	107.0	413	75.4	10.5	3.1	3.0	10.4	-27.0	42.0
	WEEK 12	410	78.1	78.0	10.3	51.0	109.0	410	75.3	10.5	2.8	2.0	10.4	-26.0	35.0
	WEEK 16	398	77.5	78.0	10.9	51.0	112.0	398	75.2	10.5	2.3	2.0	10.2	-23.0	40.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=HEART RATE SITTING (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE ___BASELINE___ n[2]	MEAN	SD	CHANGE FROM BASELINE MEAN	MEDIAN	SD	MIN	MAX
TOTAL	WEEK 20	382	79.0	78.5	10.4	50.0	116.0	382	75.1	10.6	4.0	4.0	10.7	-30.0	49.0
	WEEK 24	361	77.9	77.0	10.7	52.0	122.0	361	75.3	10.6	2.6	2.0	11.1	-34.0	37.0
	WEEK 28	349	77.3	76.0	10.9	51.0	113.0	349	75.1	10.7	2.2	2.0	11.0	-31.0	38.0
	WEEK 32	291	77.2	76.0	10.6	53.0	120.0	291	75.2	10.4	2.0	2.0	10.3	-28.0	33.0
	WEEK 36	273	76.6	76.0	10.8	49.0	111.0	273	75.1	10.4	1.5	0.0	10.9	-27.0	38.0
	WEEK 40	256	77.5	77.0	10.4	51.0	105.0	256	75.1	10.5	2.4	1.0	11.4	-31.0	37.0
	WEEK 44	250	78.0	77.0	10.4	54.0	108.0	250	75.3	10.4	2.7	2.5	11.3	-34.0	38.0
	WEEK 48	244	77.5	76.0	10.8	48.0	109.0	244	75.3	10.4	2.2	2.0	11.0	-26.0	41.0
	WEEK 52	238	75.6	76.0	11.1	47.0	110.0	238	75.3	10.4	0.4	0.0	11.4	-35.0	39.0
	LAST VISIT	463	76.8	76.0	11.1	47.0	117.0	463	75.6	10.5	1.2	0.0	11.4	-35.0	40.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	379	119.8	120.0	13.4	86.0	179.0								
	WEEK 1	364	120.2	121.0	13.4	82.0	164.0	364	119.6	13.1	0.6	0.0	10.2	-45.0	42.0
	WEEK 2	356	120.4	121.0	13.2	84.0	165.0	356	119.8	13.3	0.6	0.0	10.5	-43.0	31.0
	WEEK 3	356	119.7	120.0	12.7	80.0	173.0	356	119.7	13.5	0.0	0.0	10.9	-37.0	30.0
	WEEK 4	357	119.0	120.0	12.9	80.0	160.0	357	119.7	13.5	-0.7	0.0	11.4	-59.0	38.0
	WEEK 6	350	120.1	120.0	12.8	70.0	162.0	350	119.4	13.4	0.7	1.0	11.2	-38.0	37.0
	WEEK 8	344	119.5	120.0	13.4	70.0	165.0	344	119.6	13.4	-0.1	0.0	11.0	-39.0	48.0
	WEEK 10	337	120.2	120.0	13.9	70.0	170.0	337	119.6	13.3	0.6	0.0	10.8	-32.0	48.0
	WEEK 12	334	120.1	120.0	13.3	80.0	167.0	334	119.8	13.3	0.3	1.0	11.2	-73.0	35.0
	WEEK 16	323	119.1	118.0	12.6	78.0	163.0	323	119.5	13.2	-0.4	0.0	11.4	-52.0	34.0
	WEEK 20	308	119.8	120.0	13.1	80.0	168.0	308	119.7	13.4	0.2	0.0	10.7	-40.0	31.0
	WEEK 24	289	119.5	120.0	13.5	76.0	159.0	289	119.6	13.6	-0.1	0.0	11.2	-45.0	46.0
	WEEK 28	278	118.7	120.0	13.9	64.0	156.0	278	119.6	13.6	-0.9	0.0	12.0	-37.0	57.0
	WEEK 32	261	120.3	120.0	13.5	86.0	161.0	261	119.8	13.4	0.5	1.0	12.0	-33.0	52.0
	WEEK 36	249	119.7	120.0	13.9	92.0	168.0	249	119.9	13.7	-0.2	0.0	11.7	-41.0	30.0
	WEEK 40	238	120.3	120.0	13.6	84.0	179.0	238	119.8	13.9	0.5	0.0	12.5	-40.0	57.0
	WEEK 44	232	120.3	120.0	13.7	88.0	181.0	232	120.0	13.9	0.3	0.0	11.5	-38.0	31.0
	WEEK 48	229	119.6	120.0	12.6	87.0	152.0	229	119.7	13.0	-0.1	0.0	10.7	-37.0	34.0
	WEEK 52	224	120.4	121.0	13.2	86.0	159.0	224	119.9	13.7	0.5	0.0	11.7	-37.0	41.0
	LAST VISIT	378	120.2	120.0	13.5	86.0	161.0	378	119.9	13.4	0.4	0.0	11.8	-37.0	41.0
ROLLOVER	BASELINE	85	121.7	120.0	12.2	95.0	146.0								
	WEEK 1	78	122.0	122.0	13.3	92.0	150.0	78	121.4	12.2	0.6	0.0	7.9	-25.0	19.0
	WEEK 2	78	123.0	125.0	13.2	90.0	152.0	78	122.1	11.9	0.9	0.0	9.4	-25.0	36.0
	WEEK 3	81	122.4	120.0	12.5	89.0	147.0	81	121.6	12.1	0.9	1.0	10.4	-30.0	29.0
	WEEK 4	78	121.8	122.0	14.1	92.0	155.0	78	122.0	12.5	-0.1	0.0	11.0	-38.0	33.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ROLLOVER	WEEK 6	82	120.6	120.0	11.7	96.0	149.0	82	121.9	12.3	-1.3	0.0	10.6	-24.0	21.0
	WEEK 8	77	121.7	120.0	12.7	92.0	150.0	77	122.4	12.4	-0.7	-1.0	10.1	-31.0	26.0
	WEEK 10	76	121.5	120.5	11.2	98.0	149.0	76	121.7	12.3	-0.3	0.0	9.7	-34.0	29.0
	WEEK 12	76	121.0	120.0	11.2	98.0	141.0	76	122.0	12.6	-1.1	-1.0	8.5	-25.0	22.0
	WEEK 16	75	120.1	119.0	12.6	92.0	149.0	75	121.8	12.5	-1.7	0.0	10.0	-22.0	24.0
	WEEK 20	74	121.2	120.0	14.1	91.0	159.0	74	121.9	12.6	-0.7	-1.5	8.8	-28.0	26.0
	WEEK 24	72	121.3	120.0	12.5	98.0	155.0	72	121.8	12.6	-0.6	0.0	9.6	-26.0	22.0
	WEEK 28	71	121.1	121.0	13.8	90.0	155.0	71	121.9	12.7	-0.8	-2.0	9.6	-21.0	21.0
	WEEK 32	30	120.2	118.5	13.1	92.0	156.0	30	120.2	12.9	0.0	0.0	10.9	-21.0	20.0
	WEEK 36	24	118.4	117.5	12.2	94.0	149.0	24	121.5	13.6	-3.0	2.5	11.5	-30.0	10.0
	WEEK 40	18	123.9	122.0	12.8	106.0	156.0	18	125.8	12.5	-1.8	-4.0	8.6	-18.0	14.0
	WEEK 44	18	122.9	122.0	14.3	101.0	167.0	18	123.8	12.0	-0.8	-4.0	13.2	-21.0	25.0
	WEEK 48	15	119.5	124.0	8.8	104.0	133.0	15	123.5	12.0	-4.0	-4.0	12.1	-26.0	14.0
	WEEK 52	14	120.3	119.0	11.9	100.0	138.0	14	122.8	12.1	-2.5	-4.5	14.8	-26.0	22.0
	LAST VISIT	85	121.6	120.0	14.3	90.0	167.0	85	121.7	12.2	-0.2	-2.0	10.9	-26.0	25.0
TOTAL	BASELINE	464	120.2	120.0	13.2	86.0	179.0								
	WEEK 1	442	120.5	121.0	13.4	82.0	164.0	442	119.9	13.0	0.6	0.0	9.8	-45.0	42.0
	WEEK 2	434	120.9	122.0	13.2	84.0	165.0	434	120.2	13.1	0.7	0.0	10.3	-43.0	36.0
	WEEK 3	437	120.2	120.0	12.7	80.0	173.0	437	120.1	13.2	0.2	0.0	10.8	-37.0	30.0
	WEEK 4	435	119.5	120.0	13.2	80.0	160.0	435	120.1	13.3	-0.6	0.0	11.4	-59.0	38.0
	WEEK 6	432	120.2	120.0	12.6	70.0	162.0	432	119.9	13.2	0.3	0.0	11.1	-38.0	37.0
	WEEK 8	421	119.9	120.0	13.3	70.0	165.0	421	120.1	13.2	-0.2	0.0	10.8	-39.0	48.0
	WEEK 10	413	120.4	120.0	13.4	70.0	170.0	413	120.0	13.1	0.4	0.0	10.6	-34.0	48.0
	WEEK 12	410	120.3	120.0	12.9	80.0	167.0	410	120.2	13.2	0.0	0.0	10.8	-73.0	35.0
	WEEK 16	398	119.3	119.0	12.6	78.0	163.0	398	120.0	13.0	-0.7	0.0	11.2	-52.0	34.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.2 FINAL

表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=SYSTOLIC SITTING BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
TOTAL	WEEK 20	382	120.1	120.0	13.3	80.0	168.0	382	120.1	13.3	-0.0	0.0	10.4	-40.0	31.0
	WEEK 24	361	119.8	120.0	13.3	76.0	159.0	361	120.0	13.4	-0.2	0.0	10.9	-45.0	46.0
	WEEK 28	349	119.2	120.0	13.9	64.0	156.0	349	120.1	13.5	-0.9	0.0	11.6	-37.0	57.0
	WEEK 32	291	120.3	120.0	13.5	86.0	161.0	291	119.8	13.4	0.4	0.0	11.9	-33.0	52.0
	WEEK 36	273	119.5	120.0	13.7	92.0	168.0	273	120.0	13.7	-0.5	0.0	11.7	-41.0	30.0
	WEEK 40	256	120.5	120.0	13.6	84.0	179.0	256	120.2	13.8	0.3	0.0	12.3	-40.0	57.0
	WEEK 44	250	120.5	120.5	13.8	88.0	181.0	250	120.3	13.8	0.2	0.0	11.6	-38.0	31.0
	WEEK 48	244	119.6	120.0	12.4	87.0	152.0	244	119.9	13.0	-0.3	0.0	10.8	-37.0	34.0
	WEEK 52	238	120.4	121.0	13.1	86.0	159.0	238	120.1	13.6	0.3	0.0	11.9	-37.0	41.0
	LAST VISIT	463	120.5	120.0	13.6	86.0	167.0	463	120.2	13.2	0.3	0.0	11.6	-37.0	41.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
DE NOVO	BASELINE	379	77.7	78.0	9.0	54.0	106.0								
	WEEK 1	364	77.3	78.0	9.7	47.0	101.0	364	77.7	9.0	-0.4	0.0	8.1	-32.0	20.0
	WEEK 2	356	78.5	79.0	9.4	52.0	113.0	356	78.0	8.9	0.6	0.0	8.0	-26.0	34.0
	WEEK 3	356	78.8	80.0	9.3	56.0	118.0	356	77.6	9.0	1.1	1.0	8.5	-23.0	32.0
	WEEK 4	357	77.7	78.0	9.4	52.0	105.0	357	77.7	9.0	-0.0	0.0	8.4	-35.0	24.0
	WEEK 6	350	78.1	79.0	9.2	50.0	110.0	350	77.7	9.1	0.4	0.0	8.6	-29.0	28.0
	WEEK 8	344	77.8	78.0	9.3	51.0	109.0	344	77.6	9.0	0.2	0.0	8.4	-24.0	23.0
	WEEK 10	337	77.9	79.0	10.3	40.0	106.0	337	77.6	9.1	0.3	0.0	8.3	-28.0	24.0
	WEEK 12	334	78.4	79.0	9.7	50.0	118.0	334	77.7	8.9	0.7	1.0	8.6	-29.0	27.0
	WEEK 16	323	77.9	78.0	9.3	53.0	113.0	323	77.4	8.9	0.4	0.0	8.8	-36.0	29.0
	WEEK 20	308	78.2	79.0	10.0	51.0	110.0	308	77.5	9.0	0.7	0.0	8.6	-25.0	31.0
	WEEK 24	289	77.8	78.0	10.5	36.0	120.0	289	77.5	9.2	0.3	0.0	9.3	-46.0	26.0
	WEEK 28	278	77.7	78.0	10.0	30.0	110.0	278	77.5	9.2	0.3	0.0	8.8	-38.0	27.0
	WEEK 32	261	77.6	78.0	9.3	51.0	106.0	261	77.6	9.1	-0.0	0.0	8.5	-28.0	20.0
	WEEK 36	249	78.3	79.0	9.6	50.0	107.0	249	77.6	9.1	0.7	0.0	8.8	-23.0	26.0
	WEEK 40	238	77.3	78.0	9.8	50.0	117.0	238	77.6	9.2	-0.3	0.0	9.3	-44.0	28.0
	WEEK 44	232	78.1	79.0	10.1	51.0	102.0	232	77.7	9.1	0.4	0.0	9.3	-27.0	25.0
	WEEK 48	229	77.8	78.0	9.8	46.0	102.0	229	77.6	9.2	0.2	0.0	8.3	-23.0	27.0
	WEEK 52	224	78.2	78.0	9.8	49.0	108.0	224	77.5	9.2	0.7	1.0	9.5	-24.0	33.0
	LAST VISIT	378	78.4	78.0	10.0	49.0	118.0	378	77.8	9.0	0.7	1.0	9.3	-28.0	33.0
ROLLOVER	BASELINE	85	77.8	79.0	9.1	58.0	98.0								
	WEEK 1	78	77.6	77.5	9.9	58.0	106.0	78	77.7	9.3	-0.1	0.0	6.6	-20.0	14.0
	WEEK 2	78	79.2	79.5	9.3	61.0	101.0	78	78.0	9.4	1.2	0.0	8.7	-16.0	34.0
	WEEK 3	81	77.4	76.0	9.6	60.0	98.0	81	77.9	9.3	-0.5	-2.0	8.0	-24.0	21.0
	WEEK 4	78	77.7	76.0	10.5	52.0	104.0	78	78.0	9.4	-0.3	0.0	9.1	-28.0	22.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ROLLOVER	WEEK 6	82	76.2	76.0	9.6	52.0	109.0	82	78.0	9.2	-1.7	-2.0	9.5	-28.0	27.0
	WEEK 8	77	78.2	78.0	9.1	59.0	105.0	77	78.2	9.3	-0.0	0.0	7.7	-22.0	18.0
	WEEK 10	76	76.7	76.0	9.1	58.0	99.0	76	78.1	9.3	-1.4	-2.0	8.7	-26.0	23.0
	WEEK 12	76	77.6	79.0	8.6	61.0	99.0	76	78.2	9.4	-0.6	0.0	7.6	-17.0	19.0
	WEEK 16	75	77.1	77.0	9.0	60.0	102.0	75	77.9	9.2	-0.9	-1.0	7.7	-20.0	15.0
	WEEK 20	74	78.6	79.5	8.5	63.0	108.0	74	77.8	9.2	0.8	0.0	7.2	-18.0	23.0
	WEEK 24	72	77.5	77.5	9.7	62.0	105.0	72	78.1	9.2	-0.5	-1.5	7.8	-20.0	16.0
	WEEK 28	71	77.6	78.0	10.1	51.0	109.0	71	78.0	9.2	-0.4	0.0	7.7	-18.0	16.0
	WEEK 32	30	75.4	74.0	10.3	59.0	109.0	30	78.2	8.8	-2.7	-3.0	8.8	-27.0	11.0
	WEEK 36	24	74.5	70.0	10.8	62.0	110.0	24	78.5	9.4	-4.0	-2.5	8.9	-19.0	12.0
	WEEK 40	18	74.7	71.0	11.6	62.0	105.0	18	80.9	8.9	-6.2	-6.5	9.8	-18.0	12.0
	WEEK 44	18	77.3	74.5	11.6	62.0	108.0	18	81.0	8.9	-3.7	-2.5	9.0	-18.0	14.0
	WEEK 48	15	74.7	78.0	9.6	57.0	92.0	15	81.5	7.3	-6.7	-4.0	9.6	-23.0	10.0
	WEEK 52	14	76.9	77.0	9.2	62.0	97.0	14	81.3	7.6	-4.4	-4.0	12.0	-24.0	15.0
	LAST VISIT	85	78.0	78.0	9.2	51.0	108.0	85	77.8	9.1	0.2	0.0	8.4	-24.0	23.0
TOTAL	BASELINE	464	77.8	78.0	9.0	54.0	106.0								
	WEEK 1	442	77.4	78.0	9.7	47.0	106.0	442	77.7	9.1	-0.3	0.0	7.8	-32.0	20.0
	WEEK 2	434	78.7	79.0	9.4	52.0	113.0	434	78.0	9.0	0.7	0.0	8.1	-26.0	34.0
	WEEK 3	437	78.5	79.0	9.3	56.0	118.0	437	77.7	9.0	0.8	0.0	8.4	-24.0	32.0
	WEEK 4	435	77.7	78.0	9.6	52.0	105.0	435	77.7	9.1	-0.1	0.0	8.5	-35.0	24.0
	WEEK 6	432	77.7	78.0	9.3	50.0	110.0	432	77.7	9.1	0.0	0.0	8.8	-29.0	28.0
	WEEK 8	421	77.9	78.0	9.3	51.0	109.0	421	77.7	9.0	0.1	0.0	8.2	-24.0	23.0
	WEEK 10	413	77.7	78.0	10.1	40.0	106.0	413	77.7	9.1	-0.1	0.0	8.4	-28.0	24.0
	WEEK 12	410	78.2	79.0	9.5	50.0	118.0	410	77.8	9.0	0.5	1.0	8.5	-29.0	27.0
	WEEK 16	398	77.7	78.0	9.3	53.0	113.0	398	77.5	9.0	0.2	0.0	8.6	-36.0	29.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-122　バイタルサインの記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.2
Mean Change From Baseline in Vital Signs Parameters in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER=DIASTOLIC SITTING BP (mmHg)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
TOTAL	WEEK 20	382	78.2	79.0	9.7	51.0	110.0	382	77.5	9.0	0.7	0.0	8.3	-25.0	31.0
	WEEK 24	361	77.7	78.0	10.3	36.0	120.0	361	77.6	9.2	0.1	0.0	9.1	-46.0	26.0
	WEEK 28	349	77.7	78.0	10.0	30.0	110.0	349	77.6	9.2	0.1	0.0	8.6	-38.0	27.0
	WEEK 32	291	77.4	78.0	9.4	51.0	109.0	291	77.7	9.1	-0.3	0.0	8.5	-28.0	20.0
	WEEK 36	273	78.0	78.0	9.8	50.0	110.0	273	77.7	9.1	0.3	0.0	8.9	-23.0	26.0
	WEEK 40	256	77.1	78.0	9.9	50.0	117.0	256	77.8	9.2	-0.7	0.0	9.5	-44.0	28.0
	WEEK 44	250	78.0	78.5	10.2	51.0	108.0	250	77.9	9.1	0.1	0.0	9.3	-27.0	25.0
	WEEK 48	244	77.6	78.0	9.8	46.0	102.0	244	77.9	9.1	-0.2	0.0	8.5	-23.0	27.0
	WEEK 52	238	78.2	78.0	9.7	49.0	108.0	238	77.8	9.2	0.4	1.0	9.7	-24.0	33.0
	LAST VISIT	463	78.4	78.0	9.8	49.0	118.0	463	77.8	9.0	0.6	0.0	9.1	-28.0	33.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADVS2AA.LIS, RUN: [redacted]20[redacted] 11:59; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:25
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADVS2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-14.2　FINAL

＜資料番号 5.3.5.2-01：CT-14.2＞

表 2.7.4.7-123　体重関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.10
Incidence of Treatment-emergent Adverse Events Related to Weight in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
臨床検査	TOTAL1)	68	(17.9)	7	(8.2)	75	(16.2)
	体重減少	12	(3.2)	1	(1.2)	13	(2.8)
	体重増加	56	(14.8)	6	(7.1)	62	(13.4)
TOTAL2)		68	(17.9)	7	(8.2)	75	(16.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AK.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.10　FINAL

表 2.7.4.7-123　体重関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.10
Incidence of Treatment-emergent Adverse Events Related to Weight in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO WEIGHT: MEDDRA 19.0 PRIMARY TERMS

UNDERWEIGHT, WEIGHT DECREASED, WEIGHT INCREASED, OVERWEIGHT, WEIGHT ABNORMAL, WEIGHT FLUCTUATION, WEIGHT GAIN POOR, WEIGHT LOSS DIET, WEIGHT NORMAL, WEIGHT CONTROL, FEAR OF WEIGHT GAIN, ABNORMAL WEIGHT GAIN, ABNORMAL LOSS OF WEIGHT, BONE DENSITY DECREASED, OEDEMA, DRY WEIGHT EVALUATION

＜資料番号 5.3.5.2-01：CT-8.2.5.10＞

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=ALANINE AMINOTRANSFERASE (U/L)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	22.69	18.00	14.13	6.00	88.00								
	WEEK 28	79	25.72	20.00	17.53	7.00	82.00	75	24.56	16.49	1.65	1.00	15.82	-71.00	55.00
	WEEK 52	64	24.11	17.00	16.71	5.00	77.00	60	23.75	15.21	0.83	-1.00	11.09	-40.00	38.00
	LAST VISIT	125	23.10	18.00	14.85	5.00	77.00	120	22.82	14.44	0.48	-0.50	12.87	-71.00	48.00
PLACEBO	BASELINE	131	25.16	18.00	21.45	9.00	152.00								
	WEEK 28	57	30.33	20.00	29.09	8.00	154.00	57	26.81	22.51	3.53	0.00	21.54	-31.00	130.00
	WEEK 52	40	30.30	24.00	20.75	9.00	101.00	40	27.00	20.01	3.30	0.50	15.91	-41.00	39.00
	LAST VISIT	126	23.71	18.00	15.63	6.00	101.00	124	25.02	21.54	-1.23	-1.00	18.00	-131.00	50.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=ALBUMIN (g/dL)

									CHANGE FROM BASELINE						
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	4.13	4.20	0.36	3.00	4.90								
	WEEK 28	79	4.15	4.20	0.36	3.30	4.90	75	4.13	0.35	0.01	0.00	0.29	-0.50	0.70
	WEEK 52	64	4.20	4.20	0.30	3.30	4.80	60	4.17	0.34	0.02	0.00	0.31	-0.60	0.90
	LAST VISIT	125	4.16	4.20	0.34	3.30	4.80	120	4.15	0.34	0.01	0.00	0.32	-0.60	0.90
PLACEBO	BASELINE	131	4.14	4.10	0.31	3.10	5.10								
	WEEK 28	57	4.17	4.10	0.29	3.60	5.10	57	4.13	0.35	0.04	0.00	0.28	-0.50	0.80
	WEEK 52	40	4.23	4.20	0.29	3.60	4.80	40	4.20	0.32	0.03	0.00	0.31	-0.50	0.90
	LAST VISIT	126	4.22	4.20	0.32	3.20	5.00	124	4.14	0.31	0.08	0.10	0.31	-0.60	0.80

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=ALKALINE PHOSPHATASE (U/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	127	70.84	69.00	18.00	37.00	127.00								
	WEEK 28	79	73.66	72.00	16.34	43.00	121.00	75	71.85	16.73	2.31	2.00	12.20	-57.00	26.00
	WEEK 52	64	74.53	71.00	18.23	40.00	128.00	60	71.87	15.31	2.35	1.00	12.18	-35.00	36.00
	LAST VISIT	125	72.59	70.00	17.90	40.00	128.00	120	70.94	17.70	1.21	1.00	11.70	-57.00	36.00
PLACEBO	BASELINE	132	72.55	67.50	24.21	36.00	161.00								
	WEEK 28	57	73.37	67.00	25.53	33.00	136.00	57	74.74	27.89	-1.37	0.00	15.16	-42.00	54.00
	WEEK 52	40	69.78	66.50	23.77	36.00	135.00	40	69.73	24.97	0.05	-1.00	16.34	-58.00	31.00
	LAST VISIT	126	71.83	68.00	22.78	36.00	162.00	125	72.44	24.43	-0.78	-2.00	14.25	-58.00	34.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=ASPARTATE AMINOTRANSFERASE (U/L)

								CHANGE FROM BASELINE						
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	20.00	18.00	6.42	11.00	49.00								
	WEEK 28	79	21.35	20.00	8.71	8.00	50.00	75	20.95	7.38	0.56	0.00	8.15	-28.00	28.00
	WEEK 52	64	21.03	19.00	9.53	10.00	64.00	60	20.45	6.87	0.77	0.50	7.42	-20.00	37.00
	LAST VISIT	125	20.10	18.00	8.20	8.00	64.00	119	20.06	6.56	0.02	0.00	7.36	-28.00	37.00
PLACEBO	BASELINE	130	21.52	19.00	13.09	9.00	120.00								
	WEEK 28	56	23.05	19.50	11.45	10.00	63.00	55	21.67	11.88	1.44	1.00	7.90	-16.00	40.00
	WEEK 52	40	25.33	21.00	13.16	10.00	68.00	39	21.23	10.02	4.31	2.00	11.01	-17.00	40.00
	LAST VISIT	125	21.42	19.00	9.37	10.00	68.00	122	21.61	13.33	-0.14	0.00	12.86	-100.00	40.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=BICARBONATE (mEq/L)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	22.97	23.10	2.77	14.60	30.00								
	WEEK 28	79	22.72	22.90	3.07	12.90	29.10	74	23.06	2.95	-0.29	-0.20	3.22	-8.90	7.20
	WEEK 52	64	23.00	23.10	2.46	18.80	28.00	59	22.99	2.92	-0.04	0.00	2.71	-8.50	6.30
	LAST VISIT	124	22.97	23.00	2.34	18.80	28.00	118	23.07	2.77	-0.13	-0.35	2.75	-8.90	7.10
PLACEBO	BASELINE	129	23.57	23.60	2.81	15.60	30.50								
	WEEK 28	57	23.29	23.60	2.84	17.30	29.70	56	24.19	2.50	-0.83	-0.80	2.32	-6.80	4.20
	WEEK 52	40	24.15	24.35	2.43	17.90	29.40	39	24.12	2.63	0.12	-0.30	2.52	-3.80	6.10
	LAST VISIT	126	23.42	23.55	2.91	12.50	30.70	122	23.62	2.82	-0.09	-0.30	2.47	-7.00	6.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=BILIRUBIN (mg/dL)

								CHANGE FROM BASELINE							
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	124	0.48	0.40	0.25	0.20	1.80								
	WEEK 28	74	0.50	0.40	0.28	0.20	1.80	70	0.53	0.29	-0.02	0.00	0.22	-0.50	0.90
	WEEK 52	60	0.49	0.40	0.31	0.20	1.70	56	0.54	0.31	-0.05	0.00	0.17	-0.50	0.40
	LAST VISIT	122	0.45	0.40	0.25	0.20	1.70	114	0.50	0.25	-0.04	0.00	0.17	-0.50	0.40
PLACEBO	BASELINE	124	0.49	0.40	0.30	0.20	2.50								
	WEEK 28	54	0.48	0.40	0.26	0.20	1.70	54	0.45	0.22	0.03	0.00	0.21	-0.40	0.90
	WEEK 52	40	0.48	0.40	0.22	0.20	1.30	40	0.46	0.25	0.02	0.00	0.21	-0.80	0.50
	LAST VISIT	124	0.47	0.40	0.23	0.20	1.30	116	0.50	0.30	-0.01	0.00	0.25	-1.30	0.60

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=BLOOD UREA NITROGEN (mg/dL)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	12.73	12.00	3.58	6.00	23.00								
	WEEK 28	79	12.43	12.00	4.18	4.00	23.00	75	12.67	3.54	-0.24	0.00	3.79	-10.00	8.00
	WEEK 52	64	12.27	12.00	3.32	6.00	21.00	60	12.37	3.41	-0.08	0.00	2.79	-5.00	8.00
	LAST VISIT	125	12.65	12.00	4.37	4.00	33.00	120	12.79	3.59	-0.18	0.00	4.12	-10.00	21.00
PLACEBO	BASELINE	132	12.55	12.00	3.96	6.00	27.00								
	WEEK 28	57	13.44	13.00	5.28	5.00	39.00	57	12.91	4.09	0.53	0.00	3.68	-8.00	12.00
	WEEK 52	40	13.18	13.00	4.71	6.00	27.00	40	13.13	4.03	0.05	0.00	4.25	-9.00	14.00
	LAST VISIT	126	12.39	12.00	4.31	4.00	31.00	125	12.50	3.93	-0.10	0.00	4.11	-14.00	12.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=CALCIUM (mg/dL)

									CHANGE FROM BASELINE					
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	9.63	9.60	0.44	7.70	10.90								
	WEEK 28	79	9.63	9.70	0.38	8.70	10.50	75	9.60	0.42	0.02	0.00	0.42	-0.60	2.20
	WEEK 52	64	9.55	9.55	0.38	8.20	10.40	60	9.61	0.45	-0.06	-0.10	0.50	-1.00	2.20
	LAST VISIT	125	9.60	9.60	0.41	8.20	11.10	120	9.65	0.44	-0.05	-0.10	0.43	-1.00	2.20
PLACEBO	BASELINE	132	9.69	9.65	0.41	8.70	10.80								
	WEEK 28	57	9.68	9.70	0.42	8.40	11.00	57	9.74	0.40	-0.06	-0.10	0.38	-0.70	1.00
	WEEK 52	40	9.74	9.70	0.36	8.80	10.60	40	9.78	0.38	-0.03	-0.10	0.34	-0.80	0.70
	LAST VISIT	126	9.73	9.70	0.38	8.70	10.60	125	9.70	0.41	0.03	0.00	0.44	-1.20	1.50

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=CHLORIDE (mEq/L)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	102.69	103.00	2.38	95.00	110.00								
	WEEK 28	79	102.59	103.00	2.94	95.00	111.00	75	102.71	2.31	-0.07	0.00	2.57	-7.00	6.00
	WEEK 52	64	102.03	102.00	2.62	96.00	109.00	60	102.60	2.33	-0.48	0.00	2.38	-7.00	4.00
	LAST VISIT	124	102.35	102.00	2.55	96.00	109.00	119	102.69	2.40	-0.30	0.00	2.64	-7.00	8.00
PLACEBO	BASELINE	131	102.52	102.00	2.30	97.00	108.00								
	WEEK 28	57	101.89	102.00	2.95	97.00	108.00	57	102.18	2.31	-0.28	-1.00	2.63	-7.00	6.00
	WEEK 52	40	101.10	101.00	2.60	96.00	108.00	40	102.23	2.30	-1.13	-1.00	2.28	-6.00	5.00
	LAST VISIT	126	101.73	102.00	2.78	96.00	108.00	124	102.54	2.34	-0.90	-1.00	2.55	-6.00	6.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=CHOLESTEROL, FASTING (mg/dL)

								CHANGE FROM BASELINE							
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	112	191.11	186.00	40.00	123.00	305.00								
	WEEK 28	72	190.68	183.50	35.98	124.00	283.00	64	187.86	39.10	4.63	1.00	25.59	-47.00	103.00
	WEEK 52	59	188.29	184.00	36.34	121.00	267.00	51	189.29	39.63	0.10	1.00	22.03	-57.00	75.00
	LAST VISIT	109	188.78	186.00	37.65	119.00	303.00	93	189.24	38.50	1.48	0.00	21.31	-57.00	75.00
PLACEBO	BASELINE	119	190.88	192.00	38.10	104.00	293.00								
	WEEK 28	45	197.31	200.00	41.17	125.00	283.00	42	197.64	43.03	0.55	-1.50	25.75	-69.00	57.00
	WEEK 52	37	202.54	207.00	43.51	105.00	279.00	36	193.11	48.67	8.44	11.00	41.00	-126.00	77.00
	LAST VISIT	111	192.37	188.00	37.80	105.00	300.00	98	192.02	39.97	3.03	6.50	34.10	-126.00	81.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=CREATINE KINASE (U/L)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	133.91	93.00	118.68	34.00	817.00								
	WEEK 28	79	136.37	94.00	130.33	37.00	816.00	75	146.33	137.10	-7.03	-4.00	137.96	-513.00	666.00
	WEEK 52	64	128.28	88.00	128.82	36.00	701.00	60	147.72	145.47	-16.18	-12.00	128.46	-523.00	622.00
	LAST VISIT	125	123.07	91.00	106.50	36.00	701.00	120	131.52	115.33	-7.32	-9.00	104.62	-523.00	622.00
PLACEBO	BASELINE	131	135.34	97.00	118.79	22.00	855.00								
	WEEK 28	57	163.00	110.00	168.27	25.00	960.00	57	149.33	134.97	13.67	4.00	114.61	-263.00	676.00
	WEEK 52	40	226.93	157.50	244.69	36.00	1029.00	40	163.38	149.50	63.55	13.50	190.78	-199.00	870.00
	LAST VISIT	126	166.20	104.00	174.97	33.00	1029.00	124	135.84	120.92	30.52	7.50	146.38	-387.00	747.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=CREATININE (mg/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: BASELINE MEAN	CHANGE FROM BASELINE: BASELINE SD	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: MEDIAN	CHANGE FROM BASELINE: SD	CHANGE FROM BASELINE: MIN	CHANGE FROM BASELINE: MAX
ARIP IMD	BASELINE	127	0.90	0.90	0.20	0.50	1.50								
	WEEK 28	79	0.89	0.90	0.18	0.60	1.30	75	0.88	0.18	0.01	0.00	0.12	-0.30	0.40
	WEEK 52	64	0.86	0.80	0.17	0.50	1.40	60	0.88	0.17	-0.01	0.00	0.12	-0.30	0.40
	LAST VISIT	125	0.89	0.90	0.19	0.50	1.40	120	0.90	0.20	-0.01	0.00	0.13	-0.30	0.40
PLACEBO	BASELINE	132	0.92	0.90	0.23	0.60	1.80								
	WEEK 28	57	0.92	0.90	0.23	0.50	2.00	57	0.93	0.22	-0.01	0.00	0.12	-0.30	0.30
	WEEK 52	40	0.91	0.90	0.25	0.50	2.10	40	0.95	0.23	-0.04	0.00	0.14	-0.40	0.30
	LAST VISIT	126	0.90	0.90	0.23	0.50	1.70	125	0.92	0.23	-0.02	0.00	0.15	-0.40	0.70

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=GAMMA GLUTAMYL TRANSFERASE (U/L)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	29.46	23.00	27.43	5.00	225.00								
	WEEK 28	79	31.67	24.00	30.12	6.00	188.00	75	31.76	32.04	0.49	1.00	23.61	-136.00	88.00
	WEEK 52	64	30.34	22.00	22.41	7.00	96.00	60	30.72	31.66	0.12	0.00	23.33	-152.00	41.00
	LAST VISIT	125	29.94	23.00	21.84	5.00	119.00	120	29.69	27.71	0.39	0.50	19.05	-152.00	41.00
PLACEBO	BASELINE	132	27.64	20.50	23.96	5.00	179.00								
	WEEK 28	57	33.37	24.00	28.97	8.00	142.00	57	30.93	25.93	2.44	1.00	16.36	-32.00	90.00
	WEEK 52	40	36.58	26.50	30.42	10.00	162.00	40	34.43	27.80	2.15	0.50	15.34	-22.00	80.00
	LAST VISIT	126	27.65	21.50	22.35	8.00	162.00	125	27.90	24.54	-0.17	0.00	19.53	-150.00	82.00

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=GLUCOSE, FASTING (mg/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	___BASELINE____ MEAN	___BASELINE____ MEDIAN	___BASELINE____ SD	___BASELINE____ MIN	___BASELINE____ MAX
ARIP IMD	BASELINE	112	95.21	92.00	20.02	45.00	229.00								
	WEEK 28	72	96.69	94.50	15.64	72.00	184.00	64	94.08	11.91	2.20	2.00	16.73	-47.00	62.00
	WEEK 52	59	97.44	92.00	19.15	57.00	166.00	51	93.69	12.19	3.27	2.00	17.45	-39.00	62.00
	LAST VISIT	112	95.74	92.50	16.79	57.00	166.00	96	94.96	18.34	0.60	1.00	21.13	-137.00	62.00
PLACEBO	BASELINE	118	97.49	92.00	26.18	61.00	262.00								
	WEEK 28	45	102.82	95.00	32.07	75.00	284.00	42	95.45	17.66	3.45	4.50	14.03	-36.00	41.00
	WEEK 52	37	95.73	95.00	17.94	57.00	168.00	35	97.69	19.02	-1.69	4.00	19.32	-76.00	27.00
	LAST VISIT	111	98.29	94.00	25.15	57.00	284.00	97	96.43	21.74	0.45	2.00	22.49	-94.00	68.00

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=HDL CHOLESTEROL, FASTING (mg/dL)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	112	53.05	50.50	15.45	27.00	105.00								
	WEEK 28	72	52.44	51.00	13.76	29.00	108.00	64	54.17	15.21	-1.94	-1.00	9.43	-20.00	24.00
	WEEK 52	59	50.78	50.00	12.78	31.00	98.00	51	54.12	15.74	-3.59	-2.00	9.41	-25.00	9.00
	LAST VISIT	109	51.60	50.00	14.63	23.00	98.00	93	53.90	15.80	-1.89	-2.00	9.12	-25.00	24.00
PLACEBO	BASELINE	119	53.08	51.00	16.30	19.00	115.00								
	WEEK 28	45	51.13	47.00	14.85	30.00	96.00	42	51.45	15.20	-0.14	-1.50	11.12	-27.00	26.00
	WEEK 52	37	52.65	47.00	16.02	23.00	88.00	36	53.22	14.91	-0.42	-2.50	11.71	-24.00	24.00
	LAST VISIT	111	53.62	49.00	17.16	23.00	116.00	98	53.69	16.76	0.55	-1.00	10.50	-24.00	35.00

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=INSULIN, FASTING (uIU/mL)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	108	14.72	8.90	13.78	1.92	71.30								
	WEEK 28	70	14.80	7.91	29.55	2.18	243.60	59	14.10	14.14	-2.72	-0.76	16.43	-68.07	52.12
	WEEK 52	58	15.02	9.03	17.37	1.24	96.04	47	13.70	12.16	0.30	-0.65	18.78	-46.59	89.19
	LAST VISIT	109	14.17	8.33	17.03	1.24	96.04	90	13.76	13.01	-0.42	-0.79	16.80	-68.07	89.19
PLACEBO	BASELINE	114	16.86	7.94	26.68	2.12	185.83								
	WEEK 28	45	13.47	9.16	12.49	0.89	57.52	41	14.88	18.28	-1.46	0.70	16.14	-73.62	26.98
	WEEK 52	36	13.71	10.09	24.15	1.59	149.91	33	12.24	12.69	2.01	0.96	20.96	-48.08	99.14
	LAST VISIT	110	14.90	9.04	21.76	0.88	149.91	93	14.87	23.06	0.41	0.42	28.13	-169.32	99.14

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=LACTATE DEHYDROGENASE (U/L)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	124	155.86	153.00	28.16	106.00	287.00								
	WEEK 28	76	156.33	149.50	28.22	108.00	231.00	71	157.76	31.00	-0.90	0.00	27.69	-109.00	75.00
	WEEK 52	59	161.17	156.00	29.82	111.00	243.00	54	156.39	28.15	5.19	1.50	33.29	-111.00	87.00
	LAST VISIT	122	157.54	155.00	30.38	92.00	255.00	115	155.67	28.60	1.64	-1.00	30.92	-111.00	107.00
PLACEBO	BASELINE	126	156.15	154.00	30.15	86.00	252.00								
	WEEK 28	53	161.77	160.00	36.69	105.00	274.00	51	151.71	30.96	9.92	6.00	20.00	-20.00	97.00
	WEEK 52	39	174.21	162.00	45.96	105.00	281.00	36	152.00	33.51	19.92	17.50	29.82	-40.00	89.00
	LAST VISIT	122	165.70	159.00	35.47	100.00	281.00	117	156.01	30.39	9.38	11.00	30.83	-76.00	126.00

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=LDL CHOLESTEROL, FASTING (mg/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	110	109.58	108.00	35.11	33.00	214.00								
	WEEK 28	71	111.21	111.00	31.37	45.00	189.00	63	106.00	34.19	6.10	3.00	22.67	-31.00	84.00
	WEEK 52	58	110.16	112.50	32.85	30.00	188.00	50	107.84	34.61	2.76	2.00	23.20	-57.00	78.00
	LAST VISIT	108	110.59	108.00	32.41	30.00	209.00	92	108.28	35.09	3.35	2.00	21.09	-57.00	78.00
PLACEBO	BASELINE	117	109.92	107.00	32.64	29.00	185.00								
	WEEK 28	45	117.13	112.00	34.39	49.00	181.00	42	117.67	36.68	-0.50	-3.00	23.20	-63.00	52.00
	WEEK 52	37	118.70	108.00	38.88	38.00	191.00	35	110.26	40.70	7.60	8.00	31.34	-77.00	60.00
	LAST VISIT	108	111.54	108.50	32.58	37.00	191.00	95	111.18	34.08	2.58	4.00	27.31	-77.00	60.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=MAGNESIUM (mg/dL)

								CHANGE FROM BASELINE						
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	2.05	2.10	0.19	1.00	2.50								
	WEEK 28	79	2.06	2.10	0.15	1.60	2.40	75	2.05	0.21	0.02	0.00	0.19	-0.40	0.90
	WEEK 52	64	2.04	2.00	0.15	1.70	2.50	60	2.05	0.22	-0.01	0.00	0.20	-0.40	1.00
	LAST VISIT	124	2.06	2.00	0.15	1.60	2.50	119	2.06	0.19	0.00	0.00	0.19	-0.40	1.00
PLACEBO	BASELINE	131	2.07	2.10	0.15	1.50	2.40								
	WEEK 28	57	2.10	2.10	0.15	1.50	2.40	57	2.09	0.16	0.01	0.00	0.12	-0.30	0.20
	WEEK 52	40	2.11	2.10	0.18	1.50	2.50	40	2.08	0.17	0.03	0.00	0.14	-0.30	0.30
	LAST VISIT	126	2.11	2.10	0.18	1.50	2.70	124	2.07	0.15	0.04	0.00	0.16	-0.40	0.70

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=PHOSPHATE (mg/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	3.52	3.50	0.49	2.50	4.60								
	WEEK 28	79	3.51	3.60	0.57	2.20	4.80	75	3.57	0.47	-0.06	-0.10	0.44	-0.90	1.30
	WEEK 52	64	3.44	3.40	0.56	2.30	5.00	60	3.56	0.50	-0.14	-0.05	0.61	-1.80	1.60
	LAST VISIT	125	3.51	3.50	0.54	2.30	5.00	120	3.53	0.49	-0.03	0.00	0.57	-1.80	1.60
PLACEBO	BASELINE	132	3.57	3.60	0.45	2.30	5.20								
	WEEK 28	57	3.58	3.50	0.57	2.40	4.90	57	3.62	0.44	-0.04	0.00	0.58	-1.60	1.20
	WEEK 52	40	3.42	3.30	0.57	2.50	4.80	40	3.61	0.49	-0.18	-0.10	0.51	-1.50	0.90
	LAST VISIT	126	3.49	3.50	0.61	1.80	5.80	125	3.57	0.45	-0.08	-0.10	0.65	-1.80	2.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=POTASSIUM (mEq/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	4.26	4.20	0.39	3.60	5.50								
	WEEK 28	79	4.26	4.20	0.36	3.50	5.40	75	4.25	0.40	0.02	0.00	0.37	-1.30	1.00
	WEEK 52	64	4.17	4.10	0.38	3.60	5.60	60	4.22	0.40	-0.04	0.00	0.43	-1.30	0.80
	LAST VISIT	124	4.23	4.20	0.40	3.50	5.60	119	4.26	0.40	-0.03	0.00	0.44	-1.30	1.40
PLACEBO	BASELINE	130	4.27	4.30	0.40	3.30	5.70								
	WEEK 28	57	4.27	4.20	0.38	3.50	5.30	56	4.28	0.46	-0.00	0.00	0.33	-1.00	0.60
	WEEK 52	40	4.28	4.30	0.50	2.70	5.80	39	4.27	0.44	0.01	0.00	0.35	-0.80	0.80
	LAST VISIT	125	4.26	4.30	0.45	2.70	5.80	123	4.27	0.41	-0.01	0.00	0.45	-1.40	1.30

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=PROLACTIN (ng/mL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	122	6.25	4.50	6.71	0.52	51.25								
	WEEK 28	3	6.75	5.85	6.08	1.17	13.23	3	6.60	4.65	0.15	-0.16	4.61	-4.30	4.91
	WEEK 52	64	7.10	5.15	8.56	0.38	54.34	59	6.80	7.30	0.18	-0.20	5.07	-5.36	34.82
	LAST VISIT	117	6.57	4.31	8.33	0.38	54.34	109	6.35	6.96	0.15	-0.17	4.39	-8.17	34.82
PLACEBO	BASELINE	128	6.26	4.58	5.36	0.37	31.28								
	WEEK 28	2	10.13	10.13	9.43	3.46	16.79	2	4.99	4.86	5.14	5.14	4.56	1.91	8.36
	WEEK 52	38	10.83	9.76	8.16	3.55	47.86	37	5.32	4.18	5.70	4.38	7.02	-2.07	40.78
	LAST VISIT	117	9.14	7.45	7.69	0.68	52.26	113	6.27	5.35	3.00	1.76	6.40	-7.78	40.78

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[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=PROTEIN (g/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	7.20	7.30	0.50	5.40	8.30								
	WEEK 28	79	7.19	7.20	0.46	6.00	8.30	75	7.24	0.48	-0.07	-0.10	0.41	-0.90	1.00
	WEEK 52	64	7.20	7.15	0.45	6.20	8.20	60	7.31	0.41	-0.11	-0.10	0.35	-0.90	0.50
	LAST VISIT	125	7.15	7.10	0.46	6.00	8.40	120	7.22	0.49	-0.08	-0.10	0.41	-0.90	1.00
PLACEBO	BASELINE	132	7.17	7.20	0.44	6.20	8.70								
	WEEK 28	57	7.18	7.20	0.48	6.30	8.30	57	7.24	0.49	-0.05	-0.10	0.37	-0.70	0.70
	WEEK 52	40	7.22	7.20	0.51	6.20	8.40	40	7.25	0.51	-0.04	-0.05	0.44	-0.90	1.20
	LAST VISIT	126	7.20	7.20	0.47	6.00	8.40	125	7.18	0.45	0.03	0.00	0.44	-0.90	1.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=SODIUM (mEq/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	139.86	140.00	2.10	134.00	145.00								
	WEEK 28	79	139.81	140.00	2.00	134.00	145.00	75	139.93	2.08	-0.08	0.00	2.41	-8.00	5.00
	WEEK 52	64	139.14	139.00	2.77	134.00	144.00	60	139.92	2.15	-0.72	-0.50	2.76	-8.00	4.00
	LAST VISIT	124	139.30	139.00	2.49	134.00	145.00	119	139.90	2.10	-0.59	0.00	2.63	-10.00	4.00
PLACEBO	BASELINE	131	139.84	140.00	2.16	133.00	145.00								
	WEEK 28	57	138.96	139.00	2.28	134.00	145.00	57	139.70	2.16	-0.74	-1.00	2.53	-6.00	6.00
	WEEK 52	40	138.63	138.00	2.44	134.00	145.00	40	139.70	2.20	-1.08	-1.00	2.55	-6.00	5.00
	LAST VISIT	126	139.14	139.00	2.54	133.00	146.00	124	139.84	2.11	-0.76	-1.00	2.59	-8.00	5.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=TRIGLYCERIDES (mg/dL)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	15	158.67	144.00	73.50	62.00	321.00								
	WEEK 28	7	143.71	109.00	92.75	74.00	329.00	4	173.00	108.21	-17.75	-23.00	147.04	-189.00	164.00
	WEEK 52	5	168.60	127.00	91.88	99.00	318.00	1	192.00		-93.00	-93.00		-93.00	-93.00
	LAST VISIT	25	180.24	141.00	111.89	61.00	532.00	9	170.56	70.32	-29.78	-34.00	87.44	-189.00	91.00
PLACEBO	BASELINE	13	185.23	156.00	121.16	69.00	430.00								
	WEEK 28	12	156.67	109.50	122.74	64.00	515.00	2	186.50	105.36	133.50	133.50	170.41	13.00	254.00
	WEEK 52	3	140.33	142.00	6.66	133.00	146.00								
	LAST VISIT	28	146.25	135.50	90.73	42.00	515.00	6	194.33	115.17	-12.67	-12.50	153.30	-195.00	254.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=TRIGLYCERIDES, FASTING (mg/dL)

								CHANGE FROM BASELINE							
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	112	144.57	129.50	108.49	27.00	914.00								
	WEEK 28	72	134.53	107.50	84.02	32.00	411.00	64	134.25	78.05	5.88	14.00	64.09	-226.00	148.00
	WEEK 52	59	133.44	117.00	82.92	31.00	407.00	51	131.63	80.45	5.76	-2.00	69.98	-196.00	226.00
	LAST VISIT	109	131.43	111.00	77.93	31.00	407.00	93	132.61	74.11	0.95	-1.00	66.36	-226.00	226.00
PLACEBO	BASELINE	119	148.08	124.00	104.97	40.00	833.00								
	WEEK 28	45	145.16	121.00	79.56	36.00	364.00	42	143.10	79.54	5.57	9.00	62.82	-240.00	130.00
	WEEK 52	37	155.46	132.00	94.80	33.00	374.00	36	157.22	99.60	1.06	-5.00	79.85	-152.00	224.00
	LAST VISIT	111	137.90	116.00	99.71	33.00	585.00	98	146.43	112.19	-7.33	-2.50	82.09	-371.00	230.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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表 2.7.4.7-124　生化学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=URATE (mg/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	127	5.56	5.50	1.42	2.60	9.60								
	WEEK 28	79	5.51	5.40	1.30	2.70	8.40	75	5.51	1.42	0.04	0.10	0.79	-2.20	1.80
	WEEK 52	64	5.50	5.30	1.32	2.30	8.90	60	5.57	1.44	-0.03	0.05	0.87	-2.10	2.20
	LAST VISIT	125	5.66	5.50	1.41	2.30	10.70	120	5.55	1.40	0.11	0.05	0.98	-2.10	4.70
PLACEBO	BASELINE	132	5.59	5.30	1.59	2.30	10.00								
	WEEK 28	57	5.70	5.40	1.71	2.00	9.90	57	5.52	1.55	0.18	0.10	0.92	-1.90	3.20
	WEEK 52	40	6.09	6.25	1.89	2.50	10.70	40	5.66	1.71	0.43	0.35	1.01	-1.20	4.30
	LAST VISIT	126	5.66	5.20	1.57	2.50	9.80	125	5.55	1.57	0.12	0.20	0.93	-3.00	2.60

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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＜資料番号 5.3.5.1-01：CT-13.2.1＞

表 2.7.4.7-125　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-13.1.1
Incidence of Laboratory Values of Potential Clinical Relevance in Phase D
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
	TEST(UNITS)[1]	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	125	0	(0.0)	126	2	(1.6)	251	2	(0.8)
	ALKALINE PHOSPHATASE (U/L)	125	0	(0.0)	126	0	(0.0)	251	0	(0.0)
	ASPARTATE AMINOTRANSFERASE (U/L)	125	1	(0.8)	125	0	(0.0)	250	1	(0.4)
	BILIRUBIN (mg/dL)	122	0	(0.0)	124	1	(0.8)	246	1	(0.4)
	BLOOD UREA NITROGEN (mg/dL)	125	2	(1.6)	126	1	(0.8)	251	3	(1.2)
	CALCIUM (mg/dL)	125	1	(0.8)	126	0	(0.0)	251	1	(0.4)
	CHLORIDE (mEq/L)	124	0	(0.0)	126	0	(0.0)	250	0	(0.0)
	CHOLESTEROL, FASTING (mg/dL)	109	13	(11.9)	111	15	(13.5)	220	28	(12.7)
	CREATINE KINASE (U/L)	125	9	(7.2)	126	7	(5.6)	251	16	(6.4)
	CREATININE (mg/dL)	125	0	(0.0)	126	1	(0.8)	251	1	(0.4)
	GLUCOSE (mg/dL)	27	0	(0.0)	28	0	(0.0)	55	0	(0.0)
	GLUCOSE, FASTING (mg/dL)	112	14	(12.5)	111	17	(15.3)	223	31	(13.9)
	HDL CHOLESTEROL, FASTING (mg/dL)	109	3	(2.8)	111	6	(5.4)	220	9	(4.1)
	LACTATE DEHYDROGENASE (U/L)	122	0	(0.0)	122	0	(0.0)	244	0	(0.0)
	LDL CHOLESTEROL, FASTING (mg/dL)	108	12	(11.1)	108	14	(13.0)	216	26	(12.0)
	POTASSIUM (mEq/L)	124	2	(1.6)	125	3	(2.4)	249	5	(2.0)
	PROLACTIN (ng/mL)	117	4	(3.4)	117	8	(6.8)	234	12	(5.1)
	SODIUM (mEq/L)	124	0	(0.0)	126	0	(0.0)	250	0	(0.0)
	TRIGLYCERIDES, FASTING (mg/dL)	109	45	(41.3)	111	42	(37.8)	220	87	(39.5)
	URATE (mg/dL)	125	2	(1.6)	126	3	(2.4)	251	5	(2.0)
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	124	2	(1.6)	125	0	(0.0)	249	2	(0.8)
	HEMATOCRIT (%)	117	1	(0.9)	121	2	(1.7)	238	3	(1.3)
	HEMOGLOBIN (g/dL)	124	1	(0.8)	125	1	(0.8)	249	2	(0.8)
	LEUKOCYTES (10^9/L)	124	1	(0.8)	125	3	(2.4)	249	4	(1.6)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

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PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.1.1　FINAL

表 2.7.4.7-125　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-13.1.1
Incidence of Laboratory Values of Potential Clinical Relevance in Phase D
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
	TEST(UNITS)[1]	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
HEMATOLOGY	NEUTROPHILS (10^9/L)	124	1	(0.8)	125	3	(2.4)	249	4	(1.6)
	PLATELETS (10^9/L)	124	1	(0.8)	124	0	(0.0)	248	1	(0.4)
URINALYSIS	GLUCOSE	116	0	(0.0)	124	0	(0.0)	240	0	(0.0)
	PROTEIN	116	2	(1.7)	124	1	(0.8)	240	3	(1.3)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

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＜資料番号 5.3.5.1-01：CT-13.1.1＞

表 2.7.4.7-126　血糖値の投与前後の変化［二重盲検試験の二重盲検期（Phase D）］

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CT-13.1.4
Incidence of Potentially Clinically Relevant Shifts in Glucose in Phase D
(Phase D Safety Sample)

LIPIDS PARAMETERS	BASELINE	ANYTIME POST BASELINE	ARIP IMD (N=132) Ne[1]	ARIP IMD (N=132) n[2]	ARIP IMD (N=132) (%)	PLACEBO (N=133) Ne[1]	PLACEBO (N=133) n[2]	PLACEBO (N=133) (%)	TOTAL (N=265) Ne[1]	TOTAL (N=265) n[2]	TOTAL (N=265) (%)
GLUCOSE, FASTING (mg/dL)	NORMAL <100	HIGH >=126	71	2	(2.8)	76	4	(5.3)	147	6	(4.1)
	IMPAIRED 100~<126	HIGH >=126	23	2	(8.7)	15	1	(6.7)	38	3	(7.9)
	NORMAL/IMPAIRED <126	HIGH >=126	94	4	(4.3)	91	5	(5.5)	185	9	(4.9)
	ANY VALUE	INCREASED >=10	96	30	(31.3)	97	29	(29.9)	193	59	(30.6)

[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH SPECIFIED BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[2]n IS THE NUMBER OF SUBJECTS WITH POTENTIAL CLINICALLY RELEVANT SHIFT; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

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＜資料番号 5.3.5.1-01：CT-13.1.4＞

表 2.7.4.7-127　糖代謝関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.4
Incidence of Treatment-emergent Adverse Events Related to Glucose Metabolism in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
臨床検査	TOTAL1)	0	(0.0)	2	(1.5)	2	(0.8)
	血中ブドウ糖増加	0	(0.0)	2	(1.5)	2	(0.8)
TOTAL2)		0	(0.0)	2	(1.5)	2	(0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AE.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.4　FINAL

表 2.7.4.7-127　糖代謝関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.4
Incidence of Treatment-emergent Adverse Events Related to Glucose Metabolism in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO GLUCOSE METABOLISM: MEDDRA 19.0 PRIMARY TERMS

BLOOD GLUCOSE, CSF GLUCOSE, BLOOD GLUCOSE DECREASED, BLOOD GLUCOSE INCREASED, GLUCOSE URINE, BLOOD GLUCOSE NORMAL, BLOOD GLUCOSE ABNORMAL, GLUCOSE TOLERANCE IMPAIRED, CSF GLUCOSE NORMAL, GLUCOSE URINE PRESENT, GLUCOSE URINE ABSENT, CSF GLUCOSE DECREASED, CSF GLUCOSE INCREASED, GLUCOSE TOLERANCE TEST, SYNOVIAL FLUID GLUCOSE

＜資料番号 5.3.5.1-01：CT-8.2.5.4 より作成＞

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=ALANINE AMINOTRANSFERASE (U/L)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	586	23.52	19.00	15.14	6.00	159.00								
	WEEK 2	171	24.30	19.00	15.14	7.00	78.00	152	24.76	17.20	-0.66	0.00	11.97	-57.00	46.00
	WEEK 4	143	25.08	20.00	15.43	7.00	97.00	136	24.71	14.17	0.40	0.00	12.67	-51.00	44.00
	WEEK 6	103	22.55	18.00	16.40	6.00	129.00	97	22.67	11.64	-0.01	0.00	12.90	-29.00	102.00
	WEEK 8	137	23.14	18.00	15.11	7.00	97.00	136	22.20	13.52	1.01	0.00	14.42	-85.00	58.00
	LAST VISIT	541	23.66	19.00	15.32	6.00	129.00	516	23.55	14.33	0.11	0.00	12.92	-85.00	102.00
PHASE C	BASELINE	419	23.78	19.00	15.29	6.00	97.00								
	WEEK 12	223	24.32	18.00	17.62	6.00	152.00	218	25.23	16.02	-0.77	-1.00	14.14	-47.00	133.00
	WEEK 28	9	31.33	19.00	35.34	6.00	121.00	9	24.00	21.42	7.33	1.00	14.61	-4.00	43.00
	LAST VISIT	382	24.01	18.00	18.78	6.00	154.00	376	24.26	15.85	-0.19	0.00	14.44	-74.00	133.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=ALBUMIN (g/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	587	4.07	4.10	0.36	3.20	5.30								
	WEEK 2	171	4.10	4.10	0.32	3.20	4.80	152	4.07	0.33	0.04	0.00	0.26	-0.70	0.80
	WEEK 4	143	4.13	4.10	0.34	3.20	5.00	136	4.08	0.36	0.05	0.00	0.28	-0.60	1.10
	WEEK 6	103	4.09	4.10	0.38	3.30	5.30	98	4.10	0.40	-0.00	0.00	0.28	-0.70	0.80
	WEEK 8	137	4.06	4.10	0.37	2.90	5.00	136	4.07	0.36	-0.01	0.00	0.29	-0.70	0.80
	LAST VISIT	541	4.09	4.10	0.35	2.90	5.30	517	4.07	0.36	0.02	0.00	0.28	-0.90	1.10
PHASE C	BASELINE	419	4.09	4.10	0.36	2.90	5.30								
	WEEK 12	223	4.14	4.10	0.34	3.00	5.10	218	4.09	0.33	0.05	0.00	0.28	-0.90	0.90
	WEEK 28	9	3.94	3.90	0.47	3.10	4.70	9	3.96	0.29	-0.01	0.00	0.28	-0.50	0.40
	LAST VISIT	382	4.13	4.10	0.33	3.00	5.10	376	4.09	0.35	0.04	0.00	0.28	-0.90	0.90

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=ALKALINE PHOSPHATASE (U/L)

			CHANGE FROM BASELINE									
			BASELINE									
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	588	71.18	69.00	20.59	31.00	168.00								
	WEEK 2	171	73.63	71.00	20.82	33.00	143.00	153	73.07	20.65	0.25	1.00	9.03	-50.00	37.00
	WEEK 4	144	70.10	67.00	19.80	29.00	130.00	138	70.38	20.36	0.04	1.00	10.56	-37.00	37.00
	WEEK 6	103	71.09	67.00	20.62	34.00	130.00	98	69.53	19.68	1.33	1.00	10.97	-38.00	47.00
	WEEK 8	137	69.71	69.00	19.15	32.00	149.00	136	70.54	20.08	-0.91	-1.00	10.22	-24.00	45.00
	LAST VISIT	542	71.11	68.00	19.97	29.00	143.00	519	71.01	20.35	0.03	0.00	10.19	-50.00	47.00
PHASE C	BASELINE	420	71.23	68.50	20.47	32.00	143.00								
	WEEK 12	224	72.41	68.00	21.73	36.00	161.00	220	69.77	20.36	2.69	2.00	12.60	-36.00	78.00
	WEEK 28	9	74.22	73.00	18.16	46.00	107.00	9	77.44	22.90	-3.22	3.00	22.75	-54.00	25.00
	LAST VISIT	383	73.26	70.00	21.95	36.00	161.00	378	70.84	20.77	2.44	2.00	11.95	-54.00	78.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=ASPARTATE AMINOTRANSFERASE (U/L)

			CHANGE FROM BASELINE									
			BASELINE									
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	585	21.63	19.00	11.10	9.00	185.00								
	WEEK 2	168	21.10	20.00	8.95	10.00	87.00	147	22.20	10.22	-1.04	-1.00	8.70	-65.00	35.00
	WEEK 4	142	22.25	19.00	10.59	10.00	97.00	134	21.69	8.85	0.69	0.00	11.04	-39.00	77.00
	WEEK 6	102	20.32	19.00	8.39	10.00	79.00	97	20.30	6.09	-0.02	0.00	7.66	-15.00	58.00
	WEEK 8	135	20.40	18.00	7.96	9.00	54.00	134	21.22	8.33	-0.78	-0.50	8.65	-37.00	27.00
	LAST VISIT	534	21.04	19.00	9.11	9.00	97.00	508	21.38	8.61	-0.32	0.00	9.08	-65.00	77.00
PHASE C	BASELINE	412	20.68	19.00	7.75	10.00	65.00								
	WEEK 12	222	20.65	19.00	9.63	9.00	120.00	212	21.13	8.31	-0.30	0.00	9.30	-42.00	96.00
	WEEK 28	9	37.00	26.00	47.78	11.00	163.00	8	17.75	4.89	3.50	2.00	6.63	-5.00	15.00
	LAST VISIT	380	21.10	18.00	12.52	9.00	163.00	367	20.89	8.02	-0.09	0.00	9.72	-42.00	96.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=BICARBONATE (mEq/L)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	584	23.27	23.30	2.71	13.60	32.30								
	WEEK 2	164	23.28	23.45	2.79	15.60	29.40	145	23.52	2.67	-0.19	-0.10	2.73	-8.50	6.60
	WEEK 4	142	23.25	23.20	2.78	15.10	29.90	135	23.28	2.69	-0.12	-0.10	2.93	-6.40	10.70
	WEEK 6	103	23.26	23.20	2.69	16.70	31.00	97	22.76	2.59	0.60	0.70	2.52	-7.10	7.00
	WEEK 8	137	23.48	23.80	2.82	15.80	29.30	136	23.17	2.73	0.33	0.30	2.79	-6.90	7.00
	LAST VISIT	541	23.34	23.50	2.77	15.10	31.00	514	23.24	2.67	0.13	0.10	2.76	-8.50	10.70
PHASE C	BASELINE	419	23.27	23.40	2.73	15.10	31.00								
	WEEK 12	223	23.56	23.60	2.71	14.60	30.50	218	23.50	2.69	0.07	0.15	2.63	-8.70	6.80
	WEEK 28	9	22.58	22.80	2.83	17.70	27.30	9	21.92	3.38	0.66	1.50	4.10	-7.20	6.80
	LAST VISIT	372	23.31	23.35	2.79	14.60	30.80	366	23.25	2.74	0.04	0.05	2.80	-11.60	8.40

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=BILIRUBIN (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	567	0.45	0.40	0.24	0.20	2.10								
	WEEK 2	160	0.47	0.40	0.29	0.20	2.30	141	0.46	0.28	0.01	0.00	0.17	-0.60	0.50
	WEEK 4	137	0.46	0.40	0.23	0.20	1.80	129	0.44	0.20	0.02	0.00	0.22	-0.60	1.40
	WEEK 6	96	0.48	0.40	0.26	0.20	1.50	88	0.48	0.23	0.02	0.00	0.17	-0.30	0.60
	WEEK 8	126	0.45	0.40	0.26	0.20	1.90	121	0.45	0.25	0.00	0.00	0.20	-1.00	0.90
	LAST VISIT	508	0.46	0.40	0.26	0.20	2.30	475	0.46	0.24	0.01	0.00	0.19	-1.00	1.40
PHASE C	BASELINE	392	0.46	0.40	0.26	0.20	2.30								
	WEEK 12	213	0.47	0.40	0.25	0.20	2.50	199	0.47	0.25	0.01	0.00	0.19	-0.60	0.70
	WEEK 28	9	0.61	0.40	0.45	0.20	1.40	8	0.50	0.29	0.16	0.05	0.27	-0.10	0.60
	LAST VISIT	369	0.47	0.40	0.26	0.20	2.50	344	0.47	0.26	0.01	0.00	0.19	-0.80	0.80

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.1 FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=BLOOD UREA NITROGEN (mg/dL)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	588	12.83	12.00	3.84	5.00	31.00								
	WEEK 2	171	13.16	13.00	4.00	4.00	25.00	153	12.92	3.82	0.12	0.00	3.44	-9.00	12.00
	WEEK 4	144	13.10	13.00	4.04	5.00	28.00	138	13.30	4.02	-0.14	0.00	3.15	-7.00	10.00
	WEEK 6	103	12.64	12.00	3.93	7.00	23.00	98	12.58	3.53	0.10	0.00	3.82	-17.00	10.00
	WEEK 8	137	13.39	13.00	4.51	5.00	33.00	136	12.58	4.11	0.83	1.00	4.01	-13.00	13.00
	LAST VISIT	542	13.03	13.00	4.10	4.00	33.00	519	12.86	3.84	0.20	0.00	3.61	-17.00	13.00
PHASE C	BASELINE	420	12.92	12.00	4.13	4.00	33.00								
	WEEK 12	224	12.73	12.00	3.60	6.00	27.00	220	12.59	3.99	0.19	0.00	3.51	-13.00	11.00
	WEEK 28	9	11.78	9.00	5.19	6.00	19.00	9	12.78	5.14	-1.00	-1.00	2.60	-5.00	3.00
	LAST VISIT	383	12.79	12.00	3.94	6.00	31.00	378	12.95	4.14	-0.12	0.00	3.58	-13.00	11.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.1 FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=CALCIUM (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE B	BASELINE	588	9.59	9.60	0.43	8.30	11.70								
	WEEK 2	171	9.55	9.60	0.42	8.20	11.10	153	9.55	0.41	-0.01	0.00	0.38	-1.40	0.90
	WEEK 4	144	9.59	9.60	0.46	7.60	11.90	138	9.57	0.45	0.02	0.10	0.42	-1.70	1.10
	WEEK 6	103	9.67	9.70	0.44	8.30	11.10	98	9.62	0.43	0.04	0.10	0.42	-1.00	1.50
	WEEK 8	137	9.61	9.60	0.39	8.70	10.70	136	9.58	0.39	0.03	0.00	0.38	-0.80	1.10
	LAST VISIT	542	9.60	9.60	0.43	7.60	11.90	519	9.58	0.42	0.02	0.00	0.40	-1.70	1.50
PHASE C	BASELINE	420	9.59	9.60	0.42	8.20	11.90								
	WEEK 12	224	9.65	9.60	0.43	7.70	10.80	220	9.57	0.38	0.07	0.10	0.43	-2.20	1.50
	WEEK 28	9	9.43	9.40	0.27	9.20	10.10	9	9.49	0.33	-0.06	0.10	0.24	-0.40	0.20
	LAST VISIT	383	9.66	9.60	0.43	7.70	11.60	378	9.59	0.43	0.06	0.10	0.42	-2.20	2.00

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[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.1 FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=CHLORIDE (mEq/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	585	102.81	103.00	2.64	93.00	112.00								
	WEEK 2	164	102.70	102.00	2.51	96.00	109.00	146	102.99	2.51	-0.38	-0.50	2.36	-6.00	8.00
	WEEK 4	144	102.72	103.00	2.34	97.00	110.00	137	102.96	2.72	-0.28	0.00	2.38	-6.00	8.00
	WEEK 6	103	102.80	103.00	2.34	97.00	109.00	97	102.65	3.03	0.19	0.00	2.85	-6.00	8.00
	WEEK 8	137	102.70	103.00	2.26	96.00	109.00	136	102.65	2.61	0.04	0.00	2.62	-6.00	8.00
	LAST VISIT	542	102.73	103.00	2.36	96.00	110.00	516	102.86	2.65	-0.15	0.00	2.54	-6.00	8.00
PHASE C	BASELINE	420	102.68	103.00	2.36	96.00	110.00								
	WEEK 12	224	102.57	103.00	2.35	95.00	110.00	220	102.71	2.33	-0.18	0.00	2.48	-8.00	7.00
	WEEK 28	9	101.33	102.00	3.39	96.00	107.00	9	101.78	1.99	-0.44	0.00	2.79	-5.00	4.00
	LAST VISIT	375	102.61	103.00	2.40	95.00	110.00	370	102.78	2.34	-0.19	0.00	2.48	-8.00	7.00

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[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=CHOLESTEROL, FASTING (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	533	188.78	185.00	40.60	104.00	389.00								
	WEEK 2	129	189.58	187.00	41.85	114.00	371.00	107	192.20	44.47	-2.46	-3.00	26.31	-87.00	87.00
	WEEK 4	124	187.43	186.00	36.89	125.00	277.00	104	182.87	39.94	2.37	1.50	26.57	-63.00	96.00
	WEEK 6	86	187.22	181.00	40.07	116.00	323.00	79	190.06	43.57	-2.66	-2.00	23.89	-55.00	67.00
	WEEK 8	131	190.94	186.00	43.46	100.00	308.00	120	191.85	40.57	0.21	0.50	30.92	-117.00	119.00
	LAST VISIT	469	188.86	186.00	40.66	100.00	371.00	411	188.86	41.88	-0.29	-1.00	27.86	-117.00	119.00
PHASE C	BASELINE	369	189.73	186.00	40.50	100.00	371.00								
	WEEK 12	192	192.67	191.00	39.11	109.00	305.00	178	193.58	39.36	-0.64	0.00	25.58	-82.00	119.00
	WEEK 28	7	168.29	162.00	49.54	104.00	261.00	7	176.86	39.19	-8.57	-4.00	39.05	-83.00	31.00
	LAST VISIT	311	189.33	186.00	40.55	93.00	314.00	282	190.98	40.27	-1.01	-1.00	27.15	-93.00	119.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=CREATINE KINASE (U/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	587	156.71	112.00	157.23	28.00	1503.00								
	WEEK 2	171	185.75	115.00	274.57	40.00	2903.00	152	161.69	157.49	27.45	2.00	260.31	-598.00	2790.00
	WEEK 4	143	201.38	107.00	601.58	31.00	7173.00	136	153.38	176.15	50.93	5.00	619.69	-1316.0	7033.00
	WEEK 6	103	143.78	100.00	140.51	28.00	788.00	98	144.09	133.05	-2.43	-1.50	97.68	-467.00	311.00
	WEEK 8	137	151.76	113.00	147.85	24.00	1263.00	136	179.79	204.08	-28.26	-7.00	181.65	-1347.0	440.00
	LAST VISIT	541	172.31	108.00	355.77	24.00	7173.00	517	157.80	162.26	14.84	0.00	356.19	-1347.0	7033.00
PHASE C	BASELINE	419	155.96	107.00	194.41	24.00	2903.00								
	WEEK 12	223	136.71	93.00	119.80	22.00	855.00	218	151.42	148.71	-14.61	-2.00	105.08	-417.00	512.00
	WEEK 28	9	142.44	75.00	199.05	47.00	666.00	9	159.44	204.41	-17.00	-12.00	50.59	-128.00	54.00
	LAST VISIT	382	134.90	93.00	120.99	22.00	855.00	376	156.38	199.96	-21.65	-5.00	179.39	-2851.0	516.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=CREATININE (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE B	BASELINE	588	0.89	0.90	0.20	0.40	1.80								
	WEEK 2	171	0.89	0.90	0.20	0.50	1.80	153	0.88	0.19	-0.00	0.00	0.09	-0.20	0.30
	WEEK 4	144	0.89	0.90	0.18	0.50	1.50	138	0.88	0.19	0.01	0.00	0.09	-0.30	0.20
	WEEK 6	103	0.89	0.90	0.19	0.40	1.40	98	0.88	0.20	0.01	0.00	0.12	-0.60	0.30
	WEEK 8	137	0.91	0.90	0.22	0.60	1.90	136	0.90	0.20	0.01	0.00	0.12	-0.40	0.30
	LAST VISIT	542	0.89	0.90	0.20	0.40	1.90	519	0.89	0.20	0.01	0.00	0.11	-0.60	0.30
PHASE C	BASELINE	420	0.89	0.90	0.20	0.40	1.90								
	WEEK 12	224	0.90	0.90	0.21	0.50	1.80	220	0.88	0.20	0.02	0.00	0.10	-0.20	0.30
	WEEK 28	9	0.79	0.80	0.16	0.60	1.10	9	0.79	0.21	0.00	0.00	0.14	-0.20	0.20
	LAST VISIT	383	0.90	0.90	0.20	0.50	1.80	378	0.89	0.20	0.02	0.00	0.11	-0.30	0.40

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.1 FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=GAMMA GLUTAMYL TRANSFERASE (U/L)

			CHANGE FROM BASELINE									
			BASELINE									
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	586	30.13	21.00	34.61	5.00	475.00								
	WEEK 2	171	31.13	23.00	28.19	5.00	210.00	153	31.83	32.50	-0.52	1.00	10.79	-41.00	57.00
	WEEK 4	144	30.06	21.00	35.16	5.00	321.00	137	30.77	32.27	-0.22	0.00	16.86	-75.00	97.00
	WEEK 6	102	26.51	20.00	20.53	6.00	137.00	97	28.05	22.19	-1.69	-1.00	12.31	-43.00	39.00
	WEEK 8	137	26.15	22.00	18.26	7.00	128.00	136	31.20	48.27	-5.07	0.50	41.65	-442.00	62.00
	LAST VISIT	541	28.45	21.00	26.79	5.00	321.00	517	30.31	35.52	-1.80	0.00	24.37	-442.00	97.00
PHASE C	BASELINE	419	28.98	21.00	28.89	5.00	321.00								
	WEEK 12	224	29.18	21.00	27.03	5.00	225.00	220	28.79	23.41	0.47	-1.00	16.86	-56.00	147.00
	WEEK 28	9	46.78	20.00	77.44	12.00	252.00	9	30.22	32.14	16.56	2.00	46.13	-8.00	139.00
	LAST VISIT	383	30.19	21.00	33.96	5.00	385.00	378	29.60	29.82	0.58	-1.00	16.87	-80.00	147.00

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=GLUCOSE, FASTING (mg/dL)

			CHANGE FROM BASELINE									
			BASELINE									
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	532	95.15	92.00	26.73	56.00	508.00								
	WEEK 2	134	95.56	94.00	20.86	69.00	288.00	109	97.65	41.56	-1.97	0.00	24.30	-220.00	58.00
	WEEK 4	124	96.55	94.00	22.27	61.00	266.00	103	95.75	28.35	-0.33	0.00	18.56	-108.00	69.00
	WEEK 6	85	95.81	93.00	21.65	74.00	223.00	78	98.55	49.58	-4.64	0.00	42.16	-328.00	119.00
	WEEK 8	131	94.94	92.00	18.46	54.00	181.00	120	93.71	13.39	0.90	0.00	16.45	-45.00	62.00
	LAST VISIT	469	95.20	93.00	18.66	54.00	266.00	409	95.21	27.59	-0.78	0.00	23.21	-328.00	119.00
PHASE C	BASELINE	369	95.13	93.00	19.53	54.00	266.00								
	WEEK 12	191	95.69	92.00	18.81	61.00	227.00	177	95.11	16.07	-0.08	-2.00	15.72	-58.00	70.00
	WEEK 28	8	137.88	113.00	68.41	80.00	262.00	8	107.88	32.61	30.00	8.00	73.14	-59.00	175.00
	LAST VISIT	316	96.34	92.00	22.48	45.00	262.00	285	94.80	17.59	1.24	-1.00	21.51	-91.00	175.00

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[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=HDL CHOLESTEROL, FASTING (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	533	56.63	54.00	17.17	23.00	141.00								
	WEEK 2	129	56.64	53.00	17.68	23.00	121.00	107	58.62	18.49	-1.05	0.00	11.15	-78.00	26.00
	WEEK 4	124	54.86	53.00	15.85	22.00	106.00	104	55.33	16.32	0.33	0.00	7.48	-27.00	19.00
	WEEK 6	86	54.67	50.50	14.91	27.00	104.00	79	55.46	14.61	-0.33	-1.00	10.28	-28.00	47.00
	WEEK 8	131	55.18	54.00	17.05	25.00	121.00	120	56.84	18.39	-1.76	-2.00	11.22	-70.00	28.00
	LAST VISIT	469	55.43	53.00	16.40	22.00	121.00	411	56.59	17.15	-0.78	-1.00	10.20	-78.00	47.00
PHASE C	BASELINE	369	54.79	52.00	15.79	22.00	110.00								
	WEEK 12	192	53.06	50.50	16.40	19.00	115.00	178	54.44	16.54	-1.42	-1.00	9.11	-30.00	40.00
	WEEK 28	7	47.71	43.00	13.61	30.00	67.00	7	54.57	13.26	-6.86	-2.00	9.04	-19.00	2.00
	LAST VISIT	311	53.39	50.00	16.66	19.00	126.00	282	55.14	15.85	-1.69	-1.50	10.16	-42.00	63.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=INSULIN, FASTING (uIU/mL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	527	10.08	6.44	12.72	0.78	155.80								
	WEEK 2	126	11.14	8.20	11.46	0.50	66.67	106	9.01	6.85	1.80	0.05	9.24	-22.80	57.22
	WEEK 4	121	10.84	7.49	10.32	1.03	67.86	101	10.34	12.68	0.05	0.10	11.41	-60.44	41.76
	WEEK 6	85	14.80	7.17	29.76	1.05	212.36	77	10.51	12.20	1.48	-0.16	20.35	-32.13	163.53
	WEEK 8	130	13.84	8.77	15.38	1.64	112.58	117	11.28	18.31	1.44	1.21	20.19	-116.17	89.27
	LAST VISIT	461	12.49	7.75	17.12	0.50	212.36	402	10.08	12.64	1.39	0.63	15.58	-116.17	163.53
PHASE C	BASELINE	364	12.36	7.57	18.07	1.03	212.36								
	WEEK 12	184	15.26	8.60	20.37	2.11	185.83	169	11.74	13.44	2.68	0.49	17.30	-66.47	100.54
	WEEK 28	6	34.38	15.50	49.24	7.48	133.74	6	27.78	25.66	6.60	-0.17	42.34	-46.57	82.09
	LAST VISIT	302	14.36	7.98	19.16	1.90	185.83	269	12.55	16.50	1.40	0.26	19.71	-158.27	100.54

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=LACTATE DEHYDROGENASE (U/L)

			CHANGE FROM BASELINE											
			BASELINE											
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	581	160.53	157.00	29.98	77.00	284.00								
	WEEK 2	163	159.47	156.00	30.38	104.00	273.00	142	163.59	32.32	-2.82	-1.00	24.98	-60.00	93.00
	WEEK 4	140	162.00	158.00	41.08	102.00	464.00	129	157.47	29.65	4.35	0.00	36.94	-68.00	311.00
	WEEK 6	99	155.73	153.00	30.56	86.00	251.00	93	161.34	27.88	-5.78	-4.00	22.03	-49.00	58.00
	WEEK 8	131	157.15	153.00	28.45	100.00	242.00	130	161.95	28.58	-4.78	-1.50	24.67	-83.00	52.00
	LAST VISIT	522	159.28	155.00	33.82	86.00	464.00	493	161.10	29.70	-1.62	-2.00	28.57	-83.00	311.00
PHASE C	BASELINE	402	156.99	153.50	28.35	100.00	273.00								
	WEEK 12	215	156.56	155.00	28.22	86.00	252.00	204	156.28	27.81	0.74	2.00	21.33	-80.00	71.00
	WEEK 28	9	176.11	149.00	62.95	115.00	296.00	7	153.71	33.28	9.14	11.00	25.11	-18.00	52.00
	LAST VISIT	371	157.06	155.00	31.73	73.00	316.00	350	156.74	27.68	0.07	1.00	22.94	-80.00	153.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=LDL CHOLESTEROL, FASTING (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	527	106.99	104.00	33.63	23.00	286.00								
	WEEK 2	128	107.57	104.50	35.52	38.00	248.00	105	107.88	37.51	-0.65	0.00	23.42	-74.00	77.00
	WEEK 4	120	108.07	103.00	31.36	53.00	183.00	100	101.44	30.76	3.32	1.50	21.77	-45.00	82.00
	WEEK 6	85	107.04	104.00	33.02	38.00	202.00	78	108.40	32.64	-1.31	-0.50	19.27	-36.00	62.00
	WEEK 8	131	111.31	108.00	37.71	37.00	223.00	119	111.11	34.51	1.61	2.00	24.66	-72.00	99.00
	LAST VISIT	463	108.50	104.00	34.58	37.00	248.00	403	106.98	34.04	1.07	1.00	23.17	-74.00	109.00
PHASE C	BASELINE	364	109.58	105.00	34.60	37.00	248.00								
	WEEK 12	188	111.31	107.50	34.41	33.00	214.00	172	113.35	33.29	-2.05	-1.00	22.09	-78.00	81.00
	WEEK 28	7	88.43	93.00	42.80	29.00	147.00	7	86.14	25.89	2.29	7.00	31.62	-53.00	37.00
	LAST VISIT	306	108.75	105.00	34.53	29.00	228.00	274	109.94	34.01	-1.09	-1.00	23.39	-78.00	81.00

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=MAGNESIUM (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: ___BASELINE____ n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	585	2.07	2.10	0.16	1.20	2.60								
	WEEK 2	164	2.10	2.10	0.15	1.70	2.50	146	2.10	0.15	0.00	0.00	0.14	-0.40	0.40
	WEEK 4	144	2.08	2.10	0.16	1.50	2.60	137	2.08	0.15	-0.00	0.00	0.17	-0.60	0.40
	WEEK 6	103	2.06	2.10	0.15	1.70	2.50	97	2.05	0.15	0.01	0.00	0.14	-0.30	0.30
	WEEK 8	137	2.08	2.10	0.17	1.60	2.50	136	2.07	0.16	0.02	0.00	0.16	-0.40	0.50
	LAST VISIT	542	2.08	2.10	0.16	1.50	2.60	516	2.08	0.15	0.00	0.00	0.15	-0.60	0.50
PHASE C	BASELINE	420	2.08	2.10	0.16	1.60	2.60								
	WEEK 12	224	2.07	2.10	0.17	1.00	2.50	220	2.08	0.16	-0.01	0.00	0.15	-1.00	0.40
	WEEK 28	9	1.96	2.00	0.14	1.70	2.10	9	2.03	0.17	-0.08	-0.10	0.14	-0.30	0.20
	LAST VISIT	375	2.08	2.10	0.17	1.00	2.70	370	2.08	0.15	-0.01	0.00	0.16	-1.00	0.70

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=PHOSPHATE (mg/dL)

									CHANGE FROM BASELINE						
								BASELINE							
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	588	3.71	3.70	0.54	2.20	6.10								
	WEEK 2	171	3.73	3.70	0.55	2.30	5.00	153	3.78	0.57	-0.03	0.00	0.56	-2.30	1.10
	WEEK 4	144	3.68	3.70	0.49	2.50	4.90	138	3.64	0.48	0.06	0.10	0.55	-1.30	2.20
	WEEK 6	102	3.73	3.70	0.50	2.50	4.70	97	3.79	0.47	-0.04	0.00	0.54	-1.90	1.00
	WEEK 8	137	3.56	3.50	0.53	2.30	4.90	136	3.67	0.60	-0.12	-0.10	0.61	-1.70	1.60
	LAST VISIT	541	3.67	3.70	0.52	2.30	5.00	518	3.71	0.54	-0.02	0.00	0.57	-2.30	2.20
PHASE C	BASELINE	419	3.66	3.70	0.52	2.30	4.90								
	WEEK 12	223	3.57	3.60	0.47	2.30	5.20	219	3.67	0.52	-0.10	-0.10	0.53	-1.20	1.60
	WEEK 28	9	3.38	3.40	0.32	2.80	3.80	9	3.46	0.51	-0.08	0.00	0.63	-1.20	1.00
	LAST VISIT	383	3.57	3.60	0.48	2.30	5.20	377	3.66	0.52	-0.09	-0.10	0.54	-1.50	1.60

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=POTASSIUM (mEq/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: ___BASELINE____ n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	585	4.29	4.20	0.42	3.00	5.90								
	WEEK 2	164	4.26	4.20	0.41	3.20	5.60	146	4.30	0.40	-0.05	-0.10	0.44	-1.20	1.20
	WEEK 4	144	4.34	4.30	0.48	2.90	6.00	137	4.31	0.44	0.03	0.00	0.41	-1.20	1.30
	WEEK 6	102	4.34	4.30	0.44	3.10	5.40	96	4.33	0.43	0.02	0.10	0.49	-1.70	1.20
	WEEK 8	137	4.20	4.20	0.41	3.10	5.50	136	4.22	0.40	-0.02	0.00	0.48	-1.40	1.30
	LAST VISIT	541	4.28	4.20	0.45	2.90	6.00	515	4.29	0.42	-0.01	0.00	0.45	-1.70	1.30
PHASE C	BASELINE	419	4.28	4.30	0.42	2.90	6.00								
	WEEK 12	223	4.28	4.20	0.42	3.30	5.70	219	4.25	0.38	0.03	0.00	0.43	-1.20	2.10
	WEEK 28	9	4.13	4.10	0.24	3.60	4.50	9	4.39	0.31	-0.26	-0.30	0.36	-1.00	0.20
	LAST VISIT	374	4.28	4.20	0.41	3.30	5.90	368	4.27	0.40	0.01	0.00	0.44	-1.30	2.10

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=PROLACTIN (ng/mL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	1	2.61	2.61		2.61	2.61								
	WEEK 2	1	1.86	1.86		1.86	1.86	0							
	LAST VISIT	1	1.86	1.86		1.86	1.86	0							
PHASE C	BASELINE	1	1.86	1.86		1.86	1.86								
	WEEK 12	218	5.99	4.54	5.11	0.52	31.28	1	1.86	-0.22	-0.22	-0.22		-0.22	-0.22
	WEEK 28	7	12.89	10.17	9.36	2.95	30.58	0							
	LAST VISIT	357	6.76	5.04	6.59	0.37	64.48	1	1.86	-0.22	-0.22	-0.22		-0.22	-0.22

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表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=PROTEIN (g/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE B	BASELINE	588	7.13	7.10	0.49	5.50	9.00								
	WEEK 2	171	7.14	7.10	0.46	5.40	8.40	153	7.12	0.48	0.03	0.00	0.41	-1.00	1.40
	WEEK 4	144	7.12	7.10	0.48	5.90	8.50	138	7.12	0.51	0.01	0.00	0.42	-1.10	1.50
	WEEK 6	103	7.15	7.10	0.47	5.50	8.20	98	7.16	0.50	-0.01	0.00	0.43	-1.10	1.30
	WEEK 8	137	7.14	7.10	0.48	5.50	8.30	136	7.16	0.48	-0.01	0.00	0.44	-1.00	1.30
	LAST VISIT	542	7.13	7.10	0.48	5.40	8.50	519	7.13	0.49	0.01	0.00	0.43	-1.60	1.50
PHASE C	BASELINE	420	7.14	7.10	0.48	5.50	8.40								
	WEEK 12	224	7.19	7.20	0.48	5.40	8.70	220	7.14	0.47	0.06	0.10	0.43	-1.60	1.30
	WEEK 28	9	7.21	7.10	0.43	6.60	7.80	9	7.19	0.40	0.02	0.00	0.40	-0.80	0.60
	LAST VISIT	383	7.18	7.20	0.47	5.40	8.70	378	7.14	0.47	0.05	0.00	0.42	-1.60	1.40

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.1 FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=SODIUM (mEq/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE B	BASELINE	585	140.01	140.00	2.33	132.00	148.00								
	WEEK 2	164	140.07	140.00	2.18	132.00	145.00	146	140.22	2.43	-0.10	0.00	2.28	-8.00	6.00
	WEEK 4	144	140.02	140.00	2.09	134.00	146.00	137	139.96	2.02	0.04	0.00	2.43	-6.00	7.00
	WEEK 6	103	140.19	140.00	2.15	134.00	146.00	97	140.04	2.63	0.21	0.00	2.60	-7.00	8.00
	WEEK 8	137	140.04	140.00	2.45	135.00	149.00	136	139.91	2.28	0.15	0.00	2.46	-6.00	8.00
	LAST VISIT	542	140.10	140.00	2.23	132.00	149.00	516	140.05	2.32	0.08	0.00	2.44	-8.00	8.00
PHASE C	BASELINE	420	139.99	140.00	2.22	132.00	149.00								
	WEEK 12	224	139.93	140.00	2.24	133.00	147.00	220	139.87	2.24	0.03	0.00	2.31	-9.00	8.00
	WEEK 28	9	138.78	139.00	2.99	134.00	143.00	9	138.11	1.83	0.67	1.00	2.87	-4.00	5.00
	LAST VISIT	375	139.97	140.00	2.25	133.00	147.00	370	139.98	2.23	-0.04	0.00	2.25	-9.00	8.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=TRIGLYCERIDES (mg/dL)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	69	143.65	126.00	83.23	28.00	447.00								
	WEEK 2	37	164.54	141.00	107.35	51.00	504.00	8	107.88	47.13	30.25	29.50	57.37	-56.00	121.00
	WEEK 4	20	195.00	136.50	151.29	36.00	601.00	4	155.75	99.22	88.25	44.50	151.90	-43.00	307.00
	WEEK 6	17	151.12	123.00	91.27	59.00	319.00	2	176.00	79.20	140.50	140.50	75.66	87.00	194.00
	WEEK 8	6	161.33	106.00	154.68	55.00	473.00	1	86.00		11.00	11.00		11.00	11.00
	LAST VISIT	80	167.04	123.50	120.19	33.00	601.00	15	128.27	67.64	59.13	41.00	93.96	-56.00	307.00
PHASE C	BASELINE	53	169.06	125.00	123.44	36.00	601.00								
	WEEK 12	32	152.91	126.00	96.00	52.00	430.00	10	214.00	184.56	-25.60	12.50	198.08	-436.00	234.00
	WEEK 28	2	160.50	160.50	126.57	71.00	250.00	0							
	LAST VISIT	66	148.53	129.50	86.26	52.00	430.00	18	178.22	148.17	-3.17	14.00	155.25	-436.00	234.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=TRIGLYCERIDES, FASTING (mg/dL)

			BASELINE					CHANGE FROM BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	533	127.29	105.00	83.42	30.00	634.00								
	WEEK 2	129	127.01	107.00	69.71	33.00	404.00	107	129.24	87.19	-3.67	1.00	58.29	-346.00	129.00
	WEEK 4	124	128.95	98.50	98.70	36.00	613.00	104	132.49	85.60	-1.36	-2.50	71.50	-180.00	465.00
	WEEK 6	86	127.14	103.00	79.77	32.00	484.00	79	125.78	76.06	-0.22	-2.00	56.49	-168.00	161.00
	WEEK 8	131	122.24	110.00	67.50	25.00	375.00	120	120.98	81.12	1.36	4.50	55.16	-239.00	165.00
	LAST VISIT	469	126.34	104.00	79.26	25.00	613.00	411	126.74	82.46	-0.82	0.00	60.39	-346.00	465.00
PHASE C	BASELINE	369	129.13	107.00	81.98	32.00	613.00								
	WEEK 12	192	147.21	131.50	95.32	27.00	833.00	178	135.53	87.00	13.26	9.00	74.40	-383.00	316.00
	WEEK 28	7	160.43	98.00	135.06	37.00	384.00	7	181.00	146.39	-20.57	2.00	65.27	-160.00	36.00
	LAST VISIT	311	140.23	116.00	98.99	27.00	914.00	282	132.87	84.63	9.00	5.00	77.69	-383.00	526.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL

表 2.7.4.7-128　生化学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=URATE (mg/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE						
								___BASELINE____						
								n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	588	5.41	5.20	1.49	1.90	15.80								
	WEEK 2	171	5.45	5.10	1.50	2.70	11.80	153	5.46	1.69	-0.02	0.00	0.81	-4.00	2.10
	WEEK 4	144	5.60	5.40	1.66	2.10	11.90	138	5.52	1.66	0.09	0.00	1.19	-6.90	4.70
	WEEK 6	103	5.36	5.20	1.33	3.30	9.20	98	5.28	1.30	0.09	0.10	0.91	-2.30	3.00
	WEEK 8	137	5.45	5.40	1.39	1.90	10.90	136	5.48	1.47	-0.03	0.00	0.95	-3.70	3.40
	LAST VISIT	542	5.44	5.30	1.45	1.90	11.90	519	5.41	1.48	0.03	0.00	0.96	-6.90	4.70
PHASE C	BASELINE	420	5.49	5.30	1.47	1.90	11.90								
	WEEK 12	224	5.54	5.40	1.53	2.30	10.00	220	5.60	1.53	-0.06	0.00	0.84	-3.10	4.10
	WEEK 28	9	5.36	5.10	1.71	3.50	9.10	9	5.09	1.65	0.27	0.50	1.16	-2.50	1.60
	LAST VISIT	383	5.48	5.30	1.50	2.30	10.20	378	5.46	1.46	0.01	0.00	0.91	-3.10	4.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.1　FINAL
＜資料番号 5.3.5.1-01：CT-22.3.1＞

表 2.7.4.7-129　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.2.1.1
Incidence of Laboratory Values of Potential Clinical Relevance
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)			PHASE C (N=425)		
	TEST(UNITS)[1]	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	541	1	(0.2)	382	4	(1.0)
	ALKALINE PHOSPHATASE (U/L)	542	0	(0.0)	383	0	(0.0)
	ASPARTATE AMINOTRANSFERASE (U/L)	534	0	(0.0)	380	2	(0.5)
	BILIRUBIN (mg/dL)	508	1	(0.2)	369	1	(0.3)
	BLOOD UREA NITROGEN (mg/dL)	542	1	(0.2)	383	2	(0.5)
	CALCIUM (mg/dL)	542	3	(0.6)	383	1	(0.3)
	CHLORIDE (mEq/L)	542	0	(0.0)	375	0	(0.0)
	CHOLESTEROL, FASTING (mg/dL)	469	51	(10.9)	311	33	(10.6)
	CREATINE KINASE (U/L)	541	22	(4.1)	382	9	(2.4)
	CREATININE (mg/dL)	542	0	(0.0)	383	0	(0.0)
	GLUCOSE (mg/dL)	83	1	(1.2)	78	4	(5.1)
	GLUCOSE, FASTING (mg/dL)	469	37	(7.9)	316	29	(9.2)
	HDL CHOLESTEROL, FASTING (mg/dL)	469	10	(2.1)	311	10	(3.2)
	LACTATE DEHYDROGENASE (U/L)	522	0	(0.0)	371	0	(0.0)
	LDL CHOLESTEROL, FASTING (mg/dL)	463	43	(9.3)	306	27	(8.8)
	POTASSIUM (mEq/L)	541	11	(2.0)	374	6	(1.6)
	PROLACTIN (ng/mL)	1	0	(0.0)	357	8	(2.2)
	SODIUM (mEq/L)	542	0	(0.0)	375	0	(0.0)
	TRIGLYCERIDES, FASTING (mg/dL)	469	162	(34.5)	311	137	(44.1)
	URATE (mg/dL)	542	5	(0.9)	383	6	(1.6)
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	537	2	(0.4)	373	2	(0.5)
	HEMATOCRIT (%)	507	1	(0.2)	362	3	(0.8)
	HEMOGLOBIN (g/dL)	537	4	(0.7)	373	2	(0.5)
	LEUKOCYTES (10^9/L)	537	3	(0.6)	373	3	(0.8)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3BA.LIS, RUN: [redacted]20[redacted] 14:31; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.2.1.1　FINAL

表 2.7.4.7-129　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の IM デポ剤安定期（Phase C）］

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CT-22.2.1.1
Incidence of Laboratory Values of Potential Clinical Relevance
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)			PHASE C (N=425)		
	TEST(UNITS)[1]	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
HEMATOLOGY	NEUTROPHILS (10^9/L)	537	7	(1.3)	373	4	(1.1)
	PLATELETS (10^9/L)	535	0	(0.0)	371	0	(0.0)
URINALYSIS	GLUCOSE	513	4	(0.8)	364	9	(2.5)
	PROTEIN	513	0	(0.0)	364	5	(1.4)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3BA.LIS, RUN: [redacted]20[redacted] 14:31; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.2.1.1　FINAL

＜資料番号 5.3.5.1-01：CT-22.2.1.1＞

表 2.7.4.7-130　血糖値の投与前後の変化［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.2.3
Incidence of Potentially Clinically Relevant Shifts in Glucose
(Phase B Safety Sample and Phase C Safety Sample)

LIPIDS PARAMETERS	BASELINE	ANYTIME POST BASELINE	PHASE B (N=614) Ne[1]	n[2]	(%)	PHASE C (N=425) Ne[1]	n[2]	(%)
GLUCOSE, FASTING (mg/dL)	NORMAL <100	HIGH >=126	317	4	(1.3)	214	6	(2.8)
	IMPAIRED 100~<126	HIGH >=126	77	4	(5.2)	59	1	(1.7)
	NORMAL/IMPAIRED <126	HIGH >=126	394	8	(2.0)	273	7	(2.6)
	ANY VALUE	INCREASED >=10	409	69	(16.9)	285	59	(20.7)

[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH SPECIFIED BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[2]n IS THE NUMBER OF SUBJECTS WITH POTENTIAL CLINICALLY RELEVANT SHIFT; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

表 2.7.4.7-131　糖代謝関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.4
Incidence of Treatment-emergent Adverse Events Related to Glucose Metabolism
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
代謝および栄養障害	TOTAL1)	1	(0.2)	0	(0.0)
	耐糖能障害	1	(0.2)	0	(0.0)
臨床検査	TOTAL1)	2	(0.3)	2	(0.5)
	血中ブドウ糖増加	2	(0.3)	2	(0.5)
TOTAL2)		3	(0.5)	2	(0.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BE.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.4　FINAL

表 2.7.4.7-131　糖代謝関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.4
Incidence of Treatment-emergent Adverse Events Related to Glucose Metabolism
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO GLUCOSE METABOLISM: MEDDRA 19.0 PRIMARY TERMS

BLOOD GLUCOSE, CSF GLUCOSE, BLOOD GLUCOSE DECREASED, BLOOD GLUCOSE INCREASED, GLUCOSE URINE, BLOOD GLUCOSE NORMAL, BLOOD GLUCOSE ABNORMAL, GLUCOSE TOLERANCE IMPAIRED, CSF GLUCOSE NORMAL, GLUCOSE URINE PRESENT, GLUCOSE URINE ABSENT, CSF GLUCOSE DECREASED, CSF GLUCOSE INCREASED, GLUCOSE TOLERANCE TEST, SYNOVIAL FLUID GLUCOSE

FILE: ADAE3BE.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.4　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.5.4 より作成＞

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=ALANINE AMINOTRANSFERASE (U/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	370	27.13	20.00	44.34	6.00	803.00								
	WEEK 28	14	24.43	23.00	11.78	11.00	43.00	14	33.07	17.74	-8.64	-4.50	17.22	-65.00	5.00
	WEEK 52	222	25.08	19.00	20.60	6.00	193.00	219	29.91	56.55	-4.88	-1.00	50.11	-695.00	95.00
	LAST VISIT	335	24.76	19.00	19.27	6.00	193.00	327	28.09	46.97	-3.79	-2.00	41.76	-695.00	95.00
ROLLOVER	BASELINE	84	24.98	17.00	18.43	5.00	101.00								
	WEEK 28	43	29.81	25.00	21.32	6.00	96.00	43	29.44	22.47	0.37	1.00	13.02	-38.00	32.00
	WEEK 52	14	20.86	18.50	14.44	5.00	62.00	13	19.15	10.53	2.00	2.00	14.45	-19.00	29.00
	LAST VISIT	80	25.55	20.00	18.02	5.00	96.00	79	25.76	18.69	-0.10	0.00	12.50	-38.00	32.00
TOTAL	BASELINE	454	26.73	19.50	40.80	5.00	803.00								
	WEEK 28	57	28.49	25.00	19.46	6.00	96.00	57	30.33	21.32	-1.84	0.00	14.54	-65.00	32.00
	WEEK 52	236	24.83	19.00	20.29	5.00	193.00	232	29.31	55.05	-4.49	-1.00	48.82	-695.00	95.00
	LAST VISIT	415	24.91	19.00	19.01	5.00	193.00	406	27.64	42.94	-3.07	-2.00	37.89	-695.00	95.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AA.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=ALBUMIN (g/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	370	4.09	4.10	0.34	3.00	4.90								
	WEEK 28	14	4.09	4.20	0.37	3.60	4.50	14	3.99	0.25	0.10	0.20	0.36	-0.60	0.80
	WEEK 52	222	4.20	4.20	0.30	3.30	5.10	219	4.11	0.34	0.09	0.10	0.32	-0.80	1.10
	LAST VISIT	335	4.16	4.20	0.33	2.90	5.10	327	4.10	0.34	0.06	0.10	0.31	-0.90	1.10
ROLLOVER	BASELINE	84	4.20	4.20	0.31	3.30	4.80								
	WEEK 28	43	4.23	4.20	0.41	3.30	5.30	43	4.20	0.31	0.03	0.00	0.30	-0.60	0.60
	WEEK 52	14	4.32	4.30	0.31	3.80	5.10	13	4.15	0.31	0.18	0.20	0.28	-0.20	0.70
	LAST VISIT	80	4.22	4.20	0.36	3.30	5.30	79	4.20	0.32	0.02	0.00	0.30	-0.60	0.70
TOTAL	BASELINE	454	4.11	4.10	0.34	3.00	4.90								
	WEEK 28	57	4.20	4.20	0.40	3.30	5.30	57	4.15	0.31	0.04	0.00	0.32	-0.60	0.80
	WEEK 52	236	4.21	4.20	0.30	3.30	5.10	232	4.11	0.34	0.10	0.10	0.32	-0.80	1.10
	LAST VISIT	415	4.17	4.20	0.34	2.90	5.30	406	4.12	0.34	0.05	0.10	0.31	-0.90	1.10

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=ALKALINE PHOSPHATASE (U/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	70.73	69.00	21.77	27.00	151.00								
	WEEK 28	14	77.71	67.00	20.78	57.00	111.00	14	81.64	26.68	-3.93	2.50	16.27	-47.00	12.00
	WEEK 52	224	70.85	69.00	19.71	26.00	132.00	221	69.86	21.65	0.82	1.00	13.56	-54.00	45.00
	LAST VISIT	336	71.75	69.00	20.20	26.00	146.00	328	70.68	21.81	0.79	0.00	13.26	-54.00	65.00
ROLLOVER	BASELINE	85	72.59	70.00	20.43	39.00	135.00								
	WEEK 28	43	72.56	71.00	19.11	39.00	127.00	43	72.33	20.31	0.23	0.00	9.36	-31.00	21.00
	WEEK 52	14	75.29	75.00	18.24	52.00	115.00	14	72.29	19.80	3.00	4.50	12.29	-13.00	28.00
	LAST VISIT	80	75.18	74.50	19.23	39.00	127.00	80	73.48	20.48	1.70	2.00	11.77	-32.00	50.00
TOTAL	BASELINE	456	71.07	69.00	21.51	27.00	151.00								
	WEEK 28	57	73.82	68.00	19.47	39.00	127.00	57	74.61	22.16	-0.79	0.00	11.42	-47.00	21.00
	WEEK 52	238	71.11	70.00	19.61	26.00	132.00	235	70.01	21.51	0.95	1.00	13.47	-54.00	45.00
	LAST VISIT	416	72.41	71.00	20.04	26.00	146.00	408	71.23	21.56	0.97	1.00	12.98	-54.00	65.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=ASPARTATE AMINOTRANSFERASE (U/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	23.49	20.00	35.22	9.00	671.00								
	WEEK 28	14	20.79	19.00	8.44	11.00	42.00	13	26.15	12.80	-5.46	-3.00	10.36	-37.00	3.00
	WEEK 52	220	21.21	19.00	10.63	8.00	99.00	215	25.47	45.36	-4.33	-2.00	44.26	-629.00	57.00
	LAST VISIT	333	20.98	19.00	9.88	8.00	99.00	321	24.12	37.52	-3.40	-2.00	36.45	-629.00	57.00
ROLLOVER	BASELINE	84	22.38	18.50	11.74	10.00	68.00								
	WEEK 28	43	22.56	19.00	11.41	7.00	64.00	43	24.53	14.13	-1.98	-1.00	10.60	-43.00	21.00
	WEEK 52	13	16.77	14.00	6.89	10.00	32.00	12	16.75	6.55	0.25	1.00	8.68	-17.00	14.00
	LAST VISIT	80	20.18	17.00	9.61	7.00	64.00	79	22.63	12.04	-2.38	-1.00	9.89	-43.00	21.00
TOTAL	BASELINE	450	23.28	19.00	32.16	9.00	671.00								
	WEEK 28	57	22.12	19.00	10.72	7.00	64.00	56	24.91	13.74	-2.79	-1.00	10.55	-43.00	21.00
	WEEK 52	233	20.96	19.00	10.50	8.00	99.00	227	25.01	44.21	-4.08	-2.00	43.12	-629.00	57.00
	LAST VISIT	413	20.83	19.00	9.82	7.00	99.00	400	23.82	34.02	-3.20	-2.00	32.94	-629.00	57.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=BICARBONATE (mEq/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	370	23.46	23.60	2.93	15.10	31.50								
	WEEK 28	12	21.15	21.60	3.16	13.40	24.90	12	22.30	3.28	-1.15	-0.65	2.23	-6.40	2.60
	WEEK 52	221	23.38	24.00	3.20	11.60	31.30	218	23.61	2.98	-0.23	-0.20	2.84	-15.90	8.70
	LAST VISIT	331	23.15	23.50	3.14	11.10	31.30	323	23.48	2.96	-0.32	-0.30	2.85	-15.90	8.70
ROLLOVER	BASELINE	84	23.36	23.50	2.45	17.90	28.00								
	WEEK 28	43	23.50	23.80	2.93	17.90	29.80	43	23.93	2.33	-0.43	-0.60	2.15	-6.90	3.40
	WEEK 52	14	22.58	22.45	3.39	17.20	27.20	13	22.92	2.57	-0.10	-0.60	2.16	-3.50	3.50
	LAST VISIT	80	23.05	23.25	3.01	16.80	29.80	79	23.48	2.43	-0.38	-0.60	2.24	-6.90	6.70
TOTAL	BASELINE	454	23.44	23.60	2.84	15.10	31.50								
	WEEK 28	55	22.99	23.30	3.11	13.40	29.80	55	23.57	2.62	-0.58	-0.60	2.17	-6.90	3.40
	WEEK 52	235	23.33	24.00	3.21	11.60	31.30	231	23.57	2.96	-0.22	-0.20	2.80	-15.90	8.70
	LAST VISIT	411	23.13	23.50	3.11	11.10	31.30	402	23.48	2.86	-0.33	-0.30	2.74	-15.90	8.70

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=BILIRUBIN (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	351	0.50	0.40	0.28	0.20	2.30								
	WEEK 28	14	0.52	0.40	0.33	0.20	1.10	13	0.50	0.18	0.05	0.00	0.30	-0.40	0.60
	WEEK 52	213	0.51	0.50	0.25	0.20	2.00	201	0.52	0.28	0.00	0.00	0.22	-1.20	0.60
	LAST VISIT	322	0.48	0.40	0.22	0.20	1.40	303	0.51	0.29	-0.02	0.00	0.26	-1.70	0.80
ROLLOVER	BASELINE	81	0.51	0.40	0.29	0.20	1.70								
	WEEK 28	40	0.55	0.40	0.38	0.20	1.80	39	0.52	0.32	0.04	0.00	0.23	-0.50	0.80
	WEEK 52	14	0.51	0.40	0.40	0.20	1.80	12	0.55	0.35	-0.03	0.00	0.19	-0.50	0.30
	LAST VISIT	74	0.51	0.40	0.34	0.20	1.80	71	0.51	0.29	0.00	0.00	0.22	-0.50	0.80
TOTAL	BASELINE	432	0.50	0.40	0.28	0.20	2.30								
	WEEK 28	54	0.54	0.40	0.37	0.20	1.80	52	0.51	0.29	0.04	0.00	0.25	-0.50	0.80
	WEEK 52	227	0.51	0.40	0.26	0.20	2.00	213	0.52	0.28	-0.00	0.00	0.21	-1.20	0.60
	LAST VISIT	396	0.49	0.40	0.25	0.20	1.80	374	0.51	0.29	-0.01	0.00	0.26	-1.70	0.80

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=BLOOD UREA NITROGEN (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ROLLOVER	BASELINE	85	12.67	12.00	3.90	6.00	27.00								
TOTAL	BASELINE	85	12.67	12.00	3.90	6.00	27.00								

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=CALCIUM (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	9.63	9.60	0.44	7.50	11.00								
	WEEK 28	14	9.48	9.50	0.49	8.00	10.20	14	9.49	0.71	-0.01	0.05	0.36	-0.80	0.50
	WEEK 52	224	9.61	9.60	0.37	8.40	10.50	221	9.60	0.42	0.00	0.00	0.41	-0.90	1.70
	LAST VISIT	336	9.62	9.60	0.39	8.00	11.10	328	9.63	0.45	-0.01	0.00	0.41	-1.40	1.70
ROLLOVER	BASELINE	85	9.64	9.60	0.37	8.80	10.60								
	WEEK 28	43	9.63	9.60	0.47	8.70	10.70	43	9.64	0.38	-0.01	0.00	0.40	-0.80	1.00
	WEEK 52	14	9.66	9.60	0.38	9.10	10.40	14	9.57	0.41	0.09	0.10	0.32	-0.40	0.80
	LAST VISIT	80	9.62	9.60	0.43	8.70	10.70	80	9.63	0.37	-0.01	0.00	0.38	-0.80	1.00
TOTAL	BASELINE	456	9.63	9.60	0.43	7.50	11.00								
	WEEK 28	57	9.59	9.60	0.47	8.00	10.70	57	9.60	0.48	-0.01	0.00	0.39	-0.80	1.00
	WEEK 52	238	9.61	9.60	0.37	8.40	10.50	235	9.60	0.42	0.01	0.00	0.40	-0.90	1.70
	LAST VISIT	416	9.62	9.60	0.40	8.00	11.10	408	9.63	0.43	-0.01	0.00	0.40	-1.40	1.70

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=CHLORIDE (mEq/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	102.42	102.00	2.59	92.00	109.00								
	WEEK 28	12	102.50	103.00	1.51	100.00	105.00	12	102.75	1.71	-0.25	-0.50	1.86	-3.00	3.00
	WEEK 52	223	102.35	103.00	2.71	90.00	111.00	220	102.52	2.60	-0.15	0.00	2.74	-8.00	8.00
	LAST VISIT	332	102.36	103.00	2.60	90.00	111.00	324	102.42	2.65	-0.04	0.00	2.68	-8.00	8.00
ROLLOVER	BASELINE	85	101.86	102.00	2.61	96.00	107.00								
	WEEK 28	43	101.67	102.00	2.50	96.00	106.00	43	101.56	2.48	0.12	0.00	2.96	-6.00	7.00
	WEEK 52	14	101.93	101.00	2.92	97.00	108.00	14	103.29	2.43	-1.36	-2.00	2.53	-5.00	4.00
	LAST VISIT	80	101.68	102.00	2.77	92.00	108.00	80	101.84	2.63	-0.16	0.00	2.87	-6.00	7.00
TOTAL	BASELINE	456	102.32	102.00	2.60	92.00	109.00								
	WEEK 28	55	101.85	102.00	2.34	96.00	106.00	55	101.82	2.37	0.04	0.00	2.75	-6.00	7.00
	WEEK 52	237	102.32	103.00	2.72	90.00	111.00	234	102.56	2.60	-0.22	0.00	2.73	-8.00	8.00
	LAST VISIT	412	102.23	103.00	2.64	90.00	111.00	404	102.30	2.66	-0.07	0.00	2.72	-8.00	8.00

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[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=CHOLESTEROL, FASTING (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	___BASELINE____ MEAN	___BASELINE____ MEDIAN	___BASELINE____ SD	___BASELINE____ MIN	___BASELINE____ MAX
DE NOVO	BASELINE	323	192.04	190.00	40.14	111.00	408.00								
	WEEK 28	8	189.75	175.00	47.11	140.00	281.00	4	193.50	67.48	-20.25	-18.00	29.34	-54.00	9.00
	WEEK 52	194	195.64	194.50	40.29	114.00	353.00	179	193.51	39.09	1.87	2.00	31.31	-200.00	98.00
	LAST VISIT	269	194.87	192.00	40.31	114.00	353.00	244	195.21	39.93	-0.22	1.00	30.47	-200.00	98.00
ROLLOVER	BASELINE	79	192.66	184.00	39.05	121.00	279.00								
	WEEK 28	39	202.36	198.00	42.16	131.00	287.00	39	197.23	37.44	5.13	3.00	26.22	-40.00	67.00
	WEEK 52	14	199.36	192.00	36.30	164.00	292.00	11	190.18	42.39	11.55	14.00	14.96	-14.00	34.00
	LAST VISIT	69	196.28	193.00	39.06	126.00	292.00	65	193.88	40.28	3.12	3.00	25.14	-59.00	67.00
TOTAL	BASELINE	402	192.16	189.00	39.88	111.00	408.00								
	WEEK 28	47	200.21	196.00	42.77	131.00	287.00	43	196.88	39.93	2.77	3.00	27.19	-54.00	67.00
	WEEK 52	208	195.89	194.50	39.97	114.00	353.00	190	193.32	39.18	2.43	2.50	30.67	-200.00	98.00
	LAST VISIT	338	195.16	192.50	40.00	114.00	353.00	309	194.93	39.94	0.49	2.00	29.43	-200.00	98.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=CREATINE KINASE (U/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	370	123.85	92.00	120.05	25.00	1100.00								
	WEEK 28	14	211.64	95.00	268.93	42.00	893.00	14	161.50	132.65	50.14	-26.00	237.15	-161.00	734.00
	WEEK 52	221	143.55	88.00	404.70	25.00	5918.00	218	118.91	110.46	24.72	-3.00	414.93	-976.00	5844.00
	LAST VISIT	334	117.75	88.00	107.15	23.00	893.00	326	122.43	122.38	-5.43	-4.00	125.07	-976.00	734.00
ROLLOVER	BASELINE	84	177.82	95.50	270.36	36.00	2054.00								
	WEEK 28	43	125.95	85.00	93.27	34.00	434.00	43	139.16	131.71	-13.21	-3.00	108.01	-628.00	113.00
	WEEK 52	14	102.36	91.00	43.23	51.00	184.00	13	172.46	250.81	-71.38	4.00	226.74	-801.00	49.00
	LAST VISIT	80	132.71	99.50	102.70	26.00	626.00	79	181.81	277.86	-48.92	-1.00	246.18	-1861.0	211.00
TOTAL	BASELINE	454	133.84	92.00	159.91	25.00	2054.00								
	WEEK 28	57	147.00	95.00	157.16	34.00	893.00	57	144.65	131.11	2.35	-6.00	150.20	-628.00	734.00
	WEEK 52	235	141.10	88.00	392.66	25.00	5918.00	231	121.93	122.26	19.32	-3.00	406.95	-976.00	5844.00
	LAST VISIT	414	120.64	89.00	106.34	23.00	893.00	405	134.01	165.86	-13.91	-3.00	156.79	-1861.0	734.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=CREATININE (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	0.87	0.90	0.18	0.40	1.50								
	WEEK 28	14	0.92	0.85	0.18	0.70	1.30	14	0.87	0.17	0.05	0.00	0.09	-0.10	0.20
	WEEK 52	224	0.88	0.90	0.18	0.50	1.60	221	0.86	0.18	0.02	0.00	0.11	-0.30	0.40
	LAST VISIT	336	0.89	0.90	0.19	0.50	1.60	328	0.87	0.18	0.02	0.00	0.11	-0.30	0.40
ROLLOVER	BASELINE	85	0.88	0.90	0.20	0.50	2.10								
	WEEK 28	43	0.90	0.90	0.21	0.50	1.30	43	0.84	0.16	0.06	0.10	0.12	-0.20	0.30
	WEEK 52	14	0.84	0.85	0.16	0.60	1.10	14	0.88	0.16	-0.04	0.00	0.08	-0.20	0.10
	LAST VISIT	80	0.92	0.90	0.24	0.50	2.30	80	0.88	0.20	0.03	0.00	0.11	-0.20	0.30
TOTAL	BASELINE	456	0.87	0.90	0.19	0.40	2.10								
	WEEK 28	57	0.91	0.90	0.20	0.50	1.30	57	0.85	0.16	0.06	0.10	0.11	-0.20	0.30
	WEEK 52	238	0.88	0.90	0.18	0.50	1.60	235	0.86	0.18	0.02	0.00	0.11	-0.30	0.40
	LAST VISIT	416	0.89	0.90	0.20	0.50	2.30	408	0.87	0.19	0.02	0.00	0.11	-0.30	0.40

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=GAMMA GLUTAMYL TRANSFERASE (U/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	31.69	22.00	37.35	7.00	393.00								
	WEEK 28	14	30.36	24.50	22.86	10.00	85.00	14	35.43	32.62	-5.07	0.00	23.80	-73.00	31.00
	WEEK 52	224	29.74	22.00	25.30	5.00	174.00	221	33.14	44.95	-3.22	-1.00	32.72	-276.00	115.00
	LAST VISIT	336	30.16	22.00	25.52	5.00	174.00	328	32.50	39.44	-2.46	-1.00	29.15	-276.00	115.00
ROLLOVER	BASELINE	85	33.59	23.00	27.79	7.00	162.00								
	WEEK 28	43	45.23	30.00	38.23	9.00	146.00	43	41.84	33.30	3.40	0.00	20.55	-39.00	73.00
	WEEK 52	14	24.93	22.50	19.36	7.00	89.00	14	21.71	10.74	3.21	1.00	12.63	-12.00	41.00
	LAST VISIT	80	37.15	25.00	31.86	7.00	146.00	80	34.74	28.22	2.41	1.00	18.60	-45.00	74.00
TOTAL	BASELINE	456	32.04	22.00	35.74	7.00	393.00								
	WEEK 28	57	41.58	26.00	35.48	9.00	146.00	57	40.26	32.96	1.32	0.00	21.49	-73.00	73.00
	WEEK 52	238	29.45	22.00	24.98	5.00	174.00	235	32.46	43.74	-2.84	-1.00	31.90	-276.00	115.00
	LAST VISIT	416	31.50	23.50	26.95	5.00	174.00	408	32.94	37.48	-1.51	-1.00	27.45	-276.00	115.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=GLUCOSE, FASTING (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	322	97.35	92.00	28.58	61.00	308.00								
	WEEK 28	9	98.00	97.00	14.89	81.00	132.00	5	94.60	14.14	5.40	6.00	11.99	-8.00	20.00
	WEEK 52	193	96.71	94.00	24.00	62.00	335.00	179	94.02	21.63	2.61	2.00	12.20	-36.00	45.00
	LAST VISIT	272	98.52	94.00	32.22	52.00	441.00	247	96.89	28.05	1.91	1.00	15.40	-40.00	133.00
ROLLOVER	BASELINE	78	97.08	93.00	19.46	57.00	168.00								
	WEEK 28	39	96.05	97.00	12.58	67.00	135.00	39	97.54	18.69	-1.49	0.00	14.46	-58.00	20.00
	WEEK 52	14	102.21	94.50	25.83	83.00	177.00	10	103.90	34.28	2.90	5.50	13.14	-32.00	14.00
	LAST VISIT	70	98.14	97.00	16.62	67.00	177.00	65	97.62	20.63	1.00	2.00	14.13	-58.00	36.00
TOTAL	BASELINE	400	97.30	92.50	27.02	57.00	308.00								
	WEEK 28	48	96.42	97.00	12.90	67.00	135.00	44	97.20	18.12	-0.70	0.00	14.25	-58.00	20.00
	WEEK 52	207	97.08	94.00	24.10	62.00	335.00	189	94.54	22.45	2.63	2.00	12.22	-36.00	45.00
	LAST VISIT	342	98.44	94.00	29.68	52.00	441.00	312	97.04	26.65	1.72	2.00	15.12	-58.00	133.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=HDL CHOLESTEROL, FASTING (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	323	55.90	55.00	16.03	22.00	121.00								
	WEEK 28	8	54.38	53.00	8.98	42.00	66.00	4	52.50	4.93	-0.25	-1.50	6.70	-7.00	9.00
	WEEK 52	194	55.27	52.50	17.69	20.00	117.00	179	56.42	16.69	-1.07	-1.00	9.44	-34.00	32.00
	LAST VISIT	269	54.76	52.00	16.60	20.00	117.00	244	56.44	16.04	-1.54	-1.00	9.38	-34.00	32.00
ROLLOVER	BASELINE	79	52.63	51.00	14.68	23.00	98.00								
	WEEK 28	39	53.26	50.00	14.73	34.00	94.00	39	52.56	14.92	0.69	2.00	9.05	-17.00	23.00
	WEEK 52	14	53.93	49.50	13.53	27.00	77.00	11	50.09	7.70	2.09	2.00	11.13	-24.00	13.00
	LAST VISIT	69	53.20	50.00	14.79	27.00	94.00	65	51.91	15.02	1.05	1.00	8.80	-24.00	23.00
TOTAL	BASELINE	402	55.26	54.00	15.81	22.00	121.00								
	WEEK 28	47	53.45	51.00	13.84	34.00	94.00	43	52.56	14.25	0.60	2.00	8.80	-17.00	23.00
	WEEK 52	208	55.18	52.00	17.42	20.00	117.00	190	56.06	16.36	-0.89	-1.00	9.54	-34.00	32.00
	LAST VISIT	338	54.44	52.00	16.24	20.00	117.00	309	55.49	15.92	-1.00	-1.00	9.31	-34.00	32.00

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=INSULIN, FASTING (uIU/mL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	316	10.60	6.58	15.97	0.44	157.89								
	WEEK 28	6	11.02	8.14	9.31	2.38	28.93	4	6.34	5.75	5.56	4.30	6.24	-0.41	14.05
	WEEK 52	192	14.13	7.04	24.59	1.22	234.87	173	9.60	13.44	3.54	0.59	20.92	-127.82	159.07
	LAST VISIT	266	12.95	7.41	18.69	0.81	164.16	235	9.74	14.94	2.80	0.58	18.18	-127.82	159.07
ROLLOVER	BASELINE	78	14.04	8.95	21.31	1.24	149.91								
	WEEK 28	35	10.95	9.07	7.20	1.67	31.02	35	15.91	28.71	-4.96	0.57	26.86	-125.93	12.70
	WEEK 52	14	13.53	11.24	11.70	2.14	48.56	11	16.29	20.20	-2.42	-1.16	9.57	-26.86	9.26
	LAST VISIT	65	12.55	9.31	9.63	1.67	48.56	61	14.54	23.67	-1.84	0.57	21.53	-125.93	26.21
TOTAL	BASELINE	394	11.28	6.87	17.18	0.44	157.89								
	WEEK 28	41	10.96	9.07	7.41	1.67	31.02	39	14.93	27.37	-3.88	1.29	25.67	-125.93	14.05
	WEEK 52	206	14.09	7.13	23.92	1.22	234.87	184	10.00	13.95	3.18	0.53	20.45	-127.82	159.07
	LAST VISIT	331	12.87	7.70	17.28	0.81	164.16	296	10.73	17.17	1.84	0.58	18.98	-127.82	159.07

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=LACTATE DEHYDROGENASE (U/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	359	155.67	153.00	34.53	62.00	521.00								
	WEEK 28	14	164.79	142.00	55.43	115.00	296.00	12	164.75	42.05	0.25	-5.50	47.91	-60.00	109.00
	WEEK 52	213	154.28	152.00	28.67	97.00	261.00	207	157.82	36.82	-3.48	0.00	37.40	-403.00	123.00
	LAST VISIT	329	154.89	151.00	31.33	95.00	304.00	312	156.38	34.47	-1.60	0.00	35.68	-403.00	188.00
ROLLOVER	BASELINE	81	164.28	155.00	37.01	105.00	281.00								
	WEEK 28	42	161.86	157.00	31.11	120.00	261.00	40	163.73	31.72	-2.50	-0.50	25.19	-64.00	42.00
	WEEK 52	12	153.25	142.00	28.60	115.00	201.00	12	160.17	38.33	-6.92	-4.00	25.20	-77.00	18.00
	LAST VISIT	78	159.68	152.00	32.15	107.00	261.00	74	164.47	37.08	-4.82	-1.00	26.67	-84.00	43.00
TOTAL	BASELINE	440	157.26	153.50	35.12	62.00	521.00								
	WEEK 28	56	162.59	153.00	38.07	115.00	296.00	52	163.96	33.92	-1.87	-2.00	31.33	-64.00	109.00
	WEEK 52	225	154.23	151.00	28.61	97.00	261.00	219	157.95	36.81	-3.67	0.00	36.80	-403.00	123.00
	LAST VISIT	407	155.81	151.00	31.50	95.00	304.00	386	157.94	35.08	-2.22	0.00	34.13	-403.00	188.00

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=LDL CHOLESTEROL, FASTING (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	317	107.74	107.00	29.57	34.00	205.00								
	WEEK 28	8	116.38	103.00	44.69	69.00	203.00	4	123.75	64.15	-18.50	-15.00	27.34	-51.00	7.00
	WEEK 52	190	112.05	110.00	31.54	41.00	204.00	174	108.97	28.93	2.91	1.00	23.90	-114.00	80.00
	LAST VISIT	265	112.43	110.00	31.77	41.00	212.00	236	110.00	29.20	1.97	1.00	23.23	-114.00	80.00
ROLLOVER	BASELINE	78	112.79	109.50	33.67	30.00	191.00								
	WEEK 28	36	117.61	117.00	34.73	52.00	183.00	36	114.64	33.56	2.97	-1.00	20.29	-35.00	47.00
	WEEK 52	14	120.29	108.50	33.86	76.00	193.00	11	115.73	36.33	7.91	12.00	12.48	-15.00	21.00
	LAST VISIT	66	116.36	113.00	32.44	52.00	193.00	62	115.66	33.86	1.52	0.00	20.98	-50.00	47.00
TOTAL	BASELINE	395	108.74	107.00	30.44	30.00	205.00								
	WEEK 28	44	117.39	114.50	36.16	52.00	203.00	40	115.55	36.54	0.83	-1.00	21.67	-51.00	47.00
	WEEK 52	204	112.61	110.00	31.68	41.00	204.00	185	109.37	29.35	3.21	1.00	23.39	-114.00	80.00
	LAST VISIT	331	113.21	111.00	31.89	41.00	212.00	298	111.18	30.25	1.88	1.00	22.75	-114.00	80.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=LITHIUM (mEq/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	WEEK 28	3	0.80	0.80	0.30	0.50	1.10								
	WEEK 52	7	0.60	0.60	0.29	0.20	1.00								
	LAST VISIT	21	0.61	0.50	0.36	0.20	1.50								
TOTAL	WEEK 28	3	0.80	0.80	0.30	0.50	1.10								
	WEEK 52	7	0.60	0.60	0.29	0.20	1.00								
	LAST VISIT	21	0.61	0.50	0.36	0.20	1.50								

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=MAGNESIUM (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	2.05	2.00	0.17	1.50	2.50								
	WEEK 28	12	2.01	2.05	0.26	1.30	2.30	12	2.03	0.20	-0.03	0.00	0.13	-0.30	0.20
	WEEK 52	223	2.06	2.10	0.16	1.60	2.50	220	2.05	0.16	0.01	0.00	0.15	-0.60	0.30
	LAST VISIT	332	2.06	2.10	0.16	1.30	2.50	324	2.05	0.17	0.02	0.00	0.15	-0.60	0.30
ROLLOVER	BASELINE	85	2.06	2.10	0.17	1.50	2.50								
	WEEK 28	43	2.08	2.10	0.14	1.70	2.30	43	2.08	0.15	0.00	0.00	0.16	-0.30	0.40
	WEEK 52	14	2.11	2.10	0.14	1.90	2.30	14	2.11	0.17	0.00	0.00	0.12	-0.20	0.20
	LAST VISIT	80	2.06	2.10	0.16	1.50	2.40	80	2.07	0.17	-0.01	0.00	0.14	-0.30	0.40
TOTAL	BASELINE	456	2.05	2.00	0.17	1.50	2.50								
	WEEK 28	55	2.07	2.10	0.18	1.30	2.30	55	2.07	0.16	-0.00	0.00	0.16	-0.30	0.40
	WEEK 52	237	2.06	2.10	0.16	1.60	2.50	234	2.05	0.16	0.01	0.00	0.15	-0.60	0.30
	LAST VISIT	412	2.06	2.10	0.16	1.30	2.50	404	2.05	0.17	0.01	0.00	0.15	-0.60	0.40

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=PHOSPHATE (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	3.64	3.60	0.52	2.30	5.40								
	WEEK 28	14	3.70	3.60	0.67	2.80	5.20	14	3.66	0.41	0.04	0.10	0.60	-1.20	1.50
	WEEK 52	224	3.49	3.50	0.49	2.20	4.80	221	3.64	0.55	-0.15	-0.10	0.52	-1.60	1.40
	LAST VISIT	336	3.50	3.50	0.51	2.20	5.20	328	3.63	0.53	-0.13	-0.10	0.52	-1.60	1.50
ROLLOVER	BASELINE	85	3.42	3.40	0.54	2.30	5.00								
	WEEK 28	43	3.42	3.40	0.61	2.30	5.30	43	3.45	0.51	-0.03	0.00	0.53	-1.10	0.90
	WEEK 52	14	3.60	3.50	0.42	3.10	4.40	14	3.49	0.45	0.11	0.05	0.46	-0.50	1.20
	LAST VISIT	80	3.43	3.40	0.55	2.30	5.30	80	3.43	0.54	0.00	0.00	0.53	-1.30	1.20
TOTAL	BASELINE	456	3.60	3.60	0.53	2.30	5.40								
	WEEK 28	57	3.49	3.40	0.63	2.30	5.30	57	3.50	0.49	-0.01	0.00	0.54	-1.20	1.50
	WEEK 52	238	3.49	3.50	0.49	2.20	4.80	235	3.63	0.54	-0.13	-0.10	0.52	-1.60	1.40
	LAST VISIT	416	3.49	3.50	0.52	2.20	5.30	408	3.59	0.53	-0.11	-0.10	0.53	-1.60	1.50

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=POTASSIUM (mEq/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	4.25	4.30	0.41	3.00	6.10								
	WEEK 28	12	4.29	4.20	0.38	3.90	5.40	12	4.35	0.38	-0.06	0.00	0.24	-0.50	0.30
	WEEK 52	222	4.19	4.20	0.35	3.20	5.10	219	4.22	0.42	-0.03	0.00	0.39	-1.40	1.50
	LAST VISIT	331	4.20	4.20	0.35	3.20	5.60	323	4.25	0.41	-0.05	0.00	0.39	-1.40	1.50
ROLLOVER	BASELINE	85	4.27	4.20	0.41	3.60	5.80								
	WEEK 28	43	4.15	4.10	0.34	3.60	5.30	43	4.21	0.31	-0.06	0.00	0.39	-0.90	1.20
	WEEK 52	14	4.26	4.25	0.51	3.70	5.50	14	4.28	0.54	-0.01	-0.05	0.59	-1.10	1.20
	LAST VISIT	80	4.19	4.10	0.38	3.60	5.50	80	4.27	0.42	-0.09	-0.10	0.44	-1.10	1.20
TOTAL	BASELINE	456	4.25	4.30	0.41	3.00	6.10								
	WEEK 28	55	4.18	4.10	0.35	3.60	5.40	55	4.24	0.33	-0.06	0.00	0.36	-0.90	1.20
	WEEK 52	236	4.19	4.20	0.36	3.20	5.50	233	4.22	0.43	-0.03	0.00	0.41	-1.40	1.50
	LAST VISIT	411	4.20	4.20	0.36	3.20	5.60	403	4.25	0.41	-0.06	0.00	0.40	-1.40	1.50

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=PROLACTIN (ng/mL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	367	6.93	4.98	6.95	0.31	72.57								
	WEEK 28	13	8.18	3.05	11.32	0.61	34.17	13	5.68	5.77	2.50	-0.32	9.98	-4.67	33.25
	WEEK 52	221	6.33	4.28	7.43	0.34	84.22	216	7.09	7.50	-0.81	-0.26	4.09	-29.01	11.65
	LAST VISIT	335	6.49	4.29	7.26	0.34	84.22	323	6.94	7.09	-0.53	-0.25	4.23	-29.01	24.95
ROLLOVER	BASELINE	83	7.74	7.06	7.49	0.38	54.34								
	WEEK 28	43	5.93	4.44	6.16	0.68	36.17	43	7.79	5.95	-1.86	-0.73	3.76	-11.83	8.33
	WEEK 52	14	5.17	2.29	5.01	0.53	13.64	14	7.23	5.55	-2.07	-1.40	3.49	-9.51	4.24
	LAST VISIT	79	5.51	3.92	5.53	0.42	36.17	78	7.22	5.56	-1.75	-0.57	3.43	-11.83	8.33
TOTAL	BASELINE	450	7.08	5.25	7.05	0.31	72.57								
	WEEK 28	56	6.45	4.31	7.61	0.61	36.17	56	7.30	5.93	-0.85	-0.71	6.00	-11.83	33.25
	WEEK 52	235	6.26	4.23	7.31	0.34	84.22	230	7.10	7.39	-0.89	-0.29	4.06	-29.01	11.65
	LAST VISIT	414	6.30	4.29	6.97	0.34	84.22	401	7.00	6.81	-0.76	-0.29	4.11	-29.01	24.95

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=PROTEIN (g/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	7.18	7.20	0.48	5.80	9.00								
	WEEK 28	14	7.14	7.25	0.54	6.40	7.90	14	7.09	0.55	0.06	0.00	0.61	-0.80	1.10
	WEEK 52	224	7.14	7.10	0.44	6.10	9.00	221	7.15	0.48	-0.01	0.00	0.44	-1.40	1.40
	LAST VISIT	336	7.14	7.10	0.45	5.90	9.00	328	7.17	0.48	-0.03	0.00	0.46	-1.60	1.40
ROLLOVER	BASELINE	85	7.21	7.20	0.50	6.20	8.40								
	WEEK 28	43	7.23	7.30	0.43	6.50	8.40	43	7.21	0.46	0.02	0.00	0.45	-1.00	0.90
	WEEK 52	14	7.19	7.50	0.51	6.40	7.80	14	7.14	0.65	0.06	0.05	0.35	-0.60	0.60
	LAST VISIT	80	7.19	7.20	0.43	6.20	8.40	80	7.19	0.48	-0.00	0.00	0.41	-1.00	0.70
TOTAL	BASELINE	456	7.19	7.20	0.49	5.80	9.00								
	WEEK 28	57	7.21	7.30	0.46	6.40	8.40	57	7.18	0.48	0.03	0.00	0.49	-1.00	1.10
	WEEK 52	238	7.14	7.10	0.44	6.10	9.00	235	7.15	0.49	-0.01	0.00	0.43	-1.40	1.40
	LAST VISIT	416	7.15	7.10	0.45	5.90	9.00	408	7.17	0.48	-0.02	0.00	0.45	-1.60	1.40

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=SODIUM (mEq/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	140.05	140.00	2.19	130.00	145.00								
	WEEK 28	12	139.42	139.00	1.78	137.00	142.00	12	139.50	2.02	-0.08	0.00	1.88	-3.00	3.00
	WEEK 52	223	139.95	140.00	2.29	131.00	147.00	220	140.15	2.22	-0.21	0.00	2.63	-7.00	10.00
	LAST VISIT	332	139.96	140.00	2.31	131.00	148.00	324	140.07	2.23	-0.10	0.00	2.65	-7.00	10.00
ROLLOVER	BASELINE	85	139.05	139.00	2.71	134.00	145.00								
	WEEK 28	43	138.79	139.00	1.85	135.00	143.00	43	138.93	2.94	-0.14	-1.00	3.21	-6.00	7.00
	WEEK 52	14	138.71	138.00	2.67	135.00	143.00	14	140.07	2.70	-1.36	-1.00	1.95	-5.00	2.00
	LAST VISIT	80	138.44	139.00	2.34	130.00	143.00	80	139.14	2.68	-0.70	-1.00	2.96	-9.00	7.00
TOTAL	BASELINE	456	139.87	140.00	2.33	130.00	145.00								
	WEEK 28	55	138.93	139.00	1.83	135.00	143.00	55	139.05	2.76	-0.13	0.00	2.96	-6.00	7.00
	WEEK 52	237	139.87	140.00	2.33	131.00	147.00	234	140.15	2.24	-0.28	0.00	2.60	-7.00	10.00
	LAST VISIT	412	139.67	140.00	2.39	130.00	148.00	404	139.89	2.35	-0.22	0.00	2.72	-9.00	10.00

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表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=TRIGLYCERIDES (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	52	155.50	123.00	107.99	39.00	563.00								
	WEEK 28	5	207.00	197.00	89.62	89.00	341.00	2	256.00	62.23	-59.50	-59.50	62.93	-104.00	-15.00
	WEEK 52	29	136.52	125.00	67.49	38.00	328.00	12	118.25	47.29	21.92	11.50	83.73	-97.00	173.00
	LAST VISIT	71	154.34	127.00	82.09	38.00	391.00	22	134.45	73.51	7.05	4.00	79.78	-104.00	173.00
ROLLOVER	BASELINE	6	133.33	130.00	34.52	99.00	195.00								
	WEEK 28	4	172.50	181.00	61.80	96.00	232.00	2	164.00	43.84	-10.00	-10.00	38.18	-37.00	17.00
	LAST VISIT	11	167.45	150.00	82.47	47.00	290.00	2	164.00	43.84	-10.00	-10.00	38.18	-37.00	17.00
TOTAL	BASELINE	58	153.21	126.00	102.89	39.00	563.00								
	WEEK 28	9	191.67	197.00	76.02	89.00	341.00	4	210.00	68.94	-34.75	-26.00	51.21	-104.00	17.00
	WEEK 52	29	136.52	125.00	67.49	38.00	328.00	12	118.25	47.29	21.92	11.50	83.73	-97.00	173.00
	LAST VISIT	82	156.10	131.50	81.75	38.00	391.00	24	136.92	71.33	5.63	4.00	76.80	-104.00	173.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=TRIGLYCERIDES, FASTING (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	323	136.20	115.00	81.65	24.00	571.00								
	WEEK 28	8	95.50	94.50	43.49	46.00	180.00	4	85.00	27.87	-6.50	-4.00	19.82	-33.00	15.00
	WEEK 52	194	143.09	110.00	117.38	37.00	905.00	179	132.68	74.04	8.73	0.00	103.82	-386.00	679.00
	LAST VISIT	269	139.53	108.00	107.25	37.00	905.00	244	135.20	78.78	3.27	-2.00	96.26	-386.00	679.00
ROLLOVER	BASELINE	79	133.72	112.00	84.46	31.00	407.00								
	WEEK 28	39	147.72	111.00	109.70	36.00	508.00	39	140.38	85.72	7.33	9.00	72.19	-150.00	238.00
	WEEK 52	14	126.29	107.00	76.47	60.00	360.00	11	122.00	63.29	7.73	-6.00	79.76	-75.00	228.00
	LAST VISIT	69	138.54	110.00	98.16	29.00	508.00	65	135.77	83.24	3.97	0.00	66.51	-150.00	238.00
TOTAL	BASELINE	402	135.72	115.00	82.11	24.00	571.00								
	WEEK 28	47	138.83	110.00	103.07	36.00	508.00	43	135.23	83.48	6.05	9.00	68.99	-150.00	238.00
	WEEK 52	208	141.96	109.00	115.03	37.00	905.00	190	132.06	73.35	8.67	-1.00	102.41	-386.00	679.00
	LAST VISIT	338	139.33	109.50	105.31	29.00	905.00	309	135.32	79.60	3.42	-1.00	90.72	-386.00	679.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=URATE (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	371	5.53	5.40	1.46	2.50	10.60								
	WEEK 28	14	6.31	6.05	1.15	4.70	8.90	14	6.12	1.05	0.19	0.45	1.26	-2.20	2.10
	WEEK 52	224	5.60	5.50	1.56	1.90	11.70	221	5.56	1.52	0.02	0.00	1.00	-3.10	4.10
	LAST VISIT	336	5.63	5.50	1.51	1.90	11.20	328	5.57	1.47	0.03	0.00	0.98	-3.10	4.10
ROLLOVER	BASELINE	85	5.62	5.60	1.49	2.30	10.70								
	WEEK 28	43	5.74	5.60	1.58	2.80	10.00	43	5.63	1.42	0.11	-0.10	0.85	-1.20	2.00
	WEEK 52	14	5.38	5.00	1.41	3.60	7.60	14	5.41	1.48	-0.04	-0.00	1.12	-2.60	1.30
	LAST VISIT	80	5.63	5.55	1.53	2.40	10.60	80	5.69	1.49	-0.06	-0.10	0.99	-3.70	2.00
TOTAL	BASELINE	456	5.55	5.40	1.47	2.30	10.70								
	WEEK 28	57	5.88	6.00	1.50	2.80	10.00	57	5.75	1.34	0.13	0.00	0.96	-2.20	2.10
	WEEK 52	238	5.59	5.50	1.55	1.90	11.70	235	5.55	1.51	0.01	0.00	1.00	-3.10	4.10
	LAST VISIT	416	5.63	5.50	1.51	1.90	11.20	408	5.59	1.47	0.01	0.00	0.98	-3.70	4.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AA.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.1　FINAL

表 2.7.4.7-132　生化学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

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PROTOCOL 31-08-252

CT-13.2.1
Laboratory Test Results for Serum Chemistry - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=UREA NITROGEN (mg/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	371	12.50	12.00	3.75	5.00	27.00								
	WEEK 28	14	13.21	12.50	3.95	9.00	22.00	14	12.36	3.95	0.86	1.50	3.16	-4.00	8.00
	WEEK 52	224	12.74	12.00	3.95	5.00	31.00	221	12.44	3.81	0.30	0.00	3.57	-12.00	14.00
	LAST VISIT	336	12.63	12.00	3.82	5.00	31.00	328	12.44	3.71	0.17	0.00	3.62	-12.00	14.00
ROLLOVER	WEEK 28	43	13.14	13.00	4.36	4.00	24.00								
	WEEK 52	14	12.57	11.00	3.99	8.00	19.00								
	LAST VISIT	80	13.21	13.00	4.91	4.00	38.00								
TOTAL	BASELINE	371	12.50	12.00	3.75	5.00	27.00								
	WEEK 28	57	13.16	13.00	4.22	4.00	24.00	14	12.36	3.95	0.86	1.50	3.16	-4.00	8.00
	WEEK 52	238	12.73	12.00	3.95	5.00	31.00	221	12.44	3.81	0.30	0.00	3.57	-12.00	14.00
	LAST VISIT	416	12.74	12.00	4.05	4.00	38.00	328	12.44	3.71	0.17	0.00	3.62	-12.00	14.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AA.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.1 FINAL
＜資料番号 5.3.5.2-01：CT-13.2.1＞

表 2.7.4.7-133　臨床的に重要な臨床検査値の変動を示した被験者の割合［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.1.1
Incidence of Laboratory Values of Potential Clinical Relevance in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
	TEST(UNITS)[1]	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	335	3	(0.9)	80	0	(0.0)	415	3	(0.7)
	ALKALINE PHOSPHATASE (U/L)	336	0	(0.0)	80	0	(0.0)	416	0	(0.0)
	ASPARTATE AMINOTRANSFERASE (U/L)	333	2	(0.6)	80	0	(0.0)	413	2	(0.5)
	BILIRUBIN (mg/dL)	322	2	(0.6)	74	0	(0.0)	396	2	(0.5)
	CALCIUM (mg/dL)	336	1	(0.3)	80	0	(0.0)	416	1	(0.2)
	CHLORIDE (mEq/L)	332	1	(0.3)	80	0	(0.0)	412	1	(0.2)
	CHOLESTEROL, FASTING (mg/dL)	269	41	(15.2)	69	12	(17.4)	338	53	(15.7)
	CREATINE KINASE (U/L)	334	5	(1.5)	80	1	(1.3)	414	6	(1.4)
	CREATININE (mg/dL)	336	0	(0.0)	80	1	(1.3)	416	1	(0.2)
	GLUCOSE (mg/dL)	86	2	(2.3)	11	1	(9.1)	97	3	(3.1)
	GLUCOSE, FASTING (mg/dL)	272	29	(10.7)	70	10	(14.3)	342	39	(11.4)
	HDL CHOLESTEROL, FASTING (mg/dL)	269	7	(2.6)	69	2	(2.9)	338	9	(2.7)
	LACTATE DEHYDROGENASE (U/L)	329	0	(0.0)	78	0	(0.0)	407	0	(0.0)
	LDL CHOLESTEROL, FASTING (mg/dL)	265	23	(8.7)	66	9	(13.6)	331	32	(9.7)
	POTASSIUM (mEq/L)	331	1	(0.3)	80	1	(1.3)	411	2	(0.5)
	PROLACTIN (ng/mL)	335	10	(3.0)	79	2	(2.5)	414	12	(2.9)
	SODIUM (mEq/L)	332	0	(0.0)	80	0	(0.0)	412	0	(0.0)
	TRIGLYCERIDES, FASTING (mg/dL)	269	100	(37.2)	69	24	(34.8)	338	124	(36.7)
	URATE (mg/dL)	336	3	(0.9)	80	1	(1.3)	416	4	(1.0)
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	333	0	(0.0)	80	3	(3.8)	413	3	(0.7)
	HEMATOCRIT (%)	322	2	(0.6)	79	1	(1.3)	401	3	(0.7)
	HEMOGLOBIN (g/dL)	334	2	(0.6)	80	2	(2.5)	414	4	(1.0)
	LEUKOCYTES (10^9/L)	334	0	(0.0)	80	1	(1.3)	414	1	(0.2)
	NEUTROPHILS (10^9/L)	333	1	(0.3)	80	1	(1.3)	413	2	(0.5)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3AA.LIS, RUN: [redacted]20[redacted] 13:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.1.1 FINAL

表 2.7.4.7-133　臨床的に重要な臨床検査値の変動を示した被験者の割合［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.1.1
Incidence of Laboratory Values of Potential Clinical Relevance in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
	TEST(UNITS)[1]	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
HEMATOLOGY	PLATELETS (10^9/L)	334	0	(0.0)	80	1	(1.3)	414	1	(0.2)
URINALYSIS	GLUCOSE	326	0	(0.0)	78	2	(2.6)	404	2	(0.5)
	PROTEIN	326	4	(1.2)	78	0	(0.0)	404	4	(1.0)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3AA.LIS, RUN: [redacted]20[redacted] 13:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.1.1 FINAL

＜資料番号 5.3.5.2-01：CT-13.1.1＞

表 2.7.4.7-134　血糖値の投与前後の変化［長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-252

CT-13.1.4
Incidence of Potentially Clinically Relevant Shifts in Glucose in Phase C
(Phase C Safety Sample)

LIPIDS PARAMETERS	BASELINE	ANYTIME POST BASELINE	DE NOVO (N=379) Ne[1]	DE NOVO (N=379) n[2]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[1]	ROLLOVER (N=85) n[2]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[1]	TOTAL (N=464) n[2]	TOTAL (N=464) (%)
GLUCOSE, FASTING (mg/dL)	NORMAL <100	HIGH >=126	187	2	(1.1)	45	1	(2.2)	232	3	(1.3)
	IMPAIRED 100~<126	HIGH >=126	51	5	(9.8)	16	2	(12.5)	67	7	(10.4)
	NORMAL/IMPAIRED <126	HIGH >=126	238	7	(2.9)	61	3	(4.9)	299	10	(3.3)
	ANY VALUE	INCREASED >=10	247	55	(22.3)	65	17	(26.2)	312	72	(23.1)

[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH SPECIFIED BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[2]n IS THE NUMBER OF SUBJECTS WITH POTENTIAL CLINICALLY RELEVANT SHIFT; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB4AB.LIS, RUN: [redacted]20[redacted] 13:52; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.1.4 FINAL

＜資料番号 5.3.5.2-01：CT-13.1.4＞

表 2.7.4.7-135　糖代謝関連有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.5.4
Incidence of Treatment-emergent Adverse Events Related to Glucose Metabolism in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
代謝および栄養障害	TOTAL1)	1	(0.3)	0	(0.0)	1	(0.2)
	耐糖能障害	1	(0.3)	0	(0.0)	1	(0.2)
臨床検査	TOTAL1)	4	(1.1)	0	(0.0)	4	(0.9)
	血中ブドウ糖増加	4	(1.1)	0	(0.0)	4	(0.9)
	尿中ブドウ糖陽性	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL2)		5	(1.3)	0	(0.0)	5	(1.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AE.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.4　FINAL

表 2.7.4.7-135　糖代謝関連有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.5.4
Incidence of Treatment-emergent Adverse Events Related to Glucose Metabolism in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO GLUCOSE METABOLISM: MEDDRA 19.0 PRIMARY TERMS

BLOOD GLUCOSE, CSF GLUCOSE, BLOOD GLUCOSE DECREASED, BLOOD GLUCOSE INCREASED, GLUCOSE URINE, BLOOD GLUCOSE NORMAL, BLOOD GLUCOSE ABNORMAL, GLUCOSE TOLERANCE IMPAIRED, CSF GLUCOSE NORMAL, GLUCOSE URINE PRESENT, GLUCOSE URINE ABSENT, CSF GLUCOSE DECREASED, CSF GLUCOSE INCREASED, GLUCOSE TOLERANCE TEST, SYNOVIAL FLUID GLUCOSE

FILE: ADAE3AE.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.4　FINAL

＜資料番号 5.3.5.2-01：CT-8.2.5.4＞

表 2.7.4.7-136 脂質パラメータの投与前後の変化［二重盲検試験の二重盲検期（Phase D）］

OPC14597 1 OF 1
PROTOCOL 31-08-250

CT-13.1.3
Incidence of Potentially Clinically Relevant Shifts in Lipids in Phase D
(Phase D Safety Sample)

LIPIDS PARAMETERS	BASELINE	ANYTIME POST BASELINE	ARIP IMD (N=132) Ne[1]	n[2]	(%)	PLACEBO (N=133) Ne[1]	n[2]	(%)	TOTAL (N=265) Ne[1]	n[2]	(%)
CHOLESTEROL, FASTING (mg/dL)	NORMAL <200	HIGH >=240	57	1	(1.8)	58	1	(1.7)	115	2	(1.7)
	BORDERLINE 200~<240	HIGH >=240	29	6	(20.7)	29	7	(24.1)	58	13	(22.4)
	NORMAL/BORDERLINE <240	HIGH >=240	86	7	(8.1)	87	8	(9.2)	173	15	(8.7)
	NORMAL <200	BORDERLINE/HIGH >=200	57	7	(12.3)	58	17	(29.3)	115	24	(20.9)
	ANY VALUE	INCREASED >=40	93	8	(8.6)	98	13	(13.3)	191	21	(11.0)
LDL CHOLESTEROL, FASTING (mg/dL)	NORMAL <100	HIGH >=160	42	0	(0.0)	35	0	(0.0)	77	0	(0.0)
	BORDERLINE 100~<160	HIGH >=160	43	7	(16.3)	49	7	(14.3)	92	14	(15.2)
	NORMAL/BORDERLINE <160	HIGH >=160	85	7	(8.2)	84	7	(8.3)	169	14	(8.3)
	NORMAL <100	BORDERLINE/HIGH >=100	42	14	(33.3)	35	13	(37.1)	77	27	(35.1)
	ANY VALUE	INCREASED >=30	92	12	(13.0)	95	14	(14.7)	187	26	(13.9)
HDL CHOLESTEROL, FASTING (mg/dL)	NORMAL >=40	LOW <40	79	7	(8.9)	77	11	(14.3)	156	18	(11.5)
	ANY VALUE	DECREASED >=20	93	6	(6.5)	98	4	(4.1)	191	10	(5.2)
TRIGLYCERIDES, FASTING (mg/dL)	NORMAL <150	HIGH >=200	58	4	(6.9)	65	2	(3.1)	123	6	(4.9)
	NORMAL <150	VERY HIGH >=500	58	0	(0.0)	65	0	(0.0)	123	0	(0.0)
	BORDERLINE 150~<200	HIGH >=200	21	8	(38.1)	15	4	(26.7)	36	12	(33.3)
	BORDERLINE 150~<200	VERY HIGH >=500	21	0	(0.0)	15	0	(0.0)	36	0	(0.0)
	NORMAL/BORDERLINE <200	HIGH >=200	79	12	(15.2)	80	6	(7.5)	159	18	(11.3)
	NORMAL/BORDERLINE <200	VERY HIGH >=500	79	0	(0.0)	80	0	(0.0)	159	0	(0.0)
	NORMAL <150	BORDERLINE/HIGH/VERY HIGH >=150	58	14	(24.1)	65	8	(12.3)	123	22	(17.9)
	NORMAL/BORDERLINE/HIGH <500	VERY HIGH >=500	93	0	(0.0)	97	3	(3.1)	190	3	(1.6)
	ANY VALUE	INCREASED >=50	93	24	(25.8)	98	21	(21.4)	191	45	(23.6)

[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH SPECIFIED BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[2]n IS THE NUMBER OF SUBJECTS WITH POTENTIAL CLINICALLY RELEVANT SHIFT; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB4AA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.1.3 FINAL

＜資料番号 5.3.5.1-01：CT-13.1.3＞

表 2.7.4.7-137　脂質代謝関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.9
Incidence of Treatment-emergent Adverse Events Related to Lipid Parameters in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

NO TREATMENT-EMERGENT ADVERSE EVENTS RELATED TO LIPID PARAMETERS REPORTED

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AJ.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.9　FINAL

表 2.7.4.7-137　脂質代謝関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.9
Incidence of Treatment-emergent Adverse Events Related to Lipid Parameters in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO LIPID PARAMETERS: MEDDRA 19.0 PRIMARY TERMS

APOLIPOPROTEIN B/APOLIPOPROTEIN A-1 RATIO INCREASED, BLOOD CHOLESTEROL ABNORMAL, BLOOD CHOLESTEROL DECREASED, BLOOD CHOLESTEROL INCREASED,
BLOOD TRIGLYCERIDES ABNORMAL, BLOOD TRIGLYCERIDES DECREASED, BLOOD TRIGLYCERIDES INCREASED, DIABETIC DYSLIPIDAEMIA, DYSLIPIDAEMIA,
FAMILIAL HYPERTRIGLYCERIDAEMIA, HIGH DENSITY LIPOPROTEIN ABNORMAL, HIGH DENSITY LIPOPROTEIN DECREASED, HIGH DENSITY LIPOPROTEIN INCREASED,
HYPERCHOLESTEROLAEMIA, HYPO HDL CHOLESTEROLAEMIA, HYPOTRIGLYCERIDAEMIA, INTERMEDIATE DENSITY LIPOPROTEIN DECREASED,
INTERMEDIATE DENSITY LIPOPROTEIN INCREASED, LDL/HDL RATIO DECREASED, LDL/HDL RATIO INCREASED, LIPID METABOLISM DISORDER, LIPIDS ABNORMAL,
LIPIDS DECREASED, LIPIDS INCREASED, LIPOPROTEIN (A) ABNORMAL, LIPOPROTEIN (A) DECREASED, LIPOPROTEIN (A) INCREASED,
LOW DENSITY LIPOPROTEIN ABNORMAL, LOW DENSITY LIPOPROTEIN DECREASED, LOW DENSITY LIPOPROTEIN INCREASED,
NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL DECREASED, NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL INCREASED, REMNANT HYPERLIPIDAEMIA,
TOTAL CHOLESTEROL/HDL RATIO ABNORMAL, TOTAL CHOLESTEROL/HDL RATIO DECREASED, TOTAL CHOLESTEROL/HDL RATIO INCREASED, TYPE I HYPERLIPIDAEMIA,
TYPE II HYPERLIPIDAEMIA, TYPE V HYPERLIPIDAEMIA

FILE: ADAE3AJ.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.9　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.5.9 より作成＞

表 2.7.4.7-138　脂質パラメータの投与前後の変化［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.2.2
Incidence of Potentially Clinically Relevant Shifts in Lipids
(Phase B Safety Sample and Phase C Safety Sample)

LIPIDS PARAMETERS	BASELINE	ANYTIME POST BASELINE	PHASE B (N=614) Ne[1]	PHASE B (N=614) n[2]	PHASE B (N=614) (%)	PHASE C (N=425) Ne[1]	PHASE C (N=425) n[2]	PHASE C (N=425) (%)
CHOLESTEROL, FASTING (mg/dL)	NORMAL <200	HIGH >=240	265	4	(1.5)	176	3	(1.7)
	BORDERLINE 200~<240	HIGH >=240	101	16	(15.8)	72	9	(12.5)
	NORMAL/BORDERLINE <240	HIGH >=240	366	20	(5.5)	248	12	(4.8)
	NORMAL <200	BORDERLINE/HIGH >=200	265	35	(13.2)	176	29	(16.5)
	ANY VALUE	INCREASED >=40	411	27	(6.6)	282	14	(5.0)
LDL CHOLESTEROL, FASTING (mg/dL)	NORMAL <100	HIGH >=160	191	2	(1.0)	123	2	(1.6)
	BORDERLINE 100~<160	HIGH >=160	187	19	(10.2)	122	8	(6.6)
	NORMAL/BORDERLINE <160	HIGH >=160	378	21	(5.6)	245	10	(4.1)
	NORMAL <100	BORDERLINE/HIGH >=100	191	44	(23.0)	123	28	(22.8)
	ANY VALUE	INCREASED >=30	403	32	(7.9)	274	21	(7.7)
HDL CHOLESTEROL, FASTING (mg/dL)	NORMAL >=40	LOW <40	362	26	(7.2)	240	23	(9.6)
	ANY VALUE	DECREASED >=20	411	10	(2.4)	282	7	(2.5)
TRIGLYCERIDES, FASTING (mg/dL)	NORMAL <150	HIGH >=200	309	12	(3.9)	199	13	(6.5)
	NORMAL <150	VERY HIGH >=500	309	1	(0.3)	199	0	(0.0)
	BORDERLINE 150~<200	HIGH >=200	43	14	(32.6)	32	9	(28.1)
	BORDERLINE 150~<200	VERY HIGH >=500	43	0	(0.0)	32	0	(0.0)
	NORMAL/BORDERLINE <200	HIGH >=200	352	26	(7.4)	231	22	(9.5)
	NORMAL/BORDERLINE <200	VERY HIGH >=500	352	1	(0.3)	231	0	(0.0)
	NORMAL <150	BORDERLINE/HIGH/VERY HIGH >=150	309	40	(12.9)	199	43	(21.6)
	NORMAL/BORDERLINE/HIGH <500	VERY HIGH >=500	408	2	(0.5)	280	1	(0.4)
	ANY VALUE	INCREASED >=50	411	56	(13.6)	282	60	(21.3)

[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH SPECIFIED BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[2]n IS THE NUMBER OF SUBJECTS WITH POTENTIAL CLINICALLY RELEVANT SHIFT; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB4BA.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.2.2　FINAL

＜資料番号 5.3.5.1-01：CT-22.2.2＞

表 2.7.4.7-139　脂質代謝関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.9
Incidence of Treatment-emergent Adverse Events Related to Lipid Parameters
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
臨床検査	TOTAL1)	1	(0.2)	1	(0.2)
	血中トリグリセリド増加	1	(0.2)	1	(0.2)
	高比重リポ蛋白減少	1	(0.2)	1	(0.2)
TOTAL2)		1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BJ.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.9　FINAL

表 2.7.4.7-139　脂質代謝関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.9
Incidence of Treatment-emergent Adverse Events Related to Lipid Parameters
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO LIPID PARAMETERS: MEDDRA 19.0 PRIMARY TERMS

APOLIPOPROTEIN B/APOLIPOPROTEIN A-1 RATIO INCREASED, BLOOD CHOLESTEROL ABNORMAL, BLOOD CHOLESTEROL DECREASED, BLOOD CHOLESTEROL INCREASED,
BLOOD TRIGLYCERIDES ABNORMAL, BLOOD TRIGLYCERIDES DECREASED, BLOOD TRIGLYCERIDES INCREASED, DIABETIC DYSLIPIDAEMIA, DYSLIPIDAEMIA,
FAMILIAL HYPERTRIGLYCERIDAEMIA, HIGH DENSITY LIPOPROTEIN ABNORMAL, HIGH DENSITY LIPOPROTEIN DECREASED, HIGH DENSITY LIPOPROTEIN INCREASED,
HYPERCHOLESTEROLAEMIA, HYPO HDL CHOLESTEROLAEMIA, HYPOTRIGLYCERIDAEMIA, INTERMEDIATE DENSITY LIPOPROTEIN DECREASED,
INTERMEDIATE DENSITY LIPOPROTEIN INCREASED, LDL/HDL RATIO DECREASED, LDL/HDL RATIO INCREASED, LIPID METABOLISM DISORDER, LIPIDS ABNORMAL,
LIPIDS DECREASED, LIPIDS INCREASED, LIPOPROTEIN (A) ABNORMAL, LIPOPROTEIN (A) DECREASED, LIPOPROTEIN (A) INCREASED,
LOW DENSITY LIPOPROTEIN ABNORMAL, LOW DENSITY LIPOPROTEIN DECREASED, LOW DENSITY LIPOPROTEIN INCREASED,
NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL DECREASED, NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL INCREASED, REMNANT HYPERLIPIDAEMIA,
TOTAL CHOLESTEROL/HDL RATIO ABNORMAL, TOTAL CHOLESTEROL/HDL RATIO DECREASED, TOTAL CHOLESTEROL/HDL RATIO INCREASED, TYPE I HYPERLIPIDAEMIA,
TYPE II HYPERLIPIDAEMIA, TYPE V HYPERLIPIDAEMIA

FILE: ADAE3BJ.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.9　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.5.9 より作成＞

表 2.7.4.7-140　脂質パラメータの投与前後の変化［長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-252

CT-13.1.3
Incidence of Potentially Clinically Relevant Shifts in Lipids in Phase C
(Phase C Safety Sample)

LIPIDS PARAMETERS	BASELINE	ANYTIME POST BASELINE	DE NOVO (N=379) Ne[1]	DE NOVO (N=379) n[2]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[1]	ROLLOVER (N=85) n[2]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[1]	TOTAL (N=464) n[2]	TOTAL (N=464) (%)
CHOLESTEROL, FASTING (mg/dL)	NORMAL <200	HIGH >=240	146	3	(2.1)	40	1	(2.5)	186	4	(2.2)
	BORDERLINE 200~<240	HIGH >=240	67	17	(25.4)	16	4	(25.0)	83	21	(25.3)
	NORMAL/BORDERLINE <240	HIGH >=240	213	20	(9.4)	56	5	(8.9)	269	25	(9.3)
	NORMAL <200	BORDERLINE/HIGH >=200	146	31	(21.2)	40	7	(17.5)	186	38	(20.4)
	ANY VALUE	INCREASED >=40	244	15	(6.1)	65	7	(10.8)	309	22	(7.1)
LDL CHOLESTEROL, FASTING (mg/dL)	NORMAL <100	HIGH >=160	92	2	(2.2)	25	0	(0.0)	117	2	(1.7)
	BORDERLINE 100~<160	HIGH >=160	133	11	(8.3)	29	5	(17.2)	162	16	(9.9)
	NORMAL/BORDERLINE <160	HIGH >=160	225	13	(5.8)	54	5	(9.3)	279	18	(6.5)
	NORMAL <100	BORDERLINE/HIGH >=100	92	23	(25.0)	25	9	(36.0)	117	32	(27.4)
	ANY VALUE	INCREASED >=30	236	27	(11.4)	62	10	(16.1)	298	37	(12.4)
HDL CHOLESTEROL, FASTING (mg/dL)	NORMAL >=40	LOW <40	212	18	(8.5)	53	3	(5.7)	265	21	(7.9)
	ANY VALUE	DECREASED >=20	244	9	(3.7)	65	1	(1.5)	309	10	(3.2)
TRIGLYCERIDES, FASTING (mg/dL)	NORMAL <150	HIGH >=200	167	6	(3.6)	45	1	(2.2)	212	7	(3.3)
	NORMAL <150	VERY HIGH >=500	167	0	(0.0)	45	0	(0.0)	212	0	(0.0)
	BORDERLINE 150~<200	HIGH >=200	32	12	(37.5)	8	3	(37.5)	40	15	(37.5)
	BORDERLINE 150~<200	VERY HIGH >=500	32	2	(6.3)	8	0	(0.0)	40	2	(5.0)
	NORMAL/BORDERLINE <200	HIGH >=200	199	18	(9.0)	53	4	(7.5)	252	22	(8.7)
	NORMAL/BORDERLINE <200	VERY HIGH >=500	199	2	(1.0)	53	0	(0.0)	252	2	(0.8)
	NORMAL <150	BORDERLINE/HIGH/VERY HIGH >=150	167	25	(15.0)	45	6	(13.3)	212	31	(14.6)
	NORMAL/BORDERLINE/HIGH <500	VERY HIGH >=500	243	4	(1.6)	65	1	(1.5)	308	5	(1.6)
	ANY VALUE	INCREASED >=50	244	36	(14.8)	65	12	(18.5)	309	48	(15.5)

[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH SPECIFIED BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[2]n IS THE NUMBER OF SUBJECTS WITH POTENTIAL CLINICALLY RELEVANT SHIFT; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB4AA.LIS, RUN: [redacted]20[redacted] 13:52; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB4.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.1.3　FINAL

＜資料番号 5.3.5.2-01：CT-13.1.3＞

表 2.7.4.7-141　脂質代謝関連有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 1 OF 2

PROTOCOL 31-08-252

CT-8.2.5.9

Incidence of Treatment-emergent Adverse Events Related to Lipid Parameters in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

		DE NOVO (N=379)		ROLLOVER (N=85)		TOTAL (N=464)	
CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
臨床検査	TOTAL1)	2	(0.5)	0	(0.0)	2	(0.4)
	血中コレステロール増加	2	(0.5)	0	(0.0)	2	(0.4)
	血中トリグリセリド増加	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL2)		2	(0.5)	0	(0.0)	2	(0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AJ.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.9　FINAL

表 2.7.4.7-141　脂質代謝関連有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 2 OF 2
PROTOCOL 31-08-252

CT-8.2.5.9
Incidence of Treatment-emergent Adverse Events Related to Lipid Parameters in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO LIPID PARAMETERS: MEDDRA 19.0 PRIMARY TERMS

APOLIPOPROTEIN B/APOLIPOPROTEIN A-1 RATIO INCREASED, BLOOD CHOLESTEROL ABNORMAL, BLOOD CHOLESTEROL DECREASED, BLOOD CHOLESTEROL INCREASED,
BLOOD TRIGLYCERIDES ABNORMAL, BLOOD TRIGLYCERIDES DECREASED, BLOOD TRIGLYCERIDES INCREASED, DIABETIC DYSLIPIDAEMIA, DYSLIPIDAEMIA,
FAMILIAL HYPERTRIGLYCERIDAEMIA, HIGH DENSITY LIPOPROTEIN ABNORMAL, HIGH DENSITY LIPOPROTEIN DECREASED, HIGH DENSITY LIPOPROTEIN INCREASED,
HYPERCHOLESTEROLAEMIA, HYPO HDL CHOLESTEROLAEMIA, HYPOTRIGLYCERIDAEMIA, INTERMEDIATE DENSITY LIPOPROTEIN DECREASED,
INTERMEDIATE DENSITY LIPOPROTEIN INCREASED, LDL/HDL RATIO DECREASED, LDL/HDL RATIO INCREASED, LIPID METABOLISM DISORDER, LIPIDS ABNORMAL,
LIPIDS DECREASED, LIPIDS INCREASED, LIPOPROTEIN (A) ABNORMAL, LIPOPROTEIN (A) DECREASED, LIPOPROTEIN (A) INCREASED,
LOW DENSITY LIPOPROTEIN ABNORMAL, LOW DENSITY LIPOPROTEIN DECREASED, LOW DENSITY LIPOPROTEIN INCREASED,
NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL DECREASED, NON-HIGH DENSITY LIPOPROTEIN CHOLESTEROL INCREASED, REMNANT HYPERLIPIDAEMIA,
TOTAL CHOLESTEROL/HDL RATIO ABNORMAL, TOTAL CHOLESTEROL/HDL RATIO DECREASED, TOTAL CHOLESTEROL/HDL RATIO INCREASED, TYPE I HYPERLIPIDAEMIA,
TYPE II HYPERLIPIDAEMIA, TYPE V HYPERLIPIDAEMIA

FILE: ADAE3AJ.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.9　FINAL

＜資料番号 5.3.5.2-01：CT-8.2.5.9＞

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=BASOPHILS (10^9/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE ___BASELINE___ n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	0.05	0.04	0.03	0.00	0.16								
	WEEK 28	77	0.04	0.04	0.02	0.00	0.14	72	0.05	0.03	-0.01	-0.01	0.03	-0.13	0.05
	WEEK 52	63	0.04	0.04	0.03	0.01	0.17	58	0.05	0.03	-0.00	0.00	0.03	-0.12	0.06
	LAST VISIT	124	0.05	0.04	0.03	0.01	0.17	118	0.05	0.03	0.00	0.00	0.03	-0.12	0.11
PLACEBO	BASELINE	129	0.04	0.04	0.02	0.00	0.12								
	WEEK 28	57	0.04	0.03	0.02	0.00	0.13	57	0.04	0.02	-0.00	0.00	0.03	-0.08	0.08
	WEEK 52	40	0.04	0.04	0.02	0.02	0.08	40	0.05	0.02	-0.01	0.00	0.02	-0.05	0.06
	LAST VISIT	125	0.04	0.04	0.02	0.00	0.14	121	0.04	0.02	0.00	0.00	0.03	-0.06	0.09

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=BASOPHILS/LEUKOCYTES (%)

								CHANGE FROM BASELINE							
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	0.68	0.60	0.38	0.00	2.40								
	WEEK 28	77	0.60	0.60	0.29	0.00	1.50	72	0.67	0.40	-0.08	0.00	0.41	-2.20	0.60
	WEEK 52	63	0.62	0.60	0.30	0.10	1.50	58	0.65	0.39	-0.03	0.00	0.43	-1.80	0.80
	LAST VISIT	124	0.68	0.60	0.38	0.10	2.60	118	0.67	0.38	0.01	0.00	0.45	-1.80	1.80
PLACEBO	BASELINE	129	0.59	0.50	0.30	0.00	1.60								
	WEEK 28	57	0.60	0.50	0.37	0.00	2.00	57	0.64	0.33	-0.04	0.00	0.44	-1.10	1.50
	WEEK 52	40	0.63	0.60	0.28	0.20	1.30	40	0.71	0.35	-0.08	-0.05	0.32	-0.70	0.90
	LAST VISIT	125	0.64	0.60	0.34	0.00	1.80	121	0.57	0.29	0.06	0.00	0.39	-0.70	1.80

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=EOSINOPHILS (10^9/L)

									CHANGE FROM BASELINE						
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	0.16	0.14	0.13	0.00	1.17								
	WEEK 28	77	0.17	0.14	0.15	0.00	0.98	72	0.17	0.15	0.01	0.00	0.15	-0.69	0.76
	WEEK 52	63	0.16	0.12	0.11	0.01	0.78	58	0.18	0.17	-0.01	0.01	0.15	-0.87	0.34
	LAST VISIT	124	0.16	0.14	0.11	0.01	0.78	118	0.16	0.14	0.00	0.01	0.12	-0.87	0.34
PLACEBO	BASELINE	129	0.14	0.12	0.09	0.02	0.50								
	WEEK 28	57	0.18	0.16	0.12	0.00	0.51	57	0.15	0.10	0.02	0.02	0.08	-0.19	0.22
	WEEK 52	40	0.16	0.12	0.12	0.02	0.64	40	0.15	0.10	0.01	0.01	0.09	-0.25	0.29
	LAST VISIT	125	0.15	0.13	0.10	0.01	0.64	121	0.14	0.09	0.01	0.01	0.09	-0.25	0.43

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=EOSINOPHILS/LEUKOCYTES (%)

									CHANGE FROM BASELINE						
									BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	2.22	1.80	1.63	0.00	13.00								
	WEEK 28	77	2.55	1.90	2.00	0.10	12.80	72	2.35	1.82	0.28	0.05	1.91	-7.00	10.50
	WEEK 52	63	2.41	2.10	1.52	0.30	9.70	58	2.43	2.02	0.09	0.20	1.60	-8.40	2.90
	LAST VISIT	124	2.30	2.10	1.43	0.30	9.70	118	2.25	1.66	0.11	0.10	1.40	-8.40	4.40
PLACEBO	BASELINE	129	2.13	1.70	1.37	0.20	6.10								
	WEEK 28	57	2.65	2.40	1.65	0.00	7.00	57	2.33	1.54	0.32	0.20	1.17	-3.30	3.10
	WEEK 52	40	2.40	2.15	1.61	0.30	8.40	40	2.32	1.59	0.08	0.15	1.07	-3.10	2.50
	LAST VISIT	125	2.16	1.90	1.36	0.30	8.50	121	2.08	1.34	0.10	0.00	1.14	-3.10	4.50

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=ERYTHROCYTES (10^12/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	___BASELINE____ MEAN	___BASELINE____ MEDIAN	___BASELINE____ SD	___BASELINE____ MIN	___BASELINE____ MAX
ARIP IMD	BASELINE	126	4.76	4.70	0.46	3.80	5.90								
	WEEK 28	77	4.67	4.70	0.42	3.80	5.60	72	4.69	0.44	-0.01	0.00	0.27	-1.00	0.70
	WEEK 52	63	4.69	4.70	0.45	3.90	5.60	58	4.72	0.44	-0.02	0.00	0.29	-0.70	0.70
	LAST VISIT	124	4.73	4.70	0.46	3.90	5.80	118	4.74	0.46	-0.01	0.00	0.30	-0.70	0.70
PLACEBO	BASELINE	129	4.83	4.80	0.55	3.90	6.60								
	WEEK 28	57	4.86	4.80	0.55	3.70	6.30	57	4.87	0.58	-0.01	0.10	0.25	-0.50	0.60
	WEEK 52	40	4.89	4.90	0.60	3.80	6.50	40	4.89	0.64	-0.00	0.00	0.29	-0.60	0.70
	LAST VISIT	125	4.83	4.80	0.55	3.80	6.50	121	4.82	0.55	-0.00	0.00	0.32	-0.80	1.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=HEMATOCRIT (%)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	125	42.44	42.00	4.06	31.00	53.00								
	WEEK 28	77	41.77	42.00	4.11	28.00	53.00	71	41.96	4.17	-0.17	0.00	3.11	-9.00	7.00
	WEEK 52	63	41.90	42.00	4.15	29.00	51.00	57	42.32	3.96	-0.33	0.00	3.04	-7.00	11.00
	LAST VISIT	124	42.24	42.00	4.05	29.00	51.00	117	42.34	4.07	-0.12	0.00	3.00	-7.00	11.00
PLACEBO	BASELINE	129	42.69	42.00	4.79	31.00	54.00								
	WEEK 28	57	42.86	42.00	4.44	31.00	56.00	57	42.86	4.64	0.00	0.00	2.69	-5.00	10.00
	WEEK 52	40	43.25	43.50	4.20	34.00	54.00	40	43.00	4.62	0.25	0.50	3.42	-6.00	7.00
	LAST VISIT	125	42.79	43.00	4.66	32.00	56.00	121	42.50	4.69	0.17	0.00	3.41	-8.00	10.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=HEMOGLOBIN (g/dL)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ARIP IMD	BASELINE	126	14.17	13.90	1.56	9.70	18.40								
	WEEK 28	77	13.94	14.00	1.53	8.70	17.70	72	14.01	1.55	-0.06	0.00	0.88	-2.20	2.60
	WEEK 52	63	14.02	14.10	1.53	8.40	17.60	58	14.14	1.48	-0.09	-0.15	0.87	-2.70	3.00
	LAST VISIT	124	14.10	14.00	1.57	8.40	17.80	118	14.17	1.55	-0.07	-0.10	0.90	-2.70	3.00
PLACEBO	BASELINE	129	14.19	14.20	1.68	9.60	18.00								
	WEEK 28	57	14.29	14.20	1.50	10.10	17.90	57	14.23	1.57	0.05	0.00	0.78	-1.40	2.10
	WEEK 52	40	14.25	14.35	1.53	11.40	17.30	40	14.32	1.64	-0.06	-0.05	0.91	-1.90	1.90
	LAST VISIT	125	14.19	14.40	1.60	9.60	18.30	121	14.14	1.66	0.01	0.00	0.93	-2.10	3.10

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=LEUKOCYTES (10^9/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	126	7.35	6.86	2.12	3.77	13.70								
	WEEK 28	77	7.05	6.77	2.29	3.25	18.59	72	7.40	2.15	-0.36	-0.44	1.76	-4.04	6.94
	WEEK 52	63	6.93	6.72	1.99	3.31	14.11	58	7.42	2.21	-0.46	-0.43	1.60	-5.40	2.83
	LAST VISIT	124	7.19	6.83	2.03	3.31	14.11	118	7.32	2.16	-0.11	0.02	1.62	-5.40	4.08
PLACEBO	BASELINE	129	7.02	6.89	1.91	2.77	12.30								
	WEEK 28	57	6.95	6.45	2.65	2.92	20.70	57	6.84	1.95	0.10	0.02	2.09	-5.13	9.64
	WEEK 52	40	6.82	6.60	2.00	2.64	13.18	40	6.79	1.82	0.04	0.08	1.56	-3.14	3.07
	LAST VISIT	125	7.18	6.99	2.09	1.12	13.67	121	7.02	1.94	0.11	0.10	1.75	-4.23	5.26

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=LYMPHOCYTES (10^9/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	126	2.09	2.01	0.67	0.85	3.88								
	WEEK 28	77	2.10	2.14	0.54	1.01	3.73	72	2.05	0.61	0.06	0.06	0.36	-0.90	1.00
	WEEK 52	63	2.05	2.07	0.51	0.95	3.39	58	2.11	0.65	-0.04	0.05	0.49	-1.37	1.03
	LAST VISIT	124	2.11	2.07	0.57	0.95	3.80	118	2.10	0.67	0.03	0.06	0.49	-1.37	1.22
PLACEBO	BASELINE	129	2.05	1.93	0.65	0.81	4.71								
	WEEK 28	57	2.04	2.11	0.55	0.94	3.35	57	2.06	0.66	-0.02	0.03	0.57	-1.73	1.13
	WEEK 52	40	2.10	2.02	0.61	1.00	3.96	40	2.05	0.63	0.05	0.04	0.51	-1.30	1.14
	LAST VISIT	125	2.09	2.01	0.65	0.22	4.24	121	2.05	0.66	0.03	0.07	0.56	-1.63	1.79

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=LYMPHOCYTES/LEUKOCYTES (%)

									CHANGE FROM BASELINE						
								BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	29.44	29.00	8.18	10.10	55.10								
	WEEK 28	77	31.20	31.60	7.84	8.90	52.80	72	28.87	8.45	2.48	1.90	7.22	-16.40	26.00
	WEEK 52	63	30.77	29.60	8.26	15.20	55.50	58	29.58	8.55	1.49	1.15	7.39	-25.50	22.40
	LAST VISIT	124	30.36	29.60	7.74	15.20	55.50	118	29.66	8.18	0.82	0.20	7.54	-25.50	26.00
PLACEBO	BASELINE	129	30.02	28.50	8.36	14.80	61.00								
	WEEK 28	57	30.94	31.40	7.92	12.00	48.20	57	30.75	7.59	0.19	0.20	5.23	-12.90	10.90
	WEEK 52	40	31.74	30.40	8.46	18.60	52.10	40	30.96	8.01	0.78	-0.10	6.24	-13.40	13.50
	LAST VISIT	125	30.17	29.30	8.54	10.70	57.10	121	30.08	8.58	0.09	0.20	7.07	-19.00	22.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=MONOCYTES (10^9/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE							
								n[2]	BASELINE MEAN	BASELINE SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	0.39	0.38	0.15	0.12	0.90								
	WEEK 28	77	0.38	0.37	0.15	0.14	0.92	72	0.39	0.14	-0.00	-0.01	0.14	-0.52	0.34
	WEEK 52	63	0.37	0.36	0.13	0.11	0.65	58	0.39	0.13	-0.02	0.00	0.11	-0.44	0.20
	LAST VISIT	124	0.39	0.36	0.15	0.11	1.25	118	0.39	0.15	0.00	0.00	0.15	-0.52	0.73
PLACEBO	BASELINE	129	0.39	0.37	0.14	0.09	0.83								
	WEEK 28	57	0.43	0.39	0.19	0.15	1.19	57	0.37	0.15	0.06	0.04	0.14	-0.20	0.61
	WEEK 52	40	0.39	0.37	0.14	0.18	0.67	40	0.35	0.14	0.03	0.01	0.12	-0.26	0.29
	LAST VISIT	125	0.40	0.39	0.15	0.07	1.03	121	0.38	0.14	0.02	0.00	0.14	-0.31	0.59

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=MONOCYTES/LEUKOCYTES (%)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	126	5.45	5.10	1.89	2.00	12.90								
	WEEK 28	77	5.56	5.10	1.79	2.70	11.90	72	5.42	1.91	0.19	0.10	1.99	-8.30	6.10
	WEEK 52	63	5.42	5.10	1.74	2.30	10.40	58	5.45	1.84	0.11	0.10	1.40	-4.90	3.60
	LAST VISIT	124	5.45	5.15	1.62	2.30	10.40	118	5.47	1.93	0.05	0.05	1.73	-6.10	6.10
PLACEBO	BASELINE	129	5.55	5.30	1.54	2.00	10.20								
	WEEK 28	57	6.15	6.10	1.63	3.80	9.90	57	5.34	1.58	0.81	0.80	1.56	-3.30	4.20
	WEEK 52	40	5.80	5.65	1.67	2.70	9.30	40	5.25	1.67	0.55	0.35	1.66	-2.50	4.20
	LAST VISIT	125	5.70	5.40	1.64	2.70	13.30	121	5.45	1.50	0.27	0.20	1.73	-3.50	7.20

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=NEUTROPHILS (10^9/L)

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
ARIP IMD	BASELINE	126	4.66	4.33	1.77	1.83	10.89								
	WEEK 28	77	4.35	4.01	2.02	1.49	15.61	72	4.74	1.90	-0.41	-0.38	1.64	-4.48	6.44
	WEEK 52	63	4.31	4.17	1.72	1.51	11.08	58	4.68	1.90	-0.39	-0.29	1.46	-4.55	4.18
	LAST VISIT	124	4.48	4.29	1.66	1.51	11.08	118	4.62	1.79	-0.14	0.04	1.49	-4.55	4.18
PLACEBO	BASELINE	129	4.40	4.14	1.54	1.03	8.95								
	WEEK 28	57	4.26	3.80	2.28	1.78	17.18	57	4.22	1.48	0.04	-0.11	1.74	-3.94	9.72
	WEEK 52	40	4.13	3.98	1.59	1.17	9.26	40	4.18	1.45	-0.05	-0.22	1.23	-2.78	2.57
	LAST VISIT	125	4.49	4.15	1.73	0.82	10.14	121	4.41	1.57	0.05	0.03	1.45	-4.14	4.64

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=NEUTROPHILS/LEUKOCYTES (%)

									CHANGE FROM BASELINE					
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	126	62.21	61.80	9.00	35.10	84.70								
	WEEK 28	77	60.10	59.60	8.76	35.70	83.90	72	62.68	9.54	-2.87	-1.85	8.55	-34.10	14.90
	WEEK 52	63	60.76	61.40	8.79	34.00	78.50	58	61.88	9.44	-1.66	-0.95	8.30	-26.60	27.70
	LAST VISIT	124	61.20	61.70	8.14	34.00	78.50	118	61.94	8.99	-0.99	-0.35	8.68	-34.10	27.70
PLACEBO	BASELINE	129	61.70	62.70	8.51	31.00	76.30								
	WEEK 28	57	59.67	59.50	8.43	40.60	83.00	57	60.93	7.58	-1.26	-1.50	5.74	-12.50	15.60
	WEEK 52	40	59.44	59.10	9.23	39.80	72.80	40	60.76	8.06	-1.32	-1.10	7.25	-14.20	14.50
	LAST VISIT	125	61.34	62.00	9.39	37.80	83.30	121	61.81	8.75	-0.51	-0.60	7.79	-25.40	20.40

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-142　血液学的検査値の記述統計量［二重盲検試験の二重盲検期（Phase D）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=PLATELETS (10^9/L)

			CHANGE FROM BASELINE										
			BASELINE										
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	124	269.31	264.50	66.07	102.00	453.00								
	WEEK 28	76	261.07	255.50	62.50	115.00	485.00	71	268.06	56.29	-7.85	-6.00	40.38	-148.00	99.00
	WEEK 52	63	257.73	257.00	70.38	69.00	486.00	57	270.58	59.38	-14.98	-9.00	41.58	-194.00	69.00
	LAST VISIT	124	261.80	257.50	69.72	69.00	486.00	116	267.90	67.41	-6.65	-3.00	44.90	-194.00	125.00
PLACEBO	BASELINE	129	261.98	255.00	59.84	137.00	475.00								
	WEEK 28	56	254.79	236.50	76.70	110.00	496.00	56	252.36	65.18	2.43	5.50	45.98	-88.00	142.00
	WEEK 52	40	246.60	242.50	61.78	146.00	474.00	40	245.38	55.25	1.23	2.50	44.96	-86.00	199.00
	LAST VISIT	124	264.24	250.00	64.27	146.00	474.00	120	262.51	61.45	2.61	2.50	41.89	-86.00	199.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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＜資料番号 5.3.5.1-01：CT-13.2.2＞

表 2.7.4.7-143　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-13.1.2
Incidence of Laboratory Values of Potential Clinical Relevance in Phase D - High or Low
(Phase D Safety Sample)

			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
	TEST(UNITS)[1]		Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	HIGH	125	0	(0.0)	126	2	(1.6)	251	2	(0.8)
	ALKALINE PHOSPHATASE (U/L)	HIGH	125	0	(0.0)	126	0	(0.0)	251	0	(0.0)
	ASPARTATE AMINOTRANSFERASE (U/L)	HIGH	125	1	(0.8)	125	0	(0.0)	250	1	(0.4)
	BILIRUBIN (mg/dL)	HIGH	122	0	(0.0)	124	1	(0.8)	246	1	(0.4)
	BLOOD UREA NITROGEN (mg/dL)	HIGH	125	2	(1.6)	126	1	(0.8)	251	3	(1.2)
	CALCIUM (mg/dL)	LOW	125	1	(0.8)	126	0	(0.0)	251	1	(0.4)
		HIGH	125	0	(0.0)	126	0	(0.0)	251	0	(0.0)
	CHLORIDE (mEq/L)	LOW	124	0	(0.0)	126	0	(0.0)	250	0	(0.0)
		HIGH	124	0	(0.0)	126	0	(0.0)	250	0	(0.0)
	CHOLESTEROL, FASTING (mg/dL)	HIGH	109	13	(11.9)	111	15	(13.5)	220	28	(12.7)
	CREATINE KINASE (U/L)	HIGH	125	9	(7.2)	126	7	(5.6)	251	16	(6.4)
	CREATININE (mg/dL)	HIGH	125	0	(0.0)	126	1	(0.8)	251	1	(0.4)
	GLUCOSE (mg/dL)	HIGH	27	0	(0.0)	28	0	(0.0)	55	0	(0.0)
	GLUCOSE, FASTING (mg/dL)	HIGH	112	14	(12.5)	111	17	(15.3)	223	31	(13.9)
	HDL CHOLESTEROL, FASTING (mg/dL)	LOW	109	3	(2.8)	111	6	(5.4)	220	9	(4.1)
	LACTATE DEHYDROGENASE (U/L)	HIGH	122	0	(0.0)	122	0	(0.0)	244	0	(0.0)
	LDL CHOLESTEROL, FASTING (mg/dL)	HIGH	108	12	(11.1)	108	14	(13.0)	216	26	(12.0)
	POTASSIUM (mEq/L)	LOW	124	0	(0.0)	125	1	(0.8)	249	1	(0.4)
		HIGH	124	2	(1.6)	125	2	(1.6)	249	4	(1.6)
	PROLACTIN (ng/mL)	HIGH	117	4	(3.4)	117	8	(6.8)	234	12	(5.1)
	SODIUM (mEq/L)	LOW	124	0	(0.0)	126	0	(0.0)	250	0	(0.0)
		HIGH	124	0	(0.0)	126	0	(0.0)	250	0	(0.0)
	TRIGLYCERIDES, FASTING (mg/dL)	HIGH	109	45	(41.3)	111	42	(37.8)	220	87	(39.5)
	URATE (mg/dL)	HIGH	125	2	(1.6)	126	3	(2.4)	251	5	(2.0)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3AB.LIS, RUN: [redacted]20[redacted] 14:31; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.1.2　FINAL

表 2.7.4.7-143　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の二重盲検期（Phase D）］

CT-13.1.2
Incidence of Laboratory Values of Potential Clinical Relevance in Phase D - High or Low
(Phase D Safety Sample)

			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
	TEST(UNITS)[1]		Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	HIGH	124	2	(1.6)	125	0	(0.0)	249	2	(0.8)
	HEMATOCRIT (%)	LOW	117	1	(0.9)	121	2	(1.7)	238	3	(1.3)
	HEMOGLOBIN (g/dL)	LOW	124	1	(0.8)	125	1	(0.8)	249	2	(0.8)
	LEUKOCYTES (10^9/L)	LOW	124	0	(0.0)	125	2	(1.6)	249	2	(0.8)
		HIGH	124	1	(0.8)	125	1	(0.8)	249	2	(0.8)
	NEUTROPHILS (10^9/L)	LOW	124	1	(0.8)	125	3	(2.4)	249	4	(1.6)
	PLATELETS (10^9/L)	LOW	124	1	(0.8)	124	0	(0.0)	248	1	(0.4)
		HIGH	124	0	(0.0)	124	0	(0.0)	248	0	(0.0)
URINALYSIS	GLUCOSE	HIGH	116	0	(0.0)	124	0	(0.0)	240	0	(0.0)
	PROTEIN	HIGH	116	2	(1.7)	124	1	(0.8)	240	3	(1.3)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3AB.LIS, RUN: [redacted]20[redacted] 14:31; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.1.2　FINAL

＜資料番号 5.3.5.1-01：CT-13.1.2＞

表 2.7.4.7-144　白血球減少関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.7
Incidence of Treatment-emergent Adverse Events Related to WBC Abnormalities in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
血液およびリンパ系障害	TOTAL1)	1	(0.8)	1	(0.8)	2	(0.8)
	白血球減少症	1	(0.8)	0	(0.0)	1	(0.4)
	好中球減少症	1	(0.8)	1	(0.8)	2	(0.8)
TOTAL2)		1	(0.8)	1	(0.8)	2	(0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AH.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.7　FINAL

表 2.7.4.7-144　白血球減少関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.7
Incidence of Treatment-emergent Adverse Events Related to WBC Abnormalities in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO WBC ABNORMALITIES: MEDDRA 19.0 PRIMARY TERMS

LEUKOPENIA, NEUTROPENIA, AGRANULOCYTOSIS

FILE: ADAE3AH.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.7　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.5.7 より作成＞

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=BASOPHILS (10^9/L)

									CHANGE FROM BASELINE						
								BASELINE							
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	584	0.05	0.04	0.03	0.00	0.30								
	WEEK 2	165	0.05	0.04	0.03	0.00	0.23	146	0.05	0.03	-0.00	0.00	0.03	-0.15	0.07
	WEEK 4	141	0.05	0.04	0.03	0.00	0.18	135	0.05	0.03	-0.00	0.00	0.03	-0.12	0.06
	WEEK 6	104	0.05	0.04	0.03	0.00	0.19	99	0.05	0.03	-0.00	0.00	0.04	-0.15	0.14
	WEEK 8	136	0.04	0.04	0.02	0.00	0.12	133	0.05	0.03	-0.00	0.00	0.03	-0.15	0.08
	LAST VISIT	537	0.05	0.04	0.03	0.00	0.23	511	0.05	0.03	-0.00	0.00	0.03	-0.15	0.14
PHASE C	BASELINE	416	0.04	0.04	0.03	0.00	0.19								
	WEEK 12	221	0.04	0.04	0.02	0.00	0.16	214	0.04	0.02	0.00	0.00	0.02	-0.11	0.11
	WEEK 28	8	0.05	0.04	0.04	0.02	0.12	8	0.04	0.02	0.01	0.00	0.02	-0.01	0.05
	LAST VISIT	373	0.05	0.04	0.03	0.00	0.17	364	0.04	0.03	0.00	0.00	0.03	-0.13	0.12

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=BASOPHILS/LEUKOCYTES (%)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	0.67	0.60	0.41	0.00	3.00								
	WEEK 2	165	0.64	0.60	0.32	0.00	2.80	146	0.71	0.43	-0.08	0.00	0.42	-1.80	1.10
	WEEK 4	141	0.64	0.60	0.36	0.00	2.00	135	0.69	0.39	-0.04	0.00	0.34	-1.10	1.00
	WEEK 6	104	0.63	0.50	0.36	0.10	1.90	99	0.62	0.37	-0.02	0.00	0.45	-2.10	1.30
	WEEK 8	136	0.62	0.60	0.32	0.00	1.80	133	0.69	0.43	-0.08	-0.10	0.45	-1.90	1.20
	LAST VISIT	537	0.63	0.60	0.33	0.00	2.80	511	0.68	0.41	-0.06	0.00	0.41	-2.10	1.30
PHASE C	BASELINE	416	0.61	0.50	0.31	0.00	2.00								
	WEEK 12	221	0.61	0.60	0.30	0.00	1.80	214	0.60	0.27	0.00	0.00	0.32	-1.60	1.20
	WEEK 28	8	0.63	0.50	0.23	0.40	0.90	8	0.49	0.18	0.14	0.10	0.18	-0.10	0.40
	LAST VISIT	373	0.63	0.60	0.35	0.00	2.40	364	0.61	0.32	0.02	0.00	0.39	-1.60	2.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=EOSINOPHILS (10^9/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	0.16	0.13	0.11	0.00	0.86								
	WEEK 2	165	0.16	0.12	0.11	0.01	0.61	146	0.15	0.11	0.00	0.00	0.09	-0.52	0.24
	WEEK 4	141	0.16	0.13	0.09	0.01	0.52	135	0.17	0.11	-0.02	-0.01	0.09	-0.48	0.24
	WEEK 6	104	0.15	0.12	0.10	0.01	0.57	99	0.16	0.11	-0.01	0.00	0.06	-0.25	0.18
	WEEK 8	136	0.15	0.12	0.14	0.00	1.27	133	0.16	0.12	-0.01	-0.01	0.09	-0.22	0.41
	LAST VISIT	537	0.15	0.12	0.11	0.00	1.27	511	0.16	0.11	-0.01	-0.01	0.09	-0.52	0.43
PHASE C	BASELINE	416	0.15	0.12	0.11	0.00	1.27								
	WEEK 12	221	0.16	0.13	0.12	0.00	1.17	214	0.16	0.12	0.00	0.00	0.08	-0.20	0.33
	WEEK 28	8	0.15	0.15	0.10	0.02	0.32	8	0.11	0.06	0.04	0.03	0.06	-0.04	0.16
	LAST VISIT	373	0.15	0.13	0.12	0.00	1.17	364	0.15	0.11	0.00	0.00	0.09	-0.40	0.70

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=EOSINOPHILS/LEUKOCYTES (%)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	584	2.35	1.90	1.63	0.00	12.40								
	WEEK 2	165	2.10	1.80	1.33	0.20	9.00	146	2.14	1.41	-0.03	-0.10	1.25	-8.40	3.20
	WEEK 4	141	2.32	1.90	1.70	0.20	13.50	135	2.57	1.97	-0.25	-0.20	1.47	-7.80	4.60
	WEEK 6	104	2.07	1.65	1.37	0.10	7.60	99	2.19	1.51	-0.12	-0.10	0.83	-2.40	2.00
	WEEK 8	136	2.12	1.60	1.82	0.00	15.20	133	2.34	1.59	-0.22	-0.30	1.27	-4.90	4.70
	LAST VISIT	537	2.16	1.70	1.58	0.00	15.20	511	2.33	1.65	-0.15	-0.10	1.28	-8.40	5.00
PHASE C	BASELINE	416	2.08	1.70	1.46	0.00	15.20								
	WEEK 12	221	2.16	1.80	1.49	0.00	13.00	214	2.16	1.56	-0.00	0.00	1.07	-2.30	4.30
	WEEK 28	8	2.16	1.70	1.64	0.60	5.50	8	1.55	1.17	0.61	0.30	1.04	-0.80	2.70
	LAST VISIT	373	2.14	1.70	1.61	0.00	16.00	364	2.06	1.47	0.08	0.00	1.33	-5.30	12.80

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=ERYTHROCYTES (10^12/L)

								CHANGE FROM BASELINE							
								BASELINE							
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	584	4.68	4.60	0.50	2.70	6.30								
	WEEK 2	165	4.69	4.70	0.53	3.50	6.50	146	4.73	0.53	-0.03	0.00	0.26	-1.20	0.60
	WEEK 4	141	4.77	4.70	0.57	3.30	6.50	135	4.71	0.58	0.05	0.00	0.29	-0.80	1.50
	WEEK 6	104	4.73	4.70	0.45	3.80	6.10	99	4.67	0.44	0.04	0.00	0.24	-0.70	0.80
	WEEK 8	136	4.66	4.60	0.45	3.50	5.80	133	4.61	0.44	0.04	0.00	0.29	-0.80	0.90
	LAST VISIT	537	4.71	4.70	0.51	3.30	6.50	511	4.68	0.51	0.02	0.00	0.27	-1.20	1.50
PHASE C	BASELINE	416	4.71	4.70	0.51	3.30	6.50								
	WEEK 12	221	4.80	4.80	0.52	3.80	6.60	214	4.73	0.53	0.07	0.10	0.27	-0.60	0.90
	WEEK 28	8	4.69	4.50	0.69	4.00	5.70	8	4.55	0.29	0.14	0.05	0.60	-0.90	1.00
	LAST VISIT	373	4.76	4.70	0.50	3.80	6.60	364	4.70	0.50	0.06	0.00	0.28	-0.90	1.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=HEMATOCRIT (%)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	582	41.78	42.00	4.36	26.00	57.00								
	WEEK 2	165	41.91	42.00	4.87	28.00	57.00	145	42.50	4.80	-0.39	0.00	2.52	-9.00	5.00
	WEEK 4	140	42.15	42.00	5.12	31.00	57.00	134	41.95	4.87	0.29	0.00	2.72	-7.00	14.00
	WEEK 6	103	42.29	42.00	4.27	31.00	53.00	98	41.73	4.11	0.45	0.00	2.44	-7.00	9.00
	WEEK 8	136	41.37	41.00	4.05	32.00	52.00	131	41.15	4.16	0.15	0.00	2.70	-9.00	7.00
	LAST VISIT	535	41.91	42.00	4.52	31.00	57.00	507	41.83	4.49	0.10	0.00	2.63	-9.00	14.00
PHASE C	BASELINE	414	42.04	42.00	4.55	31.00	57.00								
	WEEK 12	220	42.52	42.00	4.36	31.00	53.00	213	42.03	4.39	0.54	1.00	2.77	-7.00	9.00
	WEEK 28	8	39.00	38.00	7.29	31.00	51.00	8	39.63	5.32	-0.63	-0.50	5.13	-9.00	8.00
	LAST VISIT	372	42.28	42.00	4.60	28.00	54.00	362	41.97	4.55	0.37	0.00	2.88	-9.00	9.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=HEMOGLOBIN (g/dL)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	13.89	13.80	1.55	8.70	18.20								
	WEEK 2	165	14.01	14.00	1.66	9.20	17.60	146	14.09	1.67	-0.06	0.10	0.73	-3.60	1.80
	WEEK 4	141	14.05	14.00	1.81	9.00	18.80	135	13.99	1.74	0.08	0.10	0.88	-2.60	4.20
	WEEK 6	104	14.11	13.95	1.51	9.90	17.30	99	13.94	1.43	0.15	0.10	0.73	-1.70	2.30
	WEEK 8	136	13.76	13.75	1.54	10.00	17.10	133	13.69	1.52	0.06	0.00	0.86	-2.50	2.30
	LAST VISIT	537	13.98	13.90	1.61	9.00	18.80	511	13.92	1.60	0.05	0.10	0.81	-3.60	4.20
PHASE C	BASELINE	416	14.02	14.00	1.62	9.00	18.80								
	WEEK 12	221	14.18	14.20	1.58	9.70	17.50	214	14.07	1.57	0.14	0.10	0.75	-1.90	2.20
	WEEK 28	8	12.88	13.20	2.86	9.60	17.20	8	12.96	1.73	-0.09	-0.50	1.89	-2.60	2.50
	LAST VISIT	373	14.08	14.10	1.66	8.40	18.40	364	13.99	1.63	0.12	0.10	0.81	-2.60	2.90

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=LEUKOCYTES (10^9/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	7.16	6.96	2.01	2.26	15.60								
	WEEK 2	165	7.49	7.24	2.27	2.27	15.08	146	7.27	2.11	0.24	-0.05	1.78	-3.65	6.80
	WEEK 4	141	7.23	6.87	2.17	2.58	12.96	135	7.10	2.14	0.08	0.10	1.67	-6.23	4.06
	WEEK 6	104	7.23	7.13	2.16	3.27	16.51	99	7.29	2.01	-0.07	-0.19	1.51	-3.51	8.57
	WEEK 8	136	7.35	7.08	2.26	3.35	15.74	133	6.99	1.91	0.39	0.13	1.98	-7.43	7.90
	LAST VISIT	537	7.34	7.11	2.15	3.14	16.51	511	7.17	1.98	0.17	0.03	1.75	-7.43	8.57
PHASE C	BASELINE	416	7.42	7.15	2.11	3.14	16.51								
	WEEK 12	221	7.37	7.22	2.08	2.77	14.72	214	7.27	2.04	0.11	0.27	1.69	-6.83	5.31
	WEEK 28	8	7.24	6.72	2.87	3.31	12.96	8	7.78	3.27	-0.54	0.12	2.18	-5.45	1.81
	LAST VISIT	373	7.29	7.01	2.05	2.77	14.72	364	7.37	2.11	-0.08	-0.04	1.68	-6.83	5.31

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.2 FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=LYMPHOCYTES (10^9/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: SD	BASELINE: MEAN	BASELINE: MEDIAN	BASELINE: SD	BASELINE: MIN	BASELINE: MAX
PHASE B	BASELINE	584	2.10	2.03	0.61	0.81	4.92								
	WEEK 2	165	2.15	2.07	0.60	1.06	4.45	146	2.12	0.62	0.02	0.02	0.44	-1.61	1.34
	WEEK 4	141	2.02	1.94	0.63	0.73	4.06	135	2.16	0.65	-0.14	-0.10	0.46	-1.95	0.82
	WEEK 6	104	2.05	2.06	0.58	0.85	3.73	99	2.12	0.63	-0.09	-0.11	0.50	-1.56	1.29
	WEEK 8	136	2.00	1.88	0.53	0.93	4.72	133	2.00	0.52	-0.00	-0.04	0.51	-1.94	2.05
	LAST VISIT	537	2.06	2.00	0.58	0.73	4.72	511	2.11	0.60	-0.06	-0.06	0.48	-1.95	2.05
PHASE C	BASELINE	416	2.07	2.00	0.59	0.73	4.72								
	WEEK 12	221	2.10	1.99	0.63	0.81	4.15	214	2.09	0.58	0.03	-0.02	0.44	-0.98	1.62
	WEEK 28	8	2.06	1.98	0.78	0.93	3.22	8	2.18	0.67	-0.12	-0.27	0.52	-0.76	0.73
	LAST VISIT	373	2.04	1.96	0.65	0.81	4.71	364	2.07	0.60	-0.02	-0.04	0.45	-1.29	1.62

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-22.3.2 FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=LYMPHOCYTES/LEUKOCYTES (%)

			CHANGE FROM BASELINE									
			BASELINE									
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	584	30.43	29.40	8.15	10.20	70.00								
	WEEK 2	165	29.96	29.70	7.82	12.40	54.60	146	30.24	7.83	-0.66	0.00	6.73	-23.90	13.70
	WEEK 4	141	29.27	28.90	8.55	9.30	48.30	135	31.58	8.21	-2.17	-1.80	6.35	-24.70	13.70
	WEEK 6	104	29.54	29.70	8.00	14.20	57.60	99	30.14	8.62	-0.85	-0.60	6.45	-20.20	17.60
	WEEK 8	136	28.55	27.65	7.63	11.80	51.70	133	29.84	8.00	-1.46	-1.20	8.07	-40.00	31.50
	LAST VISIT	537	29.26	29.00	7.91	9.30	58.00	511	30.50	8.11	-1.36	-1.10	7.06	-40.00	31.50
PHASE C	BASELINE	416	28.92	28.90	7.84	9.30	57.60								
	WEEK 12	221	29.60	28.80	8.35	10.10	60.00	214	29.89	8.13	-0.14	-0.50	6.66	-22.80	23.90
	WEEK 28	8	31.65	29.70	15.22	11.20	61.00	8	30.76	12.95	0.89	2.70	5.03	-7.00	6.90
	LAST VISIT	373	28.93	28.30	8.42	9.60	61.00	364	29.15	7.83	-0.11	-0.65	6.60	-22.80	23.90

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=MONOCYTES (10^9/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	0.40	0.38	0.16	0.08	1.24								
	WEEK 2	165	0.41	0.37	0.16	0.08	0.99	146	0.40	0.21	0.00	0.00	0.16	-0.64	0.61
	WEEK 4	141	0.39	0.35	0.15	0.11	0.96	135	0.39	0.17	-0.00	0.00	0.12	-0.59	0.38
	WEEK 6	104	0.38	0.36	0.13	0.17	0.88	99	0.40	0.12	-0.02	-0.04	0.13	-0.43	0.40
	WEEK 8	136	0.42	0.38	0.18	0.14	1.30	133	0.41	0.15	0.01	0.00	0.15	-0.44	0.64
	LAST VISIT	537	0.40	0.37	0.15	0.09	1.01	511	0.40	0.16	-0.00	0.00	0.14	-0.64	0.61
PHASE C	BASELINE	416	0.40	0.37	0.16	0.11	1.01								
	WEEK 12	221	0.40	0.38	0.16	0.09	1.08	214	0.39	0.15	0.01	0.01	0.14	-0.61	0.51
	WEEK 28	8	0.35	0.34	0.12	0.22	0.57	8	0.47	0.24	-0.12	-0.07	0.17	-0.39	0.07
	LAST VISIT	373	0.39	0.37	0.15	0.09	1.08	364	0.40	0.16	-0.00	0.00	0.14	-0.61	0.51

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=MONOCYTES/LEUKOCYTES (%)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	5.73	5.40	1.86	1.00	13.90								
	WEEK 2	165	5.52	5.20	1.80	1.90	14.20	146	5.57	2.12	-0.08	-0.10	1.67	-5.20	4.70
	WEEK 4	141	5.54	5.30	1.69	2.10	11.50	135	5.61	1.75	-0.05	-0.20	1.52	-4.20	5.10
	WEEK 6	104	5.36	5.10	1.45	2.90	11.20	99	5.73	1.63	-0.33	-0.30	1.62	-5.70	4.40
	WEEK 8	136	5.79	5.40	2.10	2.20	14.50	133	5.98	1.91	-0.23	-0.30	1.74	-7.10	4.90
	LAST VISIT	537	5.57	5.30	1.81	1.90	14.50	511	5.69	1.84	-0.14	-0.20	1.62	-7.10	5.10
PHASE C	BASELINE	416	5.51	5.20	1.80	1.90	14.50								
	WEEK 12	221	5.53	5.20	1.78	2.00	12.90	214	5.55	1.86	0.02	0.00	1.57	-5.70	6.40
	WEEK 28	8	5.19	5.15	1.55	2.70	7.70	8	5.96	1.08	-0.78	-0.45	1.61	-3.30	1.00
	LAST VISIT	373	5.46	5.30	1.63	2.00	12.90	364	5.49	1.72	-0.02	0.00	1.58	-5.70	6.40

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=NEUTROPHILS (10^9/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	4.44	4.25	1.65	0.88	10.80								
	WEEK 2	165	4.73	4.56	1.85	0.88	12.35	146	4.54	1.66	0.22	0.07	1.56	-3.12	6.18
	WEEK 4	141	4.62	4.34	1.87	1.28	9.23	135	4.33	1.73	0.24	0.21	1.51	-4.86	5.13
	WEEK 6	104	4.60	4.42	1.80	1.39	12.72	99	4.56	1.66	0.06	-0.05	1.32	-3.50	7.41
	WEEK 8	136	4.74	4.45	1.89	1.44	10.14	133	4.37	1.61	0.40	0.23	1.76	-7.23	5.80
	LAST VISIT	537	4.68	4.44	1.81	1.24	12.72	511	4.45	1.63	0.24	0.14	1.55	-7.23	7.41
PHASE C	BASELINE	416	4.76	4.52	1.78	1.32	12.72								
	WEEK 12	221	4.66	4.47	1.74	1.48	11.14	214	4.59	1.72	0.07	0.12	1.47	-5.90	4.79
	WEEK 28	8	4.63	4.15	2.55	1.03	9.10	8	4.99	2.75	-0.36	-0.23	1.93	-4.51	2.25
	LAST VISIT	373	4.66	4.40	1.70	1.03	11.14	364	4.70	1.75	-0.06	-0.06	1.47	-5.90	4.79

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=NEUTROPHILS/LEUKOCYTES (%)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	584	60.81	61.70	8.68	23.00	85.20								
	WEEK 2	165	61.78	62.40	8.43	34.80	81.90	146	61.34	8.21	0.86	0.80	7.57	-14.70	29.70
	WEEK 4	141	62.23	62.80	9.55	38.30	86.00	135	59.55	9.17	2.51	2.90	7.41	-20.10	26.10
	WEEK 6	104	62.40	62.85	8.61	35.70	80.00	99	61.32	9.13	1.32	1.50	7.20	-19.40	22.40
	WEEK 8	136	62.93	63.80	8.50	34.60	80.20	133	61.15	8.47	1.99	1.70	8.89	-32.70	41.40
	LAST VISIT	537	62.39	63.00	8.68	34.60	86.00	511	60.80	8.65	1.71	1.60	7.88	-32.70	41.40
PHASE C	BASELINE	416	62.89	63.30	8.56	35.70	86.00								
	WEEK 12	221	62.09	62.20	8.86	34.00	84.70	214	61.80	8.76	0.11	0.30	7.19	-21.30	24.00
	WEEK 28	8	60.31	62.50	16.67	31.00	84.90	8	61.25	12.97	-0.94	-3.80	6.75	-7.40	10.90
	LAST VISIT	373	62.84	62.80	9.08	31.00	84.90	364	62.70	8.55	0.02	0.20	7.38	-28.30	24.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BB.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

表 2.7.4.7-145　血液学的検査値の記述統計量［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.3.2
Laboratory Test Results for Hematology - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=PLATELETS (10^9/L)

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE B	BASELINE	583	272.55	263.00	68.87	121.00	569.00								
	WEEK 2	165	272.20	265.00	69.80	120.00	553.00	146	268.60	65.57	2.35	-1.00	36.44	-78.00	117.00
	WEEK 4	139	276.09	269.00	71.62	136.00	503.00	133	274.33	74.01	-1.03	3.00	38.72	-127.00	80.00
	WEEK 6	104	284.73	286.50	74.03	105.00	515.00	99	280.26	69.96	4.62	8.00	46.18	-145.00	152.00
	WEEK 8	136	273.03	261.50	76.99	118.00	545.00	133	267.80	67.28	6.39	4.00	43.79	-138.00	122.00
	LAST VISIT	535	275.61	267.00	72.87	105.00	553.00	509	272.31	69.05	3.09	3.00	40.82	-145.00	152.00
PHASE C	BASELINE	414	274.33	267.00	71.37	105.00	553.00								
	WEEK 12	219	269.35	259.00	64.32	137.00	475.00	212	272.17	68.83	-3.08	-4.00	41.80	-144.00	116.00
	WEEK 28	8	279.75	275.00	58.97	210.00	410.00	8	286.38	72.95	-6.63	-22.00	39.32	-51.00	54.00
	LAST VISIT	371	269.79	261.00	67.13	102.00	525.00	360	273.39	72.04	-4.24	-5.00	43.97	-149.00	152.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.2　FINAL

＜資料番号 5.3.5.1-01：CT-22.3.2＞

表 2.7.4.7-146　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.2.1.2
Incidence of Laboratory Values of Potential Clinical Relevance - High or Low
(Phase B Safety Sample and Phase C Safety Sample)

	TEST(UNITS)[1]		PHASE B (N=614) Ne[2]	n[3]	(%)	PHASE C (N=425) Ne[2]	n[3]	(%)
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	HIGH	541	1	(0.2)	382	4	(1.0)
	ALKALINE PHOSPHATASE (U/L)	HIGH	542	0	(0.0)	383	0	(0.0)
	ASPARTATE AMINOTRANSFERASE (U/L)	HIGH	534	0	(0.0)	380	2	(0.5)
	BILIRUBIN (mg/dL)	HIGH	508	1	(0.2)	369	1	(0.3)
	BLOOD UREA NITROGEN (mg/dL)	HIGH	542	1	(0.2)	383	2	(0.5)
	CALCIUM (mg/dL)	LOW	542	3	(0.6)	383	1	(0.3)
		HIGH	542	0	(0.0)	383	0	(0.0)
	CHLORIDE (mEq/L)	LOW	542	0	(0.0)	375	0	(0.0)
		HIGH	542	0	(0.0)	375	0	(0.0)
	CHOLESTEROL, FASTING (mg/dL)	HIGH	469	51	(10.9)	311	33	(10.6)
	CREATINE KINASE (U/L)	HIGH	541	22	(4.1)	382	9	(2.4)
	CREATININE (mg/dL)	HIGH	542	0	(0.0)	383	0	(0.0)
	GLUCOSE (mg/dL)	HIGH	83	1	(1.2)	78	4	(5.1)
	GLUCOSE, FASTING (mg/dL)	HIGH	469	37	(7.9)	316	29	(9.2)
	HDL CHOLESTEROL, FASTING (mg/dL)	LOW	469	10	(2.1)	311	10	(3.2)
	LACTATE DEHYDROGENASE (U/L)	HIGH	522	0	(0.0)	371	0	(0.0)
	LDL CHOLESTEROL, FASTING (mg/dL)	HIGH	463	43	(9.3)	306	27	(8.8)
	POTASSIUM (mEq/L)	LOW	541	1	(0.2)	374	0	(0.0)
		HIGH	541	10	(1.8)	374	6	(1.6)
	PROLACTIN (ng/mL)	HIGH	1	0	(0.0)	357	8	(2.2)
	SODIUM (mEq/L)	LOW	542	0	(0.0)	375	0	(0.0)
		HIGH	542	0	(0.0)	375	0	(0.0)
	TRIGLYCERIDES, FASTING (mg/dL)	HIGH	469	162	(34.5)	311	137	(44.1)
	URATE (mg/dL)	HIGH	542	5	(0.9)	383	6	(1.6)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3BB.LIS, RUN: [redacted]20[redacted] 14:31; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.2.1.2　FINAL

表 2.7.4.7-146　臨床的に重要な臨床検査値の変動を示した被験者の割合［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-22.2.1.2
Incidence of Laboratory Values of Potential Clinical Relevance - High or Low
(Phase B Safety Sample and Phase C Safety Sample)

	TEST(UNITS)[1]		PHASE B (N=614) Ne[2]	PHASE B (N=614) n[3]	PHASE B (N=614) (%)	PHASE C (N=425) Ne[2]	PHASE C (N=425) n[3]	PHASE C (N=425) (%)
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	HIGH	537	2	(0.4)	373	2	(0.5)
	HEMATOCRIT (%)	LOW	507	1	(0.2)	362	3	(0.8)
	HEMOGLOBIN (g/dL)	LOW	537	4	(0.7)	373	2	(0.5)
	LEUKOCYTES (10^9/L)	LOW	537	2	(0.4)	373	2	(0.5)
		HIGH	537	1	(0.2)	373	1	(0.3)
	NEUTROPHILS (10^9/L)	LOW	537	7	(1.3)	373	4	(1.1)
	PLATELETS (10^9/L)	LOW	535	0	(0.0)	371	0	(0.0)
		HIGH	535	0	(0.0)	371	0	(0.0)
URINALYSIS	GLUCOSE	HIGH	513	4	(0.8)	364	9	(2.5)
	PROTEIN	HIGH	513	0	(0.0)	364	5	(1.4)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3BB.LIS, RUN: [redacted]20[redacted] 14:31; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB3.SAS
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＜資料番号 5.3.5.1-01：CT-22.2.1.2＞

表 2.7.4.7-147　白血球減少関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.7
Incidence of Treatment-emergent Adverse Events Related to WBC Abnormalities
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
血液およびリンパ系障害	TOTAL1)	1	(0.2)	1	(0.2)
	好中球減少症	1	(0.2)	1	(0.2)
TOTAL2)		1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BH.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.7　FINAL

表 2.7.4.7-147　白血球減少関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.7
Incidence of Treatment-emergent Adverse Events Related to WBC Abnormalities
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO WBC ABNORMALITIES: MEDDRA 19.0 PRIMARY TERMS

LEUKOPENIA, NEUTROPENIA, AGRANULOCYTOSIS

FILE: ADAE3BH.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.7　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.5.7 より作成＞

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=BASOPHILS (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	0.05	0.04	0.03	0.00	0.22								
	WEEK 28	11	0.04	0.05	0.02	0.01	0.08	10	0.04	0.01	0.01	0.01	0.02	-0.03	0.04
	WEEK 52	219	0.05	0.04	0.03	0.00	0.27	213	0.05	0.03	-0.00	0.00	0.03	-0.15	0.24
	LAST VISIT	333	0.05	0.04	0.03	0.00	0.27	321	0.05	0.03	-0.00	0.00	0.03	-0.18	0.24
ROLLOVER	BASELINE	84	0.04	0.04	0.02	0.01	0.08								
	WEEK 28	43	0.04	0.04	0.02	0.01	0.11	43	0.04	0.02	0.00	0.00	0.02	-0.05	0.07
	WEEK 52	14	0.05	0.04	0.04	0.01	0.16	14	0.04	0.02	0.01	0.00	0.03	-0.03	0.09
	LAST VISIT	80	0.05	0.04	0.03	0.01	0.16	79	0.04	0.02	0.01	0.00	0.02	-0.05	0.09
TOTAL	BASELINE	450	0.05	0.04	0.03	0.00	0.22								
	WEEK 28	54	0.04	0.04	0.02	0.01	0.11	53	0.04	0.02	0.00	0.00	0.02	-0.05	0.07
	WEEK 52	233	0.05	0.04	0.03	0.00	0.27	227	0.05	0.03	-0.00	0.00	0.03	-0.15	0.24
	LAST VISIT	413	0.05	0.04	0.03	0.00	0.27	400	0.05	0.03	0.00	0.00	0.03	-0.18	0.24

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=BASOPHILS/LEUKOCYTES (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	0.67	0.60	0.37	0.00	2.60								
	WEEK 28	11	0.63	0.60	0.29	0.20	1.10	10	0.57	0.29	0.07	0.05	0.28	-0.40	0.60
	WEEK 52	219	0.67	0.60	0.38	0.00	3.30	213	0.69	0.36	-0.02	0.00	0.46	-1.90	2.90
	LAST VISIT	333	0.66	0.60	0.38	0.00	3.30	321	0.67	0.37	-0.01	0.00	0.46	-2.30	2.90
ROLLOVER	BASELINE	84	0.61	0.60	0.29	0.10	1.50								
	WEEK 28	43	0.67	0.60	0.33	0.10	1.60	43	0.61	0.29	0.06	0.10	0.35	-0.70	1.10
	WEEK 52	14	0.73	0.65	0.39	0.20	1.70	14	0.64	0.23	0.09	0.00	0.36	-0.60	0.90
	LAST VISIT	80	0.67	0.65	0.32	0.10	1.70	79	0.62	0.28	0.05	0.00	0.32	-0.70	1.00
TOTAL	BASELINE	450	0.66	0.60	0.36	0.00	2.60								
	WEEK 28	54	0.66	0.60	0.32	0.10	1.60	53	0.60	0.28	0.06	0.10	0.33	-0.70	1.10
	WEEK 52	233	0.67	0.60	0.38	0.00	3.30	227	0.69	0.36	-0.01	0.00	0.45	-1.90	2.90
	LAST VISIT	413	0.67	0.60	0.37	0.00	3.30	400	0.66	0.36	-0.00	0.00	0.44	-2.30	2.90

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=EOSINOPHILS (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	0.15	0.13	0.11	0.02	0.96								
	WEEK 28	11	0.12	0.11	0.05	0.04	0.20	10	0.13	0.06	-0.01	-0.00	0.09	-0.21	0.08
	WEEK 52	219	0.16	0.13	0.12	0.00	0.72	213	0.16	0.12	0.01	0.00	0.09	-0.35	0.38
	LAST VISIT	333	0.15	0.12	0.11	0.00	0.72	321	0.15	0.12	-0.00	-0.01	0.09	-0.35	0.38
ROLLOVER	BASELINE	84	0.15	0.12	0.11	0.01	0.78								
	WEEK 28	43	0.17	0.12	0.16	0.01	1.05	43	0.15	0.09	0.01	0.00	0.14	-0.26	0.76
	WEEK 52	14	0.26	0.18	0.23	0.05	0.89	14	0.21	0.20	0.05	0.04	0.05	-0.05	0.14
	LAST VISIT	80	0.18	0.14	0.16	0.01	1.05	79	0.16	0.12	0.03	0.02	0.11	-0.26	0.76
TOTAL	BASELINE	450	0.15	0.12	0.11	0.01	0.96								
	WEEK 28	54	0.16	0.12	0.15	0.01	1.05	53	0.15	0.09	0.01	0.00	0.13	-0.26	0.76
	WEEK 52	233	0.17	0.14	0.13	0.00	0.89	227	0.16	0.13	0.01	0.00	0.09	-0.35	0.38
	LAST VISIT	413	0.16	0.13	0.12	0.00	1.05	400	0.16	0.12	0.00	0.00	0.09	-0.35	0.76

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=EOSINOPHILS/LEUKOCYTES (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	2.18	1.80	1.43	0.20	12.00								
	WEEK 28	11	1.73	1.50	0.98	0.90	4.10	10	1.83	1.01	-0.08	-0.00	1.46	-3.40	2.00
	WEEK 52	219	2.38	2.00	1.63	0.00	8.70	213	2.27	1.53	0.09	-0.10	1.37	-5.40	4.20
	LAST VISIT	333	2.20	1.80	1.49	0.00	8.70	321	2.19	1.48	0.01	-0.10	1.29	-5.40	4.20
ROLLOVER	BASELINE	84	2.34	2.00	1.53	0.30	9.70								
	WEEK 28	43	2.49	2.10	2.11	0.20	12.30	43	2.34	1.38	0.14	0.00	1.60	-3.40	7.90
	WEEK 52	14	3.59	2.95	2.76	0.50	11.10	14	2.99	2.42	0.59	0.80	0.92	-1.40	1.90
	LAST VISIT	80	2.71	2.15	2.11	0.20	12.30	79	2.39	1.56	0.34	0.20	1.41	-3.40	7.90
TOTAL	BASELINE	450	2.21	1.80	1.45	0.20	12.00								
	WEEK 28	54	2.33	1.90	1.95	0.20	12.30	53	2.25	1.32	0.10	0.00	1.56	-3.40	7.90
	WEEK 52	233	2.45	2.00	1.73	0.00	11.10	227	2.31	1.60	0.13	0.00	1.35	-5.40	4.20
	LAST VISIT	413	2.30	1.90	1.64	0.00	12.30	400	2.23	1.49	0.07	0.00	1.32	-5.40	7.90

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=ERYTHROCYTES (10^12/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	4.70	4.70	0.46	3.40	6.20								
	WEEK 28	11	4.75	4.70	0.61	4.10	6.10	10	4.68	0.59	0.14	0.10	0.24	-0.30	0.50
	WEEK 52	220	4.76	4.70	0.50	3.50	6.00	214	4.69	0.47	0.06	0.00	0.32	-0.90	1.80
	LAST VISIT	334	4.77	4.70	0.48	3.50	6.10	322	4.71	0.46	0.06	0.00	0.32	-0.90	1.80
ROLLOVER	BASELINE	84	4.73	4.70	0.52	3.80	6.50								
	WEEK 28	43	4.81	4.80	0.51	3.80	5.90	43	4.77	0.47	0.04	0.10	0.29	-0.60	0.50
	WEEK 52	14	4.74	4.80	0.51	4.00	5.50	14	4.72	0.48	0.01	0.00	0.22	-0.30	0.30
	LAST VISIT	80	4.79	4.75	0.55	3.80	6.90	79	4.75	0.52	0.03	0.00	0.28	-0.70	0.50
TOTAL	BASELINE	450	4.71	4.70	0.47	3.40	6.50								
	WEEK 28	54	4.80	4.70	0.53	3.80	6.10	53	4.75	0.49	0.06	0.10	0.28	-0.60	0.50
	WEEK 52	234	4.76	4.70	0.50	3.50	6.00	228	4.69	0.47	0.06	0.00	0.31	-0.90	1.80
	LAST VISIT	414	4.77	4.70	0.50	3.50	6.90	401	4.72	0.48	0.05	0.00	0.31	-0.90	1.80

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=HEMATOCRIT (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	41.90	42.00	4.01	30.00	53.00								
	WEEK 28	11	42.55	41.00	4.72	37.00	51.00	10	40.60	4.79	2.10	2.00	2.18	-2.00	5.00
	WEEK 52	220	42.26	42.00	4.45	29.00	55.00	214	41.73	4.15	0.53	1.00	3.23	-12.00	13.00
	LAST VISIT	334	42.40	42.00	4.21	33.00	55.00	322	41.90	4.02	0.47	1.00	3.07	-12.00	13.00
ROLLOVER	BASELINE	84	42.36	42.00	4.21	29.00	51.00								
	WEEK 28	43	43.14	43.00	5.48	29.00	57.00	43	42.70	4.28	0.44	1.00	3.28	-8.00	8.00
	WEEK 52	14	42.36	42.00	3.10	37.00	48.00	14	43.21	3.12	-0.86	-1.50	2.71	-5.00	4.00
	LAST VISIT	80	42.56	42.00	4.80	29.00	52.00	79	42.48	4.18	-0.04	0.00	2.83	-8.00	7.00
TOTAL	BASELINE	450	41.98	42.00	4.05	29.00	53.00								
	WEEK 28	54	43.02	43.00	5.30	29.00	57.00	53	42.30	4.41	0.75	1.00	3.15	-8.00	8.00
	WEEK 52	234	42.26	42.00	4.38	29.00	55.00	228	41.82	4.10	0.44	0.00	3.21	-12.00	13.00
	LAST VISIT	414	42.43	42.00	4.32	29.00	55.00	401	42.02	4.05	0.37	1.00	3.03	-12.00	13.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=HEMOGLOBIN (g/dL)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	13.99	13.90	1.51	9.20	17.80								
	WEEK 28	11	13.68	13.50	1.44	11.20	16.20	10	13.43	1.96	0.25	0.25	0.73	-0.90	1.90
	WEEK 52	220	14.10	14.10	1.68	8.60	17.50	214	13.94	1.55	0.16	0.10	1.03	-5.00	4.00
	LAST VISIT	334	14.13	14.10	1.59	9.20	17.50	322	13.99	1.52	0.13	0.10	0.97	-5.00	4.00
ROLLOVER	BASELINE	84	14.04	14.15	1.56	8.40	17.60								
	WEEK 28	43	14.33	14.60	2.12	7.90	18.50	43	14.20	1.69	0.13	0.30	1.05	-3.90	2.00
	WEEK 52	14	14.29	14.35	1.14	12.70	16.40	14	14.19	1.05	0.10	-0.05	0.55	-0.60	1.00
	LAST VISIT	80	14.23	14.35	1.84	7.90	17.60	79	14.08	1.58	0.11	0.10	0.88	-3.90	2.00
TOTAL	BASELINE	450	14.00	13.90	1.51	8.40	17.80								
	WEEK 28	54	14.20	14.40	2.00	7.90	18.50	53	14.06	1.75	0.15	0.30	0.99	-3.90	2.00
	WEEK 52	234	14.11	14.10	1.65	8.60	17.50	228	13.95	1.52	0.16	0.10	1.00	-5.00	4.00
	LAST VISIT	414	14.15	14.15	1.64	7.90	17.60	401	14.01	1.53	0.12	0.10	0.95	-5.00	4.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=HEMOGLOBIN A1C/HEMOGLOBIN (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	22	7.32	6.35	2.09	4.80	11.20								
	WEEK 28	1	5.80	5.80		5.80	5.80								
	WEEK 52	11	6.97	6.50	2.17	4.70	12.00	6	7.92	2.47	0.17	0.65	1.23	-2.20	1.10
	LAST VISIT	24	7.03	6.40	2.13	4.70	12.00	12	8.05	2.20	0.12	0.30	1.27	-2.20	2.20
ROLLOVER	WEEK 28	3	5.90	5.90	0.60	5.30	6.50								
	WEEK 52	2	7.45	7.45	0.21	7.30	7.60								
	LAST VISIT	8	7.35	6.35	3.09	5.30	14.70								
TOTAL	BASELINE	22	7.32	6.35	2.09	4.80	11.20								
	WEEK 28	4	5.88	5.85	0.49	5.30	6.50								
	WEEK 52	13	7.05	7.00	1.99	4.70	12.00	6	7.92	2.47	0.17	0.65	1.23	-2.20	1.10
	LAST VISIT	32	7.11	6.40	2.35	4.70	14.70	12	8.05	2.20	0.12	0.30	1.27	-2.20	2.20

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=LEUKOCYTES (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	7.21	6.77	2.21	3.05	15.37								
	WEEK 28	11	7.17	5.95	2.40	4.41	11.20	10	7.28	2.26	-0.34	-0.58	1.85	-3.60	3.02
	WEEK 52	220	7.06	6.65	2.02	3.12	12.52	214	7.09	2.19	-0.03	0.01	1.78	-5.95	7.63
	LAST VISIT	334	7.05	6.78	1.97	3.12	13.03	322	7.21	2.16	-0.15	-0.13	1.75	-6.87	7.63
ROLLOVER	BASELINE	84	6.75	6.58	1.90	2.64	13.18								
	WEEK 28	43	6.78	6.49	1.79	4.06	12.26	43	6.83	1.80	-0.05	0.02	1.41	-5.11	3.30
	WEEK 52	14	6.91	6.89	1.72	4.62	9.73	14	6.81	1.68	0.10	0.23	1.17	-1.90	2.49
	LAST VISIT	80	6.99	6.68	1.83	3.48	12.26	79	6.83	1.91	0.14	0.12	1.26	-3.06	3.30
TOTAL	BASELINE	450	7.12	6.73	2.16	2.64	15.37								
	WEEK 28	54	6.86	6.38	1.91	4.06	12.26	53	6.91	1.88	-0.10	0.01	1.49	-5.11	3.30
	WEEK 52	234	7.05	6.67	2.00	3.12	12.52	228	7.08	2.16	-0.03	0.02	1.75	-5.95	7.63
	LAST VISIT	414	7.04	6.77	1.94	3.12	13.03	401	7.13	2.12	-0.09	-0.02	1.66	-6.87	7.63

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=LYMPHOCYTES (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	2.04	1.94	0.65	0.33	5.41								
	WEEK 28	11	2.02	1.77	0.71	1.19	3.58	10	2.15	0.64	-0.19	-0.10	0.57	-1.58	0.37
	WEEK 52	219	2.04	1.96	0.62	0.89	4.38	213	2.01	0.64	0.03	-0.01	0.52	-1.93	2.22
	LAST VISIT	333	2.01	1.96	0.61	0.75	4.38	321	2.02	0.63	-0.02	-0.02	0.50	-1.93	2.22
ROLLOVER	BASELINE	84	2.06	2.01	0.59	0.95	3.96								
	WEEK 28	43	2.06	2.11	0.50	0.88	3.16	43	2.03	0.53	0.03	0.07	0.54	-2.22	0.90
	WEEK 52	14	1.99	1.95	0.49	1.33	2.74	14	2.17	0.72	-0.18	-0.24	0.41	-1.23	0.38
	LAST VISIT	80	2.07	2.08	0.47	0.95	3.16	79	2.08	0.58	-0.00	-0.04	0.42	-1.23	0.90
TOTAL	BASELINE	450	2.04	1.95	0.64	0.33	5.41								
	WEEK 28	54	2.05	2.10	0.54	0.88	3.58	53	2.05	0.55	-0.01	0.05	0.55	-2.22	0.90
	WEEK 52	233	2.04	1.96	0.61	0.89	4.38	227	2.02	0.65	0.02	-0.02	0.51	-1.93	2.22
	LAST VISIT	413	2.02	1.97	0.59	0.75	4.38	400	2.03	0.62	-0.02	-0.02	0.49	-1.93	2.22

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.2 FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=LYMPHOCYTES/LEUKOCYTES (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	___BASELINE____ MEAN	___BASELINE____ MEDIAN	___BASELINE____ SD	___BASELINE____ MIN	___BASELINE____ MAX
DE NOVO	BASELINE	366	29.21	28.30	7.76	4.60	55.60								
	WEEK 28	11	28.89	27.20	7.16	19.80	39.10	10	30.25	6.31	-1.19	-0.15	8.68	-20.30	11.30
	WEEK 52	219	29.79	29.70	7.51	14.50	55.20	213	29.12	7.36	0.60	0.20	7.02	-20.20	27.70
	LAST VISIT	333	29.24	28.90	7.59	12.90	55.20	321	28.89	7.52	0.20	0.20	6.85	-20.30	27.70
ROLLOVER	BASELINE	84	31.52	30.70	8.37	17.70	55.50								
	WEEK 28	43	31.60	31.70	8.24	13.20	51.30	43	30.63	8.68	0.97	0.50	6.82	-18.60	12.40
	WEEK 52	14	29.51	28.30	6.89	20.10	42.70	14	32.58	9.66	-3.07	-3.35	7.07	-12.50	12.30
	LAST VISIT	80	30.64	30.30	6.94	13.20	49.80	79	31.41	8.35	-0.66	-0.50	6.65	-18.60	12.40
TOTAL	BASELINE	450	29.64	28.70	7.92	4.60	55.60								
	WEEK 28	54	31.05	30.75	8.04	13.20	51.30	53	30.56	8.23	0.57	0.20	7.17	-20.30	12.40
	WEEK 52	233	29.77	29.50	7.46	14.50	55.20	227	29.33	7.54	0.38	0.00	7.06	-20.20	27.70
	LAST VISIT	413	29.51	29.30	7.48	12.90	55.20	400	29.38	7.74	0.03	0.05	6.81	-20.30	27.70

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=MONOCYTES (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	0.39	0.36	0.15	0.10	1.19								
	WEEK 28	11	0.39	0.30	0.19	0.17	0.71	10	0.40	0.19	-0.04	-0.03	0.10	-0.19	0.13
	WEEK 52	219	0.37	0.34	0.14	0.13	0.89	213	0.39	0.15	-0.01	-0.01	0.13	-0.36	0.42
	LAST VISIT	333	0.38	0.36	0.14	0.13	0.89	321	0.39	0.15	-0.01	-0.01	0.13	-0.80	0.43
ROLLOVER	BASELINE	84	0.37	0.35	0.13	0.11	0.72								
	WEEK 28	43	0.36	0.33	0.13	0.12	0.79	43	0.37	0.13	-0.01	-0.01	0.12	-0.30	0.26
	WEEK 52	14	0.34	0.26	0.16	0.15	0.59	14	0.35	0.13	-0.01	-0.03	0.09	-0.14	0.22
	LAST VISIT	80	0.38	0.34	0.14	0.15	0.79	79	0.37	0.13	0.01	0.00	0.11	-0.30	0.26
TOTAL	BASELINE	450	0.39	0.36	0.15	0.10	1.19								
	WEEK 28	54	0.37	0.33	0.14	0.12	0.79	53	0.38	0.14	-0.01	-0.01	0.12	-0.30	0.26
	WEEK 52	233	0.37	0.34	0.14	0.13	0.89	227	0.39	0.15	-0.01	-0.01	0.12	-0.36	0.42
	LAST VISIT	413	0.38	0.35	0.14	0.13	0.89	400	0.39	0.15	-0.01	-0.00	0.13	-0.80	0.43

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=MONOCYTES/LEUKOCYTES (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	5.58	5.30	1.79	2.00	17.20								
	WEEK 28	11	5.34	5.10	1.81	3.40	9.50	10	5.50	2.32	-0.38	-0.35	1.17	-2.30	1.40
	WEEK 52	219	5.34	5.10	1.57	2.20	10.70	213	5.63	1.87	-0.25	-0.20	1.71	-10.60	6.00
	LAST VISIT	333	5.44	5.20	1.60	2.20	11.10	321	5.56	1.79	-0.11	0.00	1.72	-10.60	7.00
ROLLOVER	BASELINE	84	5.53	5.30	1.73	2.30	10.40								
	WEEK 28	43	5.50	5.40	1.66	2.10	8.60	43	5.60	1.89	-0.10	0.00	1.37	-4.70	4.10
	WEEK 52	14	4.86	4.40	1.89	3.00	9.70	14	5.21	1.80	-0.35	-0.20	1.18	-3.10	1.30
	LAST VISIT	80	5.48	5.20	1.71	2.60	10.30	79	5.54	1.74	-0.05	0.10	1.33	-4.70	4.10
TOTAL	BASELINE	450	5.57	5.30	1.77	2.00	17.20								
	WEEK 28	54	5.46	5.20	1.67	2.10	9.50	53	5.58	1.96	-0.15	0.00	1.33	-4.70	4.10
	WEEK 52	233	5.31	5.10	1.59	2.20	10.70	227	5.60	1.87	-0.25	-0.20	1.68	-10.60	6.00
	LAST VISIT	413	5.45	5.20	1.62	2.20	11.10	400	5.56	1.78	-0.10	0.00	1.65	-10.60	7.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=NEUTROPHILS (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	4.58	4.28	1.77	1.08	12.14								
	WEEK 28	11	4.60	3.94	1.79	2.59	7.67	10	4.56	1.75	-0.09	-0.08	1.68	-3.42	2.86
	WEEK 52	219	4.44	4.17	1.62	1.25	9.81	213	4.50	1.74	-0.06	0.06	1.56	-6.14	6.03
	LAST VISIT	333	4.47	4.24	1.60	1.79	9.81	321	4.60	1.74	-0.11	-0.07	1.53	-6.14	6.03
ROLLOVER	BASELINE	84	4.13	4.02	1.57	1.17	9.26								
	WEEK 28	43	4.14	3.75	1.66	2.22	9.77	43	4.23	1.54	-0.09	-0.05	1.09	-2.47	3.06
	WEEK 52	14	4.27	3.89	1.30	2.49	6.93	14	4.04	1.39	0.24	0.26	1.15	-1.75	1.88
	LAST VISIT	80	4.31	3.98	1.55	2.11	9.77	79	4.18	1.59	0.10	0.15	1.12	-2.98	3.06
TOTAL	BASELINE	450	4.49	4.16	1.74	1.08	12.14								
	WEEK 28	54	4.24	3.76	1.68	2.22	9.77	53	4.29	1.57	-0.09	-0.05	1.20	-3.42	3.06
	WEEK 52	233	4.43	4.16	1.60	1.25	9.81	227	4.47	1.72	-0.04	0.08	1.54	-6.14	6.03
	LAST VISIT	413	4.44	4.16	1.59	1.79	9.81	400	4.52	1.72	-0.07	0.00	1.46	-6.14	6.03

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=NEUTROPHILS BAND FORM/ NEUTROPHILS (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: ___BASELINE____ n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
DE NOVO	BASELINE	1	1.00	1.00		1.00	1.00								
	WEEK 52	2	1.00	1.00	0.00	1.00	1.00								
	LAST VISIT	2	1.00	1.00	0.00	1.00	1.00								
TOTAL	BASELINE	1	1.00	1.00		1.00	1.00								
	WEEK 52	2	1.00	1.00	0.00	1.00	1.00								
	LAST VISIT	2	1.00	1.00	0.00	1.00	1.00								

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=NEUTROPHILS/LEUKOCYTES (%)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	366	62.36	63.30	8.43	32.50	89.40								
	WEEK 28	11	63.42	63.30	6.70	53.90	75.10	10	61.85	8.14	1.58	1.75	8.82	-11.30	19.10
	WEEK 52	219	61.82	61.90	8.02	39.00	79.30	213	62.29	8.02	-0.44	-0.40	7.89	-30.70	27.40
	LAST VISIT	333	62.42	62.80	8.15	39.00	80.20	321	62.69	8.14	-0.11	0.00	7.80	-30.70	27.40
ROLLOVER	BASELINE	84	59.99	60.50	9.08	34.00	74.90								
	WEEK 28	43	59.77	59.70	9.14	42.10	80.40	43	60.81	9.62	-1.05	-1.20	7.55	-14.00	20.60
	WEEK 52	14	61.31	60.90	6.52	51.60	71.20	14	58.59	9.82	2.71	2.30	8.37	-13.20	14.70
	LAST VISIT	80	60.51	61.10	7.54	42.70	80.40	79	60.03	9.18	0.34	1.00	7.44	-14.00	20.60
TOTAL	BASELINE	450	61.92	63.05	8.60	32.50	89.40								
	WEEK 28	54	60.51	61.30	8.77	42.10	80.40	53	61.01	9.29	-0.55	0.00	7.79	-14.00	20.60
	WEEK 52	233	61.78	61.90	7.93	39.00	79.30	227	62.06	8.16	-0.25	0.10	7.94	-30.70	27.40
	LAST VISIT	413	62.05	62.40	8.07	39.00	80.40	400	62.17	8.41	-0.02	0.20	7.72	-30.70	27.40

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-148　血液学的検査値の記述統計量［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.2.2
Laboratory Test Results for Hematology - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=PLATELETS (10^9/L)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	364	270.17	263.00	69.74	125.00	601.00								
	WEEK 28	11	275.18	274.00	45.29	211.00	349.00	10	295.30	41.87	-24.30	-17.50	56.21	-90.00	89.00
	WEEK 52	220	257.30	247.50	66.97	132.00	570.00	213	265.86	72.39	-10.90	-7.00	57.66	-373.00	160.00
	LAST VISIT	334	260.75	252.50	67.24	131.00	570.00	321	271.47	70.26	-12.23	-9.00	55.17	-373.00	183.00
ROLLOVER	BASELINE	84	252.83	251.00	63.16	69.00	474.00								
	WEEK 28	43	255.91	256.00	65.31	60.00	472.00	43	254.79	53.70	1.12	8.00	53.26	-212.00	82.00
	WEEK 52	14	250.71	248.00	63.53	176.00	412.00	14	247.79	61.46	2.93	0.00	23.18	-25.00	62.00
	LAST VISIT	80	256.43	255.00	61.69	151.00	472.00	79	253.94	63.74	2.37	3.00	43.22	-174.00	90.00
TOTAL	BASELINE	448	266.92	259.00	68.82	69.00	601.00								
	WEEK 28	54	259.83	256.50	61.88	60.00	472.00	53	262.43	53.75	-3.68	6.00	54.21	-212.00	89.00
	WEEK 52	234	256.91	247.50	66.66	132.00	570.00	227	264.74	71.78	-10.04	-7.00	56.22	-373.00	160.00
	LAST VISIT	414	259.91	253.00	66.15	131.00	570.00	400	268.01	69.30	-9.35	-7.50	53.29	-373.00	183.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AB.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.2　FINAL

＜資料番号 5.3.5.2-01：CT-13.2.2＞

表 2.7.4.7-149　臨床的に重要な臨床検査値の変動を示した被験者の割合［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-13.1.2
Incidence of Laboratory Values of Potential Clinical Relevance in Phase C - High or Low
(Phase C Safety Sample)

			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
	TEST(UNITS)[1]		Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	HIGH	335	3	(0.9)	80	0	(0.0)	415	3	(0.7)
	ALKALINE PHOSPHATASE (U/L)	HIGH	336	0	(0.0)	80	0	(0.0)	416	0	(0.0)
	ASPARTATE AMINOTRANSFERASE (U/L)	HIGH	333	2	(0.6)	80	0	(0.0)	413	2	(0.5)
	BILIRUBIN (mg/dL)	HIGH	322	2	(0.6)	74	0	(0.0)	396	2	(0.5)
	CALCIUM (mg/dL)	LOW	336	1	(0.3)	80	0	(0.0)	416	1	(0.2)
		HIGH	336	0	(0.0)	80	0	(0.0)	416	0	(0.0)
	CHLORIDE (mEq/L)	LOW	332	1	(0.3)	80	0	(0.0)	412	1	(0.2)
		HIGH	332	0	(0.0)	80	0	(0.0)	412	0	(0.0)
	CHOLESTEROL, FASTING (mg/dL)	HIGH	269	41	(15.2)	69	12	(17.4)	338	53	(15.7)
	CREATINE KINASE (U/L)	HIGH	334	5	(1.5)	80	1	(1.3)	414	6	(1.4)
	CREATININE (mg/dL)	HIGH	336	0	(0.0)	80	1	(1.3)	416	1	(0.2)
	GLUCOSE (mg/dL)	HIGH	86	2	(2.3)	11	1	(9.1)	97	3	(3.1)
	GLUCOSE, FASTING (mg/dL)	HIGH	272	29	(10.7)	70	10	(14.3)	342	39	(11.4)
	HDL CHOLESTEROL, FASTING (mg/dL)	LOW	269	7	(2.6)	69	2	(2.9)	338	9	(2.7)
	LACTATE DEHYDROGENASE (U/L)	HIGH	329	0	(0.0)	78	0	(0.0)	407	0	(0.0)
	LDL CHOLESTEROL, FASTING (mg/dL)	HIGH	265	23	(8.7)	66	9	(13.6)	331	32	(9.7)
	POTASSIUM (mEq/L)	LOW	331	0	(0.0)	80	0	(0.0)	411	0	(0.0)
		HIGH	331	1	(0.3)	80	1	(1.3)	411	2	(0.5)
	PROLACTIN (ng/mL)	HIGH	335	10	(3.0)	79	2	(2.5)	414	12	(2.9)
	SODIUM (mEq/L)	LOW	332	0	(0.0)	80	0	(0.0)	412	0	(0.0)
		HIGH	332	0	(0.0)	80	0	(0.0)	412	0	(0.0)
	TRIGLYCERIDES, FASTING (mg/dL)	HIGH	269	100	(37.2)	69	24	(34.8)	338	124	(36.7)
	URATE (mg/dL)	HIGH	336	3	(0.9)	80	1	(1.3)	416	4	(1.0)
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	HIGH	333	0	(0.0)	80	3	(3.8)	413	3	(0.7)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3AB.LIS, RUN: [redacted]20[redacted] 13:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.1.2 FINAL

表 2.7.4.7-149　臨床的に重要な臨床検査値の変動を示した被験者の割合［長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597 2 OF 2
PROTOCOL 31-08-252

CT-13.1.2
Incidence of Laboratory Values of Potential Clinical Relevance in Phase C - High or Low
(Phase C Safety Sample)

	TEST(UNITS)[1]		DE NOVO (N=379) Ne[2]	DE NOVO (N=379) n[3]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[2]	ROLLOVER (N=85) n[3]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[2]	TOTAL (N=464) n[3]	TOTAL (N=464) (%)
HEMATOLOGY	HEMATOCRIT (%)	LOW	322	2	(0.6)	79	1	(1.3)	401	3	(0.7)
	HEMOGLOBIN (g/dL)	LOW	334	2	(0.6)	80	2	(2.5)	414	4	(1.0)
	LEUKOCYTES (10^9/L)	LOW	334	0	(0.0)	80	1	(1.3)	414	1	(0.2)
		HIGH	334	0	(0.0)	80	0	(0.0)	414	0	(0.0)
	NEUTROPHILS (10^9/L)	LOW	333	1	(0.3)	80	1	(1.3)	413	2	(0.5)
	PLATELETS (10^9/L)	LOW	334	0	(0.0)	80	1	(1.3)	414	1	(0.2)
		HIGH	334	0	(0.0)	80	0	(0.0)	414	0	(0.0)
URINALYSIS	GLUCOSE	HIGH	326	0	(0.0)	78	2	(2.6)	404	2	(0.5)
	PROTEIN	HIGH	326	4	(1.2)	78	0	(0.0)	404	4	(1.0)

[1]TESTS ARE INCLUDED ONLY IF THEY HAVE CRITERIA FOR POTENTIAL CLINICAL RELEVANCE (CT-10.3).
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN LAB TEST.
[3]n IS THE NUMBER OF SUBJECTS WITH LABORATORY TEST RESULTS OF POTENTIAL CLINICAL RELEVANCE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

FILE: ADLB3AB.LIS, RUN: [redacted]20[redacted] 13:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.1.2 FINAL

＜資料番号 5.3.5.2-01：CT-13.1.2＞

表 2.7.4.7-150　臨床的に重要なバイタルサインの異常［二重盲検試験の二重盲検期（Phase D）］

CT-14.1
Incidence of Vital Signs of Potential Clinical Relevance in Phase D
(Phase D Safety Sample)

VITAL SING PARAMETER	ABNORMALITY	ARIP IMD (N=132) Ne[1]	n[2]	(%)	PLACEBO (N=133) Ne[1]	n[2]	(%)	TOTAL (N=265) Ne[1]	n[2]	(%)
HEART RATE SUPINE (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
	< 50 BPM AND DECREASE >= 15 BPM	131	1	(0.8)	133	0	(0.0)	264	1	(0.4)
HEART RATE SITTING (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM	131	0	(0.0)	133	1	(0.8)	264	1	(0.4)
	< 50 BPM AND DECREASE >= 15 BPM	131	1	(0.8)	133	0	(0.0)	264	1	(0.4)
SYSTOLIC SUPINE BP (mmHg)	> 180 BPM AND INCREASE >= 20 BPM	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
	< 90 BPM AND DECREASE >= 20 BPM	131	0	(0.0)	133	1	(0.8)	264	1	(0.4)
SYSTOLIC SITTING BP (mmHg)	> 180 BPM AND INCREASE >= 20 BPM	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
	< 90 BPM AND DECREASE >= 20 BPM	131	1	(0.8)	133	0	(0.0)	264	1	(0.4)
DIASTOLIC SUPINE BP (mmHg)	> 105 BPM AND INCREASE >= 15 BPM	131	0	(0.0)	133	1	(0.8)	264	1	(0.4)
	< 50 BPM AND DECREASE >= 15 BPM	131	1	(0.8)	133	0	(0.0)	264	1	(0.4)
DIASTOLIC SITTING BP (mmHg)	> 105 BPM AND INCREASE >= 15 BPM	131	2	(1.5)	133	1	(0.8)	264	3	(1.1)
	< 50 BPM AND DECREASE >= 15 BPM	131	0	(0.0)	133	1	(0.8)	264	1	(0.4)
ORTHOSTATIC HYPOTENSION	>= 20 MMHG DECREASE IN SYSTOLIC BLOOD PRESSURE AND >= 25 BPM INCREASE IN HEART RATE FROM SUPINE TO SITTING	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
WEIGHT (kg)	INCREASE >= 7%	128	23	(18.0)	132	17	(12.9)	260	40	(15.4)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-11.2.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN VITALS PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH VITAL SIGN OF POTENTIAL CLINICAL RELEVANCE.

FILE: ADVS3AA.LIS, RUN: [redacted]20[redacted] 14:13; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:51
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADVS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-14.1　FINAL

表 2.7.4.7-150　臨床的に重要なバイタルサインの異常［二重盲検試験の二重盲検期（Phase D）］

OPC14597 2 OF 2
PROTOCOL 31-08-250

CT-14.1
Incidence of Vital Signs of Potential Clinical Relevance in Phase D
(Phase D Safety Sample)

VITAL SING PARAMETER	ABNORMALITY	ARIP IMD (N=132) Ne[1]	n[2]	(%)	PLACEBO (N=133) Ne[1]	n[2]	(%)	TOTAL (N=265) Ne[1]	n[2]	(%)
WEIGHT (kg)	DECREASE >= 7%	128	12	(9.4)	132	16	(12.1)	260	28	(10.8)
BODY TEMPERATURE (°C)	>= 37.8°C AND INCREASE >= 1.1°C	131	3	(2.3)	133	2	(1.5)	264	5	(1.9)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-11.2.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN VITALS PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH VITAL SIGN OF POTENTIAL CLINICAL RELEVANCE.

FILE: ADVS3AA.LIS, RUN: [redacted]20[redacted] 14:13; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:51
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADVS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-14.1　FINAL

＜資料番号 5.3.5.1-01：CT-14.1＞

表 2.7.4.7-151　起立性障害関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.8
Incidence of Treatment-emergent Adverse Events Related to Orthostasis in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
神経系障害	TOTAL1)	0	(0.0)	1	(0.8)	1	(0.4)
	失神	0	(0.0)	1	(0.8)	1	(0.4)
TOTAL2)		0	(0.0)	1	(0.8)	1	(0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AI.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.8　FINAL

表 2.7.4.7-151　起立性障害関連有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.5.8
Incidence of Treatment-emergent Adverse Events Related to Orthostasis in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO ORTHOSTASIS: MEDDRA 19.0 PRIMARY TERMS

GRAVITATIONAL OEDEMA, ORTHOSTATIC TREMOR, SYNCOPE, DIZZINESS POSTURAL, PRESYNCOPE, ORTHOSTATIC HYPOTENSION, ORTHOSTATIC PROTEINURIA, ORTHOSTATIC INTOLERANCE, ORTHOSTATIC HYPERTENSION, ORTHOSIS USER, BLOOD PRESSURE ORTHOSTATIC, BLOOD PRESSURE ORTHOSTATIC NORMAL, BLOOD PRESSURE ORTHOSTATIC ABNORMAL, BLOOD PRESSURE ORTHOSTATIC INCREASED, BLOOD PRESSURE ORTHOSTATIC DECREASED, POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME, ORTHOSTATIC HEART RATE RESPONSE INCREASED

＜資料番号 5.3.5.1-01：CT-8.2.5.8 より作成＞

表 2.7.4.7-152　臨床的に重要なバイタルサインの異常［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.1
Incidence of Vital Signs of Potential Clinical Relevance
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SING PARAMETER	ABNORMALITY	PHASE B (N=614) Ne[1]	n[2]	(%)	PHASE C (N=425) Ne[1]	n[2]	(%)
HEART RATE SUPINE (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM	590	1	(0.2)	421	0	(0.0)
	< 50 BPM AND DECREASE >= 15 BPM	590	0	(0.0)	421	3	(0.7)
HEART RATE SITTING (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM	590	0	(0.0)	421	1	(0.2)
	< 50 BPM AND DECREASE >= 15 BPM	590	1	(0.2)	421	2	(0.5)
SYSTOLIC SUPINE BP (mmHg)	> 180 BPM AND INCREASE >= 20 BPM	590	0	(0.0)	421	0	(0.0)
	< 90 BPM AND DECREASE >= 20 BPM	590	2	(0.3)	421	3	(0.7)
SYSTOLIC SITTING BP (mmHg)	> 180 BPM AND INCREASE >= 20 BPM	590	1	(0.2)	421	0	(0.0)
	< 90 BPM AND DECREASE >= 20 BPM	590	0	(0.0)	421	7	(1.7)
DIASTOLIC SUPINE BP (mmHg)	> 105 BPM AND INCREASE >= 15 BPM	590	1	(0.2)	421	3	(0.7)
	< 50 BPM AND DECREASE >= 15 BPM	590	1	(0.2)	421	1	(0.2)
DIASTOLIC SITTING BP (mmHg)	> 105 BPM AND INCREASE >= 15 BPM	590	3	(0.5)	421	2	(0.5)
	< 50 BPM AND DECREASE >= 15 BPM	590	2	(0.3)	421	1	(0.2)
ORTHOSTATIC HYPOTENSION	>= 20 MMHG DECREASE IN SYSTOLIC BLOOD PRESSURE AND >= 25 BPM INCREASE IN HEART RATE FROM SUPINE TO SITTING	590	1	(0.2)	421	1	(0.2)
WEIGHT (kg)	INCREASE >= 7%	549	14	(2.6)	403	44	(10.9)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-11.2.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN VITALS PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH VITAL SIGN OF POTENTIAL CLINICAL RELEVANCE.

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PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADVS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-23.2.1　FINAL

表 2.7.4.7-152　臨床的に重要なバイタルサインの異常［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-23.2.1
Incidence of Vital Signs of Potential Clinical Relevance
(Phase B Safety Sample and Phase C Safety Sample)

VITAL SING PARAMETER	ABNORMALITY	PHASE B (N=614) Ne[1]	n[2]	(%)	PHASE C (N=425) Ne[1]	n[2]	(%)
WEIGHT (kg)	DECREASE >= 7%	549	9	(1.6)	403	19	(4.7)
BODY TEMPERATURE (°C)	>= 37.8°C AND INCREASE >= 1.1°C	590	1	(0.2)	421	9	(2.1)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-11.2.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN VITALS PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH VITAL SIGN OF POTENTIAL CLINICAL RELEVANCE.

FILE: ADVS3BA.LIS, RUN: [redacted]20[redacted] 14:13; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:51
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADVS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-23.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-23.2.1＞

表 2.7.4.7-153　起立性障害関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.8
Incidence of Treatment-emergent Adverse Events Related to Orthostasis
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
神経系障害	TOTAL1)	2	(0.3)	1	(0.2)
	体位性めまい	1	(0.2)	0	(0.0)
	失神	1	(0.2)	1	(0.2)
血管障害	TOTAL1)	1	(0.2)	0	(0.0)
	起立性低血圧	1	(0.2)	0	(0.0)
TOTAL2)		3	(0.5)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BI.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.8　FINAL

表 2.7.4.7-153　起立性障害関連有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.5.8
Incidence of Treatment-emergent Adverse Events Related to Orthostasis
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO ORTHOSTASIS: MEDDRA 19.0 PRIMARY TERMS

GRAVITATIONAL OEDEMA, ORTHOSTATIC TREMOR, SYNCOPE, DIZZINESS POSTURAL, PRESYNCOPE, ORTHOSTATIC HYPOTENSION, ORTHOSTATIC PROTEINURIA, ORTHOSTATIC INTOLERANCE, ORTHOSTATIC HYPERTENSION, ORTHOSIS USER, BLOOD PRESSURE ORTHOSTATIC, BLOOD PRESSURE ORTHOSTATIC NORMAL, BLOOD PRESSURE ORTHOSTATIC ABNORMAL, BLOOD PRESSURE ORTHOSTATIC INCREASED, BLOOD PRESSURE ORTHOSTATIC DECREASED, POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME, ORTHOSTATIC HEART RATE RESPONSE INCREASED

FILE: ADAE3BI.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.8　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.5.8 より作成＞

表 2.7.4.7-154　臨床的に重要なバイタルサインの異常［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.1
Incidence of Vital Signs of Potential Clinical Relevance in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER	ABNORMALITY	DE NOVO (N=379) Ne[1]	DE NOVO (N=379) n[2]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[1]	ROLLOVER (N=85) n[2]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[1]	TOTAL (N=464) n[2]	TOTAL (N=464) (%)
HEART RATE SUPINE (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM	378	1	(0.3)	85	0	(0.0)	463	1	(0.2)
	< 50 BPM AND DECREASE >= 15 BPM	378	4	(1.1)	85	0	(0.0)	463	4	(0.9)
HEART RATE SITTING (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM	378	0	(0.0)	85	1	(1.2)	463	1	(0.2)
	< 50 BPM AND DECREASE >= 15 BPM	378	2	(0.5)	85	0	(0.0)	463	2	(0.4)
SYSTOLIC SUPINE BP (mmHg)	> 180 BPM AND INCREASE >= 20 BPM	378	1	(0.3)	85	0	(0.0)	463	1	(0.2)
	< 90 BPM AND DECREASE >= 20 BPM	378	4	(1.1)	85	2	(2.4)	463	6	(1.3)
SYSTOLIC SITTING BP (mmHg)	> 180 BPM AND INCREASE >= 20 BPM	378	1	(0.3)	85	0	(0.0)	463	1	(0.2)
	< 90 BPM AND DECREASE >= 20 BPM	378	9	(2.4)	85	1	(1.2)	463	10	(2.2)
DIASTOLIC SUPINE BP (mmHg)	> 105 BPM AND INCREASE >= 15 BPM	378	7	(1.9)	85	1	(1.2)	463	8	(1.7)
	< 50 BPM AND DECREASE >= 15 BPM	378	4	(1.1)	85	0	(0.0)	463	4	(0.9)
DIASTOLIC SITTING BP (mmHg)	> 105 BPM AND INCREASE >= 15 BPM	378	12	(3.2)	85	0	(0.0)	463	12	(2.6)
	< 50 BPM AND DECREASE >= 15 BPM	378	4	(1.1)	85	0	(0.0)	463	4	(0.9)
ORTHOSTATIC HYPOTENSION	>= 20 MMHG DECREASE IN SYSTOLIC BLOOD PRESSURE AND >= 25 BPM INCREASE IN HEART RATE FROM SUPINE TO SITTING	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
WEIGHT (kg)	INCREASE >= 7%	370	79	(21.4)	84	14	(16.7)	454	93	(20.5)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-11.2.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN VITALS PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH VITAL SIGN OF POTENTIAL CLINICAL RELEVANCE.

FILE: ADVS3AA.LIS, RUN: [redacted]20[redacted] 13:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:25
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADVS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-14.1 FINAL

表 2.7.4.7-154　臨床的に重要なバイタルサインの異常［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-14.1
Incidence of Vital Signs of Potential Clinical Relevance in Phase C
(Phase C Safety Sample)

VITAL SIGN PARAMETER	ABNORMALITY	DE NOVO (N=379) Ne[1]	DE NOVO (N=379) n[2]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[1]	ROLLOVER (N=85) n[2]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[1]	TOTAL (N=464) n[2]	TOTAL (N=464) (%)
WEIGHT (kg)	DECREASE >= 7%	370	57	(15.4)	84	9	(10.7)	454	66	(14.5)
BODY TEMPERATURE (°C)	>= 37.8°C AND INCREASE >= 1.1°C	378	10	(2.6)	85	1	(1.2)	463	11	(2.4)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-11.2.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN VITALS PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH VITAL SIGN OF POTENTIAL CLINICAL RELEVANCE.

FILE: ADVS3AA.LIS, RUN: [redacted]20[redacted] 13:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:25
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADVS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-14.1　FINAL

＜資料番号 5.3.5.2-01：CT-14.1＞

表 2.7.4.7-155　起立性障害関連有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.5.8
Incidence of Treatment-emergent Adverse Events Related to Orthostasis in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
神経系障害	TOTAL1)	6	(1.6)	0	(0.0)	6	(1.3)
	体位性めまい	5	(1.3)	0	(0.0)	5	(1.1)
	失神	1	(0.3)	0	(0.0)	1	(0.2)
血管障害	TOTAL1)	5	(1.3)	0	(0.0)	5	(1.1)
	起立性低血圧	5	(1.3)	0	(0.0)	5	(1.1)
臨床検査	TOTAL1)	1	(0.3)	0	(0.0)	1	(0.2)
	起立血圧上昇	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL2)		12	(3.2)	0	(0.0)	12	(2.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AI.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.8　FINAL

表 2.7.4.7-155　起立性障害関連有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.5.8
Incidence of Treatment-emergent Adverse Events Related to Orthostasis in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO ORTHOSTASIS: MEDDRA 19.0 PRIMARY TERMS

GRAVITATIONAL OEDEMA, ORTHOSTATIC TREMOR, SYNCOPE, DIZZINESS POSTURAL, PRESYNCOPE, ORTHOSTATIC HYPOTENSION, ORTHOSTATIC PROTEINURIA, ORTHOSTATIC INTOLERANCE, ORTHOSTATIC HYPERTENSION, ORTHOSIS USER, BLOOD PRESSURE ORTHOSTATIC, BLOOD PRESSURE ORTHOSTATIC NORMAL, BLOOD PRESSURE ORTHOSTATIC ABNORMAL, BLOOD PRESSURE ORTHOSTATIC INCREASED, BLOOD PRESSURE ORTHOSTATIC DECREASED, POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME, ORTHOSTATIC HEART RATE RESPONSE INCREASED

＜資料番号 5.3.5.2-01：CT-8.2.5.8＞

表 2.7.4.7-156　QTc 間隔カテゴリカル解析［二重盲検試験の二重盲検期（Phase D）］

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PROTOCOL 31-08-250

CT-15.3
Incidence of Categorical Increases in ECG - QTc in Phase D
(Phase D Safety Sample)

ECG PARAMETER	CATEGORY	ARIP IMD (N=132) Ne[2]	ARIP IMD (N=132) n[3]	ARIP IMD (N=132) (%)	PLACEBO (N=133) Ne[2]	PLACEBO (N=133) n[3]	PLACEBO (N=133) (%)	TOTAL (N=265) Ne[2]	TOTAL (N=265) n[3]	TOTAL (N=265) (%)
QTCB INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	123	0	(0.0)	125	1	(0.8)	248	1	(0.4)
	NEW ONSET[1] > 480 MSEC	123	2	(1.6)	125	2	(1.6)	248	4	(1.6)
	NEW ONSET[1] > 450 MSEC	123	20	(16.3)	125	12	(9.6)	248	32	(12.9)
	CHANGE >= 30, <60 MSEC	121	13	(10.7)	122	15	(12.3)	243	28	(11.5)
	CHANGE >= 60 MSEC	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
QTCF INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	NEW ONSET[1] > 480 MSEC	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	NEW ONSET[1] > 450 MSEC	123	5	(4.1)	125	8	(6.4)	248	13	(5.2)
	CHANGE >= 30, <60 MSEC	121	2	(1.7)	122	5	(4.1)	243	7	(2.9)
	CHANGE >= 60 MSEC	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
QTCN INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	NEW ONSET[1] > 480 MSEC	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	NEW ONSET[1] > 450 MSEC	123	6	(4.9)	125	9	(7.2)	248	15	(6.1)
	CHANGE >= 30, <60 MSEC	121	3	(2.5)	122	4	(3.3)	243	7	(2.9)
	CHANGE >= 60 MSEC	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)

[1]NEW ONSET > 500 (480/450) MSEC IS DEFINED AS THE INCIDENCE OF QTc > 500 (480/450) MSEC DURING TREATMENT AND QTc <= 500 (480/450) MSEC OR NOT EVALUATED AT BASELINE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER FOR 'NEW ONSET' CATEGORY; Ne IS THE TOTAL NUMBER OF SUBJECTS WITH BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR 'CHANGE' CATEGORY.
[3]n IS THE NUMBER OF SUBJECTS WITH SPECIFIED CATEGORICAL INCREASE.

FILE: ADEG4AA.LIS, RUN: [redacted]20[redacted] 19:33; ANALYSIS DATASET CREATED: [redacted]20[redacted] 15:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-15.3　FINAL

＜資料番号 5.3.5.1-01：CT-15.3＞

表 2.7.4.7-157　QTc 間隔カテゴリカル解析［二重盲検試験の IM デポ剤安定期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-250

CT-24.2.3
Incidence of Categorical Increases in ECG - QTc
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER	CATEGORY	PHASE B (N=614) Ne[2]	PHASE B (N=614) n[3]	PHASE B (N=614) (%)	PHASE C (N=425) Ne[2]	PHASE C (N=425) n[3]	PHASE C (N=425) (%)
QTCB INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	545	0	(0.0)	377	0	(0.0)
	NEW ONSET[1] > 480 MSEC	545	2	(0.4)	377	2	(0.5)
	NEW ONSET[1] > 450 MSEC	545	47	(8.6)	377	32	(8.5)
	CHANGE >= 30, <60 MSEC	530	14	(2.6)	374	16	(4.3)
	CHANGE >= 60 MSEC	530	1	(0.2)	374	0	(0.0)
QTCF INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	545	0	(0.0)	377	0	(0.0)
	NEW ONSET[1] > 480 MSEC	545	1	(0.2)	377	0	(0.0)
	NEW ONSET[1] > 450 MSEC	545	17	(3.1)	377	7	(1.9)
	CHANGE >= 30, <60 MSEC	530	4	(0.8)	374	2	(0.5)
	CHANGE >= 60 MSEC	530	0	(0.0)	374	0	(0.0)
QTCN INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	545	0	(0.0)	377	0	(0.0)
	NEW ONSET[1] > 480 MSEC	545	0	(0.0)	377	0	(0.0)
	NEW ONSET[1] > 450 MSEC	545	20	(3.7)	377	11	(2.9)
	CHANGE >= 30, <60 MSEC	530	6	(1.1)	374	1	(0.3)
	CHANGE >= 60 MSEC	530	0	(0.0)	374	0	(0.0)

[1]NEW ONSET > 500 (480/450) MSEC IS DEFINED AS THE INCIDENCE OF QTc > 500 (480/450) MSEC DURING TREATMENT AND QTc <= 500 (480/450) MSEC OR NOT EVALUATED AT BASELINE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER FOR 'NEW ONSET' CATEGORY; Ne IS THE TOTAL NUMBER OF SUBJECTS WITH BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR 'CHANGE' CATEGORY.
[3]n IS THE NUMBER OF SUBJECTS WITH SPECIFIED CATEGORICAL INCREASE.

FILE: ADEG4BA.LIS, RUN: [redacted]20[redacted] 19:33; ANALYSIS DATASET CREATED: [redacted]20[redacted] 15:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-24.2.3　FINAL

＜資料番号 5.3.5.1-01：CT-24.2.3＞

表 2.7.4.7-158　QTc 間隔カテゴリカル解析［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.3
Incidence of Categorical Increases in ECG - QTc in Phase C
(Phase C Safety Sample)

ECG PARAMETER	CATEGORY	DE NOVO (N=379) Ne[2]	DE NOVO (N=379) n[3]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[2]	ROLLOVER (N=85) n[3]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[2]	TOTAL (N=464) n[3]	TOTAL (N=464) (%)
QTCB INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	NEW ONSET[1] > 480 MSEC	333	1	(0.3)	79	3	(3.8)	412	4	(1.0)
	NEW ONSET[1] > 450 MSEC	333	23	(6.9)	79	7	(8.9)	412	30	(7.3)
	CHANGE >= 30, <60 MSEC	330	13	(3.9)	79	2	(2.5)	409	15	(3.7)
	CHANGE >= 60 MSEC	330	1	(0.3)	79	0	(0.0)	409	1	(0.2)
QTCF INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	NEW ONSET[1] > 480 MSEC	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	NEW ONSET[1] > 450 MSEC	333	8	(2.4)	79	2	(2.5)	412	10	(2.4)
	CHANGE >= 30, <60 MSEC	330	7	(2.1)	79	0	(0.0)	409	7	(1.7)
	CHANGE >= 60 MSEC	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)
QTCN INTERVAL (MSEC)	NEW ONSET[1] > 500 MSEC	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	NEW ONSET[1] > 480 MSEC	333	0	(0.0)	79	1	(1.3)	412	1	(0.2)
	NEW ONSET[1] > 450 MSEC	333	7	(2.1)	79	3	(3.8)	412	10	(2.4)
	CHANGE >= 30, <60 MSEC	330	6	(1.8)	79	0	(0.0)	409	6	(1.5)
	CHANGE >= 60 MSEC	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)

[1]NEW ONSET > 500 (480/450) MSEC IS DEFINED AS THE INCIDENCE OF QTc > 500 (480/450) MSEC DURING TREATMENT AND QTc <= 500 (480/450) MSEC OR NOT EVALUATED AT BASELINE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER FOR 'NEW ONSET' CATEGORY; Ne IS THE TOTAL NUMBER OF SUBJECTS WITH BASELINE AND AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR 'CHANGE' CATEGORY.
[3]n IS THE NUMBER OF SUBJECTS WITH SPECIFIED CATEGORICAL INCREASE.

FILE: ADEG4AA.LIS, RUN: [redacted]20[redacted] 12:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:53
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-15.3　FINAL

＜資料番号 5.3.5.2-01：CT-15.3＞

表 2.7.4.7-159　プロラクチンの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.4.2
Laboratory Test Results for Prolactin(ng/mL) - Mean Change From Baseline in Phase D by Gender
(Phase D Safety Sample)

Sex=FEMALE

TRIAL WEEK[1]	PHASE D TREATMENT	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX	P-VALUE[3] (VS PLACEBO)
BASELINE	ARIP IMD	76	8.58	7.89	7.52	0.76	51.25									
	PLACEBO	69	8.22	6.90	5.95	0.66	31.28									
WEEK 52	ARIP IMD	41	9.88	8.31	9.54	0.94	54.34	37	9.50	8.02	0.34	-0.95	6.36	-5.36	34.82	0.0119
	PLACEBO	16	13.57	10.28	10.76	3.66	47.86	16	6.91	4.22	6.65	4.58	10.19	-2.07	40.78	
LAST VISIT	ARIP IMD	76	8.88	6.81	9.48	0.94	54.34	70	8.59	7.76	0.30	-0.28	5.44	-8.17	34.82	0.0519
	PLACEBO	65	10.48	9.28	9.18	0.68	52.26	64	7.89	5.90	2.58	0.76	7.78	-7.78	40.78	

[1]BASELINE = BASELINE IS DEFINED AS VALUE AT THE END OF PHASE C VISIT.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]P-VALUES ARE DERIVED FROM ANALYSIS OF COVARIATE MODEL WITH TREATMENT AS TERM AND BASELINE AS COVARIATE.

FILE: SAF1P.LIS, RUN: [redacted]20[redacted] 14:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\STAT\PROGRAM.DEV\SAF1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.4.2 FINAL

表 2.7.4.7-159　プロラクチンの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.4.2
Laboratory Test Results for Prolactin(ng/mL) - Mean Change From Baseline in Phase D by Gender
(Phase D Safety Sample)

Sex=MALE

TRIAL WEEK[1]	PHASE D TREATMENT	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX	P-VALUE[3] (VS PLACEBO)
BASELINE	ARIP IMD	46	2.41	1.86	1.68	0.52	6.73									
	PLACEBO	59	3.97	3.04	3.41	0.37	18.06									
WEEK 52	ARIP IMD	23	2.13	1.50	2.06	0.38	9.72	22	2.25	1.54	-0.09	-0.16	1.22	-1.33	4.86	<.0001
	PLACEBO	22	8.84	7.51	4.98	3.55	26.83	21	4.11	3.81	4.97	4.38	3.11	0.21	12.11	
LAST VISIT	ARIP IMD	41	2.29	1.54	1.94	0.38	9.72	39	2.34	1.68	-0.11	-0.11	0.97	-1.45	4.86	<.0001
	PLACEBO	52	7.47	6.78	4.88	1.43	26.83	49	4.15	3.62	3.55	2.78	3.96	-2.28	18.14	

[1]BASELINE = BASELINE IS DEFINED AS VALUE AT THE END OF PHASE C VISIT.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]P-VALUES ARE DERIVED FROM ANALYSIS OF COVARIATE MODEL WITH TREATMENT AS TERM AND BASELINE AS COVARIATE.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.2　FINAL

表 2.7.4.7-159 プロラクチンの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.4.2
Laboratory Test Results for Prolactin(ng/mL) - Mean Change From Baseline in Phase D by Gender
(Phase D Safety Sample)

Sex=TOTAL

TRIAL WEEK[1]	PHASE D TREATMENT	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX	P-VALUE[3] (VS PLACEBO)
BASELINE	ARIP IMD	122	6.25	4.50	6.71	0.52	51.25									
	PLACEBO	128	6.26	4.58	5.36	0.37	31.28									
WEEK 52	ARIP IMD	64	7.10	5.15	8.56	0.38	54.34	59	6.80	7.30	0.18	-0.20	5.07	-5.36	34.82	<.0001
	PLACEBO	38	10.83	9.76	8.16	3.55	47.86	37	5.32	4.18	5.70	4.38	7.02	-2.07	40.78	
LAST VISIT	ARIP IMD	117	6.57	4.31	8.33	0.38	54.34	109	6.35	6.96	0.15	-0.17	4.39	-8.17	34.82	0.0002
	PLACEBO	117	9.14	7.45	7.69	0.68	52.26	113	6.27	5.35	3.00	1.76	6.40	-7.78	40.78	

[1]BASELINE = BASELINE IS DEFINED AS VALUE AT THE END OF PHASE C VISIT.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]P-VALUES ARE DERIVED FROM ANALYSIS OF COVARIATE MODEL WITH TREATMENT AS TERM AND BASELINE AS COVARIATE.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.4.2 FINAL

＜資料番号 5.3.5.1-01：CT-13.2.4.2＞

表 2.7.4.7-160　臨床的に重要なプロラクチン値の変動［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range in Phase D by Gender
(Phase D Safety Sample)

			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PROLACTIN LEVEL	TRIAL WEEK[1]	SEX	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
>1 x ULN	WEEK 28	FEMALE	3	0	(0.0)	1	0	(0.0)	4	0	(0.0)
		MALE	0	0	(0.0)	1	1	(100.0)	1	1	(100.0)
		TOTAL	3	0	(0.0)	2	1	(50.0)	5	1	(20.0)
	WEEK 52	FEMALE	41	2	(4.9)	16	2	(12.5)	57	4	(7.0)
		MALE	23	0	(0.0)	22	2	(9.1)	45	2	(4.4)
		TOTAL	64	2	(3.1)	38	4	(10.5)	102	6	(5.9)
	LAST VISIT	FEMALE	76	4	(5.3)	65	4	(6.2)	141	8	(5.7)
		MALE	41	0	(0.0)	52	4	(7.7)	93	4	(4.3)
		TOTAL	117	4	(3.4)	117	8	(6.8)	234	12	(5.1)
	ANY POST BASELINE	FEMALE	76	4	(5.3)	65	4	(6.2)	141	8	(5.7)
		MALE	41	0	(0.0)	52	4	(7.7)	93	4	(4.3)
		TOTAL	117	4	(3.4)	117	8	(6.8)	234	12	(5.1)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE SPECIFIED TRIAL WEEK.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.
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表 2.7.4.7-160　臨床的に重要なプロラクチン値の変動［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range in Phase D by Gender
(Phase D Safety Sample)

PROLACTIN LEVEL	TRIAL WEEK[1]	SEX	ARIP IMD (N=132) Ne[2]	n[3]	(%)	PLACEBO (N=133) Ne[2]	n[3]	(%)	TOTAL (N=265) Ne[2]	n[3]	(%)
>2 x ULN	WEEK 28	FEMALE	3	0	(0.0)	1	0	(0.0)	4	0	(0.0)
		MALE	0	0	(0.0)	1	0	(0.0)	1	0	(0.0)
		TOTAL	3	0	(0.0)	2	0	(0.0)	5	0	(0.0)
	WEEK 52	FEMALE	41	1	(2.4)	16	0	(0.0)	57	1	(1.8)
		MALE	23	0	(0.0)	22	1	(4.5)	45	1	(2.2)
		TOTAL	64	1	(1.6)	38	1	(2.6)	102	2	(2.0)
	LAST VISIT	FEMALE	76	1	(1.3)	65	0	(0.0)	141	1	(0.7)
		MALE	41	0	(0.0)	52	1	(1.9)	93	1	(1.1)
		TOTAL	117	1	(0.9)	117	1	(0.9)	234	2	(0.9)
	ANY POST BASELINE	FEMALE	76	1	(1.3)	65	0	(0.0)	141	1	(0.7)
		MALE	41	0	(0.0)	52	1	(1.9)	93	1	(1.1)
		TOTAL	117	1	(0.9)	117	1	(0.9)	234	2	(0.9)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE SPECIFIED TRIAL WEEK.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.1　FINAL

表 2.7.4.7-160　臨床的に重要なプロラクチン値の変動［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range in Phase D by Gender
(Phase D Safety Sample)

PROLACTIN LEVEL	TRIAL WEEK[1]	SEX	ARIP IMD (N=132) Ne[2]	n[3]	(%)	PLACEBO (N=133) Ne[2]	n[3]	(%)	TOTAL (N=265) Ne[2]	n[3]	(%)
>3 x ULN	WEEK 28	FEMALE	3	0	(0.0)	1	0	(0.0)	4	0	(0.0)
		MALE	0	0	(0.0)	1	0	(0.0)	1	0	(0.0)
		TOTAL	3	0	(0.0)	2	0	(0.0)	5	0	(0.0)
	WEEK 52	FEMALE	41	0	(0.0)	16	0	(0.0)	57	0	(0.0)
		MALE	23	0	(0.0)	22	0	(0.0)	45	0	(0.0)
		TOTAL	64	0	(0.0)	38	0	(0.0)	102	0	(0.0)
	LAST VISIT	FEMALE	76	0	(0.0)	65	0	(0.0)	141	0	(0.0)
		MALE	41	0	(0.0)	52	0	(0.0)	93	0	(0.0)
		TOTAL	117	0	(0.0)	117	0	(0.0)	234	0	(0.0)
	ANY POST BASELINE	FEMALE	76	0	(0.0)	65	0	(0.0)	141	0	(0.0)
		MALE	41	0	(0.0)	52	0	(0.0)	93	0	(0.0)
		TOTAL	117	0	(0.0)	117	0	(0.0)	234	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE SPECIFIED TRIAL WEEK.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.1　FINAL

＜資料番号 5.3.5.1-01：CT-13.2.4.1＞

表 2.7.4.7-161　プロラクチン関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.6
Incidence of Treatment-emergent Adverse Events Related to Effects on Prolactin in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
内分泌障害	TOTAL1)	0	(0.0)	1	(0.8)	1	(0.4)
	高プロラクチン血症	0	(0.0)	1	(0.8)	1	(0.4)
TOTAL2)		0	(0.0)	1	(0.8)	1	(0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

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表 2.7.4.7-161　プロラクチン関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.6
Incidence of Treatment-emergent Adverse Events Related to Effects on Prolactin in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO EFFECTS ON PROLACTIN: MEDDRA 19.0 PRIMARY TERMS

BLOOD PROLACTIN, PROLACTINOMA, BLOOD PROLACTIN DECREASED, BLOOD PROLACTIN INCREASED, BLOOD PROLACTIN NORMAL, BLOOD PROLACTIN ABNORMAL,
ECTOPIC PROLACTIN SECRETION, PROLACTIN PRODUCING PITUITARY TUMOUR, ANTIPROLACIN THERAPY, HYPOPROLACTINAEMIA, HYPERPROLACTINAEMIA

＜資料番号 5.3.5.1-01：CT-8.2.5.6 より作成＞

表 2.7.4.7-162　プロラクチンの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.4.2
Laboratory Test Results for Prolactin - Mean Change From Baseline by Gender
(Phase C Safety Sample)

SEX=MALE

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	BASELINE	1	1.86	1.86		1.86	1.86								
	WEEK 12	92	3.43	2.62	2.91	0.52	18.06	1	1.86		-0.22	-0.22		-0.22	-0.22
	WEEK 28	1	6.39	6.39		6.39	6.39	0							
	LAST VISIT	135	3.51	2.71	2.83	0.37	18.06	1	1.86		-0.22	-0.22		-0.22	-0.22

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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表 2.7.4.7-162　プロラクチンの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.4.2
Laboratory Test Results for Prolactin - Mean Change From Baseline by Gender
(Phase C Safety Sample)

SEX=FEMALE

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE C	WEEK 12	126	7.86	6.90	5.56	0.66	31.28	0							
	WEEK 28	6	13.98	10.49	9.76	2.95	30.58	0							
	LAST VISIT	222	8.73	7.07	7.40	0.66	64.48	0							

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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表 2.7.4.7-162 プロラクチンの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.4.2
Laboratory Test Results for Prolactin - Mean Change From Baseline by Gender
(Phase C Safety Sample)

SEX=TOTAL

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE C	BASELINE	1	1.86	1.86		1.86	1.86								
	WEEK 12	218	5.99	4.54	5.11	0.52	31.28	1	1.86		-0.22	-0.22		-0.22	-0.22
	WEEK 28	7	12.89	10.17	9.36	2.95	30.58	0							
	LAST VISIT	357	6.76	5.04	6.59	0.37	64.48	1	1.86		-0.22	-0.22		-0.22	-0.22

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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＜資料番号 5.3.5.1-01：CT-22.3.4.2＞

表 2.7.4.7-163　臨床的に重要なプロラクチン値の変動［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range by Gender
(Phase C Safety Sample)

PROLACTIN LEVEL	PHASE	TRIAL WEEK[1]	SEX	Ne[2]	n[3]	(%)
>1 x ULN	PHASE C	WEEK 12	FEMALE	126	3	(2.4)
			MALE	92	1	(1.1)
			TOTAL	218	4	(1.8)
		LAST VISIT	FEMALE	222	6	(2.7)
			MALE	135	1	(0.7)
			TOTAL	357	7	(2.0)
		ANY POST BASELINE	FEMALE	222	7	(3.2)
			MALE	135	1	(0.7)
			TOTAL	357	8	(2.2)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE VISIT.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.4.1　FINAL

表 2.7.4.7-163　臨床的に重要なプロラクチン値の変動［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range by Gender
(Phase C Safety Sample)

PROLACTIN LEVEL	PHASE	TRIAL WEEK[1]	SEX	Ne[2]	n[3]	(%)
>2 x ULN	PHASE C	WEEK 12	FEMALE	126	0	(0.0)
			MALE	92	0	(0.0)
			TOTAL	218	0	(0.0)
		LAST VISIT	FEMALE	222	1	(0.5)
			MALE	135	0	(0.0)
			TOTAL	357	1	(0.3)
		ANY POST BASELINE	FEMALE	222	1	(0.5)
			MALE	135	0	(0.0)
			TOTAL	357	1	(0.3)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE VISIT.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

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表 2.7.4.7-163　臨床的に重要なプロラクチン値の変動［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range by Gender
(Phase C Safety Sample)

PROLACTIN LEVEL	PHASE	TRIAL WEEK[1]	SEX	Ne[2]	n[3]	(%)
>3 x ULN	PHASE C	WEEK 12	FEMALE	126	0	(0.0)
			MALE	92	0	(0.0)
			TOTAL	218	0	(0.0)
		LAST VISIT	FEMALE	222	0	(0.0)
			MALE	135	0	(0.0)
			TOTAL	357	0	(0.0)
		ANY POST BASELINE	FEMALE	222	0	(0.0)
			MALE	135	0	(0.0)
			TOTAL	357	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE VISIT.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.

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＜資料番号 5.3.5.1-01：CT-22.3.4.1＞

表 2.7.4.7-164　プロラクチン関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.6
Incidence of Treatment-emergent Adverse Events Related to Effects on Prolactin
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
臨床検査	TOTAL1)	0	(0.0)	1	(0.2)
	血中プロラクチン増加	0	(0.0)	1	(0.2)
TOTAL2)		0	(0.0)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.6　FINAL

表 2.7.4.7-164　プロラクチン関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.6
Incidence of Treatment-emergent Adverse Events Related to Effects on Prolactin
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO EFFECTS ON PROLACTIN: MEDDRA 19.0 PRIMARY TERMS

BLOOD PROLACTIN, PROLACTINOMA, BLOOD PROLACTIN DECREASED, BLOOD PROLACTIN INCREASED, BLOOD PROLACTIN NORMAL, BLOOD PROLACTIN ABNORMAL, ECTOPIC PROLACTIN SECRETION, PROLACTIN PRODUCING PITUITARY TUMOUR, ANTIPROLACIN THERAPY, HYPOPROLACTINAEMIA, HYPERPROLACTINAEMIA

FILE: ADAE3BG.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.6　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.5.6 より作成＞

表 2.7.4.7-165　プロラクチンの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.4.2
Laboratory Test Results for Prolactin - Mean Change From Baseline in Phase C by Sex
(Phase C Safety Sample)

SEX=MALE

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE FROM BASELINE: MEAN	MEDIAN	SD	MIN	MAX
DE NOVO	BASELINE	153	4.18	3.03	6.45	0.31	72.57								
	WEEK 28	5	1.34	1.07	0.77	0.61	2.17	5	2.44	1.92	-1.10	-0.32	1.17	-2.50	-0.19
	WEEK 52	90	3.89	1.98	9.05	0.34	84.22	87	4.54	8.05	-0.58	-0.24	2.48	-9.82	11.65
	LAST VISIT	138	3.64	2.08	7.55	0.34	84.22	132	4.20	6.79	-0.57	-0.28	2.09	-9.82	11.65
ROLLOVER	BASELINE	36	5.12	3.53	5.33	0.38	26.83								
	WEEK 28	21	3.67	1.90	4.10	0.68	16.84	21	6.01	6.28	-2.34	-0.10	4.11	-11.83	2.10
	WEEK 52	4	2.88	1.27	3.67	0.62	8.37	4	3.65	3.01	-0.77	-0.05	2.07	-3.80	0.81
	LAST VISIT	35	3.07	1.51	3.50	0.42	16.84	35	5.14	5.40	-2.07	-0.33	3.60	-11.83	2.10
TOTAL	BASELINE	189	4.36	3.11	6.25	0.31	72.57								
	WEEK 28	26	3.22	1.71	3.80	0.61	16.84	26	5.32	5.85	-2.10	-0.28	3.74	-11.83	2.10
	WEEK 52	94	3.84	1.91	8.88	0.34	84.22	91	4.50	7.89	-0.58	-0.24	2.46	-9.82	11.65
	LAST VISIT	173	3.52	1.91	6.91	0.34	84.22	167	4.40	6.52	-0.89	-0.29	2.55	-11.83	11.65

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.2　FINAL

表 2.7.4.7-165　プロラクチンの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.4.2
Laboratory Test Results for Prolactin - Mean Change From Baseline in Phase C by Sex
(Phase C Safety Sample)

SEX=FEMALE

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	214	8.90	7.14	6.63	0.41	45.22								
	WEEK 28	8	12.46	7.23	12.85	2.89	34.17	8	7.70	6.54	4.76	0.08	12.44	-4.67	33.25
	WEEK 52	131	8.00	6.59	5.52	0.58	32.09	129	8.81	6.60	-0.97	-0.43	4.88	-29.01	9.54
	LAST VISIT	197	8.48	6.89	6.36	0.58	40.10	191	8.84	6.67	-0.50	-0.22	5.23	-29.01	24.95
ROLLOVER	BASELINE	47	9.74	8.44	8.30	0.94	54.34								
	WEEK 28	22	8.09	6.89	7.06	1.93	36.17	22	9.49	5.20	-1.40	-1.04	3.41	-6.82	8.33
	WEEK 52	10	6.08	4.02	5.34	0.53	13.64	10	8.67	5.78	-2.59	-2.53	3.89	-9.51	4.24
	LAST VISIT	44	7.46	6.28	6.09	0.53	36.17	43	8.91	5.14	-1.48	-0.70	3.29	-9.51	8.33
TOTAL	BASELINE	261	9.05	7.58	6.95	0.41	54.34								
	WEEK 28	30	9.25	6.89	8.93	1.93	36.17	30	9.01	5.53	0.24	-0.87	7.31	-6.82	33.25
	WEEK 52	141	7.87	6.52	5.51	0.53	32.09	139	8.80	6.53	-1.08	-0.46	4.83	-29.01	9.54
	LAST VISIT	241	8.29	6.79	6.31	0.53	40.10	234	8.85	6.41	-0.68	-0.35	4.94	-29.01	24.95

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
FILE: ADLB2AE.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.2　FINAL

表 2.7.4.7-165　プロラクチンの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.4.2
Laboratory Test Results for Prolactin - Mean Change From Baseline in Phase C by Sex
(Phase C Safety Sample)

SEX=TOTAL

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	367	6.93	4.98	6.95	0.31	72.57								
	WEEK 28	13	8.18	3.05	11.32	0.61	34.17	13	5.68	5.77	2.50	-0.32	9.98	-4.67	33.25
	WEEK 52	221	6.33	4.28	7.43	0.34	84.22	216	7.09	7.50	-0.81	-0.26	4.09	-29.01	11.65
	LAST VISIT	335	6.49	4.29	7.26	0.34	84.22	323	6.94	7.09	-0.53	-0.25	4.23	-29.01	24.95
ROLLOVER	BASELINE	83	7.74	7.06	7.49	0.38	54.34								
	WEEK 28	43	5.93	4.44	6.16	0.68	36.17	43	7.79	5.95	-1.86	-0.73	3.76	-11.83	8.33
	WEEK 52	14	5.17	2.29	5.01	0.53	13.64	14	7.23	5.55	-2.07	-1.40	3.49	-9.51	4.24
	LAST VISIT	79	5.51	3.92	5.53	0.42	36.17	78	7.22	5.56	-1.75	-0.57	3.43	-11.83	8.33
TOTAL	BASELINE	450	7.08	5.25	7.05	0.31	72.57								
	WEEK 28	56	6.45	4.31	7.61	0.61	36.17	56	7.30	5.93	-0.85	-0.71	6.00	-11.83	33.25
	WEEK 52	235	6.26	4.23	7.31	0.34	84.22	230	7.10	7.39	-0.89	-0.29	4.06	-29.01	11.65
	LAST VISIT	414	6.30	4.29	6.97	0.34	84.22	401	7.00	6.81	-0.76	-0.29	4.11	-29.01	24.95

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
FILE: ADLB2AE.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
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＜資料番号 5.3.5.2-01：CT-13.2.4.2＞

表 2.7.4.7-166　臨床的に重要なプロラクチン値の変動［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range in Phase C by Sex
(Phase C Safety Sample)

			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PROLACTIN LEVEL	TRIAL WEEK[1]	SEX	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
>1 x ULN	BASELINE	FEMALE	214	4	(1.9)	47	2	(4.3)	261	6	(2.3)
		MALE	153	5	(3.3)	36	2	(5.6)	189	7	(3.7)
		TOTAL	367	9	(2.5)	83	4	(4.8)	450	13	(2.9)
	WEEK 28	FEMALE	8	2	(25.0)	22	1	(4.5)	30	3	(10.0)
		MALE	5	0	(0.0)	21	1	(4.8)	26	1	(3.8)
		TOTAL	13	2	(15.4)	43	2	(4.7)	56	4	(7.1)
	WEEK 52	FEMALE	131	1	(0.8)	10	0	(0.0)	141	1	(0.7)
		MALE	91	3	(3.3)	4	0	(0.0)	95	3	(3.2)
		TOTAL	222	4	(1.8)	14	0	(0.0)	236	4	(1.7)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE SPECIFIED TRIAL WEEK.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.
FILE: ADLB3AC.LIS, RUN: [redacted]20[redacted] 13:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.1　FINAL

表 2.7.4.7-166　臨床的に重要なプロラクチン値の変動［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range in Phase C by Sex
(Phase C Safety Sample)

PROLACTIN LEVEL	TRIAL WEEK[1]	SEX	DE NOVO (N=379) Ne[2]	DE NOVO (N=379) n[3]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[2]	ROLLOVER (N=85) n[3]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[2]	TOTAL (N=464) n[3]	TOTAL (N=464) (%)
>2 x ULN	BASELINE	FEMALE	214	0	(0.0)	47	1	(2.1)	261	1	(0.4)
		MALE	153	1	(0.7)	36	1	(2.8)	189	2	(1.1)
		TOTAL	367	1	(0.3)	83	2	(2.4)	450	3	(0.7)
	WEEK 28	FEMALE	8	0	(0.0)	22	0	(0.0)	30	0	(0.0)
		MALE	5	0	(0.0)	21	0	(0.0)	26	0	(0.0)
		TOTAL	13	0	(0.0)	43	0	(0.0)	56	0	(0.0)
	WEEK 52	FEMALE	131	0	(0.0)	10	0	(0.0)	141	0	(0.0)
		MALE	91	1	(1.1)	4	0	(0.0)	95	1	(1.1)
		TOTAL	222	1	(0.5)	14	0	(0.0)	236	1	(0.4)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE SPECIFIED TRIAL WEEK.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.
FILE: ADLB3AC.LIS, RUN: [redacted]20[redacted] 13:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.4.1　FINAL

表 2.7.4.7-166　臨床的に重要なプロラクチン値の変動［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.4.1
Incidence of Prolactin Level Above Upper Limit of Normal Range in Phase C by Sex
(Phase C Safety Sample)

PROLACTIN LEVEL	TRIAL WEEK[1]	SEX	DE NOVO (N=379) Ne[2]	DE NOVO (N=379) n[3]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[2]	ROLLOVER (N=85) n[3]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[2]	TOTAL (N=464) n[3]	TOTAL (N=464) (%)
>3 x ULN	BASELINE	FEMALE	214	0	(0.0)	47	0	(0.0)	261	0	(0.0)
		MALE	153	1	(0.7)	36	0	(0.0)	189	1	(0.5)
		TOTAL	367	1	(0.3)	83	0	(0.0)	450	1	(0.2)
	WEEK 28	FEMALE	8	0	(0.0)	22	0	(0.0)	30	0	(0.0)
		MALE	5	0	(0.0)	21	0	(0.0)	26	0	(0.0)
		TOTAL	13	0	(0.0)	43	0	(0.0)	56	0	(0.0)
	WEEK 52	FEMALE	131	0	(0.0)	10	0	(0.0)	141	0	(0.0)
		MALE	91	1	(1.1)	4	0	(0.0)	95	1	(1.1)
		TOTAL	222	1	(0.5)	14	0	(0.0)	236	1	(0.4)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH TEST RESULT AT THE SPECIFIED TRIAL WEEK.
[3]n IS THE NUMBER OF SUBJECTS WITH PROLACTIN LEVEL ABOVE UPPER LIMIT OF NORMAL RANGE; THE DENOMINATOR FOR PERCENTAGE CALCULATION IS Ne.
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＜資料番号 5.3.5.2-01：CT-13.2.4.1＞

表 2.7.4.7-167　プロラクチン関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.6
Incidence of Treatment-emergent Adverse Events Related to Effects on Prolactin in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
内分泌障害	TOTAL1)	3	(0.8)	0	(0.0)	3	(0.6)
	高プロラクチン血症	3	(0.8)	0	(0.0)	3	(0.6)
臨床検査	TOTAL1)	2	(0.5)	0	(0.0)	2	(0.4)
	血中プロラクチン減少	1	(0.3)	0	(0.0)	1	(0.2)
	血中プロラクチン増加	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL2)		5	(1.3)	0	(0.0)	5	(1.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AG.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.6　FINAL

表 2.7.4.7-167　プロラクチン関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.6
Incidence of Treatment-emergent Adverse Events Related to Effects on Prolactin in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO EFFECTS ON PROLACTIN: MEDDRA 19.0 PRIMARY TERMS

BLOOD PROLACTIN, PROLACTINOMA, BLOOD PROLACTIN DECREASED, BLOOD PROLACTIN INCREASED, BLOOD PROLACTIN NORMAL, BLOOD PROLACTIN ABNORMAL,
ECTOPIC PROLACTIN SECRETION, PROLACTIN PRODUCING PITUITARY TUMOUR, ANTIPROLACIN THERAPY, HYPOPROLACTINAEMIA, HYPERPROLACTINAEMIA

＜資料番号 5.3.5.2-01：CT-8.2.5.6＞

表 2.7.4.7-168　自殺関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.2
Incidence of Treatment-emergent Adverse Events Related to Suicidal Ideation/Suicide in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
精神障害	TOTAL1)	1	(0.8)	1	(0.8)	2	(0.8)
	自殺企図	1	(0.8)	1	(0.8)	2	(0.8)
TOTAL2)		1	(0.8)	1	(0.8)	2	(0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AC.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.2　FINAL

表 2.7.4.7-168　自殺関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.2
Incidence of Treatment-emergent Adverse Events Related to Suicidal Ideation/Suicide in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO SUICIDAL IDEATION/SUICIDE: MEDDRA 19.0 PRIMARY TERMS

COMPLETED SUICIDE, SUICIDE OF RELATIVE, SUICIDE ATTEMPT, SUICIDAL BEHAVIOUR, SUICIDE OF COMPANION, FAMILIAL RISK FACTOR, SUICIDAL IDEATION
DEPRESSION SUICIDAL, INTENTIONAL SELF-INJURY

FILE: ADAE3AC.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.2　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.5.2 より作成＞

表 2.7.4.7-169　自殺関連有害事象一覧表［二重盲検試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	6[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-09-27 13:00	同年*-10-10 11:31	12	MODERATE
		[redacted]	4[redacted]/F/BLACK	自殺念慮*/SUICIDAL IDEATION WITHOUT INTENT	精神障害	20[redacted]-03-07	同年*-03-29	24	MODERATE
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-16 15:25	同年*-06-21 10:15	25	MILD
		[redacted]	5[redacted]/F/BLACK	自殺念慮*/ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	精神障害	20[redacted]-02-15	同年*-02-19	17	MODERATE
PHASE B	ARIP 10-30MG	[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-12-12 12:00	同年*-12-17 12:00	22	MODERATE
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-04-11 09:00	同年*-04-14 09:00	45	MODERATE
		[redacted]	4[redacted]/F/BLACK	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-03-29	同年*-03-29	39	SEVERE
				自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-04-03	同年*-04-03	44	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 11:06; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-169　自殺関連有害事象一覧表［二重盲検試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	6[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	自殺念慮*/SUICIDAL IDEATION WITHOUT INTENT	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	自殺念慮*/ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	精神障害	NO	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE B	ARIP 10-30MG	[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 11:06; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

表 2.7.4.7-169　自殺関連有害事象一覧表［二重盲検試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 10-30MG	[redacted]	5[redacted]/M/BLACK	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-03-08	同年*-03-08	25	MODERATE
				自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-03-08	同年*-03-08	25	MODERATE
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-11-09	同年*-11-12	34	MODERATE
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-05-12	同年*-05-15	12	MILD
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-11-30 08:00	同年*-12-03 09:00	140	MODERATE
		[redacted]	2[redacted]/M/CAUC.	自殺企図*/SUICIDE ATTEMPT	精神障害	20[redacted]-12-13 18:00	同年*-12-15	36	MODERATE
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-05-01	同年*-05-12	53	MILD
		[redacted]	2[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-02-11	同年*-02-13	47	MODERATE
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDALITY	精神障害	20[redacted]-04-09	同年*-04-11	36	MILD

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 11:06; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-169　自殺関連有害事象一覧表［二重盲検試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 10-30MG	[redacted]	5[redacted]/M/BLACK	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				自殺念慮*/SUICIDAL IDEATION	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	自殺企図*/SUICIDE ATTEMPT	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDALITY	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 11:06; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

表 2.7.4.7-169　自殺関連有害事象一覧表［二重盲検試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/BLACK	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-02-11	同年*-02-11	82	MILD
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION. NO SUICIDAL BEHAVIOUR.	精神障害	20[redacted]-01-14	同年*-01-21	91	MILD
PHASE D	ARIP IMD	[redacted]	2[redacted]/F/BLACK	自殺企図*/SUICIDE ATTEMPT	精神障害	20[redacted]-02-28 17:00	同年*-02-28 17:00	171	SEVERE
	PLACEBO	[redacted]	2[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-04-11	同年*-04-11	172	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 11:06; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-169　自殺関連有害事象一覧表［二重盲検試験］

OPC14597　　6 OF 6

PROTOCOL 31-08-250

CT-9.4

Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/M/BLACK	自殺念慮*/SUICIDAL IDEATION	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION. NO SUICIDAL BEHAVIOUR.	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
PHASE D	ARIP IMD	[redacted]	2[redacted]/F/BLACK	自殺企図*/SUICIDE ATTEMPT	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
	PLACEBO	[redacted]	2[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 11:06; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　　FINAL

＜資料番号 5.3.5.1-01：CT-9.4 より作成＞

表 2.7.4.7-170　C-SSRS のベースラインからの変化量［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase D Safety Sample)

											CHANGE FROM BASELINE				
								BASELINE							
PHASE	TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE A	ARIP 5-15MG	BASELINE	159	0.4	0.0	2.1	0.0	14.0								
		WEEK 1	158	0.3	0.0	1.7	0.0	14.0	158	0.4	2.1	-0.2	0.0	2.0	-10.0	13.0
		WEEK 2	159	0.1	0.0	1.0	0.0	12.0	159	0.4	2.0	-0.3	0.0	2.2	-14.0	12.0
		WEEK 3	160	0.1	0.0	1.1	0.0	11.0	160	0.5	2.1	-0.4	0.0	2.4	-14.0	11.0
		WEEK 4	158	0.1	0.0	0.9	0.0	9.0	158	0.4	2.1	-0.3	0.0	2.3	-14.0	9.0
		WEEK 5	98	0.2	0.0	1.3	0.0	13.0	98	0.2	1.5	-0.0	0.0	0.8	-7.0	3.0
		WEEK 6	59	0.2	0.0	1.2	0.0	9.0	59	0.0	0.0	0.2	0.0	1.2	0.0	9.0
		LAST VISIT	159	0.3	0.0	1.5	0.0	13.0	159	0.4	2.1	-0.2	0.0	2.2	-14.0	9.0
PHASE B	ARIP 10-30MG	BASELINE	265	0.2	0.0	1.4	0.0	13.0								
		WEEK 2	258	0.1	0.0	1.0	0.0	12.0	258	0.2	1.3	-0.1	0.0	1.1	-10.0	10.0
		WEEK 4	202	0.1	0.0	0.8	0.0	11.0	202	0.2	1.4	-0.1	0.0	1.0	-10.0	0.0
		WEEK 6	118	0.0	0.0	0.0	0.0	0.0	118	0.1	1.2	-0.1	0.0	1.2	-13.0	0.0
		WEEK 8	75	0.0	0.0	0.0	0.0	0.0	75	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		LAST VISIT	265	0.0	0.0	0.2	0.0	4.0	265	0.2	1.4	-0.2	0.0	1.3	-13.0	0.0
PHASE C	ARIP IMD 400/300MG	BASELINE	265	0.0	0.0	0.2	0.0	4.0								
		WEEK 1	259	0.0	0.0	0.2	0.0	4.0	259	0.0	0.2	0.0	0.0	0.0	0.0	0.0
		WEEK 2	264	0.1	0.0	0.9	0.0	11.0	264	0.0	0.2	0.1	0.0	0.9	-4.0	11.0
		WEEK 3	262	0.1	0.0	1.1	0.0	11.0	262	0.0	0.2	0.1	0.0	1.0	0.0	11.0
		WEEK 4	263	0.0	0.0	0.6	0.0	9.0	263	0.0	0.2	0.0	0.0	0.7	-4.0	9.0
		WEEK 6	270	0.0	0.0	0.0	0.0	0.0	270	0.0	0.2	-0.0	0.0	0.2	-4.0	0.0
		WEEK 8	263	0.2	0.0	1.3	0.0	11.0	263	0.0	0.2	0.2	0.0	1.3	-4.0	11.0
		WEEK 10	268	0.1	0.0	1.1	0.0	13.0	268	0.0	0.2	0.1	0.0	1.1	-4.0	13.0
		WEEK 12	264	0.2	0.0	1.2	0.0	11.0	264	0.0	0.2	0.2	0.0	1.3	-4.0	11.0
		WEEK 14	74	0.4	0.0	1.9	0.0	13.0	74	0.0	0.0	0.4	0.0	1.9	0.0	13.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADCSSR2AC.LIS, RUN: [redacted]20[redacted] 14:09; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:48
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADCSSR2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.4.3　FINAL

表 2.7.4.7-170　C-SSRS のベースラインからの変化量［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase D Safety Sample)

											CHANGE FROM BASELINE				
									BASELINE						
PHASE	TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ARIP IMD 400/300MG	WEEK 16	67	0.0	0.0	0.0	0.0	0.0	67	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 18	47	0.0	0.0	0.0	0.0	0.0	47	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 20	38	0.0	0.0	0.0	0.0	0.0	38	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 22	23	0.0	0.0	0.0	0.0	0.0	23	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 24	19	0.0	0.0	0.0	0.0	0.0	19	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 26	6	0.0	0.0	0.0	0.0	0.0	6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 28	6	0.0	0.0	0.0	0.0	0.0	6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		LAST VISIT	265	0.1	0.0	0.7	0.0	8.0	265	0.0	0.2	0.0	0.0	0.7	-4.0	8.0
PHASE D	ARIP IMD	BASELINE	132	0.1	0.0	0.9	0.0	8.0								
		WEEK 2	123	0.1	0.0	0.8	0.0	7.0	123	0.1	1.0	-0.0	0.0	1.0	-8.0	7.0
		WEEK 4	134	0.3	0.0	2.1	0.0	19.0	134	0.1	0.9	0.2	0.0	2.2	-8.0	19.0
		WEEK 6	120	0.0	0.0	0.0	0.0	0.0	120	0.1	1.0	-0.1	0.0	1.0	-8.0	0.0
		WEEK 8	105	0.0	0.0	0.4	0.0	4.0	105	0.1	1.0	-0.1	0.0	1.1	-8.0	4.0
		WEEK 10	107	0.0	0.0	0.0	0.0	0.0	107	0.1	0.7	-0.1	0.0	0.7	-7.0	0.0
		WEEK 12	99	0.0	0.0	0.0	0.0	0.0	99	0.1	0.7	-0.1	0.0	0.7	-7.0	0.0
		WEEK 14	101	0.0	0.0	0.0	0.0	0.0	101	0.1	0.7	-0.1	0.0	0.7	-7.0	0.0
		WEEK 16	93	0.1	0.0	0.6	0.0	6.0	93	0.1	0.7	-0.0	0.0	1.0	-7.0	6.0
		WEEK 18	88	0.1	0.0	0.5	0.0	5.0	88	0.1	0.7	-0.0	0.0	0.2	-2.0	0.0
		WEEK 20	83	0.0	0.0	0.0	0.0	0.0	83	0.1	0.8	-0.1	0.0	0.8	-7.0	0.0
		WEEK 22	88	0.0	0.0	0.0	0.0	0.0	88	0.1	0.7	-0.1	0.0	0.7	-7.0	0.0
		WEEK 24	80	0.0	0.0	0.0	0.0	0.0	80	0.1	0.8	-0.1	0.0	0.8	-7.0	0.0
		WEEK 26	80	0.2	0.0	1.7	0.0	15.0	80	0.1	0.8	0.1	0.0	1.9	-7.0	15.0
		WEEK 28	89	0.1	0.0	1.1	0.0	10.0	89	0.1	0.7	0.0	0.0	1.3	-7.0	10.0
		WEEK 32	77	0.1	0.0	1.3	0.0	11.0	77	0.1	0.8	0.1	0.0	1.5	-7.0	11.0
		WEEK 36	71	0.1	0.0	1.1	0.0	9.0	71	0.1	0.8	0.0	0.0	1.4	-7.0	9.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-170　C-SSRS のベースラインからの変化量［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase D Safety Sample)

											CHANGE FROM BASELINE				
									BASELINE						
PHASE	TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE D	ARIP IMD	WEEK 40	71	0.1	0.0	0.6	0.0	5.0	71	0.1	0.8	-0.0	0.0	1.0	-7.0	5.0
		WEEK 44	69	0.0	0.0	0.0	0.0	0.0	69	0.1	0.8	-0.1	0.0	0.8	-7.0	0.0
		WEEK 48	68	0.0	0.0	0.0	0.0	0.0	68	0.1	0.8	-0.1	0.0	0.8	-7.0	0.0
		WEEK 52	65	0.0	0.0	0.0	0.0	0.0	65	0.1	0.9	-0.1	0.0	0.9	-7.0	0.0
		LAST VISIT	131	0.4	0.0	2.4	0.0	19.0	131	0.1	0.9	0.3	0.0	2.6	-8.0	19.0
	PLACEBO	BASELINE	133	0.0	0.0	0.0	0.0	0.0								
		WEEK 2	127	0.3	0.0	2.6	0.0	21.0	127	0.0	0.0	0.3	0.0	2.6	0.0	21.0
		WEEK 4	128	0.1	0.0	1.1	0.0	13.0	128	0.0	0.0	0.1	0.0	1.1	0.0	13.0
		WEEK 6	108	0.3	0.0	1.9	0.0	13.0	108	0.0	0.0	0.3	0.0	1.9	0.0	13.0
		WEEK 8	103	0.0	0.0	0.0	0.0	0.0	103	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 10	99	0.3	0.0	1.5	0.0	11.0	99	0.0	0.0	0.3	0.0	1.5	0.0	11.0
		WEEK 12	88	0.0	0.0	0.0	0.0	0.0	88	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 14	86	0.0	0.0	0.0	0.0	0.0	86	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 16	83	0.1	0.0	1.1	0.0	10.0	83	0.0	0.0	0.1	0.0	1.1	0.0	10.0
		WEEK 18	80	0.2	0.0	1.0	0.0	7.0	80	0.0	0.0	0.2	0.0	1.0	0.0	7.0
		WEEK 20	75	0.0	0.0	0.0	0.0	0.0	75	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 22	71	0.2	0.0	1.8	0.0	15.0	71	0.0	0.0	0.2	0.0	1.8	0.0	15.0
		WEEK 24	69	0.0	0.0	0.0	0.0	0.0	69	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 26	65	0.2	0.0	1.2	0.0	10.0	65	0.0	0.0	0.2	0.0	1.2	0.0	10.0
		WEEK 28	63	0.2	0.0	1.3	0.0	10.0	63	0.0	0.0	0.2	0.0	1.3	0.0	10.0
		WEEK 32	56	0.0	0.0	0.0	0.0	0.0	56	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 36	55	0.2	0.0	1.2	0.0	9.0	55	0.0	0.0	0.2	0.0	1.2	0.0	9.0
		WEEK 40	53	0.1	0.0	0.4	0.0	3.0	53	0.0	0.0	0.1	0.0	0.4	0.0	3.0
		WEEK 44	47	0.0	0.0	0.0	0.0	0.0	47	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 48	47	0.2	0.0	1.6	0.0	11.0	47	0.0	0.0	0.2	0.0	1.6	0.0	11.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-170　C-SSRS のベースラインからの変化量［二重盲検試験，二重盲検期（Phase D）］

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CT-6.4.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase D Safety Sample)

										CHANGE FROM BASELINE						
									BASELINE							
PHASE	TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE D	PLACEBO	WEEK 52	41	0.3	0.0	2.0	0.0	13.0	41	0.0	0.0	0.3	0.0	2.0	0.0	13.0
		LAST VISIT	133	0.5	0.0	2.6	0.0	20.0	133	0.0	0.0	0.5	0.0	2.6	0.0	20.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.1-01：CT-6.4.3＞

表 2.7.4.7-171　C-CASA/C-SSRS［二重盲検試験，二重盲検期（Phase D）］

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CT-6.4.4
Incidence of Treatment-emergent Possible Suicidal Events - C-CASA Category Analysis Using C-SSRS Assessment
(Phase D Safety Sample)

CATEGORY	C-CASA RATING	PHASE A (N=159) Ne[2]	PHASE A (N=159) n[3]	PHASE A (N=159) (%)	PHASE B (N=265) Ne[2]	PHASE B (N=265) n[3]	PHASE B (N=265) (%)	PHASE C (N=265) Ne[2]	PHASE C (N=265) n[3]	PHASE C (N=265) (%)
POTENTIAL SUICIDAL	TOTAL[1]	159	8	(5.0)	265	3	(1.1)	265	16	(6.0)
	COMPLETED SUICIDE	159	0	(0.0)	265	0	(0.0)	265	0	(0.0)
	SUICIDE ATTEMPT	159	0	(0.0)	265	0	(0.0)	265	0	(0.0)
	PREPARATORY ACTIONS TOWARD IMMINENT SUICIDAL BEHAVIOR	159	0	(0.0)	265	0	(0.0)	265	1	(0.4)
	SUICIDAL IDEATION	159	8	(5.0)	265	3	(1.1)	265	16	(6.0)
	NON-SUICIDAL SELF-INJURIOUS BEHAVIOR	159	0	(0.0)	265	0	(0.0)	265	1	(0.4)

[1]SUBJECTS WITH MULTIPLE RATINGS WITHIN THE SAME CATEGORY WERE COUNTED ONCE TOWARDS THE TOTAL.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS POTENTIAL SUICIDALITY EVALUATION DURING THE TRIAL.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED POTENTIAL SUICIDALITY DURING THE TRIAL.

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表 2.7.4.7-171　C-CASA/C-SSRS［二重盲検試験，二重盲検期（Phase D）］

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PROTOCOL 31-08-250

CT-6.4.4
Incidence of Treatment-emergent Possible Suicidal Events - C-CASA Category Analysis Using C-SSRS Assessment
(Phase D Safety Sample)

			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE D	CATEGORY	C-CASA RATING	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	POTENTIAL SUICIDAL	TOTAL[1]	131	9	(6.9)	133	16	(12.0)	264	25	(9.5)
		COMPLETED SUICIDE	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
		SUICIDE ATTEMPT	131	1	(0.8)	133	0	(0.0)	264	1	(0.4)
		PREPARATORY ACTIONS TOWARD IMMINENT SUICIDAL BEHAVIOR	131	0	(0.0)	133	1	(0.8)	264	1	(0.4)
		SUICIDAL IDEATION	131	9	(6.9)	133	15	(11.3)	264	24	(9.1)
		NON-SUICIDAL SELF-INJURIOUS BEHAVIOR	131	0	(0.0)	133	1	(0.8)	264	1	(0.4)

[1]SUBJECTS WITH MULTIPLE RATINGS WITHIN THE SAME CATEGORY WERE COUNTED ONCE TOWARDS THE TOTAL.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS POTENTIAL SUICIDALITY EVALUATION DURING THE TRIAL.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED POTENTIAL SUICIDALITY DURING THE TRIAL.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	TOTAL (N=265) Ne[2]	n[3]	(%)
SCREENING	LIFETIME	SUICIDALITY	265	42	(53.6)
		SUICIDAL BEHAVIOR	265	94	(35.5)
		SUICIDAL IDEATION	265	38	(52.1)
	PAST 90 DAYS	SUICIDALITY	254	20	(7.9)
		SUICIDAL BEHAVIOR	254	1	(0.4)
		SUICIDAL IDEATION	254	20	(7.9)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP 5-15MG (N=159) Ne[2]	n[3]	(%)
PHASE A	BASELINE	SUICIDALITY	159	7	(4.4)
		SUICIDAL BEHAVIOR	159	0	(0.0)
		SUICIDAL IDEATION	159	7	(4.4)
	LAST VISIT	COMPLETE SUICIDALITY	159	0	(0.0)
		SUICIDALITY	159	5	(3.1)
		SUICIDAL BEHAVIOR	159	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	159	0	(0.0)
		SUICIDAL IDEATION	159	5	(3.1)
		EMERGENCE OF SUICIDAL IDEATION	159	4	(2.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	159	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	159	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	159	0	(0.0)
		SUICIDALITY	159	8	(5.0)
		SUICIDAL BEHAVIOR	159	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	159	0	(0.0)
		SUICIDAL IDEATION	159	8	(5.0)
		EMERGENCE OF SUICIDAL IDEATION	159	6	(3.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	159	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	159	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP 10-30MG (N=265) Ne[2]	n[3]	(%)
PHASE B	BASELINE	SUICIDALITY	265	7	(2.6)
		SUICIDAL BEHAVIOR	265	0	(0.0)
		SUICIDAL IDEATION	265	7	(2.6)
	LAST VISIT	COMPLETE SUICIDALITY	265	0	(0.0)
		SUICIDALITY	265	1	(0.4)
		SUICIDAL BEHAVIOR	265	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	265	0	(0.0)
		SUICIDAL IDEATION	265	1	(0.4)
		EMERGENCE OF SUICIDAL IDEATION	265	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	265	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	265	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	265	0	(0.0)
		SUICIDALITY	265	3	(1.1)
		SUICIDAL BEHAVIOR	265	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	265	0	(0.0)
		SUICIDAL IDEATION	265	3	(1.1)
		EMERGENCE OF SUICIDAL IDEATION	265	1	(0.4)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	265	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	265	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=265) Ne[2]	n[3]	(%)
PHASE C	BASELINE	SUICIDALITY	265	1	(0.4)
		SUICIDAL BEHAVIOR	265	0	(0.0)
		SUICIDAL IDEATION	265	1	(0.4)
	LAST VISIT	COMPLETE SUICIDALITY	265	0	(0.0)
		SUICIDALITY	265	2	(0.8)
		SUICIDAL BEHAVIOR	265	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	265	0	(0.0)
		SUICIDAL IDEATION	265	2	(0.8)
		EMERGENCE OF SUICIDAL IDEATION	265	2	(0.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	265	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	265	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	265	0	(0.0)
		SUICIDALITY	265	16	(6.0)
		SUICIDAL BEHAVIOR	265	1	(0.4)
		EMERGENCE OF SUICIDAL BEHAVIOR	265	1	(0.4)
		SUICIDAL IDEATION	265	16	(6.0)
		EMERGENCE OF SUICIDAL IDEATION	265	15	(5.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	265	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	265	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	BASELINE	SUICIDALITY	132	2	(1.5)	133	0	(0.0)	265	2	(0.8)
		SUICIDAL BEHAVIOR	132	0	(0.0)	133	0	(0.0)	265	0	(0.0)
		SUICIDAL IDEATION	132	2	(1.5)	133	0	(0.0)	265	2	(0.8)
	WEEK 2	COMPLETE SUICIDALITY	123	0	(0.0)	126	0	(0.0)	249	0	(0.0)
		SUICIDALITY	123	2	(1.6)	126	2	(1.6)	249	4	(1.6)
		SUICIDAL BEHAVIOR	123	0	(0.0)	126	0	(0.0)	249	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	123	0	(0.0)	126	0	(0.0)	249	0	(0.0)
		SUICIDAL IDEATION	123	2	(1.6)	126	2	(1.6)	249	4	(1.6)
		EMERGENCE OF SUICIDAL IDEATION	123	1	(0.8)	126	2	(1.6)	249	3	(1.2)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	123	0	(0.0)	126	0	(0.0)	249	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	123	0	(0.0)	126	0	(0.0)	249	0	(0.0)
	WEEK 4	COMPLETE SUICIDALITY	125	0	(0.0)	122	0	(0.0)	247	0	(0.0)
		SUICIDALITY	125	4	(3.2)	122	1	(0.8)	247	5	(2.0)
		SUICIDAL BEHAVIOR	125	0	(0.0)	122	0	(0.0)	247	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	125	0	(0.0)	122	0	(0.0)	247	0	(0.0)
		SUICIDAL IDEATION	125	4	(3.2)	122	1	(0.8)	247	5	(2.0)
		EMERGENCE OF SUICIDAL IDEATION	125	3	(2.4)	122	1	(0.8)	247	4	(1.6)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	125	0	(0.0)	122	0	(0.0)	247	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	125	0	(0.0)	122	0	(0.0)	247	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 6	COMPLETE SUICIDALITY	117	0	(0.0)	107	0	(0.0)	224	0	(0.0)
		SUICIDALITY	117	0	(0.0)	107	3	(2.8)	224	3	(1.3)
		SUICIDAL BEHAVIOR	117	0	(0.0)	107	0	(0.0)	224	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	117	0	(0.0)	107	0	(0.0)	224	0	(0.0)
		SUICIDAL IDEATION	117	0	(0.0)	107	3	(2.8)	224	3	(1.3)
		EMERGENCE OF SUICIDAL IDEATION	117	0	(0.0)	107	3	(2.8)	224	3	(1.3)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	117	0	(0.0)	107	0	(0.0)	224	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	117	0	(0.0)	107	0	(0.0)	224	0	(0.0)
	WEEK 8	COMPLETE SUICIDALITY	104	0	(0.0)	101	0	(0.0)	205	0	(0.0)
		SUICIDALITY	104	1	(1.0)	101	0	(0.0)	205	1	(0.5)
		SUICIDAL BEHAVIOR	104	0	(0.0)	101	0	(0.0)	205	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	104	0	(0.0)	101	0	(0.0)	205	0	(0.0)
		SUICIDAL IDEATION	104	1	(1.0)	101	0	(0.0)	205	1	(0.5)
		EMERGENCE OF SUICIDAL IDEATION	104	1	(1.0)	101	0	(0.0)	205	1	(0.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	104	0	(0.0)	101	0	(0.0)	205	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	104	0	(0.0)	101	0	(0.0)	205	0	(0.0)
	WEEK 10	COMPLETE SUICIDALITY	104	0	(0.0)	96	0	(0.0)	200	0	(0.0)
		SUICIDALITY	104	0	(0.0)	96	3	(3.1)	200	3	(1.5)
		SUICIDAL BEHAVIOR	104	0	(0.0)	96	0	(0.0)	200	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	104	0	(0.0)	96	0	(0.0)	200	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 10	SUICIDAL IDEATION	104	0	(0.0)	96	3	(3.1)	200	3	(1.5)
		EMERGENCE OF SUICIDAL IDEATION	104	0	(0.0)	96	3	(3.1)	200	3	(1.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	104	0	(0.0)	96	0	(0.0)	200	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	104	0	(0.0)	96	0	(0.0)	200	0	(0.0)
	WEEK 12	COMPLETE SUICIDALITY	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		SUICIDALITY	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		SUICIDAL BEHAVIOR	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		SUICIDAL IDEATION	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	97	0	(0.0)	88	0	(0.0)	185	0	(0.0)
	WEEK 14	COMPLETE SUICIDALITY	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		SUICIDALITY	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		SUICIDAL BEHAVIOR	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		SUICIDAL IDEATION	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	99	0	(0.0)	84	0	(0.0)	183	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 16	COMPLETE SUICIDALITY	91	0	(0.0)	82	0	(0.0)	173	0	(0.0)
		SUICIDALITY	91	1	(1.1)	82	1	(1.2)	173	2	(1.2)
		SUICIDAL BEHAVIOR	91	0	(0.0)	82	0	(0.0)	173	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	91	0	(0.0)	82	0	(0.0)	173	0	(0.0)
		SUICIDAL IDEATION	91	1	(1.1)	82	1	(1.2)	173	2	(1.2)
		EMERGENCE OF SUICIDAL IDEATION	91	1	(1.1)	82	1	(1.2)	173	2	(1.2)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	91	0	(0.0)	82	0	(0.0)	173	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	91	0	(0.0)	82	0	(0.0)	173	0	(0.0)
	WEEK 18	COMPLETE SUICIDALITY	87	0	(0.0)	80	0	(0.0)	167	0	(0.0)
		SUICIDALITY	87	1	(1.1)	80	2	(2.5)	167	3	(1.8)
		SUICIDAL BEHAVIOR	87	0	(0.0)	80	0	(0.0)	167	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	87	0	(0.0)	80	0	(0.0)	167	0	(0.0)
		SUICIDAL IDEATION	87	1	(1.1)	80	2	(2.5)	167	3	(1.8)
		EMERGENCE OF SUICIDAL IDEATION	87	0	(0.0)	80	2	(2.5)	167	2	(1.2)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	87	0	(0.0)	80	0	(0.0)	167	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	87	0	(0.0)	80	0	(0.0)	167	0	(0.0)
	WEEK 20	COMPLETE SUICIDALITY	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
		SUICIDALITY	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
		SUICIDAL BEHAVIOR	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 20	SUICIDAL IDEATION	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	82	0	(0.0)	74	0	(0.0)	156	0	(0.0)
	WEEK 22	COMPLETE SUICIDALITY	85	0	(0.0)	71	0	(0.0)	156	0	(0.0)
		SUICIDALITY	85	0	(0.0)	71	1	(1.4)	156	1	(0.6)
		SUICIDAL BEHAVIOR	85	0	(0.0)	71	0	(0.0)	156	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	85	0	(0.0)	71	0	(0.0)	156	0	(0.0)
		SUICIDAL IDEATION	85	0	(0.0)	71	1	(1.4)	156	1	(0.6)
		EMERGENCE OF SUICIDAL IDEATION	85	0	(0.0)	71	1	(1.4)	156	1	(0.6)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	85	0	(0.0)	71	0	(0.0)	156	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	85	0	(0.0)	71	0	(0.0)	156	0	(0.0)
	WEEK 24	COMPLETE SUICIDALITY	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		SUICIDALITY	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		SUICIDAL BEHAVIOR	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		SUICIDAL IDEATION	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	80	0	(0.0)	69	0	(0.0)	149	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 26	COMPLETE SUICIDALITY	77	0	(0.0)	63	0	(0.0)	140	0	(0.0)
		SUICIDALITY	77	1	(1.3)	63	1	(1.6)	140	2	(1.4)
		SUICIDAL BEHAVIOR	77	1	(1.3)	63	1	(1.6)	140	2	(1.4)
		EMERGENCE OF SUICIDAL BEHAVIOR	77	1	(1.3)	63	1	(1.6)	140	2	(1.4)
		SUICIDAL IDEATION	77	1	(1.3)	63	1	(1.6)	140	2	(1.4)
		EMERGENCE OF SUICIDAL IDEATION	77	1	(1.3)	63	1	(1.6)	140	2	(1.4)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	77	0	(0.0)	63	0	(0.0)	140	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	77	0	(0.0)	63	0	(0.0)	140	0	(0.0)
	WEEK 28	COMPLETE SUICIDALITY	81	0	(0.0)	58	0	(0.0)	139	0	(0.0)
		SUICIDALITY	81	1	(1.2)	58	1	(1.7)	139	2	(1.4)
		SUICIDAL BEHAVIOR	81	0	(0.0)	58	0	(0.0)	139	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	81	0	(0.0)	58	0	(0.0)	139	0	(0.0)
		SUICIDAL IDEATION	81	1	(1.2)	58	1	(1.7)	139	2	(1.4)
		EMERGENCE OF SUICIDAL IDEATION	81	1	(1.2)	58	1	(1.7)	139	2	(1.4)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	81	0	(0.0)	58	0	(0.0)	139	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	81	0	(0.0)	58	0	(0.0)	139	0	(0.0)
	WEEK 32	COMPLETE SUICIDALITY	77	0	(0.0)	56	0	(0.0)	133	0	(0.0)
		SUICIDALITY	77	1	(1.3)	56	0	(0.0)	133	1	(0.8)
		SUICIDAL BEHAVIOR	77	0	(0.0)	56	0	(0.0)	133	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	77	0	(0.0)	56	0	(0.0)	133	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 32	SUICIDAL IDEATION	77	1	(1.3)	56	0	(0.0)	133	1	(0.8)
		EMERGENCE OF SUICIDAL IDEATION	77	1	(1.3)	56	0	(0.0)	133	1	(0.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	77	0	(0.0)	56	0	(0.0)	133	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	77	0	(0.0)	56	0	(0.0)	133	0	(0.0)
	WEEK 36	COMPLETE SUICIDALITY	72	0	(0.0)	52	0	(0.0)	124	0	(0.0)
		SUICIDALITY	72	1	(1.4)	52	1	(1.9)	124	2	(1.6)
		SUICIDAL BEHAVIOR	72	0	(0.0)	52	0	(0.0)	124	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	71	0	(0.0)	52	0	(0.0)	123	0	(0.0)
		SUICIDAL IDEATION	72	1	(1.4)	52	1	(1.9)	124	2	(1.6)
		EMERGENCE OF SUICIDAL IDEATION	71	1	(1.4)	52	1	(1.9)	123	2	(1.6)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	71	0	(0.0)	52	0	(0.0)	123	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	71	0	(0.0)	52	0	(0.0)	123	0	(0.0)
	WEEK 40	COMPLETE SUICIDALITY	70	0	(0.0)	51	0	(0.0)	121	0	(0.0)
		SUICIDALITY	70	1	(1.4)	51	1	(2.0)	121	2	(1.7)
		SUICIDAL BEHAVIOR	70	0	(0.0)	51	0	(0.0)	121	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	70	0	(0.0)	51	0	(0.0)	121	0	(0.0)
		SUICIDAL IDEATION	70	1	(1.4)	51	1	(2.0)	121	2	(1.7)
		EMERGENCE OF SUICIDAL IDEATION	70	1	(1.4)	51	1	(2.0)	121	2	(1.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	70	0	(0.0)	51	0	(0.0)	121	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	70	0	(0.0)	51	0	(0.0)	121	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.4.1　FINAL

表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 44	COMPLETE SUICIDALITY	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		SUICIDALITY	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		SUICIDAL BEHAVIOR	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		SUICIDAL IDEATION	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	69	0	(0.0)	46	0	(0.0)	115	0	(0.0)
	WEEK 48	COMPLETE SUICIDALITY	68	0	(0.0)	46	0	(0.0)	114	0	(0.0)
		SUICIDALITY	68	0	(0.0)	46	1	(2.2)	114	1	(0.9)
		SUICIDAL BEHAVIOR	68	0	(0.0)	46	0	(0.0)	114	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	68	0	(0.0)	46	0	(0.0)	114	0	(0.0)
		SUICIDAL IDEATION	68	0	(0.0)	46	1	(2.2)	114	1	(0.9)
		EMERGENCE OF SUICIDAL IDEATION	68	0	(0.0)	46	1	(2.2)	114	1	(0.9)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	68	0	(0.0)	46	0	(0.0)	114	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	68	0	(0.0)	46	0	(0.0)	114	0	(0.0)
	WEEK 52	COMPLETE SUICIDALITY	64	0	(0.0)	41	0	(0.0)	105	0	(0.0)
		SUICIDALITY	64	0	(0.0)	41	1	(2.4)	105	1	(1.0)
		SUICIDAL BEHAVIOR	64	0	(0.0)	41	0	(0.0)	105	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	64	0	(0.0)	41	0	(0.0)	105	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-172　C-SSRS［二重盲検試験，二重盲検期（Phase D）］

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CT-6.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase D Safety Sample)

			PHASE D TREATMENT								
			ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE D	WEEK 52	SUICIDAL IDEATION	64	0	(0.0)	41	1	(2.4)	105	1	(1.0)
		EMERGENCE OF SUICIDAL IDEATION	64	0	(0.0)	41	1	(2.4)	105	1	(1.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	64	0	(0.0)	41	0	(0.0)	105	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	64	0	(0.0)	41	0	(0.0)	105	0	(0.0)
	LAST VISIT	COMPLETE SUICIDALITY	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
		SUICIDALITY	131	4	(3.1)	133	6	(4.5)	264	10	(3.8)
		SUICIDAL BEHAVIOR	131	1	(0.8)	133	1	(0.8)	264	2	(0.8)
		EMERGENCE OF SUICIDAL BEHAVIOR	131	1	(0.8)	133	1	(0.8)	264	2	(0.8)
		SUICIDAL IDEATION	131	4	(3.1)	133	6	(4.5)	264	10	(3.8)
		EMERGENCE OF SUICIDAL IDEATION	131	4	(3.1)	133	6	(4.5)	264	10	(3.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
		SUICIDALITY	131	9	(6.9)	133	15	(11.3)	264	24	(9.1)
		SUICIDAL BEHAVIOR	131	1	(0.8)	133	1	(0.8)	264	2	(0.8)
		EMERGENCE OF SUICIDAL BEHAVIOR	131	1	(0.8)	133	1	(0.8)	264	2	(0.8)
		SUICIDAL IDEATION	131	9	(6.9)	133	15	(11.3)	264	24	(9.1)
		EMERGENCE OF SUICIDAL IDEATION	131	8	(6.1)	133	15	(11.3)	264	23	(8.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	131	0	(0.0)	133	0	(0.0)	264	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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＜資料番号 5.3.5.1-01：CT-6.4.1＞

表 2.7.4.7-173　自殺関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.2
Incidence of Treatment-emergent Adverse Events Related to Suicidal Ideation/Suicide
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
精神障害	TOTAL1)	5	(0.8)	8	(1.9)
	自殺念慮	4	(0.7)	7	(1.6)
	自殺企図	2	(0.3)	1	(0.2)
TOTAL2)		5	(0.8)	8	(1.9)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

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表 2.7.4.7-173　自殺関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.2
Incidence of Treatment-emergent Adverse Events Related to Suicidal Ideation/Suicide
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO SUICIDAL IDEATION/SUICIDE: MEDDRA 19.0 PRIMARY TERMS

COMPLETED SUICIDE, SUICIDE OF RELATIVE, SUICIDE ATTEMPT, SUICIDAL BEHAVIOUR, SUICIDE OF COMPANION, FAMILIAL RISK FACTOR, SUICIDAL IDEATION
DEPRESSION SUICIDAL, INTENTIONAL SELF-INJURY

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＜資料番号 5.3.5.1-01：CT-21.2.5.2 より作成＞

表 2.7.4.7-174　C-SSRS のベースラインからの変化量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-19.4.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

									CHANGE FROM BASELINE						
									BASELINE						
PHASE	TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE A	ARIP 5-15MG	BASELINE	459	0.4	0.0	2.0	0.0	15.0								
		WEEK 1	447	0.1	0.0	1.2	0.0	14.0	447	0.4	2.1	-0.3	0.0	1.8	-13.0	13.0
		WEEK 2	434	0.2	0.0	1.3	0.0	12.0	434	0.3	1.9	-0.2	0.0	2.3	-14.0	12.0
		WEEK 3	423	0.2	0.0	2.0	0.0	24.0	423	0.4	1.9	-0.1	0.0	2.8	-14.0	24.0
		WEEK 4	408	0.2	0.0	1.7	0.0	18.0	408	0.4	1.9	-0.1	0.0	2.4	-14.0	18.0
		WEEK 5	249	0.4	0.0	2.0	0.0	16.0	249	0.3	1.7	0.1	0.0	2.4	-13.0	16.0
		WEEK 6	143	0.3	0.0	1.9	0.0	15.0	143	0.3	1.8	-0.0	0.0	2.7	-13.0	15.0
		LAST VISIT	455	0.6	0.0	2.7	0.0	24.0	455	0.4	2.0	0.2	0.0	3.1	-14.0	24.0
PHASE B	ARIP 10-30MG	BASELINE	614	0.2	0.0	1.5	0.0	18.0								
		WEEK 2	557	0.2	0.0	1.8	0.0	21.0	557	0.2	1.6	0.0	0.0	2.2	-18.0	21.0
		WEEK 4	441	0.2	0.0	1.4	0.0	18.0	441	0.1	1.1	0.1	0.0	1.6	-10.0	18.0
		WEEK 6	261	0.5	0.0	2.4	0.0	18.0	261	0.1	1.0	0.4	0.0	2.6	-13.0	18.0
		WEEK 8	142	0.2	0.0	1.7	0.0	18.0	142	0.1	0.8	0.1	0.0	1.9	-9.0	18.0
		LAST VISIT	588	0.2	0.0	1.8	0.0	19.0	588	0.2	1.4	0.0	0.0	2.3	-18.0	19.0
PHASE C	ARIP IMD 400/300MG	BASELINE	425	0.0	0.0	0.6	0.0	11.0								
		WEEK 1	406	0.1	0.0	0.8	0.0	13.0	406	0.0	0.6	0.0	0.0	1.0	-11.0	13.0
		WEEK 2	409	0.1	0.0	0.7	0.0	11.0	409	0.0	0.6	0.0	0.0	0.9	-11.0	11.0
		WEEK 3	386	0.2	0.0	1.5	0.0	16.0	386	0.0	0.6	0.2	0.0	1.6	-11.0	16.0
		WEEK 4	392	0.0	0.0	0.6	0.0	9.0	392	0.0	0.6	0.0	0.0	0.8	-11.0	9.0
		WEEK 6	379	0.2	0.0	1.5	0.0	15.0	379	0.0	0.6	0.2	0.0	1.7	-11.0	15.0
		WEEK 8	360	0.5	0.0	2.4	0.0	18.0	360	0.0	0.6	0.5	0.0	2.4	-11.0	18.0
		WEEK 10	354	0.1	0.0	1.1	0.0	13.0	354	0.0	0.6	0.1	0.0	1.2	-11.0	13.0
		WEEK 12	324	0.3	0.0	1.8	0.0	12.0	324	0.0	0.6	0.3	0.0	1.9	-11.0	12.0
		WEEK 14	115	0.6	0.0	2.6	0.0	17.0	115	0.1	1.0	0.5	0.0	2.8	-11.0	17.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-174　C-SSRS のベースラインからの変化量［二重盲検試験，IM デポ剤安定期（Phase C）］

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PROTOCOL 31-08-250

CT-19.4.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

											CHANGE FROM BASELINE				
				BASELINE											
PHASE	TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE C	ARIP IMD 400/300MG	WEEK 16	95	0.1	0.0	1.0	0.0	10.0	95	0.1	1.1	-0.0	0.0	1.5	-11.0	10.0
		WEEK 18	73	0.0	0.0	0.0	0.0	0.0	73	0.2	1.3	-0.2	0.0	1.3	-11.0	0.0
		WEEK 20	61	0.3	0.0	1.9	0.0	14.0	61	0.2	1.4	0.1	0.0	2.4	-11.0	14.0
		WEEK 22	43	0.7	0.0	3.3	0.0	16.0	43	0.3	1.7	0.5	0.0	3.8	-11.0	16.0
		WEEK 24	27	0.4	0.0	1.9	0.0	10.0	27	0.0	0.0	0.4	0.0	1.9	0.0	10.0
		WEEK 26	10	1.3	0.0	4.1	0.0	13.0	10	0.0	0.0	1.3	0.0	4.1	0.0	13.0
		WEEK 28	8	0.0	0.0	0.0	0.0	0.0	8	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		LAST VISIT	421	0.4	0.0	2.0	0.0	15.0	421	0.0	0.6	0.3	0.0	2.1	-11.0	15.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.1-01：CT-19.4.3＞

表 2.7.4.7-175　C-CASA/C-SSRS［二重盲検試験，IM デポ剤安定期（Phase C）］

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CT-19.4.4
Incidence of Treatment-emergent Possible Suicidal Events - C-CASA Category Analysis Using C-SSRS Assessment
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	C-CASA RATING	PHASE A (N=459) Ne[2]	PHASE A (N=459) n[3]	PHASE A (N=459) (%)	PHASE B (N=614) Ne[2]	PHASE B (N=614) n[3]	PHASE B (N=614) (%)	PHASE C (N=425) Ne[2]	PHASE C (N=425) n[3]	PHASE C (N=425) (%)
POTENTIAL SUICIDAL	TOTAL[1]	455	36	(7.9)	588	28	(4.8)	421	47	(11.2)
	COMPLETED SUICIDE	455	0	(0.0)	588	0	(0.0)	421	0	(0.0)
	SUICIDE ATTEMPT	455	0	(0.0)	588	1	(0.2)	421	1	(0.2)
	PREPARATORY ACTIONS TOWARD IMMINENT SUICIDAL BEHAVIOR	455	1	(0.2)	588	3	(0.5)	421	1	(0.2)
	SUICIDAL IDEATION	455	36	(7.9)	588	26	(4.4)	421	47	(11.2)
	NON-SUICIDAL SELF-INJURIOUS BEHAVIOR	455	1	(0.2)	588	2	(0.3)	421	2	(0.5)

[1]SUBJECTS WITH MULTIPLE RATINGS WITHIN THE SAME CATEGORY WERE COUNTED ONCE TOWARDS THE TOTAL.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS POTENTIAL SUICIDALITY EVALUATION DURING THE TRIAL.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED POTENTIAL SUICIDALITY DURING THE TRIAL.

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＜資料番号 5.3.5.1-01：CT-19.4.4＞

表 2.7.4.7-176　C-SSRS［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	TOTAL (N=720) Ne[2]	n[3]	(%)
SCREENING	LIFETIME	SUICIDALITY	719	410	(57.0)
		SUICIDAL BEHAVIOR	719	290	(40.3)
		SUICIDAL IDEATION	719	394	(54.8)
	PAST 90 DAYS	SUICIDALITY	690	60	(8.7)
		SUICIDAL BEHAVIOR	690	2	(0.3)
		SUICIDAL IDEATION	690	60	(8.7)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-176　C-SSRS［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP 5-15MG (N=459) Ne[2]	n[3]	(%)
PHASE A	BASELINE	SUICIDALITY	459	18	(3.9)
		SUICIDAL BEHAVIOR	459	0	(0.0)
		SUICIDAL IDEATION	459	18	(3.9)
	LAST VISIT	COMPLETE SUICIDALITY	455	0	(0.0)
		SUICIDALITY	455	22	(4.8)
		SUICIDAL BEHAVIOR	455	1	(0.2)
		EMERGENCE OF SUICIDAL BEHAVIOR	455	1	(0.2)
		SUICIDAL IDEATION	455	22	(4.8)
		EMERGENCE OF SUICIDAL IDEATION	455	18	(4.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	455	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	455	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	455	0	(0.0)
		SUICIDALITY	455	36	(7.9)
		SUICIDAL BEHAVIOR	455	1	(0.2)
		EMERGENCE OF SUICIDAL BEHAVIOR	455	1	(0.2)
		SUICIDAL IDEATION	455	36	(7.9)
		EMERGENCE OF SUICIDAL IDEATION	455	29	(6.4)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	455	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	455	0	(0.0)

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表 2.7.4.7-176　C-SSRS［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP 10-30MG (N=614) Ne[2]	n[3]	(%)
PHASE B	BASELINE	SUICIDALITY	614	13	(2.1)
		SUICIDAL BEHAVIOR	614	0	(0.0)
		SUICIDAL IDEATION	614	13	(2.1)
	LAST VISIT	COMPLETE SUICIDALITY	588	0	(0.0)
		SUICIDALITY	588	12	(2.0)
		SUICIDAL BEHAVIOR	588	2	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	588	2	(0.3)
		SUICIDAL IDEATION	588	11	(1.9)
		EMERGENCE OF SUICIDAL IDEATION	588	10	(1.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	588	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	588	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	588	0	(0.0)
		SUICIDALITY	588	26	(4.4)
		SUICIDAL BEHAVIOR	588	3	(0.5)
		EMERGENCE OF SUICIDAL BEHAVIOR	588	3	(0.5)
		SUICIDAL IDEATION	588	26	(4.4)
		EMERGENCE OF SUICIDAL IDEATION	588	23	(3.9)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	588	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	588	0	(0.0)

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[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-176　C-SSRS［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	BASELINE	SUICIDALITY	425	2	(0.5)
		SUICIDAL BEHAVIOR	425	0	(0.0)
		SUICIDAL IDEATION	425	2	(0.5)
	WEEK 1	COMPLETE SUICIDALITY	405	0	(0.0)
		SUICIDALITY	405	3	(0.7)
		SUICIDAL BEHAVIOR	405	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	405	0	(0.0)
		SUICIDAL IDEATION	405	3	(0.7)
		EMERGENCE OF SUICIDAL IDEATION	405	2	(0.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	405	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	405	0	(0.0)
	WEEK 2	COMPLETE SUICIDALITY	400	0	(0.0)
		SUICIDALITY	400	3	(0.8)
		SUICIDAL BEHAVIOR	400	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	400	0	(0.0)
		SUICIDAL IDEATION	400	3	(0.8)
		EMERGENCE OF SUICIDAL IDEATION	400	3	(0.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	400	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	400	0	(0.0)
	WEEK 3	COMPLETE SUICIDALITY	380	0	(0.0)

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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	WEEK 3	SUICIDALITY	380	9	(2.4)
		SUICIDAL BEHAVIOR	380	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	380	0	(0.0)
		SUICIDAL IDEATION	380	9	(2.4)
		EMERGENCE OF SUICIDAL IDEATION	380	8	(2.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	380	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	380	0	(0.0)
	WEEK 4	COMPLETE SUICIDALITY	382	0	(0.0)
		SUICIDALITY	382	3	(0.8)
		SUICIDAL BEHAVIOR	382	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	382	0	(0.0)
		SUICIDAL IDEATION	382	3	(0.8)
		EMERGENCE OF SUICIDAL IDEATION	382	3	(0.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	382	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	382	0	(0.0)
	WEEK 6	COMPLETE SUICIDALITY	370	0	(0.0)
		SUICIDALITY	370	6	(1.6)
		SUICIDAL BEHAVIOR	370	1	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	370	1	(0.3)
		SUICIDAL IDEATION	370	6	(1.6)
		EMERGENCE OF SUICIDAL IDEATION	370	6	(1.6)

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[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	WEEK 6	EMERGENCE OF SERIOUS SUICIDAL IDEATION	370	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	370	0	(0.0)
	WEEK 8	COMPLETE SUICIDALITY	356	0	(0.0)
		SUICIDALITY	356	17	(4.8)
		SUICIDAL BEHAVIOR	356	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	356	0	(0.0)
		SUICIDAL IDEATION	356	17	(4.8)
		EMERGENCE OF SUICIDAL IDEATION	356	17	(4.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	356	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	356	0	(0.0)
	WEEK 10	COMPLETE SUICIDALITY	344	0	(0.0)
		SUICIDALITY	344	5	(1.5)
		SUICIDAL BEHAVIOR	344	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	344	0	(0.0)
		SUICIDAL IDEATION	344	5	(1.5)
		EMERGENCE OF SUICIDAL IDEATION	344	5	(1.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	344	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	344	0	(0.0)
	WEEK 12	COMPLETE SUICIDALITY	320	0	(0.0)
		SUICIDALITY	320	13	(4.1)

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[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	WEEK 12	SUICIDAL BEHAVIOR	320	1	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	320	1	(0.3)
		SUICIDAL IDEATION	320	13	(4.1)
		EMERGENCE OF SUICIDAL IDEATION	320	13	(4.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	320	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	320	0	(0.0)
	WEEK 14	COMPLETE SUICIDALITY	105	0	(0.0)
		SUICIDALITY	105	6	(5.7)
		SUICIDAL BEHAVIOR	105	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	105	0	(0.0)
		SUICIDAL IDEATION	105	6	(5.7)
		EMERGENCE OF SUICIDAL IDEATION	105	6	(5.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	105	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	105	0	(0.0)
	WEEK 16	COMPLETE SUICIDALITY	94	0	(0.0)
		SUICIDALITY	94	1	(1.1)
		SUICIDAL BEHAVIOR	94	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	94	0	(0.0)
		SUICIDAL IDEATION	94	1	(1.1)
		EMERGENCE OF SUICIDAL IDEATION	94	1	(1.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	94	0	(0.0)

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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	WEEK 16	WORSENING OF SUICIDAL IDEATION	94	0	(0.0)
	WEEK 18	COMPLETE SUICIDALITY	68	0	(0.0)
		SUICIDALITY	68	0	(0.0)
		SUICIDAL BEHAVIOR	68	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	68	0	(0.0)
		SUICIDAL IDEATION	68	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	68	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	68	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	68	0	(0.0)
	WEEK 20	COMPLETE SUICIDALITY	60	0	(0.0)
		SUICIDALITY	60	2	(3.3)
		SUICIDAL BEHAVIOR	60	1	(1.7)
		EMERGENCE OF SUICIDAL BEHAVIOR	60	1	(1.7)
		SUICIDAL IDEATION	60	2	(3.3)
		EMERGENCE OF SUICIDAL IDEATION	60	2	(3.3)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	60	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	60	0	(0.0)
	WEEK 22	COMPLETE SUICIDALITY	41	0	(0.0)
		SUICIDALITY	41	2	(4.9)
		SUICIDAL BEHAVIOR	41	0	(0.0)

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[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	WEEK 22	EMERGENCE OF SUICIDAL BEHAVIOR	41	0	(0.0)
		SUICIDAL IDEATION	41	2	(4.9)
		EMERGENCE OF SUICIDAL IDEATION	41	2	(4.9)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	41	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	41	0	(0.0)
	WEEK 24	COMPLETE SUICIDALITY	27	0	(0.0)
		SUICIDALITY	27	1	(3.7)
		SUICIDAL BEHAVIOR	27	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	27	0	(0.0)
		SUICIDAL IDEATION	27	1	(3.7)
		EMERGENCE OF SUICIDAL IDEATION	27	1	(3.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	27	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	27	0	(0.0)
	WEEK 26	COMPLETE SUICIDALITY	10	0	(0.0)
		SUICIDALITY	10	1	(10.0)
		SUICIDAL BEHAVIOR	10	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	10	0	(0.0)
		SUICIDAL IDEATION	10	1	(10.0)
		EMERGENCE OF SUICIDAL IDEATION	10	1	(10.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	10	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	10	0	(0.0)

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[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	WEEK 28	COMPLETE SUICIDALITY	8	0	(0.0)
		SUICIDALITY	8	0	(0.0)
		SUICIDAL BEHAVIOR	8	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	8	0	(0.0)
		SUICIDAL IDEATION	8	0	(0.0)
		EMERGENCE OF SUICIDAL IDEATION	8	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	8	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	8	0	(0.0)
	LAST VISIT	COMPLETE SUICIDALITY	421	0	(0.0)
		SUICIDALITY	421	16	(3.8)
		SUICIDAL BEHAVIOR	421	2	(0.5)
		EMERGENCE OF SUICIDAL BEHAVIOR	421	2	(0.5)
		SUICIDAL IDEATION	421	16	(3.8)
		EMERGENCE OF SUICIDAL IDEATION	421	16	(3.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	421	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	421	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	421	0	(0.0)
		SUICIDALITY	421	47	(11.2)
		SUICIDAL BEHAVIOR	421	3	(0.7)
		EMERGENCE OF SUICIDAL BEHAVIOR	421	3	(0.7)
		SUICIDAL IDEATION	421	47	(11.2)

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[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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CT-19.4.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase A Safety Sample, Phase B Safety Sample and Phase C Safety Sample)

PHASE	TRIAL WEEK[1]	CATEGORY	ARIP IMD 400/300MG (N=425) Ne[2]	n[3]	(%)
PHASE C	OVERALL	EMERGENCE OF SUICIDAL IDEATION	421	46	(10.9)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	421	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	421	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

FILE: ADCSSR2BA.LIS, RUN: [redacted]20[redacted] 14:09; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:48
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADCSSR2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-19.4.1　FINAL

＜資料番号 5.3.5.1-01：CT-19.4.1＞

表 2.7.4.7-177　自殺関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.2
Incidence of Treatment-emergent Adverse Events Related to Suicidal Ideation/Suicide in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
精神障害	TOTAL1)	9	(2.4)	2	(2.4)	11	(2.4)
	故意の自傷行為	1	(0.3)	0	(0.0)	1	(0.2)
	自殺念慮	7	(1.8)	2	(2.4)	9	(1.9)
	自殺企図	3	(0.8)	0	(0.0)	3	(0.6)
TOTAL2)		9	(2.4)	2	(2.4)	11	(2.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AC.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.2　FINAL

表 2.7.4.7-177　自殺関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.2
Incidence of Treatment-emergent Adverse Events Related to Suicidal Ideation/Suicide in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO SUICIDAL IDEATION/SUICIDE: MEDDRA 19.0 PRIMARY TERMS

COMPLETED SUICIDE, SUICIDE OF RELATIVE, SUICIDE ATTEMPT, SUICIDAL BEHAVIOUR, SUICIDE OF COMPANION, FAMILIAL RISK FACTOR, SUICIDAL IDEATION
DEPRESSION SUICIDAL, INTENTIONAL SELF-INJURY

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-05 19:30	同年*-06-06 19:30	20	MILD
				故意の自傷行為*/SUPERFICIAL CUTS ON LEFT WRIST, SELF INFLICTED; NO SUICIDAL INTENT	精神障害	20[redacted]-06-06 19:30	同年*-07-10 10:00	21	MILD
		[redacted]	3[redacted]/F/BLACK	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-08-06 11:00	同年*-08-06 12:00	58	MILD
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/FLEETING SUICIDAL IDEATION	精神障害	20[redacted]-08-01	同年*-08-01	-1	MILD
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL THOUGHTS	精神障害	20[redacted]-11-29	同年*-11-29	17	MODERATE
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-08-21 16:00	同年*-08-24 16:00	16	SEVERE
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-05-20 16:37	同年*-05-28 12:44	12	SEVERE
PHASE B	ARIP 15-30MG	[redacted]	4[redacted]/F/BLACK	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-03 10:00	同年*-06-03 20:00	68	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 5-15MG	[redacted]	4[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				故意の自傷行為*/SUPERFICIAL CUTS ON LEFT WRIST, SELF INFLICTED; NO SUICIDAL INTENT	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	自殺念慮*/SUICIDAL IDEATION	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/FLEETING SUICIDAL IDEATION	精神障害	NO	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL THOUGHTS	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE B	ARIP 15-30MG	[redacted]	4[redacted]/F/BLACK	自殺念慮*/SUICIDAL IDEATION	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 15-30MG	[redacted]	2[redacted]/F/AM.IND.	自殺念慮*/FLEETING SUICIDAL THOUGHTS	精神障害	20[redacted]-02-07	同年*-02-07	14	MILD
		[redacted]	5[redacted]/F/CAUC.	自殺念慮*/FLEETING SUICIDAL IDEATION WITH PLAN TO JUMP OFF 2ND STORY BALCONY	精神障害	20[redacted]-11-13	同年*-11-13	36	MODERATE
		[redacted]	4[redacted]/F/BLACK	自殺企図*/SUICIDAL ATTEMPT	精神障害	20[redacted]-11-30	同年*-11-30	75	MODERATE
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/PSYCHIATRIC HOSPITALIZATION DUE TO SUICIDIAL THOUGTHS	精神障害	20[redacted]-02-08	同年*-03-18	97	MILD
		[redacted]	3[redacted]/M/ASIAN	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-11-10	同年*-11-15	216	MILD
		[redacted]	6[redacted]/F/ASIAN	自殺企図*/SUICIDE ATTEMPT	精神障害	20[redacted]-08-29 06:00	同年*-08-29 06:00	206	MILD
		[redacted]	2[redacted]/F/ASIAN	自殺企図*/SUICIDE ATTEMPT	精神障害	20[redacted]-03-16 18:00	同年*-03-16 18:00	12	MILD
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/ACTIVE SUICIDAL IDEATION	精神障害	20[redacted]-09	同年*-10-22	300	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 15-30MG	[redacted]	2[redacted]/F/AM.IND.	自殺念慮*/FLEETING SUICIDAL THOUGHTS	精神障害	NO	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	自殺念慮*/FLEETING SUICIDAL IDEATION WITH PLAN TO JUMP OFF 2ND STORY BALCONY	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	自殺企図*/SUICIDAL ATTEMPT	精神障害	YES	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/PSYCHIATRIC HOSPITALIZATION DUE TO SUICIDIAL THOUGTHS	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	自殺念慮*/SUICIDAL IDEATION	精神障害	NO	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/ASIAN	自殺企図*/SUICIDE ATTEMPT	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/ASIAN	自殺企図*/SUICIDE ATTEMPT	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	自殺念慮*/ACTIVE SUICIDAL IDEATION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-23	同年*-06-27	237	SEVERE
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/ISOLATED SUICIDAL IDEATION WITH NO PLAN OR INTENT	精神障害	20[redacted]-06-05	同年*-06-05	55	MILD
				自殺念慮*/FLEETING SUICIDAL IDEATION	精神障害	20[redacted]-07-15	同年*-07-15	95	MILD
				自殺念慮*/FLEETING SUICIDAL IDEATION	精神障害	20[redacted]-04-23	同年*-04-23	377	MILD
		[redacted]	2[redacted]/F/AM.IND.	自殺念慮*/FLEETING SUICIDAL THOUGHTS	精神障害	20[redacted]-09-11	同年*-09-11	160	MILD
				故意の自傷行為*/SELF INFLICTED SUPERFICIAL SCRATCHES TO BOTH WRISTS WITH NO SUICIDAL INTENT	精神障害	20[redacted]-01-01	同年*-01-01	272	MILD
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/INTERMITTENT SUICIDAL IDEATION	精神障害	20[redacted]-01-06	同年*-01-16	5	MILD
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-06-17 08:00	同年*-06-23 08:00	141	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺念慮*/ISOLATED SUICIDAL IDEATION WITH NO PLAN OR INTENT	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				自殺念慮*/FLEETING SUICIDAL IDEATION	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				自殺念慮*/FLEETING SUICIDAL IDEATION	精神障害	NO	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/AM.IND.	自殺念慮*/FLEETING SUICIDAL THOUGHTS	精神障害	NO	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				故意の自傷行為*/SELF INFLICTED SUPERFICIAL SCRATCHES TO BOTH WRISTS WITH NO SUICIDAL INTENT	精神障害	NO	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/INTERMITTENT SUICIDAL IDEATION	精神障害	NO	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	20[redacted]-06-24 08:00	同年*-06-24 08:00	148	SEVERE
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL THOUGHTS WITHOUT INTENT	精神障害	20[redacted]-06-07	同年*-06-07	257	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-9.4　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-178　自殺関連有害事象一覧表［長期投与試験］

CT-9.4
Listing of Adverse Events Related to Suicidal Ideation/Suicide by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	YES	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	自殺念慮*/SUICIDAL THOUGHTS WITHOUT INTENT	精神障害	YES	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1F.LIS, RUN: [redacted]20[redacted] 15:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.4　FINAL

＜資料番号 5.3.5.2-01：CT-9.4 より作成＞

表 2.7.4.7-179　C-SSRS のベースラインからの変化量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase C Safety Sample)

												CHANGE FROM BASELINE				
									BASELINE							
PHASE	ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE A	DE NOVO	BASELINE	272	0.3	0.0	1.5	0.0	13.0								
		WEEK 1	270	0.1	0.0	0.9	0.0	12.0	270	0.3	1.6	-0.2	0.0	1.7	-13.0	12.0
		WEEK 2	266	0.0	0.0	0.6	0.0	9.0	266	0.3	1.5	-0.2	0.0	1.5	-13.0	3.0
		WEEK 3	273	0.2	0.0	1.3	0.0	13.0	273	0.3	1.5	-0.1	0.0	1.7	-13.0	10.0
		WEEK 4	269	0.0	0.0	0.4	0.0	7.0	269	0.3	1.5	-0.2	0.0	1.5	-13.0	1.0
		WEEK 5	194	0.2	0.0	1.4	0.0	15.0	194	0.2	1.5	-0.1	0.0	1.6	-13.0	11.0
		WEEK 6	119	0.1	0.0	0.9	0.0	10.0	119	0.1	0.9	0.0	0.0	1.3	-10.0	10.0
		LAST VISIT	272	0.2	0.0	1.5	0.0	15.0	272	0.3	1.5	-0.1	0.0	1.8	-13.0	11.0
PHASE B	DE NOVO	BASELINE	379	0.3	0.0	1.7	0.0	15.0								
		WEEK 2	372	0.2	0.0	1.4	0.0	13.0	372	0.3	1.9	-0.1	0.0	1.8	-15.0	13.0
		WEEK 4	389	0.2	0.0	1.5	0.0	16.0	389	0.3	1.7	-0.0	0.0	1.7	-13.0	10.0
		WEEK 6	150	0.2	0.0	1.5	0.0	12.0	150	0.5	2.4	-0.3	0.0	2.3	-15.0	12.0
		WEEK 8	95	0.2	0.0	1.2	0.0	9.0	95	0.6	2.5	-0.4	0.0	2.9	-15.0	9.0
		WEEK 10	57	0.2	0.0	1.6	0.0	12.0	57	1.0	3.0	-0.8	0.0	2.5	-11.0	0.0
		WEEK 12	27	0.0	0.0	0.0	0.0	0.0	27	1.1	3.1	-1.1	0.0	3.1	-11.0	0.0
		LAST VISIT	379	0.1	0.0	0.8	0.0	12.0	379	0.3	1.7	-0.2	0.0	1.6	-15.0	8.0
PHASE C	DE NOVO	BASELINE	378	0.1	0.0	0.8	0.0	12.0								
		WEEK 1	366	0.0	0.0	0.3	0.0	5.0	365	0.1	0.8	-0.1	0.0	0.8	-12.0	0.0
		WEEK 2	366	0.2	0.0	1.3	0.0	16.0	365	0.0	0.7	0.1	0.0	1.2	-1.0	16.0
		WEEK 3	364	0.1	0.0	1.1	0.0	15.0	363	0.1	0.9	0.1	0.0	1.3	-12.0	15.0
		WEEK 4	372	0.1	0.0	1.4	0.0	19.0	371	0.1	0.8	0.1	0.0	1.1	-2.0	19.0
		WEEK 6	363	0.2	0.0	1.5	0.0	16.0	362	0.1	1.0	0.1	0.0	1.6	-12.0	16.0
		WEEK 8	356	0.3	0.0	1.9	0.0	20.0	355	0.1	0.8	0.2	0.0	1.8	-8.0	20.0
		WEEK 10	352	0.3	0.0	1.9	0.0	16.0	351	0.1	0.8	0.2	0.0	1.7	-5.0	16.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-179　C-SSRS のベースラインからの変化量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE C	DE NOVO	WEEK 12	377	0.3	0.0	2.0	0.0	15.0	376	0.1	0.8	0.3	0.0	1.9	-8.0	15.0
		WEEK 16	360	0.2	0.0	1.4	0.0	14.0	359	0.1	0.8	0.1	0.0	1.3	-5.0	14.0
		WEEK 20	348	0.4	0.0	2.1	0.0	14.0	347	0.1	1.0	0.3	0.0	1.9	-8.0	14.0
		WEEK 24	335	0.5	0.0	2.4	0.0	15.0	334	0.2	1.5	0.2	0.0	1.7	-8.0	14.0
		WEEK 28	314	0.2	0.0	1.6	0.0	14.0	313	0.2	1.5	0.0	0.0	0.7	-3.0	10.0
		WEEK 32	302	0.3	0.0	1.9	0.0	12.0	301	0.2	1.5	0.1	0.0	1.6	-8.0	12.0
		WEEK 36	279	0.4	0.0	2.2	0.0	16.0	278	0.2	1.5	0.2	0.0	1.8	-8.0	16.0
		WEEK 40	273	0.4	0.0	2.0	0.0	15.0	273	0.1	1.2	0.2	0.0	1.8	-8.0	13.0
		WEEK 44	252	0.0	0.0	0.7	0.0	11.0	251	0.1	0.6	-0.0	0.0	0.9	-8.0	11.0
		WEEK 48	246	0.2	0.0	1.5	0.0	17.0	245	0.1	0.6	0.1	0.0	1.6	-8.0	17.0
		WEEK 52	238	0.2	0.0	1.7	0.0	13.0	238	0.1	0.6	0.2	0.0	1.8	-8.0	13.0
		LAST VISIT	378	0.4	0.0	2.2	0.0	20.0	377	0.1	0.8	0.3	0.0	2.2	-8.0	20.0
	ROLLOVER	BASELINE	85	0.0	0.0	0.0	0.0	0.0								
		WEEK 1	77	0.0	0.0	0.0	0.0	0.0	77	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 2	82	0.0	0.0	0.0	0.0	0.0	82	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 3	83	0.0	0.0	0.0	0.0	0.0	83	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 4	80	0.0	0.0	0.0	0.0	0.0	80	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 6	81	0.0	0.0	0.0	0.0	0.0	81	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 8	77	0.0	0.0	0.0	0.0	0.0	77	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 10	75	0.0	0.0	0.0	0.0	0.0	75	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 12	79	0.0	0.0	0.0	0.0	0.0	79	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 16	75	0.2	0.0	1.4	0.0	12.0	75	0.0	0.0	0.2	0.0	1.4	0.0	12.0
		WEEK 20	74	0.0	0.0	0.0	0.0	0.0	74	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 24	73	0.0	0.0	0.0	0.0	0.0	73	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 28	73	0.0	0.0	0.0	0.0	0.0	73	0.0	0.0	0.0	0.0	0.0	0.0	0.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-179　C-SSRS のベースラインからの変化量［長期投与試験，IM デポ剤維持治療期（Phase C）］

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CT-6.2.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE C	ROLLOVER	WEEK 32	27	0.0	0.0	0.0	0.0	0.0	27	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 36	24	0.0	0.0	0.0	0.0	0.0	24	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 40	18	0.0	0.0	0.0	0.0	0.0	18	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 44	18	0.5	0.0	2.1	0.0	9.0	18	0.0	0.0	0.5	0.0	2.1	0.0	9.0
		WEEK 48	15	0.0	0.0	0.0	0.0	0.0	15	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		WEEK 52	14	0.0	0.0	0.0	0.0	0.0	14	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		LAST VISIT	85	0.1	0.0	1.3	0.0	12.0	85	0.0	0.0	0.1	0.0	1.3	0.0	12.0
	TOTAL	BASELINE	463	0.1	0.0	0.7	0.0	12.0								
		WEEK 1	443	0.0	0.0	0.2	0.0	5.0	442	0.1	0.7	-0.0	0.0	0.7	-12.0	0.0
		WEEK 2	448	0.1	0.0	1.2	0.0	16.0	447	0.0	0.6	0.1	0.0	1.0	-1.0	16.0
		WEEK 3	447	0.1	0.0	1.0	0.0	15.0	446	0.1	0.8	0.0	0.0	1.2	-12.0	15.0
		WEEK 4	452	0.1	0.0	1.2	0.0	19.0	451	0.1	0.7	0.1	0.0	1.0	-2.0	19.0
		WEEK 6	444	0.2	0.0	1.3	0.0	16.0	443	0.1	0.9	0.1	0.0	1.4	-12.0	16.0
		WEEK 8	433	0.2	0.0	1.7	0.0	20.0	432	0.1	0.7	0.2	0.0	1.6	-8.0	20.0
		WEEK 10	427	0.2	0.0	1.7	0.0	16.0	426	0.1	0.7	0.2	0.0	1.5	-5.0	16.0
		WEEK 12	456	0.3	0.0	1.8	0.0	15.0	455	0.1	0.7	0.2	0.0	1.8	-8.0	15.0
		WEEK 16	435	0.2	0.0	1.4	0.0	14.0	434	0.1	0.7	0.1	0.0	1.3	-5.0	14.0
		WEEK 20	422	0.3	0.0	1.9	0.0	14.0	421	0.1	0.9	0.2	0.0	1.7	-8.0	14.0
		WEEK 24	408	0.4	0.0	2.2	0.0	15.0	407	0.2	1.4	0.2	0.0	1.6	-8.0	14.0
		WEEK 28	387	0.2	0.0	1.5	0.0	14.0	386	0.2	1.3	0.0	0.0	0.6	-3.0	10.0
		WEEK 32	329	0.3	0.0	1.9	0.0	12.0	328	0.2	1.5	0.1	0.0	1.5	-8.0	12.0
		WEEK 36	303	0.4	0.0	2.2	0.0	16.0	302	0.2	1.5	0.2	0.0	1.7	-8.0	16.0
		WEEK 40	291	0.3	0.0	2.0	0.0	15.0	291	0.1	1.1	0.2	0.0	1.8	-8.0	13.0
		WEEK 44	270	0.1	0.0	0.9	0.0	11.0	269	0.0	0.6	0.0	0.0	1.0	-8.0	11.0
		WEEK 48	261	0.1	0.0	1.5	0.0	17.0	260	0.1	0.6	0.1	0.0	1.6	-8.0	17.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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表 2.7.4.7-179　C-SSRS のベースラインからの変化量［長期投与試験，IM デポ剤維持治療期（Phase C）］

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CT-6.2.3
Columbia-Suicide Severity Rating Scale (C-SSRS) - Mean Change from Baseline in Suicidal Ideation Intensity Total Score
(Phase C Safety Sample)

PHASE	ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
PHASE C	TOTAL	WEEK 52	252	0.2	0.0	1.6	0.0	13.0	252	0.1	0.6	0.2	0.0	1.7	-8.0	13.0
		LAST VISIT	463	0.3	0.0	2.1	0.0	20.0	462	0.1	0.7	0.3	0.0	2.1	-8.0	20.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.2-01：CT-6.2.3＞

表 2.7.4.7-180　C-CASA/C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.4
Incidence of Treatment-emergent Possible Suicidal Events - C-CASA Category Analysis Using C-SSRS Assessment
(Phase C Safety Sample)

			ENROLLMENT SOURCE DE NOVO (N=272)		
PHASE	CATEGORY	C-CASA RATING	Ne[2]	n[3]	(%)
PHASE A	POTENTIAL SUICIDAL	TOTAL[1]	272	10	(3.7)
		COMPLETED SUICIDE	272	0	(0.0)
		SUICIDE ATTEMPT	272	0	(0.0)
		PREPARATORY ACTIONS TOWARD IMMINENT SUICIDAL BEHAVIOR	272	0	(0.0)
		SUICIDAL IDEATION	272	10	(3.7)
		NON-SUICIDAL SELF-INJURIOUS BEHAVIOR	272	0	(0.0)

[1]SUBJECTS WITH MULTIPLE RATINGS WITHIN THE SAME CATEGORY WERE COUNTED ONCE TOWARDS THE TOTAL.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS POTENTIAL SUICIDALITY EVALUATION DURING THE TRIAL.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED POTENTIAL SUICIDALITY DURING THE TRIAL.

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表 2.7.4.7-180　C-CASA/C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.4
Incidence of Treatment-emergent Possible Suicidal Events - C-CASA Category Analysis Using C-SSRS Assessment
(Phase C Safety Sample)

			ENROLLMENT SOURCE		
			DE NOVO (N=379)		
PHASE	CATEGORY	C-CASA RATING	Ne[2]	n[3]	(%)
PHASE B	POTENTIAL SUICIDAL	TOTAL[1]	379	16	(4.2)
		COMPLETED SUICIDE	379	0	(0.0)
		SUICIDE ATTEMPT	379	0	(0.0)
		PREPARATORY ACTIONS TOWARD IMMINENT SUICIDAL BEHAVIOR	379	0	(0.0)
		SUICIDAL IDEATION	379	16	(4.2)
		NON-SUICIDAL SELF-INJURIOUS BEHAVIOR	379	0	(0.0)

[1]SUBJECTS WITH MULTIPLE RATINGS WITHIN THE SAME CATEGORY WERE COUNTED ONCE TOWARDS THE TOTAL.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS POTENTIAL SUICIDALITY EVALUATION DURING THE TRIAL.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED POTENTIAL SUICIDALITY DURING THE TRIAL.

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表 2.7.4.7-180　C-CASA/C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

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CT-6.2.4
Incidence of Treatment-emergent Possible Suicidal Events - C-CASA Category Analysis Using C-SSRS Assessment
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	CATEGORY	C-CASA RATING	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	POTENTIAL SUICIDAL	TOTAL[1]	378	44	(11.6)	85	2	(2.4)	463	46	(9.9)
		COMPLETED SUICIDE	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
		SUICIDE ATTEMPT	378	3	(0.8)	85	0	(0.0)	463	3	(0.6)
		PREPARATORY ACTIONS TOWARD IMMINENT SUICIDAL BEHAVIOR	378	4	(1.1)	85	0	(0.0)	463	4	(0.9)
		SUICIDAL IDEATION	378	44	(11.6)	85	2	(2.4)	463	46	(9.9)
		NON-SUICIDAL SELF-INJURIOUS BEHAVIOR	378	4	(1.1)	85	0	(0.0)	463	4	(0.9)

[1]SUBJECTS WITH MULTIPLE RATINGS WITHIN THE SAME CATEGORY WERE COUNTED ONCE TOWARDS THE TOTAL.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS POTENTIAL SUICIDALITY EVALUATION DURING THE TRIAL.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED POTENTIAL SUICIDALITY DURING THE TRIAL.

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＜資料番号 5.3.5.2-01：CT-6.2.4＞

表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
SCREENING	LIFETIME	SUICIDALITY	379	235	(62.0)	85	39	(45.9)	464	274	(59.1)
		SUICIDAL BEHAVIOR	379	157	(41.4)	85	22	(25.9)	464	179	(38.6)
		SUICIDAL IDEATION	379	233	(61.5)	85	38	(44.7)	464	271	(58.4)
	PAST 90 DAYS	SUICIDALITY	361	35	(9.7)	77	5	(6.5)	438	40	(9.1)
		SUICIDAL BEHAVIOR	361	1	(0.3)	77	0	(0.0)	438	1	(0.2)
		SUICIDAL IDEATION	361	35	(9.7)	77	5	(6.5)	438	40	(9.1)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE DE NOVO (N=272)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)
PHASE A	BASELINE	SUICIDALITY	272	9	(3.3)
		SUICIDAL BEHAVIOR	272	0	(0.0)
		SUICIDAL IDEATION	272	9	(3.3)
	LAST VISIT	COMPLETE SUICIDALITY	272	0	(0.0)
		SUICIDALITY	272	5	(1.8)
		SUICIDAL BEHAVIOR	272	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	272	0	(0.0)
		SUICIDAL IDEATION	272	5	(1.8)
		EMERGENCE OF SUICIDAL IDEATION	272	3	(1.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	272	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	272	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	272	0	(0.0)
		SUICIDALITY	272	10	(3.7)
		SUICIDAL BEHAVIOR	272	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	272	0	(0.0)
		SUICIDAL IDEATION	272	10	(3.7)
		EMERGENCE OF SUICIDAL IDEATION	272	7	(2.6)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	272	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	272	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE		
			DE NOVO (N=379)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)
PHASE B	BASELINE	SUICIDALITY	379	10	(2.6)
		SUICIDAL BEHAVIOR	379	0	(0.0)
		SUICIDAL IDEATION	379	10	(2.6)
	LAST VISIT	COMPLETE SUICIDALITY	379	0	(0.0)
		SUICIDALITY	379	4	(1.1)
		SUICIDAL BEHAVIOR	379	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	379	0	(0.0)
		SUICIDAL IDEATION	379	4	(1.1)
		EMERGENCE OF SUICIDAL IDEATION	379	2	(0.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	379	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	379	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	379	0	(0.0)
		SUICIDALITY	379	16	(4.2)
		SUICIDAL BEHAVIOR	379	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	379	0	(0.0)
		SUICIDAL IDEATION	379	16	(4.2)
		EMERGENCE OF SUICIDAL IDEATION	379	12	(3.2)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	379	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	379	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	BASELINE	SUICIDALITY	379	4	(1.1)	85	0	(0.0)	464	4	(0.9)
		SUICIDAL BEHAVIOR	379	0	(0.0)	85	0	(0.0)	464	0	(0.0)
		SUICIDAL IDEATION	379	4	(1.1)	85	0	(0.0)	464	4	(0.9)
	WEEK 1	COMPLETE SUICIDALITY	365	0	(0.0)	77	0	(0.0)	442	0	(0.0)
		SUICIDALITY	365	1	(0.3)	77	0	(0.0)	442	1	(0.2)
		SUICIDAL BEHAVIOR	365	0	(0.0)	77	0	(0.0)	442	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	365	0	(0.0)	77	0	(0.0)	442	0	(0.0)
		SUICIDAL IDEATION	365	1	(0.3)	77	0	(0.0)	442	1	(0.2)
		EMERGENCE OF SUICIDAL IDEATION	365	0	(0.0)	77	0	(0.0)	442	0	(0.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	365	0	(0.0)	77	0	(0.0)	442	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	365	0	(0.0)	77	0	(0.0)	442	0	(0.0)
	WEEK 2	COMPLETE SUICIDALITY	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
		SUICIDALITY	356	7	(2.0)	78	0	(0.0)	434	7	(1.6)
		SUICIDAL BEHAVIOR	356	1	(0.3)	78	0	(0.0)	434	1	(0.2)
		EMERGENCE OF SUICIDAL BEHAVIOR	356	1	(0.3)	78	0	(0.0)	434	1	(0.2)
		SUICIDAL IDEATION	356	7	(2.0)	78	0	(0.0)	434	7	(1.6)
		EMERGENCE OF SUICIDAL IDEATION	356	5	(1.4)	78	0	(0.0)	434	5	(1.2)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 3	COMPLETE SUICIDALITY	356	0	(0.0)	81	0	(0.0)	437	0	(0.0)
		SUICIDALITY	356	6	(1.7)	81	0	(0.0)	437	6	(1.4)
		SUICIDAL BEHAVIOR	356	0	(0.0)	81	0	(0.0)	437	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	356	0	(0.0)	81	0	(0.0)	437	0	(0.0)
		SUICIDAL IDEATION	356	6	(1.7)	81	0	(0.0)	437	6	(1.4)
		EMERGENCE OF SUICIDAL IDEATION	356	4	(1.1)	81	0	(0.0)	437	4	(0.9)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	356	0	(0.0)	81	0	(0.0)	437	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	356	0	(0.0)	81	0	(0.0)	437	0	(0.0)
	WEEK 4	COMPLETE SUICIDALITY	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
		SUICIDALITY	356	5	(1.4)	78	0	(0.0)	434	5	(1.2)
		SUICIDAL BEHAVIOR	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
		SUICIDAL IDEATION	356	5	(1.4)	78	0	(0.0)	434	5	(1.2)
		EMERGENCE OF SUICIDAL IDEATION	356	2	(0.6)	78	0	(0.0)	434	2	(0.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	356	0	(0.0)	78	0	(0.0)	434	0	(0.0)
	WEEK 6	COMPLETE SUICIDALITY	350	0	(0.0)	81	0	(0.0)	431	0	(0.0)
		SUICIDALITY	350	7	(2.0)	81	0	(0.0)	431	7	(1.6)
		SUICIDAL BEHAVIOR	350	0	(0.0)	81	0	(0.0)	431	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	350	0	(0.0)	81	0	(0.0)	431	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 6	SUICIDAL IDEATION	350	7	(2.0)	81	0	(0.0)	431	7	(1.6)
		EMERGENCE OF SUICIDAL IDEATION	350	5	(1.4)	81	0	(0.0)	431	5	(1.2)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	350	0	(0.0)	81	0	(0.0)	431	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	350	0	(0.0)	81	0	(0.0)	431	0	(0.0)
	WEEK 8	COMPLETE SUICIDALITY	343	0	(0.0)	77	0	(0.0)	420	0	(0.0)
		SUICIDALITY	343	8	(2.3)	77	0	(0.0)	420	8	(1.9)
		SUICIDAL BEHAVIOR	343	1	(0.3)	77	0	(0.0)	420	1	(0.2)
		EMERGENCE OF SUICIDAL BEHAVIOR	343	1	(0.3)	77	0	(0.0)	420	1	(0.2)
		SUICIDAL IDEATION	343	8	(2.3)	77	0	(0.0)	420	8	(1.9)
		EMERGENCE OF SUICIDAL IDEATION	343	7	(2.0)	77	0	(0.0)	420	7	(1.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	343	0	(0.0)	77	0	(0.0)	420	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	343	0	(0.0)	77	0	(0.0)	420	0	(0.0)
	WEEK 10	COMPLETE SUICIDALITY	338	0	(0.0)	75	0	(0.0)	413	0	(0.0)
		SUICIDALITY	338	9	(2.7)	75	0	(0.0)	413	9	(2.2)
		SUICIDAL BEHAVIOR	338	1	(0.3)	75	0	(0.0)	413	1	(0.2)
		EMERGENCE OF SUICIDAL BEHAVIOR	338	1	(0.3)	75	0	(0.0)	413	1	(0.2)
		SUICIDAL IDEATION	338	8	(2.4)	75	0	(0.0)	413	8	(1.9)
		EMERGENCE OF SUICIDAL IDEATION	338	6	(1.8)	75	0	(0.0)	413	6	(1.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	338	0	(0.0)	75	0	(0.0)	413	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	338	0	(0.0)	75	0	(0.0)	413	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 12	COMPLETE SUICIDALITY	335	0	(0.0)	76	0	(0.0)	411	0	(0.0)
		SUICIDALITY	335	7	(2.1)	76	0	(0.0)	411	7	(1.7)
		SUICIDAL BEHAVIOR	335	0	(0.0)	76	0	(0.0)	411	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	335	0	(0.0)	76	0	(0.0)	411	0	(0.0)
		SUICIDAL IDEATION	335	7	(2.1)	76	0	(0.0)	411	7	(1.7)
		EMERGENCE OF SUICIDAL IDEATION	335	6	(1.8)	76	0	(0.0)	411	6	(1.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	335	0	(0.0)	76	0	(0.0)	411	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	335	0	(0.0)	76	0	(0.0)	411	0	(0.0)
	WEEK 16	COMPLETE SUICIDALITY	325	0	(0.0)	75	0	(0.0)	400	0	(0.0)
		SUICIDALITY	325	6	(1.8)	75	1	(1.3)	400	7	(1.8)
		SUICIDAL BEHAVIOR	325	1	(0.3)	75	0	(0.0)	400	1	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	325	1	(0.3)	75	0	(0.0)	400	1	(0.3)
		SUICIDAL IDEATION	325	6	(1.8)	75	1	(1.3)	400	7	(1.8)
		EMERGENCE OF SUICIDAL IDEATION	325	3	(0.9)	75	1	(1.3)	400	4	(1.0)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	325	0	(0.0)	75	0	(0.0)	400	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	325	0	(0.0)	75	0	(0.0)	400	0	(0.0)
	WEEK 20	COMPLETE SUICIDALITY	308	0	(0.0)	74	0	(0.0)	382	0	(0.0)
		SUICIDALITY	308	10	(3.2)	74	0	(0.0)	382	10	(2.6)
		SUICIDAL BEHAVIOR	308	1	(0.3)	74	0	(0.0)	382	1	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	308	1	(0.3)	74	0	(0.0)	382	1	(0.3)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 20	SUICIDAL IDEATION	308	9	(2.9)	74	0	(0.0)	382	9	(2.4)
		EMERGENCE OF SUICIDAL IDEATION	308	8	(2.6)	74	0	(0.0)	382	8	(2.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	308	0	(0.0)	74	0	(0.0)	382	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	308	0	(0.0)	74	0	(0.0)	382	0	(0.0)
	WEEK 24	COMPLETE SUICIDALITY	290	0	(0.0)	72	0	(0.0)	362	0	(0.0)
		SUICIDALITY	290	9	(3.1)	72	0	(0.0)	362	9	(2.5)
		SUICIDAL BEHAVIOR	290	1	(0.3)	72	0	(0.0)	362	1	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	290	1	(0.3)	72	0	(0.0)	362	1	(0.3)
		SUICIDAL IDEATION	290	9	(3.1)	72	0	(0.0)	362	9	(2.5)
		EMERGENCE OF SUICIDAL IDEATION	290	6	(2.1)	72	0	(0.0)	362	6	(1.7)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	290	0	(0.0)	72	0	(0.0)	362	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	290	0	(0.0)	72	0	(0.0)	362	0	(0.0)
	WEEK 28	COMPLETE SUICIDALITY	278	0	(0.0)	71	0	(0.0)	349	0	(0.0)
		SUICIDALITY	278	5	(1.8)	71	0	(0.0)	349	5	(1.4)
		SUICIDAL BEHAVIOR	278	1	(0.4)	71	0	(0.0)	349	1	(0.3)
		EMERGENCE OF SUICIDAL BEHAVIOR	278	1	(0.4)	71	0	(0.0)	349	1	(0.3)
		SUICIDAL IDEATION	278	5	(1.8)	71	0	(0.0)	349	5	(1.4)
		EMERGENCE OF SUICIDAL IDEATION	278	2	(0.7)	71	0	(0.0)	349	2	(0.6)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	278	0	(0.0)	71	0	(0.0)	349	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	278	0	(0.0)	71	0	(0.0)	349	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.2.1　FINAL

表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 32	COMPLETE SUICIDALITY	261	0	(0.0)	27	0	(0.0)	288	0	(0.0)
		SUICIDALITY	261	5	(1.9)	27	0	(0.0)	288	5	(1.7)
		SUICIDAL BEHAVIOR	261	0	(0.0)	27	0	(0.0)	288	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	261	0	(0.0)	27	0	(0.0)	288	0	(0.0)
		SUICIDAL IDEATION	261	5	(1.9)	27	0	(0.0)	288	5	(1.7)
		EMERGENCE OF SUICIDAL IDEATION	261	4	(1.5)	27	0	(0.0)	288	4	(1.4)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	261	0	(0.0)	27	0	(0.0)	288	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	261	0	(0.0)	27	0	(0.0)	288	0	(0.0)
	WEEK 36	COMPLETE SUICIDALITY	249	0	(0.0)	24	0	(0.0)	273	0	(0.0)
		SUICIDALITY	249	5	(2.0)	24	0	(0.0)	273	5	(1.8)
		SUICIDAL BEHAVIOR	249	0	(0.0)	24	0	(0.0)	273	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	249	0	(0.0)	24	0	(0.0)	273	0	(0.0)
		SUICIDAL IDEATION	249	5	(2.0)	24	0	(0.0)	273	5	(1.8)
		EMERGENCE OF SUICIDAL IDEATION	249	4	(1.6)	24	0	(0.0)	273	4	(1.5)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	249	0	(0.0)	24	0	(0.0)	273	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	249	0	(0.0)	24	0	(0.0)	273	0	(0.0)
	WEEK 40	COMPLETE SUICIDALITY	239	0	(0.0)	18	0	(0.0)	257	0	(0.0)
		SUICIDALITY	239	6	(2.5)	18	0	(0.0)	257	6	(2.3)
		SUICIDAL BEHAVIOR	239	0	(0.0)	18	0	(0.0)	257	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	239	0	(0.0)	18	0	(0.0)	257	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 40	SUICIDAL IDEATION	239	6	(2.5)	18	0	(0.0)	257	6	(2.3)
		EMERGENCE OF SUICIDAL IDEATION	239	5	(2.1)	18	0	(0.0)	257	5	(1.9)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	239	0	(0.0)	18	0	(0.0)	257	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	239	0	(0.0)	18	0	(0.0)	257	0	(0.0)
	WEEK 44	COMPLETE SUICIDALITY	232	0	(0.0)	18	0	(0.0)	250	0	(0.0)
		SUICIDALITY	232	1	(0.4)	18	1	(5.6)	250	2	(0.8)
		SUICIDAL BEHAVIOR	232	0	(0.0)	18	0	(0.0)	250	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	232	0	(0.0)	18	0	(0.0)	250	0	(0.0)
		SUICIDAL IDEATION	232	1	(0.4)	18	1	(5.6)	250	2	(0.8)
		EMERGENCE OF SUICIDAL IDEATION	232	1	(0.4)	18	1	(5.6)	250	2	(0.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	232	0	(0.0)	18	0	(0.0)	250	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	232	0	(0.0)	18	0	(0.0)	250	0	(0.0)
	WEEK 48	COMPLETE SUICIDALITY	229	0	(0.0)	15	0	(0.0)	244	0	(0.0)
		SUICIDALITY	229	3	(1.3)	15	0	(0.0)	244	3	(1.2)
		SUICIDAL BEHAVIOR	229	1	(0.4)	15	0	(0.0)	244	1	(0.4)
		EMERGENCE OF SUICIDAL BEHAVIOR	229	1	(0.4)	15	0	(0.0)	244	1	(0.4)
		SUICIDAL IDEATION	229	3	(1.3)	15	0	(0.0)	244	3	(1.2)
		EMERGENCE OF SUICIDAL IDEATION	229	2	(0.9)	15	0	(0.0)	244	2	(0.8)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	229	0	(0.0)	15	0	(0.0)	244	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	229	0	(0.0)	15	0	(0.0)	244	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-6.2.1　FINAL

表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	WEEK 52	COMPLETE SUICIDALITY	224	0	(0.0)	14	0	(0.0)	238	0	(0.0)
		SUICIDALITY	224	5	(2.2)	14	0	(0.0)	238	5	(2.1)
		SUICIDAL BEHAVIOR	224	0	(0.0)	14	0	(0.0)	238	0	(0.0)
		EMERGENCE OF SUICIDAL BEHAVIOR	224	0	(0.0)	14	0	(0.0)	238	0	(0.0)
		SUICIDAL IDEATION	224	5	(2.2)	14	0	(0.0)	238	5	(2.1)
		EMERGENCE OF SUICIDAL IDEATION	224	5	(2.2)	14	0	(0.0)	238	5	(2.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	224	0	(0.0)	14	0	(0.0)	238	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	224	0	(0.0)	14	0	(0.0)	238	0	(0.0)
	LAST VISIT	COMPLETE SUICIDALITY	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
		SUICIDALITY	378	13	(3.4)	85	1	(1.2)	463	14	(3.0)
		SUICIDAL BEHAVIOR	378	3	(0.8)	85	0	(0.0)	463	3	(0.6)
		EMERGENCE OF SUICIDAL BEHAVIOR	378	3	(0.8)	85	0	(0.0)	463	3	(0.6)
		SUICIDAL IDEATION	378	13	(3.4)	85	1	(1.2)	463	14	(3.0)
		EMERGENCE OF SUICIDAL IDEATION	378	11	(2.9)	85	1	(1.2)	463	12	(2.6)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
	OVERALL	COMPLETE SUICIDALITY	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
		SUICIDALITY	378	45	(11.9)	85	2	(2.4)	463	47	(10.2)
		SUICIDAL BEHAVIOR	378	8	(2.1)	85	0	(0.0)	463	8	(1.7)
		EMERGENCE OF SUICIDAL BEHAVIOR	378	8	(2.1)	85	0	(0.0)	463	8	(1.7)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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表 2.7.4.7-181　C-SSRS［長期投与試験，IM デポ剤維持治療期（Phase C）］

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CT-6.2.1
Columbia-Suicide Severity Rating Scale (C-SSRS) - Incidence of Suicidality
(Phase C Safety Sample)

			ENROLLMENT SOURCE								
			DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
PHASE	TRIAL WEEK[1]	CATEGORY	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)	Ne[2]	n[3]	(%)
PHASE C	OVERALL	SUICIDAL IDEATION	378	44	(11.6)	85	2	(2.4)	463	46	(9.9)
		EMERGENCE OF SUICIDAL IDEATION	378	40	(10.6)	85	2	(2.4)	463	42	(9.1)
		EMERGENCE OF SERIOUS SUICIDAL IDEATION	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)
		WORSENING OF SUICIDAL IDEATION	378	0	(0.0)	85	0	(0.0)	463	0	(0.0)

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]Ne = TOTAL NUMBER OF SUBJECTS WITH C-SSRS EVALUATION AT THE GIVEN TIMEPOINT.
[3]n = NUMBER OF SUBJECT WITH SPECIFIED SUICIDAL IDEATION/BEHAVIOR AT THE GIVEN TIMEPOINT.

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＜資料番号 5.3.5.2-01：CT-6.2.1＞

表 2.7.4.7-182　VAS による注射部位疼痛の自己評価の記述統計量［二重盲検試験，二重盲検期（Phase D）］

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CT-16.1.1
Visual Analog Scale Score for Subject-reported Rating of Pain at Most Recent Injection Site - Mean Score by Injection in Phase D
(Phase D Safety Sample)

TREATMENT	INJECTION	n[1]	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	1ST INJECTION	132	5.2	1.0	9.0	0.0	51.0
	2ND INJECTION	120	5.2	1.0	10.1	0.0	64.0
	3RD INJECTION	105	4.4	1.0	7.8	0.0	47.0
	4TH INJECTION	99	4.8	1.0	9.0	0.0	44.0
	5TH INJECTION	87	4.9	1.0	8.3	0.0	40.0
	6TH INJECTION	84	5.0	1.0	8.5	0.0	43.0
	7TH INJECTION	82	4.9	1.0	9.9	0.0	61.0
	8TH INJECTION	77	4.6	1.0	10.6	0.0	80.0
	9TH INJECTION	73	3.7	1.0	5.8	0.0	24.0
	10TH INJECTION	70	3.5	1.0	5.5	0.0	26.0
	11TH INJECTION	69	3.5	1.0	5.8	0.0	32.0
	12TH INJECTION	68	4.0	1.5	6.4	0.0	28.0
	13TH INJECTION	65	4.0	1.0	7.5	0.0	42.0
	LAST INJECTION	132	4.0	1.0	7.6	0.0	44.0
PLACEBO	1ST INJECTION	133	5.7	2.0	9.4	0.0	57.0
	2ND INJECTION	111	4.3	1.0	9.0	0.0	60.0
	3RD INJECTION	97	4.5	2.0	7.7	0.0	37.0
	4TH INJECTION	87	4.9	1.0	9.5	0.0	48.0
	5TH INJECTION	81	3.8	1.0	7.4	0.0	41.0
	6TH INJECTION	72	4.0	1.0	9.2	0.0	49.0
	7TH INJECTION	65	3.5	1.0	8.1	0.0	53.0
	8TH INJECTION	57	5.2	1.0	12.2	0.0	66.0
	9TH INJECTION	53	3.2	0.0	6.8	0.0	35.0
	10TH INJECTION	51	4.8	0.0	12.2	0.0	73.0
	11TH INJECTION	49	4.9	1.0	12.6	0.0	76.0
	12TH INJECTION	46	4.7	0.5	10.9	0.0	59.0
	13TH INJECTION	41	3.9	1.0	13.1	0.0	83.0
	LAST INJECTION	133	5.8	1.0	12.1	0.0	83.0

[1]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

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＜資料番号 5.3.5.1-01：CT-16.1.1＞

表 2.7.4.7-183　治験責任医師等による注射部位の評価ー疼痛［二重盲検試験，二重盲検期（Phase D）］

CT-16.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)									PLACEBO (N=133)								
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	132	108	(81.8)	23	(17.4)	1	(0.8)	0	(0.0)	133	108	(81.2)	25	(18.8)	0	(0.0)	0	(0.0)
2ND INJECTION	120	103	(85.8)	17	(14.2)	0	(0.0)	0	(0.0)	111	96	(86.5)	13	(11.7)	2	(1.8)	0	(0.0)
3RD INJECTION	104	88	(84.6)	16	(15.4)	0	(0.0)	0	(0.0)	97	78	(80.4)	19	(19.6)	0	(0.0)	0	(0.0)
4TH INJECTION	99	81	(81.8)	18	(18.2)	0	(0.0)	0	(0.0)	87	73	(83.9)	11	(12.6)	3	(3.4)	0	(0.0)
5TH INJECTION	87	70	(80.5)	17	(19.5)	0	(0.0)	0	(0.0)	81	68	(84.0)	12	(14.8)	1	(1.2)	0	(0.0)
6TH INJECTION	84	67	(79.8)	17	(20.2)	0	(0.0)	0	(0.0)	72	61	(84.7)	9	(12.5)	2	(2.8)	0	(0.0)
7TH INJECTION	82	65	(79.3)	16	(19.5)	1	(1.2)	0	(0.0)	65	54	(83.1)	10	(15.4)	1	(1.5)	0	(0.0)
8TH INJECTION	77	63	(81.8)	13	(16.9)	1	(1.3)	0	(0.0)	57	47	(82.5)	9	(15.8)	1	(1.8)	0	(0.0)
9TH INJECTION	73	59	(80.8)	14	(19.2)	0	(0.0)	0	(0.0)	53	47	(88.7)	6	(11.3)	0	(0.0)	0	(0.0)
10TH INJECTION	70	56	(80.0)	14	(20.0)	0	(0.0)	0	(0.0)	51	44	(86.3)	7	(13.7)	0	(0.0)	0	(0.0)
11TH INJECTION	69	55	(79.7)	14	(20.3)	0	(0.0)	0	(0.0)	49	43	(87.8)	6	(12.2)	0	(0.0)	0	(0.0)
12TH INJECTION	68	55	(80.9)	13	(19.1)	0	(0.0)	0	(0.0)	46	38	(82.6)	8	(17.4)	0	(0.0)	0	(0.0)
13TH INJECTION	65	55	(84.6)	9	(13.8)	1	(1.5)	0	(0.0)	41	36	(87.8)	5	(12.2)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

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表 2.7.4.7-183　治験責任医師等による注射部位の評価ー疼痛［二重盲検試験，二重盲検期（Phase D）］

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CT-16.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	132	115	(87.1)	16	(12.1)	1	(0.8)	0	(0.0)	133	113	(85.0)	17	(12.8)	3	(2.3)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

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＜資料番号 5.3.5.1-01：CT-16.1.2.1＞

表 2.7.4.7-184　治験責任医師等による注射部位の評価－腫脹［二重盲検試験，二重盲検期（Phase D）］

CT-16.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	132	132	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
2ND INJECTION	120	120	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	111	111	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
3RD INJECTION	104	103	(99.0)	1	(1.0)	0	(0.0)	0	(0.0)	97	97	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
4TH INJECTION	99	99	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	87	87	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
5TH INJECTION	87	87	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	81	81	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	84	84	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	72	72	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
7TH INJECTION	82	82	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	65	65	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
8TH INJECTION	77	77	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	57	57	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
9TH INJECTION	73	73	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	53	53	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	70	70	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	51	51	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	69	69	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	49	49	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	68	68	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	46	46	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	65	65	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	41	41	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3AB.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.2 FINAL

表 2.7.4.7-184　治験責任医師等による注射部位の評価－腫脹［二重盲検試験，二重盲検期（Phase D）］

CT-16.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	132	132	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3AB.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.2　FINAL

＜資料番号 5.3.5.1-01：CT-16.1.2.2＞

表 2.7.4.7-185　治験責任医師等による注射部位の評価－発赤［二重盲検試験，二重盲検期（Phase D）］

CT-16.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	132	130	(98.5)	2	(1.5)	0	(0.0)	0	(0.0)	133	131	(98.5)	2	(1.5)	0	(0.0)	0	(0.0)
2ND INJECTION	120	120	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	111	110	(99.1)	1	(0.9)	0	(0.0)	0	(0.0)
3RD INJECTION	104	103	(99.0)	1	(1.0)	0	(0.0)	0	(0.0)	97	97	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
4TH INJECTION	99	98	(99.0)	1	(1.0)	0	(0.0)	0	(0.0)	87	86	(98.9)	1	(1.1)	0	(0.0)	0	(0.0)
5TH INJECTION	87	85	(97.7)	2	(2.3)	0	(0.0)	0	(0.0)	81	80	(98.8)	1	(1.2)	0	(0.0)	0	(0.0)
6TH INJECTION	84	81	(96.4)	3	(3.6)	0	(0.0)	0	(0.0)	72	72	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
7TH INJECTION	82	81	(98.8)	1	(1.2)	0	(0.0)	0	(0.0)	65	65	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
8TH INJECTION	77	76	(98.7)	1	(1.3)	0	(0.0)	0	(0.0)	57	57	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
9TH INJECTION	73	72	(98.6)	1	(1.4)	0	(0.0)	0	(0.0)	53	53	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	70	70	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	51	51	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	69	68	(98.6)	1	(1.4)	0	(0.0)	0	(0.0)	49	49	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	68	67	(98.5)	1	(1.5)	0	(0.0)	0	(0.0)	46	46	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	65	64	(98.5)	1	(1.5)	0	(0.0)	0	(0.0)	41	41	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

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PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.3 FINAL

表 2.7.4.7-185　治験責任医師等による注射部位の評価－発赤［二重盲検試験，二重盲検期（Phase D）］

CT-16.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	132	131	(99.2)	1	(0.8)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3AC.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.3　FINAL

＜資料番号 5.3.5.1-01：CT-16.1.2.3＞

表 2.7.4.7-186　治験責任医師等による注射部位の評価－硬結［二重盲検試験，二重盲検期（Phase D）］

OPC14597 1 OF 2
PROTOCOL 31-08-250

CT-16.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	132	132	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
2ND INJECTION	120	120	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	111	110	(99.1)	1	(0.9)	0	(0.0)	0	(0.0)
3RD INJECTION	104	104	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	97	96	(99.0)	1	(1.0)	0	(0.0)	0	(0.0)
4TH INJECTION	99	99	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	87	87	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
5TH INJECTION	87	87	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	81	81	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	84	83	(98.8)	1	(1.2)	0	(0.0)	0	(0.0)	72	72	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
7TH INJECTION	82	82	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	65	65	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
8TH INJECTION	77	77	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	57	57	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
9TH INJECTION	73	73	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	53	53	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	70	70	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	51	51	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	69	69	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	49	49	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	68	68	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	46	46	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	65	65	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	41	41	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3AD.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.4 FINAL

表 2.7.4.7-186　治験責任医師等による注射部位の評価－硬結［二重盲検試験，二重盲検期（Phase D）］

OPC14597 2 OF 2
PROTOCOL 31-08-250

CT-16.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase D (Phase D Safety Sample)

	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	132	132	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3AD.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.4 FINAL

＜資料番号 5.3.5.1-01：CT-16.1.2.4＞

表 2.7.4.7-187　注射部位反応関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=132) n	(%)	PLACEBO (N=133) n	(%)	TOTAL (N=265) n	(%)
一般・全身障害および投与部位の状態	TOTAL1)	1	(0.8)	2	(1.5)	3	(1.1)
	注射部位疼痛	1	(0.8)	1	(0.8)	2	(0.8)
	注射部位そう痒感	0	(0.0)	1	(0.8)	1	(0.4)
TOTAL2)		1	(0.8)	2	(1.5)	3	(1.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AD.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.3　FINAL

表 2.7.4.7-187　注射部位反応関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO INJECTION SITE: MEDDRA 19.0 PRIMARY TERMS

ADMINISTRATION RELATED REACTION, ADMINISTRATION SITE ABSCESS, ADMINISTRATION SITE INFECTION, ADMINISTRATION SITE PAIN, APPLICATION SITE ABSCESS, APPLICATION SITE ALOPECIA, APPLICATION SITE ANAESTHESIA, APPLICATION SITE ATROPHY, APPLICATION SITE HAEMORRHAGE, APPLICATION SITE BURN, APPLICATION SITE CELLULITIS, APPLICATION SITE COLD FEELING, APPLICATION SITE DERMATITIS, APPLICATION SITE DISCHARGE, APPLICATION SITE DISCOLOURATION, APPLICATION SITE DISCOMFORT, APPLICATION SITE DRYNESS, APPLICATION SITE ECZEMA, APPLICATION SITE EROSION, APPLICATION SITE ERYTHEMA, APPLICATION SITE EXFOLIATION, APPLICATION SITE FISSURE, APPLICATION SITE FOLLICULITIS, APPLICATION SITE HAEMATOMA, APPLICATION SITE HYPERAESTHESIA, APPLICATION SITE HYPERSENSITIVITY, APPLICATION SITE INDURATION, APPLICATION SITE INFECTION, APPLICATION SITE INFLAMMATION, APPLICATION SITE IRRITATION, APPLICATION SITE MASS, APPLICATION SITE NECROSIS, APPLICATION SITE NODULE, APPLICATION SITE ODOUR, APPLICATION SITE OEDEMA, APPLICATION SITE PAIN, APPLICATION SITE PALLOR, APPLICATION SITE PAPULES, APPLICATION SITE PARAESTHESIA, APPLICATION SITE PERSPIRATION, APPLICATION SITE PHOTOSENSITIVITY REACTION, APPLICATION SITE PRURITUS, APPLICATION SITE PUSTULES, APPLICATION SITE RASH, APPLICATION SITE REACTION, APPLICATION SITE SCAB, APPLICATION SITE SCAR, APPLICATION SITE SWELLING, APPLICATION SITE ULCER, APPLICATION SITE URTICARIA, APPLICATION SITE VESICLES, APPLICATION SITE WARMTH, EMBOLIA CUTIS MEDICAMENTOSA, INJECTED LIMB MOBILITY DECREASED, INJECTION SITE ABSCESS, INJECTION SITE ABSCESS STERILE, INJECTION SITE ANAESTHESIA, INJECTION SITE ATROPHY, INJECTION SITE CALCIFICATION, INJECTION SITE CELLULITIS, INJECTION SITE COLDNESS, INJECTION SITE CYST, INJECTION SITE DERMATITIS, INJECTION SITE DISCHARGE, INJECTION SITE DISCOLOURATION, INJECTION SITE DISCOMFORT, INJECTION SITE DRYNESS, INJECTION SITE DYSAESTHESIA, INJECTION SITE ECZEMA, INJECTION SITE EROSION, INJECTION SITE ERYTHEMA, INJECTION SITE EXFOLIATION, INJECTION SITE EXTRAVASATION, INJECTION SITE FIBROSIS, INJECTION SITE HAEMATOMA, INJECTION SITE HAEMORRHAGE, INJECTION SITE HYPERSENSITIVITY, INJECTION SITE HYPERTROPHY, INJECTION SITE INDURATION, INJECTION SITE INFECTION, INJECTION SITE INFLAMMATION, INJECTION SITE INJURY, INJECTION SITE IRRITATION, INJECTION SITE ISCHAEMIA, INJECTION SITE JOINT EFFUSION, INJECTION SITE JOINT INFLAMMATION, INJECTION SITE JOINT MOVEMENT IMPAIRMENT, INJECTION SITE JOINT PAIN, INJECTION SITE JOINT REDNESS, INJECTION SITE JOINT SWELLING, INJECTION SITE JOINT WARMTH, INJECTION SITE LACERATION, INJECTION SITE LYMPHADENOPATHY, INJECTION SITE MACULE, INJECTION SITE MASS, INJECTION SITE MOVEMENT IMPAIRMENT, INJECTION SITE NECROSIS, INJECTION SITE NERVE DAMAGE, INJECTION SITE NODULE, INJECTION SITE OEDEMA, INJECTION SITE PAIN, INJECTION SITE PALLOR, INJECTION SITE PAPULE, INJECTION SITE PARAESTHESIA, INJECTION SITE PHLEBITIS, INJECTION SITE PHOTOSENSITIVITY REACTION, INJECTION SITE PRURITUS, INJECTION SITE PUSTULE, INJECTION SITE RASH, INJECTION SITE REACTION, INJECTION SITE RECALL REACTION, INJECTION SITE SCAB, INJECTION SITE SCAR, INJECTION SITE STREAKING, INJECTION SITE SWELLING, INJECTION SITE THROMBOSIS, INJECTION SITE ULCER, INJECTION SITE URTICARIA, INJECTION SITE VASCULITIS, INJECTION SITE VESICLES, INJECTION SITE WARMTH, INSTILLATION SITE PARAESTHESIA, INSTILLATION SITE DISCOMFORT, INSTILLATION SITE DRYNESS, INSTILLATION SITE ERYTHEMA, INSTILLATION SITE FOREIGN BODY SENSATION, INSTILLATION SITE IRRITATION, INSTILLATION SITE LACRIMATION, INSTILLATION SITE PAIN, INSTILLATION SITE PRURITUS, INSTILLATION SITE REACTION, MALABSORPTION FROM INJECTION SITE, PUNCTURE SITE ABSCESS, PUNCTURE SITE DISCHARGE, PUNCTURE SITE HAEMORRHAGE, PUNCTURE SITE INDURATION, PUNCTURE SITE INFECTION, PUNCTURE SITE PAIN, PUNCTURE SITE REACTION, SYSTEMIC LEAKAGE, VESSEL PUNCTURE SITE ANAESTHESIA, VESSEL PUNCTURE SITE DISCHARGE, VESSEL PUNCTURE SITE HAEMATOMA, VESSEL PUNCTURE SITE HAEMORRHAGE, VESSEL PUNCTURE SITE INFLAMMATION, VESSEL PUNCTURE SITE PAIN, VESSEL PUNCTURE SITE PARAESTHESIA, VESSEL PUNCTURE SITE PRURITUS, VESSEL PUNCTURE SITE REACTION, VESSEL PUNCTURE SITE SWELLING, VESSEL PUNCTURE SITE THROMBOSIS, APPLICATION SITE ACNE, APPLICATION SITE BRUISE, APPLICATION SITE TELANGIECTASIA, INSTILLATION SITE COMPLICATION, INJECTION SITE BRUISING, INJECTION

表 2.7.4.7-187　注射部位反応関連有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-8.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site in Phase D
by System Organ Class and MedDRA Preferred Term (Phase D Safety Sample)

ADVERSE EVENTS RELATED TO INJECTION SITE: MEDDRA 19.0 PRIMARY TERMS

SITE GRANULOMA, INJECTION SITE HYPERAESTHESIA, INJECTION SITE PLAQUE, INJECTION SITE JOINT DISCOMFORT, ADMINISTRATION SITE RASH, ADMINISTRATION SITE REACTION, PUNCTURE SITE SWELLING, VESSEL PUNCTURE SITE BRUISE, VESSEL PUNCTURE SITE INFECTION, VESSEL PUNCTURE SITE INDURATION

FILE: ADAE3AD.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.5.3　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.5.3 より作成＞

表 2.7.4.7-188　VAS による注射部位疼痛の自己評価の記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-25.1.1
Visual Analog Scale Score for Subject-reported Rating of Pain at Most Recent Injection Site - Mean Score by Injection in Phase C
(Phase C Safety Sample)

ARIPIPRAZOLE IM DEPOT INJECTION	n[1]	MEAN	MEDIAN	SD	MIN	MAX
1ST INJECTION[2]	421	6.1	2.0	11.0	0.0	67.0
2ND INJECTION	377	5.9	2.0	10.0	0.0	61.0
3RD INJECTION	351	5.7	2.0	10.3	0.0	64.0
4TH INJECTION	105	6.2	2.0	10.2	0.0	47.0
5TH INJECTION	67	5.8	2.0	9.6	0.0	45.0
6TH INJECTION	36	8.3	1.5	14.5	0.0	53.0
7TH INJECTION	8	12.9	3.5	23.9	0.0	71.0
LAST INJECTION[3]	423	5.6	1.0	10.8	0.0	71.0

[1]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.

FILE: ADVAS3BA.LIS, RUN: [redacted]20[redacted] 10:58; ANALYSIS DATASET CREATED: [redacted]20[redacted] 17:02
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADVAS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-25.1.1　FINAL

＜資料番号 5.3.5.1-01：CT-25.1.1＞

表 2.7.4.7-189　治験責任医師等による注射部位の評価ー疼痛［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-25.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase C (Phase C Safety Sample)

		ARIP IMD (N=425)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	422	342	(81.0)	78	(18.5)	2	(0.5)	0	(0.0)
2ND INJECTION	377	311	(82.5)	65	(17.2)	1	(0.3)	0	(0.0)
3RD INJECTION	352	287	(81.5)	63	(17.9)	2	(0.6)	0	(0.0)
4TH INJECTION	105	75	(71.4)	29	(27.6)	1	(1.0)	0	(0.0)
5TH INJECTION	66	44	(66.7)	21	(31.8)	1	(1.5)	0	(0.0)
6TH INJECTION	36	27	(75.0)	8	(22.2)	1	(2.8)	0	(0.0)
7TH INJECTION	8	5	(62.5)	3	(37.5)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	424	357	(84.2)	64	(15.1)	3	(0.7)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.

FILE: ADINJ3DA.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-25.1.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-25.1.2.1＞

表 2.7.4.7-190　治験責任医師等による注射部位の評価－腫脹［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-25.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase C (Phase C Safety Sample)

	ARIP IMD (N=425)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	421	421	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
2ND INJECTION	377	374	(99.2)	3	(0.8)	0	(0.0)	0	(0.0)
3RD INJECTION	352	350	(99.4)	1	(0.3)	1	(0.3)	0	(0.0)
4TH INJECTION	105	103	(98.1)	2	(1.9)	0	(0.0)	0	(0.0)
5TH INJECTION	66	66	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	36	35	(97.2)	1	(2.8)	0	(0.0)	0	(0.0)
7TH INJECTION	8	8	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	424	422	(99.5)	2	(0.5)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.

FILE: ADINJ3DB.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-25.1.2.2　FINAL

＜資料番号 5.3.5.1-01：CT-25.1.2.2＞

表 2.7.4.7-191　治験責任医師等による注射部位の評価－発赤［二重盲検試験，IM デポ剤安定期（Phase C）］

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CT-25.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase C (Phase C Safety Sample)

		ARIP IMD (N=425)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	421	408	(96.9)	13	(3.1)	0	(0.0)	0	(0.0)
2ND INJECTION	377	371	(98.4)	5	(1.3)	1	(0.3)	0	(0.0)
3RD INJECTION	352	347	(98.6)	5	(1.4)	0	(0.0)	0	(0.0)
4TH INJECTION	105	101	(96.2)	4	(3.8)	0	(0.0)	0	(0.0)
5TH INJECTION	66	64	(97.0)	2	(3.0)	0	(0.0)	0	(0.0)
6TH INJECTION	36	34	(94.4)	2	(5.6)	0	(0.0)	0	(0.0)
7TH INJECTION	8	8	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	424	417	(98.3)	7	(1.7)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.

FILE: ADINJ3DC.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-25.1.2.3 FINAL
＜資料番号 5.3.5.1-01：CT-25.1.2.3＞

表 2.7.4.7-192　治験責任医師等による注射部位の評価－硬結［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-25.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase C (Phase C Safety Sample)

	ARIP IMD (N=425)								
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	422	420	(99.5)	2	(0.5)	0	(0.0)	0	(0.0)
2ND INJECTION	377	372	(98.7)	5	(1.3)	0	(0.0)	0	(0.0)
3RD INJECTION	352	348	(98.9)	4	(1.1)	0	(0.0)	0	(0.0)
4TH INJECTION	105	104	(99.0)	1	(1.0)	0	(0.0)	0	(0.0)
5TH INJECTION	66	65	(98.5)	1	(1.5)	0	(0.0)	0	(0.0)
6TH INJECTION	36	35	(97.2)	1	(2.8)	0	(0.0)	0	(0.0)
7TH INJECTION	8	8	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	424	420	(99.1)	4	(0.9)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.

FILE: ADINJ3DD.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-25.1.2.4 FINAL

＜資料番号 5.3.5.1-01：CT-25.1.2.4＞

表 2.7.4.7-193　注射部位反応関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	PHASE B (N=614) n	(%)	PHASE C (N=425) n	(%)
一般・全身障害および投与部位の状態	TOTAL1)	2	(0.3)	23	(5.4)
	注射部位硬結	0	(0.0)	1	(0.2)
	注射部位疼痛	2	(0.3)	21	(4.9)
	注射部位腫脹	0	(0.0)	1	(0.2)
TOTAL2)		2	(0.3)	23	(5.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3BD.LIS, RUN: [redacted]20[redacted] 10:45; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.5.3　FINAL

表 2.7.4.7-193　注射部位反応関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO INJECTION SITE: MEDDRA 19.0 PRIMARY TERMS

ADMINISTRATION RELATED REACTION, ADMINISTRATION SITE ABSCESS, ADMINISTRATION SITE INFECTION, ADMINISTRATION SITE PAIN, APPLICATION SITE ABSCESS, APPLICATION SITE ALOPECIA, APPLICATION SITE ANAESTHESIA, APPLICATION SITE ATROPHY, APPLICATION SITE HAEMORRHAGE, APPLICATION SITE BURN, APPLICATION SITE CELLULITIS, APPLICATION SITE COLD FEELING, APPLICATION SITE DERMATITIS, APPLICATION SITE DISCHARGE, APPLICATION SITE DISCOLOURATION, APPLICATION SITE DISCOMFORT, APPLICATION SITE DRYNESS, APPLICATION SITE ECZEMA, APPLICATION SITE EROSION, APPLICATION SITE ERYTHEMA, APPLICATION SITE EXFOLIATION, APPLICATION SITE FISSURE, APPLICATION SITE FOLLICULITIS, APPLICATION SITE HAEMATOMA, APPLICATION SITE HYPERAESTHESIA, APPLICATION SITE HYPERSENSITIVITY, APPLICATION SITE INDURATION, APPLICATION SITE INFECTION, APPLICATION SITE INFLAMMATION, APPLICATION SITE IRRITATION, APPLICATION SITE MASS, APPLICATION SITE NECROSIS, APPLICATION SITE NODULE, APPLICATION SITE ODOUR, APPLICATION SITE OEDEMA, APPLICATION SITE PAIN, APPLICATION SITE PALLOR, APPLICATION SITE PAPULES, APPLICATION SITE PARAESTHESIA, APPLICATION SITE PERSPIRATION, APPLICATION SITE PHOTOSENSITIVITY REACTION, APPLICATION SITE PRURITUS, APPLICATION SITE PUSTULES, APPLICATION SITE RASH, APPLICATION SITE REACTION, APPLICATION SITE SCAB, APPLICATION SITE SCAR, APPLICATION SITE SWELLING, APPLICATION SITE ULCER, APPLICATION SITE URTICARIA, APPLICATION SITE VESICLES, APPLICATION SITE WARMTH, EMBOLIA CUTIS MEDICAMENTOSA, INJECTED LIMB MOBILITY DECREASED, INJECTION SITE ABSCESS, INJECTION SITE ABSCESS STERILE, INJECTION SITE ANAESTHESIA, INJECTION SITE ATROPHY, INJECTION SITE CALCIFICATION, INJECTION SITE CELLULITIS, INJECTION SITE COLDNESS, INJECTION SITE CYST, INJECTION SITE DERMATITIS, INJECTION SITE DISCHARGE, INJECTION SITE DISCOLOURATION, INJECTION SITE DISCOMFORT, INJECTION SITE DRYNESS, INJECTION SITE DYSAESTHESIA, INJECTION SITE ECZEMA, INJECTION SITE EROSION, INJECTION SITE ERYTHEMA, INJECTION SITE EXFOLIATION, INJECTION SITE EXTRAVASATION, INJECTION SITE FIBROSIS, INJECTION SITE HAEMATOMA, INJECTION SITE HAEMORRHAGE, INJECTION SITE HYPERSENSITIVITY, INJECTION SITE HYPERTROPHY, INJECTION SITE INDURATION, INJECTION SITE INFECTION, INJECTION SITE INFLAMMATION, INJECTION SITE INJURY, INJECTION SITE IRRITATION, INJECTION SITE ISCHAEMIA, INJECTION SITE JOINT EFFUSION, INJECTION SITE JOINT INFLAMMATION, INJECTION SITE JOINT MOVEMENT IMPAIRMENT, INJECTION SITE JOINT PAIN, INJECTION SITE JOINT REDNESS, INJECTION SITE JOINT SWELLING, INJECTION SITE JOINT WARMTH, INJECTION SITE LACERATION, INJECTION SITE LYMPHADENOPATHY, INJECTION SITE MACULE, INJECTION SITE MASS, INJECTION SITE MOVEMENT IMPAIRMENT, INJECTION SITE NECROSIS, INJECTION SITE NERVE DAMAGE, INJECTION SITE NODULE, INJECTION SITE OEDEMA, INJECTION SITE PAIN, INJECTION SITE PALLOR, INJECTION SITE PAPULE, INJECTION SITE PARAESTHESIA, INJECTION SITE PHLEBITIS, INJECTION SITE PHOTOSENSITIVITY REACTION, INJECTION SITE PRURITUS, INJECTION SITE PUSTULE, INJECTION SITE RASH, INJECTION SITE REACTION, INJECTION SITE RECALL REACTION, INJECTION SITE SCAB, INJECTION SITE SCAR, INJECTION SITE STREAKING, INJECTION SITE SWELLING, INJECTION SITE THROMBOSIS, INJECTION SITE ULCER, INJECTION SITE URTICARIA, INJECTION SITE VASCULITIS, INJECTION SITE VESICLES, INJECTION SITE WARMTH, INSTILLATION SITE PARAESTHESIA, INSTILLATION SITE DISCOMFORT, INSTILLATION SITE DRYNESS, INSTILLATION SITE ERYTHEMA, INSTILLATION SITE FOREIGN BODY SENSATION, INSTILLATION SITE IRRITATION, INSTILLATION SITE LACRIMATION, INSTILLATION SITE PAIN, INSTILLATION SITE PRURITUS, INSTILLATION SITE REACTION, MALABSORPTION FROM INJECTION SITE, PUNCTURE SITE ABSCESS, PUNCTURE SITE DISCHARGE, PUNCTURE SITE HAEMORRHAGE, PUNCTURE SITE INDURATION, PUNCTURE SITE INFECTION, PUNCTURE SITE PAIN, PUNCTURE SITE REACTION, SYSTEMIC LEAKAGE, VESSEL PUNCTURE SITE ANAESTHESIA, VESSEL PUNCTURE SITE DISCHARGE, VESSEL PUNCTURE SITE HAEMATOMA, VESSEL PUNCTURE SITE HAEMORRHAGE, VESSEL PUNCTURE SITE INFLAMMATION, VESSEL PUNCTURE SITE PAIN, VESSEL PUNCTURE SITE PARAESTHESIA, VESSEL PUNCTURE SITE PRURITUS, VESSEL PUNCTURE SITE REACTION, VESSEL PUNCTURE SITE SWELLING, VESSEL PUNCTURE SITE THROMBOSIS, APPLICATION SITE ACNE, APPLICATION SITE BRUISE, APPLICATION SITE TELANGIECTASIA, INSTILLATION SITE COMPLICATION, INJECTION SITE BRUISING, INJECTION

表 2.7.4.7-193　注射部位反応関連有害事象［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-21.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site
by System Organ Class and MedDRA Preferred Term (Phase B Safety Sample and Phase C Safety Sample)

ADVERSE EVENTS RELATED TO INJECTION SITE: MEDDRA 19.0 PRIMARY TERMS

SITE GRANULOMA, INJECTION SITE HYPERAESTHESIA, INJECTION SITE PLAQUE, INJECTION SITE JOINT DISCOMFORT, ADMINISTRATION SITE RASH, ADMINISTRATION SITE REACTION, PUNCTURE SITE SWELLING, VESSEL PUNCTURE SITE BRUISE, VESSEL PUNCTURE SITE INFECTION, VESSEL PUNCTURE SITE INDURATION

＜資料番号 5.3.5.1-01：CT-21.2.5.3 より作成＞

表 2.7.4.7-194　VAS による注射部位疼痛の自己評価の記述統計量［二重盲検試験，IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-16.3.1
Visual Analog Scale Score for Subject-reported Rating of Pain at Most Recent Injection Site - Mean Score by Injection in Phase C/D
(Phase D Safety Sample)

PHASE D TREATMENT	INJECTION	n[1]	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	1ST INJECTION[2]	131	6.4	2.0	11.2	0.0	63.0
	LAST INJECTION[3]	132	4.0	1.0	7.6	0.0	44.0
PLACEBO	1ST INJECTION[2]	133	5.7	1.0	9.7	0.0	66.0
	LAST INJECTION[3]	133	5.8	1.0	12.1	0.0	83.0

[1]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT OR PLACEBO INJECTION IN PHASE D.

FILE: ADVAS3AC.LIS, RUN: [redacted]20[redacted] 10:58
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADVAS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.3.1　FINAL

＜資料番号 5.3.5.1-01：CT-16.3.1＞

表 2.7.4.7-195　VAS による注射部位疼痛の自己評価－疼痛［二重盲検試験，IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-16.3.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase C/D (Phase D Safety Sample)

	TREATMENT IN PHASE D															
	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	131	103	(78.6)	27	(20.6)	1	(0.8)	0	(0.0)	133	101	(75.9)	31	(23.3)	1	(0.8)	0	(0.0)
LAST INJECTION[3]	132	115	(87.1)	16	(12.1)	1	(0.8)	0	(0.0)	133	113	(85.0)	17	(12.8)	3	(2.3)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT OR PLACEBO INJECTION IN PHASE D.

FILE: ADINJ3CA.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.3.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-16.3.2.1＞

表 2.7.4.7-196　VAS による注射部位疼痛の自己評価－腫脹［二重盲検試験，IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-16.3.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase C/D (Phase D Safety Sample)

	TREATMENT IN PHASE D															
	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	131	131	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	132	132	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT OR PLACEBO INJECTION IN PHASE D.

FILE: ADINJ3CB.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.3.2.2　FINAL
＜資料番号 5.3.5.1-01：CT-16.3.2.2＞

表 2.7.4.7-197　VAS による注射部位疼痛の自己評価－発赤［二重盲検試験，IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

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CT-16.3.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase C/D (Phase D Safety Sample)

	TREATMENT IN PHASE D															
	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	131	127	(96.9)	4	(3.1)	0	(0.0)	0	(0.0)	133	129	(97.0)	4	(3.0)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	132	131	(99.2)	1	(0.8)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT OR PLACEBO INJECTION IN PHASE D.

FILE: ADINJ3CC.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.3.2.3　FINAL
＜資料番号 5.3.5.1-01：CT-16.3.2.3＞

表 2.7.4.7-198　VAS による注射部位疼痛の自己評価－硬結［二重盲検試験，IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-16.3.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase C/D (Phase D Safety Sample)

	TREATMENT IN PHASE D															
	ARIP IMD (N=132)								PLACEBO (N=133)							
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION[2]	131	129	(98.5)	2	(1.5)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
LAST INJECTION[3]	132	132	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	133	133	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.
[2]1ST ARIPIPRAZOLE IM DEPOT INJECTION IN PHASE C.
[3]LAST ARIPIPRAZOLE IM DEPOT OR PLACEBO INJECTION IN PHASE D.

FILE: ADINJ3CD.LIS, RUN: [redacted]20[redacted] 10:57; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:34
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.3.2.4　FINAL

＜資料番号 5.3.5.1-01：CT-16.3.2.4＞

表 2.7.4.7-199　VAS による注射部位疼痛の自己評価の記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.1
Visual Analog Scale Score for Subject-reported Rating of Pain at Most Recent Injection Site - Mean Score by Injection in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	INJECTION	n[1]	MEAN	MEDIAN	SD	MIN	MAX
DE NOVO	1ST INJECTION	377	5.0	1.0	10.4	0.0	72.0
	2ND INJECTION	355	4.2	1.0	8.4	0.0	52.0
	3RD INJECTION	346	3.4	0.0	8.0	0.0	66.0
	4TH INJECTION	327	3.7	0.0	9.0	0.0	68.0
	5TH INJECTION	313	2.9	0.0	8.4	0.0	72.0
	6TH INJECTION	294	2.3	0.0	6.1	0.0	60.0
	7TH INJECTION	282	2.6	0.0	7.5	0.0	80.0
	8TH INJECTION	266	2.3	0.0	4.8	0.0	32.0
	9TH INJECTION	259	2.5	0.0	6.6	0.0	51.0
	10TH INJECTION	245	2.5	0.0	7.7	0.0	80.0
	11TH INJECTION	236	2.4	0.0	6.4	0.0	44.0
	12TH INJECTION	232	1.7	0.0	4.1	0.0	42.0
	13TH INJECTION	210	2.1	0.0	5.4	0.0	41.0
	LAST INJECTION	378	2.4	0.0	6.2	0.0	55.0
ROLLOVER	1ST INJECTION	85	4.6	1.0	12.0	0.0	94.0
	2ND INJECTION	80	3.6	1.0	8.3	0.0	54.0
	3RD INJECTION	76	3.1	1.0	5.0	0.0	21.0
	4TH INJECTION	75	3.1	0.0	6.8	0.0	46.0
	5TH INJECTION	74	3.1	1.0	5.8	0.0	34.0
	6TH INJECTION	72	2.6	0.0	4.5	0.0	21.0
	7TH INJECTION	71	2.7	1.0	4.7	0.0	25.0
	8TH INJECTION	27	3.6	1.0	6.2	0.0	26.0
	9TH INJECTION	25	3.6	1.0	6.9	0.0	32.0
	10TH INJECTION	19	2.4	1.0	5.3	0.0	23.0
	11TH INJECTION	19	2.6	1.0	6.0	0.0	26.0
	12TH INJECTION	15	2.8	1.0	6.3	0.0	25.0
	13TH INJECTION	13	3.5	1.0	7.9	0.0	29.0

[1]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADVAS3A.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:22
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADVAS3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.1　FINAL

表 2.7.4.7-199　VAS による注射部位疼痛の自己評価の記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.1
Visual Analog Scale Score for Subject-reported Rating of Pain at Most Recent Injection Site - Mean Score by Injection in Phase C
(Phase C Safety Sample)

ENROLLMENT SOURCE	INJECTION	n[1]	MEAN	MEDIAN	SD	MIN	MAX
ROLLOVER	LAST INJECTION	85	2.7	1.0	4.7	0.0	29.0
TOTAL	1ST INJECTION	462	4.9	1.0	10.7	0.0	94.0
	2ND INJECTION	435	4.1	1.0	8.4	0.0	54.0
	3RD INJECTION	422	3.4	0.5	7.5	0.0	66.0
	4TH INJECTION	402	3.6	0.0	8.6	0.0	68.0
	5TH INJECTION	387	2.9	0.0	7.9	0.0	72.0
	6TH INJECTION	366	2.4	0.0	5.8	0.0	60.0
	7TH INJECTION	353	2.6	0.0	7.0	0.0	80.0
	8TH INJECTION	293	2.4	0.0	4.9	0.0	32.0
	9TH INJECTION	284	2.6	0.0	6.6	0.0	51.0
	10TH INJECTION	264	2.5	0.0	7.5	0.0	80.0
	11TH INJECTION	255	2.4	0.0	6.3	0.0	44.0
	12TH INJECTION	247	1.8	0.0	4.3	0.0	42.0
	13TH INJECTION	223	2.2	0.0	5.5	0.0	41.0
	LAST INJECTION	463	2.4	0.0	5.9	0.0	55.0

[1]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

表 2.7.4.7-200　治験責任医師等による注射部位の評価－疼痛［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)									ROLLOVER (N=85)								
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	378	334	(88.4)	41	(10.8)	3	(0.8)	0	(0.0)	85	73	(85.9)	12	(14.1)	0	(0.0)	0	(0.0)
2ND INJECTION	355	310	(87.3)	44	(12.4)	1	(0.3)	0	(0.0)	80	70	(87.5)	10	(12.5)	0	(0.0)	0	(0.0)
3RD INJECTION	346	317	(91.6)	27	(7.8)	2	(0.6)	0	(0.0)	76	64	(84.2)	12	(15.8)	0	(0.0)	0	(0.0)
4TH INJECTION	326	300	(92.0)	26	(8.0)	0	(0.0)	0	(0.0)	75	66	(88.0)	9	(12.0)	0	(0.0)	0	(0.0)
5TH INJECTION	313	289	(92.3)	24	(7.7)	0	(0.0)	0	(0.0)	74	65	(87.8)	9	(12.2)	0	(0.0)	0	(0.0)
6TH INJECTION	294	274	(93.2)	20	(6.8)	0	(0.0)	0	(0.0)	72	63	(87.5)	9	(12.5)	0	(0.0)	0	(0.0)
7TH INJECTION	282	259	(91.8)	23	(8.2)	0	(0.0)	0	(0.0)	71	60	(84.5)	11	(15.5)	0	(0.0)	0	(0.0)
8TH INJECTION	268	253	(94.4)	15	(5.6)	0	(0.0)	0	(0.0)	27	23	(85.2)	4	(14.8)	0	(0.0)	0	(0.0)
9TH INJECTION	259	244	(94.2)	14	(5.4)	1	(0.4)	0	(0.0)	25	19	(76.0)	6	(24.0)	0	(0.0)	0	(0.0)
10TH INJECTION	245	228	(93.1)	16	(6.5)	1	(0.4)	0	(0.0)	19	16	(84.2)	3	(15.8)	0	(0.0)	0	(0.0)
11TH INJECTION	236	221	(93.6)	15	(6.4)	0	(0.0)	0	(0.0)	19	18	(94.7)	1	(5.3)	0	(0.0)	0	(0.0)
12TH INJECTION	232	221	(95.3)	11	(4.7)	0	(0.0)	0	(0.0)	15	14	(93.3)	1	(6.7)	0	(0.0)	0	(0.0)
13TH INJECTION	210	199	(94.8)	11	(5.2)	0	(0.0)	0	(0.0)	13	12	(92.3)	1	(7.7)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3A.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.1 FINAL

表 2.7.4.7-200　治験責任医師等による注射部位の評価－疼痛［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase C (Phase C Safety Sample)

	TOTAL (N=464)								
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	463	407	(87.9)	53	(11.4)	3	(0.6)	0	(0.0)
2ND INJECTION	435	380	(87.4)	54	(12.4)	1	(0.2)	0	(0.0)
3RD INJECTION	422	381	(90.3)	39	(9.2)	2	(0.5)	0	(0.0)
4TH INJECTION	401	366	(91.3)	35	(8.7)	0	(0.0)	0	(0.0)
5TH INJECTION	387	354	(91.5)	33	(8.5)	0	(0.0)	0	(0.0)
6TH INJECTION	366	337	(92.1)	29	(7.9)	0	(0.0)	0	(0.0)
7TH INJECTION	353	319	(90.4)	34	(9.6)	0	(0.0)	0	(0.0)
8TH INJECTION	295	276	(93.6)	19	(6.4)	0	(0.0)	0	(0.0)
9TH INJECTION	284	263	(92.6)	20	(7.0)	1	(0.4)	0	(0.0)
10TH INJECTION	264	244	(92.4)	19	(7.2)	1	(0.4)	0	(0.0)
11TH INJECTION	255	239	(93.7)	16	(6.3)	0	(0.0)	0	(0.0)
12TH INJECTION	247	235	(95.1)	12	(4.9)	0	(0.0)	0	(0.0)
13TH INJECTION	223	211	(94.6)	12	(5.4)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3A.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.1　FINAL

表 2.7.4.7-200　治験責任医師等による注射部位の評価－疼痛［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)									ROLLOVER (N=85)								
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	378	350	(92.6)	28	(7.4)	0	(0.0)	0	(0.0)	85	74	(87.1)	11	(12.9)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

表 2.7.4.7-200　治験責任医師等による注射部位の評価－疼痛［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.1
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Pain
by Injection in Phase C (Phase C Safety Sample)

	TOTAL (N=464)								
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	463	424	(91.6)	39	(8.4)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3A.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.1 FINAL

＜資料番号 5.3.5.2-01：CT-16.1.2.1＞

表 2.7.4.7-201　治験責任医師等による注射部位の評価－腫脹［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)								ROLLOVER (N=85)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	378	376	(99.5)	2	(0.5)	0	(0.0)	0	(0.0)	85	85	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
2ND INJECTION	355	354	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)	80	80	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
3RD INJECTION	346	345	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)	76	76	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
4TH INJECTION	326	326	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	75	75	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
5TH INJECTION	313	313	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	74	74	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	294	293	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)	72	72	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
7TH INJECTION	282	281	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)	71	71	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
8TH INJECTION	268	267	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)	27	27	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
9TH INJECTION	259	259	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	25	25	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	245	244	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)	19	19	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	236	236	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	19	19	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	232	232	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	15	15	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	210	210	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	13	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3B.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.2　FINAL

表 2.7.4.7-201　治験責任医師等による注射部位の評価－腫脹［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase C (Phase C Safety Sample)

	TOTAL (N=464)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	463	461	(99.6)	2	(0.4)	0	(0.0)	0	(0.0)
2ND INJECTION	435	434	(99.8)	1	(0.2)	0	(0.0)	0	(0.0)
3RD INJECTION	422	421	(99.8)	1	(0.2)	0	(0.0)	0	(0.0)
4TH INJECTION	401	401	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
5TH INJECTION	387	387	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	366	365	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)
7TH INJECTION	353	352	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)
8TH INJECTION	295	294	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)
9TH INJECTION	284	284	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	264	263	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)
11TH INJECTION	255	255	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	247	247	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	223	223	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

表 2.7.4.7-201　治験責任医師等による注射部位の評価－腫脹［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)								ROLLOVER (N=85)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	378	378	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	85	85	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3B.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.2　FINAL

表 2.7.4.7-201　治験責任医師等による注射部位の評価－腫脹［長期投与試験，IM デポ剤維持治療期（Phase C）］

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CT-16.1.2.2
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Swelling
by Injection in Phase C (Phase C Safety Sample)

		TOTAL (N=464)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	463	463	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3B.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.2 FINAL

＜資料番号 5.3.5.2-01：CT-16.1.2.2＞

表 2.7.4.7-202　治験責任医師等による注射部位の評価－発赤［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)									ROLLOVER (N=85)								
		ABSENT		MILD		MODERATE		SEVERE			ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	378	357	(94.4)	21	(5.6)	0	(0.0)	0	(0.0)	85	84	(98.8)	1	(1.2)	0	(0.0)	0	(0.0)
2ND INJECTION	355	341	(96.1)	14	(3.9)	0	(0.0)	0	(0.0)	80	79	(98.8)	1	(1.3)	0	(0.0)	0	(0.0)
3RD INJECTION	346	332	(96.0)	14	(4.0)	0	(0.0)	0	(0.0)	76	76	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
4TH INJECTION	326	314	(96.3)	12	(3.7)	0	(0.0)	0	(0.0)	75	75	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
5TH INJECTION	313	301	(96.2)	12	(3.8)	0	(0.0)	0	(0.0)	74	74	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	294	290	(98.6)	4	(1.4)	0	(0.0)	0	(0.0)	72	72	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
7TH INJECTION	282	274	(97.2)	8	(2.8)	0	(0.0)	0	(0.0)	71	71	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
8TH INJECTION	268	258	(96.3)	10	(3.7)	0	(0.0)	0	(0.0)	27	27	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
9TH INJECTION	259	251	(96.9)	8	(3.1)	0	(0.0)	0	(0.0)	25	25	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	245	237	(96.7)	8	(3.3)	0	(0.0)	0	(0.0)	19	19	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	236	227	(96.2)	9	(3.8)	0	(0.0)	0	(0.0)	19	19	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	232	229	(98.7)	3	(1.3)	0	(0.0)	0	(0.0)	15	15	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	210	208	(99.0)	2	(1.0)	0	(0.0)	0	(0.0)	13	13	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3C.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.3 FINAL

表 2.7.4.7-202　治験責任医師等による注射部位の評価－発赤［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase C (Phase C Safety Sample)

	TOTAL (N=464)								
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	463	441	(95.2)	22	(4.8)	0	(0.0)	0	(0.0)
2ND INJECTION	435	420	(96.6)	15	(3.4)	0	(0.0)	0	(0.0)
3RD INJECTION	422	408	(96.7)	14	(3.3)	0	(0.0)	0	(0.0)
4TH INJECTION	401	389	(97.0)	12	(3.0)	0	(0.0)	0	(0.0)
5TH INJECTION	387	375	(96.9)	12	(3.1)	0	(0.0)	0	(0.0)
6TH INJECTION	366	362	(98.9)	4	(1.1)	0	(0.0)	0	(0.0)
7TH INJECTION	353	345	(97.7)	8	(2.3)	0	(0.0)	0	(0.0)
8TH INJECTION	295	285	(96.6)	10	(3.4)	0	(0.0)	0	(0.0)
9TH INJECTION	284	276	(97.2)	8	(2.8)	0	(0.0)	0	(0.0)
10TH INJECTION	264	256	(97.0)	8	(3.0)	0	(0.0)	0	(0.0)
11TH INJECTION	255	246	(96.5)	9	(3.5)	0	(0.0)	0	(0.0)
12TH INJECTION	247	244	(98.8)	3	(1.2)	0	(0.0)	0	(0.0)
13TH INJECTION	223	221	(99.1)	2	(0.9)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3C.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.3　FINAL

表 2.7.4.7-202　治験責任医師等による注射部位の評価－発赤［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)								ROLLOVER (N=85)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	378	370	(97.9)	8	(2.1)	0	(0.0)	0	(0.0)	85	85	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3C.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.3　FINAL

表 2.7.4.7-202　治験責任医師等による注射部位の評価－発赤［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.3
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Redness
by Injection in Phase C (Phase C Safety Sample)

		TOTAL (N=464)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	463	455	(98.3)	8	(1.7)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3C.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.3　FINAL

＜資料番号 5.3.5.2-01：CT-16.1.2.3＞

表 2.7.4.7-203　治験責任医師等による注射部位の評価－硬結［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)								ROLLOVER (N=85)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	378	375	(99.2)	3	(0.8)	0	(0.0)	0	(0.0)	85	85	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
2ND INJECTION	355	352	(99.2)	3	(0.8)	0	(0.0)	0	(0.0)	80	80	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
3RD INJECTION	346	346	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	76	76	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
4TH INJECTION	326	325	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)	75	75	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
5TH INJECTION	313	313	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	74	74	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	294	293	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)	72	72	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
7TH INJECTION	282	281	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)	71	71	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
8TH INJECTION	268	266	(99.3)	2	(0.7)	0	(0.0)	0	(0.0)	27	27	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
9TH INJECTION	259	257	(99.2)	2	(0.8)	0	(0.0)	0	(0.0)	25	25	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
10TH INJECTION	245	245	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	19	19	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	236	236	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	19	19	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	232	231	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)	15	15	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
13TH INJECTION	210	210	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	13	13	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3D.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.4 FINAL

表 2.7.4.7-203　治験責任医師等による注射部位の評価－硬結［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase C (Phase C Safety Sample)

	TOTAL (N=464)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
1ST INJECTION	463	460	(99.4)	3	(0.6)	0	(0.0)	0	(0.0)
2ND INJECTION	435	432	(99.3)	3	(0.7)	0	(0.0)	0	(0.0)
3RD INJECTION	422	422	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
4TH INJECTION	401	400	(99.8)	1	(0.2)	0	(0.0)	0	(0.0)
5TH INJECTION	387	387	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
6TH INJECTION	366	365	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)
7TH INJECTION	353	352	(99.7)	1	(0.3)	0	(0.0)	0	(0.0)
8TH INJECTION	295	293	(99.3)	2	(0.7)	0	(0.0)	0	(0.0)
9TH INJECTION	284	282	(99.3)	2	(0.7)	0	(0.0)	0	(0.0)
10TH INJECTION	264	264	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
11TH INJECTION	255	255	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)
12TH INJECTION	247	246	(99.6)	1	(0.4)	0	(0.0)	0	(0.0)
13TH INJECTION	223	223	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3D.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-16.1.2.4　FINAL

表 2.7.4.7-203　治験責任医師等による注射部位の評価－硬結［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase C (Phase C Safety Sample)

	DE NOVO (N=379)								ROLLOVER (N=85)							
		ABSENT		MILD		MODERATE		SEVERE		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	378	378	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)	85	85	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

FILE: ADINJ3D.LIS, RUN: [redacted]20[redacted] 12:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 11:02
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADINJ3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-16.1.2.4 FINAL

表 2.7.4.7-203　治験責任医師等による注射部位の評価－硬結［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-16.1.2.4
Proportion of Subjects at Each Severity Level of Investigator's Assessment of Most Recent Injection Site - Induration
by Injection in Phase C (Phase C Safety Sample)

	TOTAL (N=464)							
		ABSENT		MILD		MODERATE		SEVERE	
INJECTION	Ne[1]	n	(%)	n	(%)	n	(%)	n	(%)
LAST INJECTION	463	463	(100.0)	0	(0.0)	0	(0.0)	0	(0.0)

[1]Ne = NUMBER OF EVALUATED SUBJECTS.

表 2.7.4.7-204　注射部位反応関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

CATEGORY	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
一般・全身障害および投与部位の状態	TOTAL1)	41	(10.8)	1	(1.2)	42	(9.1)
	注射部位内出血	2	(0.5)	0	(0.0)	2	(0.4)
	注射部位紅斑	1	(0.3)	0	(0.0)	1	(0.2)
	注射部位硬結	1	(0.3)	0	(0.0)	1	(0.2)
	注射部位腫瘤	1	(0.3)	1	(1.2)	2	(0.4)
	注射部位疼痛	34	(9.0)	0	(0.0)	34	(7.3)
	注射部位腫脹	4	(1.1)	0	(0.0)	4	(0.9)
TOTAL2)		41	(10.8)	1	(1.2)	42	(9.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH MULTIPLE ADVERSE EVENTS TERMS WITHIN THE SAME CATEGORY WERE COUNTED ONLY ONCE TOWARDS THE CATEGORY TOTAL.
2)SUBJECTS WITH MULTIPLE ADVERSE EVENTS WERE COUNTED ONLY ONCE TOWARDS THE OVERALL TOTAL OF SUBJECTS WITH SPECIFIED ADVERSE EVENTS.

FILE: ADAE3AD.LIS, RUN: [redacted]20[redacted] 15:44; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.5.3　FINAL

表 2.7.4.7-204　注射部位反応関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO INJECTION SITE: MEDDRA 19.0 PRIMARY TERMS

ADMINISTRATION RELATED REACTION, ADMINISTRATION SITE ABSCESS, ADMINISTRATION SITE INFECTION, ADMINISTRATION SITE PAIN, APPLICATION SITE ABSCESS, APPLICATION SITE ALOPECIA, APPLICATION SITE ANAESTHESIA, APPLICATION SITE ATROPHY, APPLICATION SITE HAEMORRHAGE, APPLICATION SITE BURN, APPLICATION SITE CELLULITIS, APPLICATION SITE COLD FEELING, APPLICATION SITE DERMATITIS, APPLICATION SITE DISCHARGE, APPLICATION SITE DISCOLOURATION, APPLICATION SITE DISCOMFORT, APPLICATION SITE DRYNESS, APPLICATION SITE ECZEMA, APPLICATION SITE EROSION, APPLICATION SITE ERYTHEMA, APPLICATION SITE EXFOLIATION, APPLICATION SITE FISSURE, APPLICATION SITE FOLLICULITIS, APPLICATION SITE HAEMATOMA, APPLICATION SITE HYPERAESTHESIA, APPLICATION SITE HYPERSENSITIVITY, APPLICATION SITE INDURATION, APPLICATION SITE INFECTION, APPLICATION SITE INFLAMMATION, APPLICATION SITE IRRITATION, APPLICATION SITE MASS, APPLICATION SITE NECROSIS, APPLICATION SITE NODULE, APPLICATION SITE ODOUR, APPLICATION SITE OEDEMA, APPLICATION SITE PAIN, APPLICATION SITE PALLOR, APPLICATION SITE PAPULES, APPLICATION SITE PARAESTHESIA, APPLICATION SITE PERSPIRATION, APPLICATION SITE PHOTOSENSITIVITY REACTION, APPLICATION SITE PRURITUS, APPLICATION SITE PUSTULES, APPLICATION SITE RASH, APPLICATION SITE REACTION, APPLICATION SITE SCAB, APPLICATION SITE SCAR, APPLICATION SITE SWELLING, APPLICATION SITE ULCER, APPLICATION SITE URTICARIA, APPLICATION SITE VESICLES, APPLICATION SITE WARMTH, EMBOLIA CUTIS MEDICAMENTOSA, INJECTED LIMB MOBILITY DECREASED, INJECTION SITE ABSCESS, INJECTION SITE ABSCESS STERILE, INJECTION SITE ANAESTHESIA, INJECTION SITE ATROPHY, INJECTION SITE CALCIFICATION, INJECTION SITE CELLULITIS, INJECTION SITE COLDNESS, INJECTION SITE CYST, INJECTION SITE DERMATITIS, INJECTION SITE DISCHARGE, INJECTION SITE DISCOLOURATION, INJECTION SITE DISCOMFORT, INJECTION SITE DRYNESS, INJECTION SITE DYSAESTHESIA, INJECTION SITE ECZEMA, INJECTION SITE EROSION, INJECTION SITE ERYTHEMA, INJECTION SITE EXFOLIATION, INJECTION SITE EXTRAVASATION, INJECTION SITE FIBROSIS, INJECTION SITE HAEMATOMA, INJECTION SITE HAEMORRHAGE, INJECTION SITE HYPERSENSITIVITY, INJECTION SITE HYPERTROPHY, INJECTION SITE INDURATION, INJECTION SITE INFECTION, INJECTION SITE INFLAMMATION, INJECTION SITE INJURY, INJECTION SITE IRRITATION, INJECTION SITE ISCHAEMIA, INJECTION SITE JOINT EFFUSION, INJECTION SITE JOINT INFLAMMATION, INJECTION SITE JOINT MOVEMENT IMPAIRMENT, INJECTION SITE JOINT PAIN, INJECTION SITE JOINT REDNESS, INJECTION SITE JOINT SWELLING, INJECTION SITE JOINT WARMTH, INJECTION SITE LACERATION, INJECTION SITE LYMPHADENOPATHY, INJECTION SITE MACULE, INJECTION SITE MASS, INJECTION SITE MOVEMENT IMPAIRMENT, INJECTION SITE NECROSIS, INJECTION SITE NERVE DAMAGE, INJECTION SITE NODULE, INJECTION SITE OEDEMA, INJECTION SITE PAIN, INJECTION SITE PALLOR, INJECTION SITE PAPULE, INJECTION SITE PARAESTHESIA, INJECTION SITE PHLEBITIS, INJECTION SITE PHOTOSENSITIVITY REACTION, INJECTION SITE PRURITUS, INJECTION SITE PUSTULE, INJECTION SITE RASH, INJECTION SITE REACTION, INJECTION SITE RECALL REACTION, INJECTION SITE SCAB, INJECTION SITE SCAR, INJECTION SITE STREAKING, INJECTION SITE SWELLING, INJECTION SITE THROMBOSIS, INJECTION SITE ULCER, INJECTION SITE URTICARIA, INJECTION SITE VASCULITIS, INJECTION SITE VESICLES, INJECTION SITE WARMTH, INSTILLATION SITE PARAESTHESIA, INSTILLATION SITE DISCOMFORT, INSTILLATION SITE DRYNESS, INSTILLATION SITE ERYTHEMA, INSTILLATION SITE FOREIGN BODY SENSATION, INSTILLATION SITE IRRITATION, INSTILLATION SITE LACRIMATION, INSTILLATION SITE PAIN, INSTILLATION SITE PRURITUS, INSTILLATION SITE REACTION, MALABSORPTION FROM INJECTION SITE, PUNCTURE SITE ABSCESS, PUNCTURE SITE DISCHARGE, PUNCTURE SITE HAEMORRHAGE, PUNCTURE SITE INDURATION, PUNCTURE SITE INFECTION, PUNCTURE SITE PAIN, PUNCTURE SITE REACTION, SYSTEMIC LEAKAGE, VESSEL PUNCTURE SITE ANAESTHESIA, VESSEL PUNCTURE SITE DISCHARGE, VESSEL PUNCTURE SITE HAEMATOMA, VESSEL PUNCTURE SITE HAEMORRHAGE, VESSEL PUNCTURE SITE INFLAMMATION, VESSEL PUNCTURE SITE PAIN, VESSEL PUNCTURE SITE PARAESTHESIA, VESSEL PUNCTURE SITE PRURITUS, VESSEL PUNCTURE SITE REACTION, VESSEL PUNCTURE SITE SWELLING, VESSEL PUNCTURE SITE THROMBOSIS, APPLICATION SITE ACNE, APPLICATION SITE BRUISE, APPLICATION SITE TELANGIECTASIA, INSTILLATION SITE COMPLICATION, INJECTION SITE BRUISING, INJECTION

表 2.7.4.7-204　注射部位反応関連有害事象［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.5.3
Incidence of Treatment-emergent Adverse Events Related to Injection Site in Phase C
by System Organ Class and MedDRA Preferred Term (Phase C Safety Sample)

ADVERSE EVENTS RELATED TO INJECTION SITE: MEDDRA 19.0 PRIMARY TERMS

SITE GRANULOMA, INJECTION SITE HYPERAESTHESIA, INJECTION SITE PLAQUE, INJECTION SITE JOINT DISCOMFORT, ADMINISTRATION SITE RASH, ADMINISTRATION SITE REACTION, PUNCTURE SITE SWELLING, VESSEL PUNCTURE SITE BRUISE, VESSEL PUNCTURE SITE INFECTION, VESSEL PUNCTURE SITE INDURATION

＜資料番号 5.3.5.2-01：CT-8.2.5.3＞

表 2.7.4.7-205　Hy’s Law の基準に合致した被験者［二重盲検試験］

OPC14597 1 OF 1
PROTOCOL 31-08-250

CT-9.5
Listing of Potential Hy`s Law Cases by Phase
(Enrolled Sample)

NO RESULTS SATISFY HY`S LAW CRITERIA

HY'S LAW: AST OR ALT >= 3X UPPER LIMIT OF NORMAL VALUE IF BASELINE VALUE WAS NORMAL (AST OR ALT >= 3X BASELINE IF BASELINE VALUE WAS ABNORMAL) AND TOTAL BILIRUBIN >= 2X UPPER LIMIT OF NORMAL VALUE IF BASELINE VALUE WAS NORMAL (TOTAL BILIRUBIN >= 2X BASELINE IF BASELINE VALUE WAS ABNORMAL).
[1]SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.

FILE: ADLB5A.LIS, RUN: [redacted]20[redacted] 14:33; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:30
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB5.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.5　FINAL

＜資料番号 5.3.5.1-01：CT-9.5＞

表 2.7.4.7-206　尿検査値の記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.3
Laboratory Test Results for Urinalysis - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=PH

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: ___BASELINE____ n[2]	CHANGE FROM BASELINE: ___BASELINE____ MEAN	CHANGE FROM BASELINE: ___BASELINE____ SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	123	5.65	5.50	0.59	5.00	9.00								
	WEEK 28	78	5.72	5.50	0.56	5.00	8.50	72	5.65	0.61	0.09	0.00	0.48	-1.00	1.50
	WEEK 52	64	5.66	5.50	0.53	5.00	8.50	58	5.71	0.67	-0.06	0.00	0.45	-1.00	0.50
	LAST VISIT	124	5.68	5.50	0.60	5.00	8.50	116	5.66	0.61	0.02	0.00	0.59	-1.50	2.00
PLACEBO	BASELINE	131	5.64	5.50	0.49	5.00	7.00								
	WEEK 28	58	5.54	5.50	0.52	5.00	7.00	58	5.61	0.45	-0.07	0.00	0.63	-2.00	1.50
	WEEK 52	39	5.56	5.50	0.53	5.00	7.00	39	5.65	0.49	-0.09	0.00	0.65	-1.50	1.50
	LAST VISIT	126	5.64	5.50	0.62	5.00	8.50	124	5.65	0.50	-0.01	0.00	0.76	-2.00	3.00

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AC.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:31
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.3　FINAL

表 2.7.4.7-206　尿検査値の記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-13.2.3
Laboratory Test Results for Urinalysis - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

TEST=SPECIFIC GRAVITY

TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
ARIP IMD	BASELINE	123	1.0163	1.018	0.0075	1.002	1.034								
	WEEK 28	78	1.0170	1.018	0.0066	1.002	1.032	72	1.0164	0.0080	0.0003	0.000	0.0063	-0.014	0.020
	WEEK 52	64	1.0177	1.019	0.0070	1.003	1.033	58	1.0165	0.0079	0.0007	0.000	0.0075	-0.015	0.020
	LAST VISIT	124	1.0169	1.018	0.0072	1.003	1.033	116	1.0161	0.0076	0.0004	0.001	0.0080	-0.018	0.024
PLACEBO	BASELINE	131	1.0161	1.016	0.0073	1.003	1.032								
	WEEK 28	58	1.0175	1.019	0.0068	1.003	1.034	58	1.0171	0.0065	0.0004	0.000	0.0060	-0.014	0.013
	WEEK 52	39	1.0163	1.015	0.0074	1.003	1.033	39	1.0172	0.0068	-0.0009	-0.001	0.0084	-0.021	0.017
	LAST VISIT	126	1.0169	1.017	0.0072	1.003	1.033	124	1.0163	0.0072	0.0007	0.000	0.0077	-0.021	0.020

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AC.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:31
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.3　FINAL

＜資料番号 5.3.5.1-01：CT-13.2.3＞

表 2.7.4.7-207　尿検査値の記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.3
Laboratory Test Results for Urinalysis - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=PH

								CHANGE FROM BASELINE						
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	584	5.65	5.50	0.54	5.00	8.50								
	WEEK 2	162	5.78	5.50	0.55	5.00	7.50	143	5.70	0.50	0.09	0.00	0.71	-1.50	2.00
	WEEK 4	142	5.71	5.50	0.55	5.00	8.50	135	5.75	0.58	-0.05	0.00	0.67	-2.00	2.50
	WEEK 6	103	5.64	5.50	0.56	5.00	7.00	97	5.64	0.56	0.00	0.00	0.56	-1.50	1.50
	WEEK 8	137	5.58	5.50	0.52	5.00	7.50	136	5.58	0.57	0.00	0.00	0.68	-3.00	2.00
	LAST VISIT	539	5.68	5.50	0.55	5.00	8.50	513	5.67	0.55	0.01	0.00	0.67	-3.00	2.50
PHASE C	BASELINE	418	5.67	5.50	0.54	5.00	8.50								
	WEEK 12	222	5.65	5.50	0.49	5.00	7.50	217	5.65	0.53	0.00	0.00	0.63	-2.00	1.50
	WEEK 28	7	6.36	6.00	1.25	5.50	9.00	7	5.79	0.64	0.57	0.00	1.34	-0.50	3.50
	LAST VISIT	371	5.67	5.50	0.56	5.00	9.00	364	5.67	0.55	0.00	0.00	0.67	-2.50	3.50

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BC.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:31
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.3　FINAL

表 2.7.4.7-207　尿検査値の記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-22.3.3
Laboratory Test Results for Urinalysis - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

TEST=SPECIFIC GRAVITY

PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
PHASE B	BASELINE	584	1.0156	1.016	0.0074	1.003	1.036								
	WEEK 2	162	1.0173	1.018	0.0072	1.003	1.033	143	1.0166	0.0075	0.0006	0.000	0.0079	-0.021	0.020
	WEEK 4	142	1.0167	1.017	0.0077	1.004	1.033	135	1.0167	0.0071	0.0000	0.000	0.0081	-0.021	0.023
	WEEK 6	103	1.0156	1.016	0.0069	1.004	1.037	97	1.0143	0.0070	0.0011	0.001	0.0074	-0.019	0.018
	WEEK 8	137	1.0158	1.017	0.0074	1.002	1.033	136	1.0147	0.0075	0.0012	0.000	0.0079	-0.022	0.021
	LAST VISIT	539	1.0164	1.017	0.0073	1.002	1.037	513	1.0157	0.0074	0.0007	0.000	0.0079	-0.022	0.023
PHASE C	BASELINE	418	1.0163	1.016	0.0073	1.002	1.033								
	WEEK 12	222	1.0162	1.017	0.0071	1.004	1.032	217	1.0159	0.0072	0.0003	0.000	0.0078	-0.018	0.021
	WEEK 28	7	1.0200	1.015	0.0088	1.011	1.031	7	1.0163	0.0056	0.0037	0.006	0.0111	-0.012	0.017
	LAST VISIT	371	1.0162	1.017	0.0073	1.002	1.034	364	1.0160	0.0073	0.0003	0.000	0.0081	-0.021	0.021

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2BC.LIS, RUN: [redacted]20[redacted] 14:34; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:31
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-22.3.3　FINAL
＜資料番号 5.3.5.1-01：CT-22.3.3＞

表 2.7.4.7-208　尿検査値の記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.3
Laboratory Test Results for Urinalysis - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=PH

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: n[2]	CHANGE FROM BASELINE: MEAN	CHANGE FROM BASELINE: SD	BASELINE: MEAN	BASELINE: MEDIAN	BASELINE: SD	BASELINE: MIN	BASELINE: MAX
DE NOVO	BASELINE	370	5.66	5.50	0.50	5.00	7.50								
	WEEK 28	14	5.86	6.00	0.31	5.50	6.50	14	5.64	0.36	0.21	0.50	0.47	-0.50	1.00
	WEEK 52	220	5.63	5.50	0.52	5.00	8.50	217	5.65	0.49	-0.03	0.00	0.60	-1.50	3.50
	LAST VISIT	335	5.65	5.50	0.50	5.00	8.50	326	5.66	0.50	-0.01	0.00	0.59	-1.50	3.50
ROLLOVER	BASELINE	85	5.66	5.50	0.55	5.00	8.50								
	WEEK 28	42	5.65	5.50	0.52	5.00	7.00	42	5.74	0.66	-0.08	0.00	0.67	-2.50	1.00
	WEEK 52	14	5.50	5.50	0.34	5.00	6.00	14	5.50	0.39	0.00	0.00	0.44	-1.00	0.50
	LAST VISIT	78	5.62	5.50	0.52	5.00	7.00	78	5.67	0.56	-0.06	0.00	0.60	-2.50	1.50
TOTAL	BASELINE	455	5.66	5.50	0.51	5.00	8.50								
	WEEK 28	56	5.71	5.50	0.48	5.00	7.00	56	5.71	0.59	-0.01	0.00	0.64	-2.50	1.00
	WEEK 52	234	5.62	5.50	0.51	5.00	8.50	231	5.65	0.48	-0.02	0.00	0.59	-1.50	3.50
	LAST VISIT	413	5.64	5.50	0.50	5.00	8.50	404	5.66	0.51	-0.02	0.00	0.59	-2.50	3.50

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AC.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-13.2.3　FINAL

表 2.7.4.7-208 尿検査値の記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-13.2.3
Laboratory Test Results for Urinalysis - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

TEST=SPECIFIC GRAVITY

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	370	1.0163	1.017	0.0069	1.002	1.037								
	WEEK 28	14	1.0168	1.018	0.0094	1.003	1.031	14	1.0173	0.0080	-0.0005	0.001	0.0071	-0.019	0.007
	WEEK 52	220	1.0159	1.017	0.0070	1.002	1.036	217	1.0163	0.0069	-0.0003	0.000	0.0079	-0.024	0.023
	LAST VISIT	335	1.0161	1.016	0.0073	1.002	1.036	326	1.0163	0.0069	-0.0003	0.000	0.0080	-0.025	0.023
ROLLOVER	BASELINE	85	1.0171	1.018	0.0074	1.003	1.033								
	WEEK 28	42	1.0163	1.017	0.0066	1.003	1.027	42	1.0173	0.0073	-0.0010	0.000	0.0072	-0.018	0.016
	WEEK 52	14	1.0180	1.019	0.0079	1.006	1.030	14	1.0171	0.0065	0.0009	0.002	0.0057	-0.014	0.007
	LAST VISIT	78	1.0168	1.018	0.0072	1.003	1.033	78	1.0168	0.0069	0.0000	0.001	0.0080	-0.018	0.028
TOTAL	BASELINE	455	1.0165	1.017	0.0070	1.002	1.037								
	WEEK 28	56	1.0164	1.017	0.0073	1.003	1.031	56	1.0173	0.0074	-0.0009	0.001	0.0071	-0.019	0.016
	WEEK 52	234	1.0161	1.017	0.0071	1.002	1.036	231	1.0163	0.0068	-0.0002	0.000	0.0077	-0.024	0.023
	LAST VISIT	413	1.0162	1.017	0.0073	1.002	1.036	404	1.0164	0.0069	-0.0003	0.000	0.0080	-0.025	0.028

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.

FILE: ADLB2AC.LIS, RUN: [redacted]20[redacted] 13:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:46
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-13.2.3 FINAL

＜資料番号 5.3.5.2-01：CT-13.2.3＞

表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=VENTRICULAR RATE (BEATS/MIN)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	73.4	73.0	13.1	42.0	133.0								
	WEEK 28	77	72.3	73.0	10.9	48.0	97.0	75	72.1	11.8	0.0	1.0	10.9	-26.0	35.0
	WEEK 52	64	72.4	71.0	13.5	38.0	103.0	62	73.0	12.1	-0.6	-2.5	10.4	-19.0	33.0
	LAST VISIT	123	73.1	73.0	13.7	38.0	103.0	121	73.0	13.3	0.0	0.0	11.2	-53.0	33.0
PLACEBO	BASELINE	130	70.0	69.0	11.4	41.0	105.0								
	WEEK 28	58	69.4	70.0	11.6	40.0	95.0	56	70.0	9.8	-0.8	0.0	8.8	-28.0	20.0
	WEEK 52	41	70.8	71.0	12.4	50.0	107.0	41	70.1	10.3	0.7	2.0	9.5	-18.0	31.0
	LAST VISIT	125	71.6	71.0	11.9	49.0	107.0	122	70.3	11.0	1.3	2.0	10.2	-28.0	33.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=PR INTERVAL (MSEC)

										CHANGE FROM BASELINE				
							BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	129	159.9	155.0	22.2	116.0	250.0								
	WEEK 28	77	163.1	160.0	25.4	124.0	296.0	75	159.2	22.8	4.4	3.0	12.2	-21.0	46.0
	WEEK 52	64	162.5	159.5	21.3	115.0	220.0	62	158.9	20.1	3.9	3.0	10.1	-18.0	29.0
	LAST VISIT	123	162.3	158.0	24.7	115.0	296.0	120	159.7	22.5	2.8	2.0	11.6	-28.0	46.0
PLACEBO	BASELINE	130	161.6	162.0	19.8	107.0	218.0								
	WEEK 28	58	164.2	162.0	21.0	97.0	222.0	56	163.1	18.7	1.0	0.0	10.8	-22.0	30.0
	WEEK 52	41	163.2	163.0	18.4	110.0	196.0	41	163.2	20.1	0.0	0.0	11.3	-28.0	30.0
	LAST VISIT	125	160.2	159.0	19.0	110.0	200.0	122	161.3	19.9	-1.2	-1.5	11.0	-39.0	31.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=RR INTERVAL (MSEC)

								CHANGE FROM BASELINE						
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	844.9	824.0	155.7	455.0	1433.0								
	WEEK 28	77	851.7	821.0	137.6	626.0	1263.0	75	857.9	157.3	-4.1	-12.0	135.8	-428.0	450.0
	WEEK 52	64	861.1	844.5	178.0	581.0	1579.0	62	847.8	156.1	12.8	27.0	126.3	-416.0	274.0
	LAST VISIT	123	854.1	828.0	175.0	581.0	1579.0	121	850.4	158.8	3.3	2.0	125.4	-416.0	463.0
PLACEBO	BASELINE	130	882.5	872.0	150.0	573.0	1461.0								
	WEEK 28	58	893.0	858.5	163.0	629.0	1505.0	56	875.9	126.6	20.1	4.0	118.2	-244.0	338.0
	WEEK 52	41	873.2	845.0	149.2	562.0	1206.0	41	876.0	136.1	-2.8	-11.0	112.9	-232.0	217.0
	LAST VISIT	125	861.4	850.0	141.5	562.0	1227.0	122	874.7	135.6	-13.0	-21.0	126.5	-429.0	338.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=QRS INTERVAL (MSEC)

										CHANGE FROM BASELINE				
							BASELINE							
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	92.3	92.0	5.6	81.0	107.0								
	WEEK 28	77	91.7	91.0	5.7	81.0	104.0	75	92.0	5.2	-0.2	0.0	5.0	-14.0	10.0
	WEEK 52	64	91.5	91.5	5.8	78.0	101.0	62	91.9	5.3	-0.3	-1.0	4.5	-11.0	11.0
	LAST VISIT	123	91.8	91.0	6.4	78.0	107.0	121	92.4	5.6	-0.5	-1.0	4.6	-12.0	11.0
PLACEBO	BASELINE	130	93.0	92.0	8.5	79.0	142.0								
	WEEK 28	58	93.0	92.0	9.4	79.0	140.0	56	93.3	9.1	-0.5	0.0	5.1	-14.0	13.0
	WEEK 52	41	93.3	90.0	10.6	81.0	142.0	41	93.7	10.0	-0.5	0.0	5.2	-10.0	13.0
	LAST VISIT	125	93.7	93.0	8.6	81.0	142.0	122	93.1	8.7	0.7	1.0	5.7	-12.0	19.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=QT INTERVAL (MSEC)

										CHANGE FROM BASELINE				
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	382.5	381.0	30.2	301.0	493.0								
	WEEK 28	77	386.2	385.0	28.4	322.0	467.0	75	384.7	29.2	1.3	0.0	21.3	-47.0	64.0
	WEEK 52	64	385.3	383.0	31.2	330.0	474.0	62	381.8	30.1	3.2	2.0	19.6	-49.0	46.0
	LAST VISIT	123	384.9	379.0	33.1	303.0	475.0	121	383.3	30.9	1.4	0.0	20.8	-49.0	72.0
PLACEBO	BASELINE	130	385.9	382.5	31.1	303.0	497.0								
	WEEK 28	58	390.7	392.0	30.0	316.0	461.0	56	385.5	29.7	5.6	4.5	20.7	-30.0	65.0
	WEEK 52	41	391.3	386.0	32.6	323.0	468.0	41	383.3	30.1	8.0	7.0	21.0	-32.0	46.0
	LAST VISIT	125	385.9	384.0	29.3	323.0	468.0	122	384.2	28.7	1.7	-1.5	24.1	-60.0	61.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=QTcB INTERVAL (MSEC)[3]

			BASELINE					CHANGE FROM BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	419.1	420.0	20.4	362.0	464.0								
	WEEK 28	77	420.9	420.0	21.5	367.0	477.0	75	418.3	21.6	1.8	-1.0	18.8	-35.0	51.0
	WEEK 52	64	418.9	419.0	24.8	365.0	471.0	62	417.6	21.4	1.1	-0.5	19.5	-38.0	45.0
	LAST VISIT	123	419.9	423.0	22.9	360.0	471.0	121	418.7	20.8	1.1	0.0	18.0	-41.0	45.0
PLACEBO	BASELINE	130	413.1	410.5	21.2	361.0	468.0								
	WEEK 28	58	416.1	418.0	18.8	366.0	461.0	56	413.5	20.3	2.4	3.0	16.1	-31.0	46.0
	WEEK 52	41	421.1	419.0	22.2	376.0	472.0	41	411.2	20.6	9.9	8.0	15.8	-34.0	47.0
	LAST VISIT	125	418.4	419.0	22.3	357.0	485.0	122	413.0	21.5	5.3	7.0	17.2	-34.0	47.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=QTcF INTERVAL (MSEC)[3]

								CHANGE FROM BASELINE						
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	406.1	408.0	17.6	360.0	447.0								
	WEEK 28	77	408.8	409.0	19.1	362.0	457.0	75	406.4	18.5	1.7	-1.0	13.2	-25.0	33.0
	WEEK 52	64	407.0	406.5	20.0	365.0	448.0	62	405.0	18.8	1.8	3.0	13.9	-31.0	29.0
	LAST VISIT	123	407.4	407.0	19.5	359.0	453.0	121	406.1	18.0	1.2	1.0	12.7	-31.0	30.0
PLACEBO	BASELINE	130	403.6	400.5	19.6	363.0	458.0								
	WEEK 28	58	407.1	407.0	16.7	369.0	444.0	56	403.8	20.2	3.3	3.0	12.9	-25.0	30.0
	WEEK 52	41	410.6	408.0	20.6	374.0	460.0	41	401.5	20.0	9.1	10.0	12.4	-19.0	33.0
	LAST VISIT	125	406.9	406.0	19.5	358.0	462.0	122	403.0	19.5	3.9	6.0	14.4	-37.0	33.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-209　心電図パラメータの記述統計量［二重盲検試験，二重盲検期（Phase D）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase D
(Phase D Safety Sample)

ECG PARAMETER=QTcN INTERVAL (MSEC)[3]

								CHANGE FROM BASELINE						
								BASELINE						
TREATMENT	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
ARIP IMD	BASELINE	130	408.9	411.0	17.6	365.0	451.0								
	WEEK 28	77	411.3	412.0	19.2	367.0	461.0	75	408.9	18.6	1.7	-2.0	13.8	-25.0	36.0
	WEEK 52	64	409.6	408.5	20.4	365.0	450.0	62	407.6	18.8	1.7	3.0	14.7	-32.0	31.0
	LAST VISIT	123	410.1	409.0	19.5	361.0	452.0	121	408.8	18.0	1.2	1.0	13.3	-32.0	32.0
PLACEBO	BASELINE	130	405.6	402.0	19.4	363.0	460.0								
	WEEK 28	58	409.0	409.5	16.5	370.0	448.0	56	405.8	19.8	3.1	4.0	13.1	-26.0	33.0
	WEEK 52	41	412.9	411.0	20.3	375.0	459.0	41	403.6	19.7	9.2	11.0	12.7	-20.0	34.0
	LAST VISIT	125	409.4	408.0	19.6	358.0	467.0	122	405.1	19.5	4.2	6.0	14.5	-35.0	34.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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＜資料番号 5.3.5.1-01：CT-15.2＞

表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=VENTRICULAR RATE (BEATS/MIN)

								CHANGE FROM BASELINE						
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	70.3	69.0	11.4	44.0	107.0								
	WEEK 2	158	71.8	71.0	11.8	49.0	105.0	148	70.5	10.9	1.1	2.0	10.2	-30.0	30.0
	WEEK 4	143	70.4	70.0	12.5	44.0	107.0	140	69.8	11.1	0.5	1.0	9.3	-30.0	24.0
	WEEK 6	103	71.6	72.0	13.8	41.0	137.0	99	69.1	11.9	2.2	1.0	12.8	-21.0	81.0
	WEEK 8	140	72.0	71.5	11.7	46.0	107.0	139	71.6	11.8	0.3	2.0	11.7	-42.0	24.0
	LAST VISIT	545	71.5	71.0	12.4	41.0	137.0	530	70.4	11.5	1.0	2.0	10.9	-42.0	81.0
PHASE C	BASELINE	422	71.4	71.0	12.3	41.0	137.0								
	WEEK 12	224	71.4	70.0	11.7	41.0	108.0	222	71.6	13.3	-0.2	0.0	11.3	-69.0	35.0
	WEEK 28	8	84.4	75.0	21.1	69.0	133.0	8	73.6	14.9	10.8	5.0	20.0	-10.0	56.0
	LAST VISIT	377	71.6	71.0	11.9	41.0	133.0	374	71.4	12.2	0.3	0.0	11.2	-69.0	56.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=PR INTERVAL (MSEC)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	597	159.9	157.0	20.9	103.0	276.0								
	WEEK 2	157	158.9	157.0	19.4	121.0	250.0	146	158.9	21.2	0.0	1.0	10.8	-65.0	27.0
	WEEK 4	143	162.2	160.0	25.4	124.0	361.0	140	160.5	19.6	1.4	-1.0	16.5	-23.0	166.0
	WEEK 6	102	159.9	158.0	20.4	119.0	215.0	98	160.6	21.5	-0.9	-1.0	10.8	-31.0	31.0
	WEEK 8	140	157.9	155.5	18.0	117.0	213.0	138	157.9	18.4	0.1	1.0	12.6	-35.0	45.0
	LAST VISIT	543	160.0	158.0	21.7	117.0	361.0	527	159.6	20.5	0.3	0.0	13.1	-65.0	166.0
PHASE C	BASELINE	421	160.2	158.0	22.0	117.0	361.0								
	WEEK 12	224	160.0	159.0	21.1	107.0	250.0	221	159.2	18.8	1.0	1.0	10.8	-33.0	42.0
	WEEK 28	7	169.4	173.0	28.5	130.0	218.0	7	163.3	24.3	6.1	7.0	6.4	-1.0	18.0
	LAST VISIT	376	160.2	159.0	21.9	107.0	298.0	372	160.0	22.4	0.2	1.0	11.6	-63.0	42.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=RR INTERVAL (MSEC)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	877.4	874.0	142.6	562.0	1362.0								
	WEEK 2	158	859.7	851.0	140.5	573.0	1250.0	148	873.9	139.1	-11.8	-19.0	125.2	-294.0	319.0
	WEEK 4	143	881.1	858.0	160.3	567.0	1374.0	140	883.9	144.7	-2.6	-15.0	119.1	-355.0	344.0
	WEEK 6	103	868.2	843.0	156.3	439.0	1463.0	99	895.5	152.1	-23.2	-9.0	141.7	-636.0	425.0
	WEEK 8	140	857.1	837.5	140.4	563.0	1319.0	139	862.6	141.7	-4.8	-24.0	140.5	-333.0	485.0
	LAST VISIT	545	865.5	845.0	149.1	439.0	1463.0	530	876.7	143.8	-10.1	-20.5	130.8	-636.0	485.0
PHASE C	BASELINE	422	866.4	846.5	147.8	439.0	1463.0								
	WEEK 12	224	865.0	860.0	145.8	558.0	1461.0	222	867.2	155.4	-2.2	0.5	135.9	-373.0	511.0
	WEEK 28	8	741.8	800.0	136.6	455.0	872.0	8	846.0	174.8	-104.3	-53.0	143.5	-326.0	71.0
	LAST VISIT	377	862.4	840.0	146.9	455.0	1461.0	374	866.3	147.3	-3.8	-2.0	134.4	-403.0	511.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-24.2.2 FINAL

表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=QRS INTERVAL (MSEC)

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	92.6	92.0	7.5	77.0	148.0								
	WEEK 2	158	93.0	92.0	9.3	77.0	138.0	148	93.0	9.4	-0.2	0.0	4.7	-11.0	14.0
	WEEK 4	143	93.3	93.0	9.0	77.0	169.0	140	92.4	6.3	0.4	0.0	5.3	-18.0	14.0
	WEEK 6	103	92.6	92.0	5.9	79.0	109.0	99	92.3	6.1	0.2	0.0	5.8	-11.0	16.0
	WEEK 8	140	93.1	92.0	7.1	77.0	134.0	139	92.3	8.0	0.7	1.0	4.6	-15.0	13.0
	LAST VISIT	545	93.0	92.0	8.1	77.0	169.0	530	92.5	7.7	0.2	0.0	5.1	-18.0	16.0
PHASE C	BASELINE	422	92.8	92.0	7.8	77.0	169.0								
	WEEK 12	224	93.0	92.0	9.3	78.0	160.0	222	93.2	8.9	-0.2	0.0	5.5	-19.0	22.0
	WEEK 28	8	89.1	87.0	8.1	79.0	101.0	8	93.1	8.3	-4.0	-4.0	6.0	-11.0	6.0
	LAST VISIT	377	92.7	92.0	8.4	78.0	160.0	374	93.0	8.0	-0.3	0.0	5.3	-19.0	22.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=QT INTERVAL (MSEC)

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	389.3	387.0	30.1	319.0	474.0								
	WEEK 2	158	384.7	384.0	31.0	311.0	498.0	148	387.9	30.3	-2.9	-2.0	22.8	-60.0	64.0
	WEEK 4	143	389.1	383.0	33.1	318.0	473.0	140	391.6	30.7	-2.7	-3.0	21.2	-75.0	64.0
	WEEK 6	103	385.8	385.0	28.6	315.0	452.0	99	392.6	30.0	-5.6	-7.0	23.9	-94.0	74.0
	WEEK 8	140	381.2	379.0	29.5	312.0	492.0	139	386.0	28.2	-4.6	-4.0	25.4	-72.0	66.0
	LAST VISIT	545	385.0	383.0	30.7	311.0	498.0	530	389.1	29.8	-3.9	-4.0	23.4	-94.0	74.0
PHASE C	BASELINE	422	385.0	383.0	30.9	311.0	492.0								
	WEEK 12	224	385.2	383.5	30.9	301.0	497.0	222	385.0	33.5	0.1	2.0	24.1	-82.0	63.0
	WEEK 28	8	363.0	370.0	25.6	309.0	393.0	8	376.6	24.7	-13.6	-3.0	32.0	-68.0	19.0
	LAST VISIT	377	384.2	382.0	30.0	301.0	497.0	374	384.9	31.3	-0.7	0.0	23.1	-82.0	63.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=QTcB INTERVAL (MSEC)[3]

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	418.0	418.0	21.8	360.0	477.0								
	WEEK 2	158	417.2	417.5	21.2	356.0	463.0	148	417.0	22.1	-0.1	2.0	14.8	-46.0	37.0
	WEEK 4	143	417.3	418.0	20.8	357.0	468.0	140	418.8	19.6	-1.9	-1.5	16.8	-49.0	42.0
	WEEK 6	103	417.2	419.0	22.9	346.0	476.0	99	417.7	21.5	-0.1	-3.0	18.9	-36.0	81.0
	WEEK 8	140	414.1	412.5	20.6	366.0	494.0	139	418.3	22.9	-4.2	-3.0	18.9	-58.0	52.0
	LAST VISIT	545	416.4	417.0	21.3	346.0	494.0	530	418.1	21.6	-1.6	-1.0	17.3	-58.0	81.0
PHASE C	BASELINE	422	416.2	416.0	20.4	346.0	476.0								
	WEEK 12	224	416.4	416.0	20.5	361.0	468.0	222	416.2	21.3	0.3	1.5	17.0	-76.0	38.0
	WEEK 28	8	425.1	419.0	20.7	393.0	460.0	8	413.4	21.0	11.8	9.5	19.8	-24.0	34.0
	LAST VISIT	377	416.2	416.0	21.0	357.0	468.0	374	416.0	20.5	0.2	1.0	16.9	-76.0	39.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=QTcF INTERVAL (MSEC)[3]

										CHANGE FROM BASELINE				
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	407.9	407.0	19.8	357.0	467.0								
	WEEK 2	158	405.7	405.0	19.8	352.0	473.0	148	406.7	20.6	-1.0	1.0	11.7	-31.0	24.0
	WEEK 4	143	407.3	406.0	19.3	359.0	459.0	140	409.2	18.7	-2.2	-2.0	13.4	-40.0	27.0
	WEEK 6	103	406.1	406.0	18.4	360.0	450.0	99	408.8	18.7	-2.1	-2.0	13.5	-34.0	43.0
	WEEK 8	140	402.5	402.0	18.8	359.0	469.0	139	406.9	19.5	-4.3	-5.0	15.0	-52.0	36.0
	LAST VISIT	545	405.3	405.0	19.1	352.0	473.0	530	407.9	19.5	-2.5	-2.0	13.5	-52.0	43.0
PHASE C	BASELINE	422	405.2	405.0	18.7	352.0	459.0								
	WEEK 12	224	405.5	404.5	19.1	360.0	458.0	222	405.2	20.0	0.3	1.0	13.1	-30.0	38.0
	WEEK 28	8	403.1	403.5	11.1	379.0	416.0	8	400.1	11.6	3.0	6.0	17.1	-32.0	25.0
	LAST VISIT	377	405.0	404.0	18.8	357.0	458.0	374	405.1	19.1	-0.1	0.0	12.8	-40.0	38.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-210　心電図パラメータの記述統計量［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.2
ECG Parameters - Mean Change From Baseline
(Phase B Safety Sample and Phase C Safety Sample)

ECG PARAMETER=QTcN INTERVAL (MSEC)[3]

									CHANGE FROM BASELINE					
								BASELINE						
PHASE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	n[2]	MEAN	SD	MEAN	MEDIAN	SD	MIN	MAX
PHASE B	BASELINE	598	410.1	410.0	19.7	358.0	466.0								
	WEEK 2	158	408.2	407.5	19.6	354.0	470.0	148	408.9	20.4	-0.8	1.0	11.7	-31.0	22.0
	WEEK 4	143	409.5	408.0	18.9	362.0	458.0	140	411.3	18.3	-2.2	-2.0	13.6	-42.0	27.0
	WEEK 6	103	408.5	409.0	18.8	360.0	453.0	99	410.7	18.7	-1.6	-3.0	14.0	-32.0	39.0
	WEEK 8	140	405.0	404.5	18.6	361.0	475.0	139	409.4	19.7	-4.3	-5.0	15.2	-52.0	41.0
	LAST VISIT	545	407.7	407.0	19.0	354.0	475.0	530	410.0	19.4	-2.2	-2.0	13.8	-52.0	41.0
PHASE C	BASELINE	422	407.6	407.0	18.5	354.0	458.0								
	WEEK 12	224	407.8	406.0	18.8	363.0	460.0	222	407.5	19.6	0.2	1.0	13.3	-35.0	36.0
	WEEK 28	8	407.6	410.0	12.0	382.0	421.0	8	403.0	13.0	4.6	4.5	16.4	-30.0	25.0
	LAST VISIT	377	407.4	406.0	18.8	357.0	460.0	374	407.4	18.8	-0.1	1.0	13.1	-41.0	36.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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＜資料番号 5.3.5.1-01：CT-24.2.2＞

表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=VENTRICULAR RATE (BEATS/MIN)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	376	69.6	69.0	10.3	47.0	104.0								
	WEEK 28	12	73.9	74.0	12.4	56.0	104.0	12	67.6	7.2	6.3	1.5	13.8	-9.0	38.0
	WEEK 52	223	70.1	69.0	11.5	45.0	111.0	221	69.7	10.4	0.3	0.0	11.3	-36.0	30.0
	LAST VISIT	333	70.6	69.0	11.5	45.0	111.0	330	69.5	10.0	1.1	1.0	11.5	-36.0	38.0
ROLLOVER	BASELINE	85	71.8	71.0	12.6	38.0	103.0								
	WEEK 28	42	73.9	72.5	11.5	52.0	106.0	42	71.5	12.9	2.4	2.0	9.2	-18.0	21.0
	WEEK 52	14	72.6	71.5	11.7	55.0	99.0	14	73.1	13.8	-0.4	-1.5	10.0	-17.0	22.0
	LAST VISIT	79	74.1	72.0	11.4	52.0	106.0	79	72.1	12.6	2.0	2.0	8.8	-18.0	22.0
TOTAL	BASELINE	461	70.0	70.0	10.8	38.0	104.0								
	WEEK 28	54	73.9	73.5	11.6	52.0	106.0	54	70.6	11.9	3.2	2.0	10.4	-18.0	38.0
	WEEK 52	237	70.2	69.0	11.5	45.0	111.0	235	69.9	10.6	0.3	0.0	11.2	-36.0	30.0
	LAST VISIT	412	71.2	70.0	11.6	45.0	111.0	409	70.0	10.6	1.2	1.0	11.0	-36.0	38.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=PR INTERVAL (MSEC)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	375	162.7	160.0	24.6	112.0	395.0								
	WEEK 28	12	162.5	168.5	19.0	127.0	184.0	12	161.8	16.6	0.8	-1.5	10.3	-20.0	16.0
	WEEK 52	222	165.1	164.0	22.2	124.0	271.0	220	164.7	23.1	0.3	1.0	12.8	-67.0	38.0
	LAST VISIT	332	164.4	162.0	25.2	123.0	408.0	329	164.0	25.1	0.4	0.0	11.9	-67.0	38.0
ROLLOVER	BASELINE	85	162.8	161.0	21.5	110.0	220.0								
	WEEK 28	42	165.0	163.0	21.3	124.0	219.0	42	167.0	20.7	-2.0	-1.0	7.8	-16.0	13.0
	WEEK 52	14	159.3	156.0	27.6	109.0	213.0	14	160.1	25.5	-0.8	-0.5	13.0	-30.0	16.0
	LAST VISIT	79	162.1	161.0	21.4	109.0	219.0	79	164.0	21.3	-1.8	-1.0	9.7	-30.0	16.0
TOTAL	BASELINE	460	162.7	160.0	24.0	110.0	395.0								
	WEEK 28	54	164.4	165.5	20.7	124.0	219.0	54	165.9	19.8	-1.4	-1.0	8.4	-20.0	16.0
	WEEK 52	236	164.8	164.0	22.5	109.0	271.0	234	164.4	23.3	0.3	0.5	12.8	-67.0	38.0
	LAST VISIT	411	164.0	162.0	24.5	109.0	408.0	408	164.0	24.4	-0.0	0.0	11.6	-67.0	38.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=RR INTERVAL (MSEC)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	376	882.7	868.5	131.6	575.0	1267.0								
	WEEK 28	12	833.7	812.5	132.2	580.0	1090.0	12	901.9	94.0	-68.3	-22.5	153.0	-331.0	140.0
	WEEK 52	223	880.3	870.0	144.6	541.0	1323.0	221	881.9	133.6	-0.8	1.0	138.4	-427.0	486.0
	LAST VISIT	333	874.1	866.0	142.2	541.0	1323.0	330	883.0	128.9	-9.1	-9.5	139.1	-430.0	486.0
ROLLOVER	BASELINE	85	864.4	842.0	165.8	581.0	1579.0								
	WEEK 28	42	833.4	825.5	132.3	566.0	1158.0	42	869.8	182.9	-36.4	-17.5	136.9	-567.0	196.0
	WEEK 52	14	846.2	835.0	135.3	604.0	1099.0	14	850.6	166.1	-4.4	13.5	117.5	-296.0	152.0
	LAST VISIT	79	830.6	827.0	128.5	566.0	1158.0	79	861.5	168.0	-30.9	-17.0	121.4	-567.0	196.0
TOTAL	BASELINE	461	879.3	863.0	138.5	575.0	1579.0								
	WEEK 28	54	833.5	815.5	131.1	566.0	1158.0	54	876.9	167.0	-43.5	-18.5	139.8	-567.0	196.0
	WEEK 52	237	878.3	866.0	144.0	541.0	1323.0	235	880.0	135.5	-1.0	3.0	137.0	-427.0	486.0
	LAST VISIT	412	865.7	857.0	140.5	541.0	1323.0	409	878.9	137.4	-13.3	-12.0	136.0	-567.0	486.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=QRS INTERVAL (MSEC)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	376	93.4	93.0	7.9	78.0	163.0								
	WEEK 28	12	93.3	93.5	3.5	86.0	99.0	12	93.7	5.1	-0.3	-1.0	4.9	-9.0	7.0
	WEEK 52	223	93.6	93.0	8.8	78.0	163.0	221	93.6	8.4	0.0	0.0	5.7	-13.0	38.0
	LAST VISIT	333	93.4	92.0	8.2	78.0	163.0	330	93.7	8.1	-0.3	0.0	5.4	-16.0	38.0
ROLLOVER	BASELINE	85	92.4	91.0	8.5	78.0	142.0								
	WEEK 28	42	93.2	92.0	9.7	79.0	142.0	42	93.8	9.9	-0.6	-0.5	3.3	-6.0	7.0
	WEEK 52	14	89.9	89.0	6.4	81.0	104.0	14	89.9	6.3	-0.1	-1.5	4.0	-5.0	8.0
	LAST VISIT	79	91.5	91.0	8.6	74.0	142.0	79	92.3	8.8	-0.8	-1.0	4.3	-13.0	9.0
TOTAL	BASELINE	461	93.2	93.0	8.0	78.0	163.0								
	WEEK 28	54	93.2	92.0	8.7	79.0	142.0	54	93.8	9.1	-0.6	-1.0	3.6	-9.0	7.0
	WEEK 52	237	93.4	93.0	8.7	78.0	163.0	235	93.4	8.4	0.0	0.0	5.6	-13.0	38.0
	LAST VISIT	412	93.0	92.0	8.3	74.0	163.0	409	93.4	8.2	-0.4	-1.0	5.2	-16.0	38.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=QT INTERVAL (MSEC)

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE n[2]	CHANGE FROM BASELINE MEAN	CHANGE FROM BASELINE SD	BASELINE MEAN	BASELINE MEDIAN	BASELINE SD	BASELINE MIN	BASELINE MAX
DE NOVO	BASELINE	376	388.2	386.0	27.5	322.0	487.0								
	WEEK 28	12	378.6	374.5	23.2	347.0	428.0	12	382.8	25.7	-4.2	2.0	29.0	-66.0	37.0
	WEEK 52	223	389.6	387.0	30.8	317.0	496.0	221	389.1	28.1	0.6	3.0	24.1	-79.0	82.0
	LAST VISIT	333	387.8	385.0	29.5	317.0	496.0	330	388.5	27.0	-0.7	0.0	24.8	-79.0	82.0
ROLLOVER	BASELINE	85	388.5	383.0	32.2	323.0	474.0								
	WEEK 28	42	384.8	384.5	26.0	333.0	443.0	42	391.5	31.5	-6.7	-11.5	22.2	-73.0	42.0
	WEEK 52	14	386.6	383.5	24.4	356.0	445.0	14	389.9	30.6	-3.3	-0.5	22.4	-57.0	24.0
	LAST VISIT	79	380.7	381.0	28.2	305.0	443.0	79	387.9	31.8	-7.2	-7.0	21.8	-73.0	42.0
TOTAL	BASELINE	461	388.3	386.0	28.4	322.0	487.0								
	WEEK 28	54	383.4	382.0	25.3	333.0	443.0	54	389.6	30.3	-6.1	-9.5	23.6	-73.0	42.0
	WEEK 52	237	389.5	387.0	30.4	317.0	496.0	235	389.1	28.2	0.4	3.0	23.9	-79.0	82.0
	LAST VISIT	412	386.5	384.0	29.4	305.0	496.0	409	388.4	28.0	-1.9	-1.0	24.4	-79.0	82.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=QTcB INTERVAL (MSEC)[3]

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	376	415.3	415.0	20.3	360.0	489.0								
	WEEK 28	12	417.3	416.0	25.4	379.0	471.0	12	403.8	21.2	13.5	17.5	18.1	-16.0	45.0
	WEEK 52	223	417.6	417.0	19.3	352.0	480.0	221	416.4	20.3	1.1	1.0	16.5	-57.0	46.0
	LAST VISIT	333	417.2	417.0	20.8	349.0	480.0	330	415.5	20.7	1.8	2.0	17.6	-57.0	66.0
ROLLOVER	BASELINE	85	420.9	419.0	23.5	366.0	472.0								
	WEEK 28	42	424.1	421.0	24.1	384.0	475.0	42	423.5	24.8	0.6	-0.5	16.8	-53.0	32.0
	WEEK 52	14	423.1	423.0	26.2	386.0	472.0	14	426.1	25.1	-3.0	-2.0	19.7	-45.0	25.0
	LAST VISIT	79	420.1	418.0	22.9	383.0	475.0	79	421.1	23.7	-1.0	-3.0	16.6	-53.0	33.0
TOTAL	BASELINE	461	416.3	416.0	21.0	360.0	489.0								
	WEEK 28	54	422.6	420.5	24.3	379.0	475.0	54	419.1	25.2	3.5	3.5	17.8	-53.0	45.0
	WEEK 52	237	417.9	418.0	19.7	352.0	480.0	235	417.0	20.7	0.8	1.0	16.7	-57.0	46.0
	LAST VISIT	412	417.8	417.0	21.2	349.0	480.0	409	416.6	21.4	1.2	1.0	17.4	-57.0	66.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=QTcF INTERVAL (MSEC)[3]

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	376	405.7	405.0	18.3	352.0	466.0								
	WEEK 28	12	403.7	405.5	18.8	375.0	430.0	12	396.4	20.9	7.3	8.5	14.5	-15.0	31.0
	WEEK 52	223	407.7	406.0	18.2	347.0	469.0	221	406.8	18.6	0.9	1.0	12.7	-65.0	41.0
	LAST VISIT	333	406.9	406.0	18.7	347.0	469.0	330	405.9	18.7	0.9	1.0	13.8	-65.0	53.0
ROLLOVER	BASELINE	85	409.4	409.0	20.5	370.0	460.0								
	WEEK 28	42	410.3	410.5	19.7	376.0	459.0	42	412.1	20.0	-1.9	-1.0	13.2	-39.0	27.0
	WEEK 52	14	410.2	414.5	20.3	379.0	451.0	14	413.4	19.8	-3.1	-2.0	15.3	-34.0	21.0
	LAST VISIT	79	406.2	409.0	20.4	360.0	459.0	79	409.4	20.2	-3.1	-4.0	13.8	-39.0	28.0
TOTAL	BASELINE	461	406.4	405.0	18.8	352.0	466.0								
	WEEK 28	54	408.8	410.5	19.5	375.0	459.0	54	408.6	21.1	0.1	-0.5	13.9	-39.0	31.0
	WEEK 52	237	407.9	406.0	18.3	347.0	469.0	235	407.1	18.7	0.7	1.0	12.8	-65.0	41.0
	LAST VISIT	412	406.8	406.0	19.0	347.0	469.0	409	406.6	19.0	0.2	0.0	13.9	-65.0	53.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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表 2.7.4.7-211　心電図パラメータの記述統計量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.2
ECG Parameters - Mean Change From Baseline in Phase C
(Phase C Safety Sample)

ECG PARAMETER=QTcN INTERVAL (MSEC)[3]

ENROLLMENT SOURCE	TRIAL WEEK[1]	n[2]	MEAN	MEDIAN	SD	MIN	MAX	CHANGE FROM BASELINE: BASELINE n[2]	BASELINE MEAN	BASELINE SD	CHANGE MEAN	CHANGE MEDIAN	CHANGE SD	CHANGE MIN	CHANGE MAX
DE NOVO	BASELINE	376	407.8	407.0	18.3	354.0	470.0								
	WEEK 28	12	406.7	409.5	19.8	376.0	439.0	12	398.1	20.6	8.6	10.5	14.1	-15.0	33.0
	WEEK 52	223	409.8	408.0	17.7	348.0	467.0	221	408.9	18.5	0.9	2.0	12.8	-63.0	36.0
	LAST VISIT	333	409.1	408.0	18.6	348.0	467.0	330	408.0	18.6	1.1	2.0	13.9	-63.0	55.0
ROLLOVER	BASELINE	85	411.9	411.0	20.5	372.0	459.0								
	WEEK 28	42	413.3	414.5	20.3	378.0	461.0	42	414.6	20.4	-1.3	-1.0	13.3	-42.0	27.0
	WEEK 52	14	412.9	417.0	21.2	382.0	455.0	14	416.1	20.4	-3.1	-2.0	16.0	-37.0	22.0
	LAST VISIT	79	409.2	411.0	20.5	366.0	461.0	79	411.9	20.3	-2.7	-3.0	13.9	-42.0	29.0
TOTAL	BASELINE	461	408.6	408.0	18.8	354.0	470.0								
	WEEK 28	54	411.8	414.0	20.2	376.0	461.0	54	410.9	21.4	0.9	-1.0	14.0	-42.0	33.0
	WEEK 52	237	410.0	408.0	17.9	348.0	467.0	235	409.3	18.6	0.7	2.0	13.0	-63.0	36.0
	LAST VISIT	412	409.1	408.0	18.9	348.0	467.0	409	408.8	19.0	0.4	1.0	14.0	-63.0	55.0

[1]BASELINE = LAST AVAILABLE VALUE PRIOR TO DOSING IN THE PHASE; LAST VISIT = LAST AVAILABLE POST-BASELINE EVALUATION IN THE PHASE.
[2]n = TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE OBSERVATION OF THE GIVEN PARAMETER.
[3]QTcB = CORRECTED QT BASED ON BAZETT FORMULA; QTcF = CORRECTED QT BASED ON FRIDERICIA FORMULA;
QTcN = QT / (RR/1000)**0.37.

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＜資料番号 5.3.5.2-01：CT-15.2＞

表 2.7.4.7-212　臨床的に重要な心電図所見［二重盲検試験，二重盲検期（Phase D）］

CT-15.1
Incidence of ECG Measurements of Potential Clinical Relevance In Phase D
(Phase D Safety Sample)

TYPE	ABNORMALITY	ARIP IMD (N=132) Ne[1]	n[2]	(%)	PLACEBO (N=133) Ne[1]	n[2]	(%)	TOTAL (N=265) Ne[1]	n[2]	(%)
RATE	TACHYCARDIA	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
	BRADYCARDIA	121	1	(0.8)	122	0	(0.0)	243	1	(0.4)
RHYTHM	SINUS TACHYCARDIA	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
	SINUS BRADYCARDIA	121	1	(0.8)	122	0	(0.0)	243	1	(0.4)
	SUPRAVENTRICULAR PREMATURE BEAT	123	3	(2.4)	125	2	(1.6)	248	5	(2.0)
	VENTRICULAR PREMATURE BEAT	123	5	(4.1)	125	2	(1.6)	248	7	(2.8)
	SUPRAVENTRICULAR TACHYCARDIA	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	VENTRICULAR TACHYCARDIA	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	ATRIAL FIBRILLATION	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	ATRIAL FLUTTER	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
CONDUCTION	1° ATRIOVENTRICULAR BLOCK	120	0	(0.0)	122	0	(0.0)	242	0	(0.0)
	2° ATRIOVENTRICULAR BLOCK	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	3° ATRIOVENTRICULAR BLOCK	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	LEFT BUNDLE BRANCH BLOCK	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	RIGHT BUNDLE BRANCH BLOCK	123	0	(0.0)	125	1	(0.8)	248	1	(0.4)
	PRE-EXCITATION SYNDROME	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	OTHER INTRAVENTRICULAR CONDUCTION BLOCK	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
INFARCTION	ACUTE OR SUBACUTE	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)
	OLD	123	0	(0.0)	125	0	(0.0)	248	0	(0.0)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-12.2, 12.3.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH ECG MEASUREMENT OF POTENTIAL CLINICAL RELEVANCE.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-15.1 FINAL

表 2.7.4.7-212　臨床的に重要な心電図所見［二重盲検試験，二重盲検期（Phase D）］

CT-15.1
Incidence of ECG Measurements of Potential Clinical Relevance In Phase D
(Phase D Safety Sample)

TYPE	ABNORMALITY	ARIP IMD (N=132) Ne[1]	n[2]	(%)	PLACEBO (N=133) Ne[1]	n[2]	(%)	TOTAL (N=265) Ne[1]	n[2]	(%)
ST/T MORPHOLOGY	MYOCARDIAL ISCHEMIA	123	1	(0.8)	125	0	(0.0)	248	1	(0.4)
	SYMMETRICAL T-WAVE INVERSION	123	3	(2.4)	125	2	(1.6)	248	5	(2.0)
	QTcB	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
	QTcF	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)
	QTcN	121	0	(0.0)	122	0	(0.0)	243	0	(0.0)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-12.2, 12.3.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH ECG MEASUREMENT OF POTENTIAL CLINICAL RELEVANCE.

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＜資料番号 5.3.5.1-01：CT-15.1＞

表 2.7.4.7-213　臨床的に重要な心電図所見［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.1
Incidence of ECG Measurements of Potential Clinical Relevance
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)			PHASE C (N=425)		
TYPE	ABNORMALITY	Ne[1]	n[2]	(%)	Ne[1]	n[2]	(%)
RATE	TACHYCARDIA	530	1	(0.2)	374	1	(0.3)
	BRADYCARDIA	530	2	(0.4)	374	2	(0.5)
RHYTHM	SINUS TACHYCARDIA	530	0	(0.0)	374	0	(0.0)
	SINUS BRADYCARDIA	530	2	(0.4)	374	1	(0.3)
	SUPRAVENTRICULAR PREMATURE BEAT	545	10	(1.8)	377	6	(1.6)
	VENTRICULAR PREMATURE BEAT	545	6	(1.1)	377	6	(1.6)
	SUPRAVENTRICULAR TACHYCARDIA	545	1	(0.2)	377	0	(0.0)
	VENTRICULAR TACHYCARDIA	545	0	(0.0)	377	0	(0.0)
	ATRIAL FIBRILLATION	545	0	(0.0)	377	1	(0.3)
	ATRIAL FLUTTER	545	0	(0.0)	377	0	(0.0)
CONDUCTION	1° ATRIOVENTRICULAR BLOCK	527	1	(0.2)	372	0	(0.0)
	2° ATRIOVENTRICULAR BLOCK	545	0	(0.0)	377	0	(0.0)
	3° ATRIOVENTRICULAR BLOCK	545	0	(0.0)	377	0	(0.0)
	LEFT BUNDLE BRANCH BLOCK	545	1	(0.2)	377	0	(0.0)
	RIGHT BUNDLE BRANCH BLOCK	545	2	(0.4)	377	1	(0.3)
	PRE-EXCITATION SYNDROME	545	0	(0.0)	377	0	(0.0)
	OTHER INTRAVENTRICULAR CONDUCTION BLOCK	530	0	(0.0)	374	1	(0.3)
INFARCTION	ACUTE OR SUBACUTE	545	0	(0.0)	377	1	(0.3)
	OLD	545	0	(0.0)	377	0	(0.0)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-12.2, 12.3.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH ECG MEASUREMENT OF POTENTIAL CLINICAL RELEVANCE.

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表 2.7.4.7-213　臨床的に重要な心電図所見［二重盲検試験，IM デポ剤安定期（Phase C）］

CT-24.2.1
Incidence of ECG Measurements of Potential Clinical Relevance
(Phase B Safety Sample and Phase C Safety Sample)

		PHASE B (N=614)			PHASE C (N=425)		
TYPE	ABNORMALITY	Ne[1]	n[2]	(%)	Ne[1]	n[2]	(%)
ST/T MORPHOLOGY	MYOCARDIAL ISCHEMIA	545	2	(0.4)	377	2	(0.5)
	SYMMETRICAL T-WAVE INVERSION	545	12	(2.2)	377	4	(1.1)
	QTcB	530	3	(0.6)	374	0	(0.0)
	QTcF	530	0	(0.0)	374	0	(0.0)
	QTcN	530	0	(0.0)	374	0	(0.0)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-12.2, 12.3.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH ECG MEASUREMENT OF POTENTIAL CLINICAL RELEVANCE.

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＜資料番号 5.3.5.1-01：CT-24.2.1＞

表 2.7.4.7-214　臨床的に重要な心電図所見［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.1
Incidence of ECG Measurements of Potential Clinical Relevance in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)			ROLLOVER (N=85)			TOTAL (N=464)		
TYPE	ABNORMALITY	Ne[1]	n[2]	(%)	Ne[1]	n[2]	(%)	Ne[1]	n[2]	(%)
RATE	TACHYCARDIA	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)
	BRADYCARDIA	330	1	(0.3)	79	0	(0.0)	409	1	(0.2)
RHYTHM	SINUS TACHYCARDIA	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)
	SINUS BRADYCARDIA	330	1	(0.3)	79	0	(0.0)	409	1	(0.2)
	SUPRAVENTRICULAR PREMATURE BEAT	333	5	(1.5)	79	3	(3.8)	412	8	(1.9)
	VENTRICULAR PREMATURE BEAT	333	3	(0.9)	79	1	(1.3)	412	4	(1.0)
	SUPRAVENTRICULAR TACHYCARDIA	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	VENTRICULAR TACHYCARDIA	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	ATRIAL FIBRILLATION	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	ATRIAL FLUTTER	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
CONDUCTION	1° ATRIOVENTRICULAR BLOCK	329	0	(0.0)	79	0	(0.0)	408	0	(0.0)
	2° ATRIOVENTRICULAR BLOCK	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	3° ATRIOVENTRICULAR BLOCK	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	LEFT BUNDLE BRANCH BLOCK	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	RIGHT BUNDLE BRANCH BLOCK	333	1	(0.3)	79	0	(0.0)	412	1	(0.2)
	PRE-EXCITATION SYNDROME	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	OTHER INTRAVENTRICULAR CONDUCTION BLOCK	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)
INFARCTION	ACUTE OR SUBACUTE	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)
	OLD	333	0	(0.0)	79	0	(0.0)	412	0	(0.0)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-12.2, 12.3.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH ECG MEASUREMENT OF POTENTIAL CLINICAL RELEVANCE.

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表 2.7.4.7-214　臨床的に重要な心電図所見［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-15.1
Incidence of ECG Measurements of Potential Clinical Relevance in Phase C
(Phase C Safety Sample)

TYPE	ABNORMALITY	DE NOVO (N=379) Ne[1]	DE NOVO (N=379) n[2]	DE NOVO (N=379) (%)	ROLLOVER (N=85) Ne[1]	ROLLOVER (N=85) n[2]	ROLLOVER (N=85) (%)	TOTAL (N=464) Ne[1]	TOTAL (N=464) n[2]	TOTAL (N=464) (%)
ST/T MORPHOLOGY	MYOCARDIAL ISCHEMIA	333	1	(0.3)	79	1	(1.3)	412	2	(0.5)
	SYMMETRICAL T-WAVE INVERSION	333	8	(2.4)	79	1	(1.3)	412	9	(2.2)
	QTcB	330	1	(0.3)	79	0	(0.0)	409	1	(0.2)
	QTcF	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)
	QTcN	330	0	(0.0)	79	0	(0.0)	409	0	(0.0)

NOTE: CRITERIA FOR POTENTIAL CLINICAL RELEVANCE ARE DEFINED IN CT-12.2, 12.3.
[1]Ne IS THE TOTAL NUMBER OF SUBJECTS WITH AT LEAST ONE POST-BASELINE NUMERIC RESULT FOR THE GIVEN ECG PARAMETER.
[2]n IS THE NUMBER OF SUBJECTS WITH ECG MEASUREMENT OF POTENTIAL CLINICAL RELEVANCE.

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＜資料番号 5.3.5.2-01：CT-15.1＞

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n (%)	3-6 MONTHS (N=108) n (%)	6-9 MONTHS (N=84) n (%)	9-12 MONTHS (N=71) n (%)	> 12 MONTHS (N=41) n (%)	TOTAL (N=132) n (%)
感染症および寄生虫症	乳房蜂巣炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	気管支炎	1 (0.8)	3 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)
	蜂巣炎	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	ウイルス性胃腸炎	2 (1.5)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	麦粒腫	1 (0.8)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	インフルエンザ	2 (1.5)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	3 (2.3)
	喉頭炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.8)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	4 (3.0)	3 (2.8)	3 (3.6)	1 (1.4)	0 (0.0)	10 (7.6)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外耳炎	0 (0.0)	2 (1.9)	0 (0.0)	1 (1.4)	0 (0.0)	2 (1.5)
	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (2.4)	2 (1.5)
	咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)
	レンサ球菌性咽頭炎	1 (0.8)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
感染症および寄生虫症	鼻炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	副鼻腔炎	2	(1.5)	1	(0.9)	1	(1.2)	0	(0.0)	1	(2.4)	5	(3.8)
	須毛瘡	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	足部白癬	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	歯膿瘍	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	トリコモナス症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	上気道感染	2	(1.5)	0	(0.0)	1	(1.2)	0	(0.0)	1	(2.4)	4	(3.0)
	尿路感染	2	(1.5)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	ウイルス性上気道感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯感染	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	無症候性細菌尿	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	クラミジア感染	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	ウイルス性耳感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	真菌性口腔咽頭炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	ウイルス性気道感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	気道感染	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	口腔ヘルペス	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	カンジダ感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
血液およびリンパ系障害	貧血	0	(0.0)	0	(0.0)	1	(1.2)	1	(1.4)	0	(0.0)	2	(1.5)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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PROGRAM: C:¥OPC14597¥SCS¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
血液およびリンパ系障害	白血球減少症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	好中球減少症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
内分泌障害	高プロラクチン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
代謝および栄養障害	脱水	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高血糖	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	食欲亢進	1	(0.8)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	2	(1.5)
	高インスリン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食欲減退	0	(0.0)	1	(0.9)	0	(0.0)	1	(1.4)	0	(0.0)	2	(1.5)
	高脂血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	２型糖尿病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
精神障害	感情障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	攻撃性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	激越	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	3	(2.3)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	無感情	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	双極１型障害	1	(0.8)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	2	(1.5)
	抑うつ気分	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
精神障害	うつ病	3	(2.3)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	軽躁	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	初期不眠症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	不眠症	4	(3.0)	2	(1.9)	1	(1.2)	2	(2.8)	0	(0.0)	8	(6.1)
	易刺激性	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	リビドー減退	2	(1.5)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	躁病	2	(1.5)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	神経過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪夢	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	パニック発作	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	精神運動制止遅滞	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	落ち着きのなさ	3	(2.3)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	4	(3.0)
	睡眠障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	社会逃避行動	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	夢遊症	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	自殺企図	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	緊張	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	感情不安定	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	双極性障害	3	(2.3)	1	(0.9)	1	(1.2)	0	(0.0)	0	(0.0)	5	(3.8)
	大うつ病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
神経系障害	アカシジア	8	(6.1)	1	(0.9)	3	(3.6)	2	(2.8)	0	(0.0)	12	(9.1)
	運動緩慢	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	注意力障害	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	浮動性めまい	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	構語障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ジスキネジア	0	(0.0)	0	(0.0)	1	(1.2)	2	(2.8)	0	(0.0)	2	(1.5)
	錐体外路障害	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	頭痛	2	(1.5)	2	(1.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	過眠症	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	感覚鈍麻	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	嗜眠	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	片頭痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	精神運動亢進	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	坐骨神経痛	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	鎮静	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	傾眠	2	(1.5)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	失神	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	遅発性ジスキネジア	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
神経系障害	一過性脳虚血発作	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	振戦	2	(1.5)	0	(0.0)	1	(1.2)	1	(1.4)	0	(0.0)	3	(2.3)
	下肢静止不能症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脳損傷	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
眼障害	眼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	霧視	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
心臓障害	心房細動	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	徐脈	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	心肺停止	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
血管障害	本態性高血圧症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
呼吸器、胸郭および縦隔障害	喘息	0	(0.0)	1	(0.9)	1	(1.2)	0	(0.0)	0	(0.0)	2	(1.5)
	咳嗽	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	呼吸不全	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	アレルギー性副鼻腔炎	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	気道うっ血	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
呼吸器、胸郭および縦隔障害	口腔咽頭痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
胃腸障害	腹部膨満	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	腹痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上腹部痛	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	潰瘍性大腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	1	(0.8)	1	(0.9)	1	(1.2)	0	(0.0)	0	(0.0)	3	(2.3)
	齲歯	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.4)	1	(0.8)
	下痢	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	口内乾燥	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	1	(2.4)	2	(1.5)
	消化不良	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	食中毒	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	胃食道逆流性疾患	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯肉痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血便排泄	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪心	0	(0.0)	1	(0.9)	2	(2.4)	0	(0.0)	0	(0.0)	3	(2.3)
	口腔内不快感	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	流涎過多	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯の知覚過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌腫脹	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
胃腸障害	歯痛	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	嘔吐	0	(0.0)	1	(0.9)	1	(1.2)	0	(0.0)	0	(0.0)	2	(1.5)
	腹壁嚢胞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	痔出血	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
肝胆道系障害	脂肪肝	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
皮膚および皮下組織障害	ざ瘡	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	皮膚炎	0	(0.0)	2	(1.9)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	接触性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	皮膚乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	湿疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	紅斑	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	寝汗	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	粃糠疹	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	そう痒症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
筋骨格系および結合組織障害	関節痛	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	関節炎	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)	0	(0.0)	2	(1.5)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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PROGRAM: C:¥OPC14597¥SCS¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
筋骨格系および結合組織障害	背部痛	2	(1.5)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	3	(2.3)
	筋肉内出血	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋痙縮	1	(0.8)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	筋攣縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋力低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋肉痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頚部痛	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	四肢痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	顎痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	足底筋膜炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肩回旋筋腱板症候群	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	顎関節症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	開口障害	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	筋骨格硬直	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	筋浮腫	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
腎および尿路障害	排尿困難	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	緊張性膀胱	0	(0.0)	1	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	腎結石症	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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PROGRAM: C:¥OPC14597¥SCS¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n (%)	3-6 MONTHS (N=108) n (%)	6-9 MONTHS (N=84) n (%)	9-12 MONTHS (N=71) n (%)	> 12 MONTHS (N=41) n (%)	TOTAL (N=132) n (%)
生殖系および乳房障害	子宮頚部嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
一般・全身障害および投与部位の状態	無力症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	疲労	1 (0.8)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	2 (1.5)
	注射部位疼痛	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	1 (0.8)	1 (0.9)	0 (0.0)	1 (1.4)	0 (0.0)	2 (1.5)
	不活発	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	非心臓性胸痛	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.4)	0 (0.0)	1 (0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n	(%)	3-6 MONTHS (N=108) n	(%)	6-9 MONTHS (N=84) n	(%)	9-12 MONTHS (N=71) n	(%)	> 12 MONTHS (N=41) n	(%)	TOTAL (N=132) n	(%)
臨床検査	アラニンアミノトランスフェラーゼ増加	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	アスパラギン酸アミノトランスフェラーゼ増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中クレアチンホスホキナーゼ増加	1	(0.8)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	2	(1.5)
	血中ブドウ糖増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中インスリン増加	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	血中カリウム減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血圧上昇	1	(0.8)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	心電図ＳＴ部分下降	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	グリコヘモグロビン増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	体重減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	体重増加	4	(3.0)	4	(3.7)	3	(3.6)	0	(0.0)	0	(0.0)	11	(8.3)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.4)	1	(0.8)
傷害、中毒および処置合併症	節足動物咬傷	1	(0.8)	1	(0.9)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)
	転倒	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	足骨折	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.8)
	裂傷	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=132) n (%)	3-6 MONTHS (N=108) n (%)	6-9 MONTHS (N=84) n (%)	9-12 MONTHS (N=71) n (%)	> 12 MONTHS (N=41) n (%)	TOTAL (N=132) n (%)
傷害、中毒および処置合併症	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	挫傷	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	胸部損傷	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	1 (0.8)
	処置による疼痛	0 (0.0)	1 (0.9)	2 (2.4)	1 (1.4)	0 (0.0)	4 (3.0)
	脊柱損傷	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (0.8)
	注射に伴う反応	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	外傷後頚部症候群	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
社会環境	個人衛生不良	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
TOTAL1)		59 (44.7)	37 (34.3)	31 (36.9)	19 (26.8)	5 (12.2)	87 (65.9)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
		<=3 MONTHS (N=133)		3-6 MONTHS (N=96)		6-9 MONTHS (N=71)		9-12 MONTHS (N=53)		> 12 MONTHS (N=26)		TOTAL (N=133)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症	乳房蜂巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	気管支炎	0	(0.0)	1	(1.0)	1	(1.4)	0	(0.0)	0	(0.0)	2	(1.5)
	蜂巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	結膜炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	真菌感染	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	胃腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性胃腸炎	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	麦粒腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	インフルエンザ	0	(0.0)	0	(0.0)	2	(2.8)	0	(0.0)	0	(0.0)	2	(1.5)
	喉頭炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	シラミ寄生	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	限局性感染	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	鼻咽頭炎	4	(3.0)	3	(3.1)	6	(8.5)	4	(7.5)	1	(3.8)	13	(9.8)
	精巣炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	外耳炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	中耳炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽頭炎	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	レンサ球菌性咽頭炎	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	肺炎	0	(0.0)	0	(0.0)	1	(1.4)	1	(1.9)	0	(0.0)	2	(1.5)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
感染症および寄生虫症	鼻炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	副鼻腔炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	須毛瘡	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	足部白癬	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯膿瘍	0	(0.0)	1	(1.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	トリコモナス症	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	上気道感染	2	(1.5)	0	(0.0)	4	(5.6)	0	(0.0)	0	(0.0)	6	(4.5)
	尿路感染	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	ウイルス性上気道感染	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯感染	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	無症候性細菌尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	クラミジア感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性耳感染	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	真菌性口腔咽頭炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性気道感染	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	気道感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口腔ヘルペス	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	カンジダ感染	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
血液およびリンパ系障害	貧血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
		<=3 MONTHS (N=133)		3-6 MONTHS (N=96)		6-9 MONTHS (N=71)		9-12 MONTHS (N=53)		> 12 MONTHS (N=26)		TOTAL (N=133)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
血液およびリンパ系障害	白血球減少症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	好中球減少症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
内分泌障害	高プロラクチン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(3.8)	1	(0.8)
代謝および栄養障害	脱水	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	高血糖	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食欲亢進	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高インスリン血症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	食欲減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高脂血症	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	２型糖尿病	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
精神障害	感情障害	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	攻撃性	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	激越	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	不安	2	(1.5)	1	(1.0)	1	(1.4)	1	(1.9)	0	(0.0)	5	(3.8)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	双極１型障害	3	(2.3)	3	(3.1)	1	(1.4)	1	(1.9)	0	(0.0)	8	(6.0)
	抑うつ気分	1	(0.8)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	2	(1.5)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　CT-3.2　FINAL

表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
精神障害	うつ病	0	(0.0)	2	(2.1)	1	(1.4)	0	(0.0)	0	(0.0)	3	(2.3)
	軽躁	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	初期不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不眠症	3	(2.3)	2	(2.1)	1	(1.4)	3	(5.7)	0	(0.0)	7	(5.3)
	易刺激性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	躁病	5	(3.8)	3	(3.1)	1	(1.4)	5	(9.4)	0	(0.0)	14	(10.5)
	神経過敏	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	悪夢	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	パニック発作	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	精神運動制止遅滞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	落ち着きのなさ	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	睡眠障害	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	社会逃避行動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	夢遊症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺企図	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	緊張	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	感情不安定	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	双極性障害	2	(1.5)	2	(2.1)	0	(0.0)	1	(1.9)	0	(0.0)	5	(3.8)
	大うつ病	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n (%)	3-6 MONTHS (N=96) n (%)	6-9 MONTHS (N=71) n (%)	9-12 MONTHS (N=53) n (%)	> 12 MONTHS (N=26) n (%)	TOTAL (N=133) n (%)
神経系障害	アカシジア	2 (1.5)	1 (1.0)	0 (0.0)	1 (1.9)	1 (3.8)	4 (3.0)
	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (0.8)
	浮動性めまい	0 (0.0)	1 (1.0)	0 (0.0)	1 (1.9)	0 (0.0)	2 (1.5)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.9)	0 (0.0)	1 (0.8)
	ジスキネジア	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	錐体外路障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	頭痛	5 (3.8)	2 (2.1)	0 (0.0)	3 (5.7)	0 (0.0)	9 (6.8)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神運動亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	失神	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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PROGRAM: C:¥OPC14597¥SCS¥ADAE22.SAS
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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
神経系障害	一過性脳虚血発作	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	振戦	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	下肢静止不能症候群	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	脳損傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
眼障害	眼痛	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	霧視	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
心臓障害	心房細動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	徐脈	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心肺停止	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
血管障害	本態性高血圧症	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	高血圧	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
呼吸器、胸郭および縦隔障害	喘息	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咳嗽	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	呼吸不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	アレルギー性副鼻腔炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	気道うっ血	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
呼吸器、胸郭および縦隔障害	口腔咽頭痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
胃腸障害	腹部膨満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腹痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	上腹部痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(3.8)	1	(0.8)
	潰瘍性大腸炎	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	便秘	0	(0.0)	2	(2.1)	1	(1.4)	2	(3.8)	0	(0.0)	4	(3.0)
	齲歯	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	下痢	4	(3.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	口内乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	消化不良	1	(0.8)	2	(2.1)	0	(0.0)	1	(1.9)	0	(0.0)	4	(3.0)
	食中毒	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胃食道逆流性疾患	0	(0.0)	1	(1.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	歯肉痛	0	(0.0)	0	(0.0)	0	(0.0)	2	(3.8)	0	(0.0)	2	(1.5)
	血便排泄	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	悪心	2	(1.5)	3	(3.1)	0	(0.0)	1	(1.9)	0	(0.0)	6	(4.5)
	口腔内不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	流涎過多	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯の知覚過敏	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	舌腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
胃腸障害	歯痛	1	(0.8)	1	(1.0)	1	(1.4)	1	(1.9)	0	(0.0)	3	(2.3)
	嘔吐	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	腹壁嚢胞	1	(0.8)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	痔出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
肝胆道系障害	脂肪肝	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
皮膚および皮下組織障害	ざ瘡	1	(0.8)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	接触性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	皮膚乾燥	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	湿疹	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
	紅斑	1	(0.8)	0	(0.0)	1	(1.4)	1	(1.9)	0	(0.0)	1	(0.8)
	寝汗	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	粃糠疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	そう痒症	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	発疹	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
筋骨格系および結合組織障害	関節痛	2	(1.5)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	3	(2.3)
	関節炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
筋骨格系および結合組織障害	背部痛	1	(0.8)	3	(3.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	筋肉内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋痙縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋攣縮	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	筋力低下	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋骨格痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	1	(0.8)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	2	(1.5)
	頚部痛	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	四肢痛	3	(2.3)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	顎痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	足底筋膜炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	肩回旋筋腱板症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	顎関節症候群	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	開口障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格硬直	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(3.8)	2	(1.5)
	筋浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
腎および尿路障害	排尿困難	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(3.8)	1	(0.8)
	緊張性膀胱	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎結石症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
生殖系および乳房障害	子宮頚部嚢胞	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	月経困難症	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	射精障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(3.8)	1	(0.8)
	不規則月経	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	骨盤癒着症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	性機能不全	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	陰茎分泌物	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	勃起不全	1	(0.8)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)
一般・全身障害および投与部位の状態	無力症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疲労	0	(0.0)	1	(1.0)	0	(0.0)	1	(1.9)	0	(0.0)	2	(1.5)
	注射部位疼痛	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	注射部位そう痒感	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	倦怠感	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	末梢性浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不活発	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	非心臓性胸痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n	(%)	3-6 MONTHS (N=96) n	(%)	6-9 MONTHS (N=71) n	(%)	9-12 MONTHS (N=53) n	(%)	> 12 MONTHS (N=26) n	(%)	TOTAL (N=133) n	(%)
臨床検査	アラニンアミノトランスフェラーゼ増加	0	(0.0)	0	(0.0)	1	(1.4)	1	(1.9)	0	(0.0)	2	(1.5)
	アスパラギン酸アミノトランスフェラーゼ増加	0	(0.0)	0	(0.0)	1	(1.4)	1	(1.9)	0	(0.0)	2	(1.5)
	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	(3.8)	1	(0.8)
	血中ブドウ糖増加	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	血中インスリン増加	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	血中カリウム減少	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.9)	0	(0.0)	1	(0.8)
	血圧上昇	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	心電図ＳＴ部分下降	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	グリコヘモグロビン増加	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	体重減少	1	(0.8)	1	(1.0)	3	(4.2)	0	(0.0)	0	(0.0)	5	(3.8)
	体重増加	1	(0.8)	2	(2.1)	2	(2.8)	2	(3.8)	1	(3.8)	8	(6.0)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(3.8)	1	(0.8)
傷害、中毒および処置合併症	節足動物咬傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	転倒	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	足骨折	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	裂傷	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

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表 2.7.4.7-215　初回発現時期別有害事象［二重盲検試験，二重盲検期（Phase D）］

CT-3.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and
MedDRA Preferred Term Started within Certain Time Period after First Injection in Trial 31-08-250 Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=133) n (%)	3-6 MONTHS (N=96) n (%)	6-9 MONTHS (N=71) n (%)	9-12 MONTHS (N=53) n (%)	> 12 MONTHS (N=26) n (%)	TOTAL (N=133) n (%)
傷害、中毒および処置合併症	靱帯捻挫	1 (0.8)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	橈骨骨折	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.8)
	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	脊柱損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
社会環境	個人衛生不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		54 (40.6)	37 (38.5)	24 (33.8)	22 (41.5)	4 (15.4)	89 (66.9)

NOTE: All adverse events started after first injection in placebo-controlled randomization phase are included in the analysis.
Subjects are counted once per term for multiple occurrences of a specific MedDRA preferred term within the specified time interval.
Denominator (N) for percentages is number of subjects staying in the specified time interval.
1)Subjects with adverse events in multiple system organ classes were counted only once towards the total.

FILE: ADAE22B.LIS, RUN: [redacted]20[redacted] 10:02; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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＜資料番号 5.3.5.3-01：SCS CT-3.2 より作成＞

表 2.7.4.7-216　Hy’s Law の基準に合致した被験者［長期投与試験］

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CT-9.5
Listing of Potential Hy`s Law Cases by Phase
(Enrolled Sample)

NO RESULTS SATISFY HY`S LAW CRITERIA

HY'S LAW: AST OR ALT >= 3X UPPER LIMIT OF NORMAL VALUE IF BASELINE VALUE WAS NORMAL (AST OR ALT >= 3X BASELINE IF BASELINE VALUE WAS ABNORMAL) AND TOTAL BILIRUBIN >= 2X UPPER LIMIT OF NORMAL VALUE IF BASELINE VALUE WAS NORMAL (TOTAL BILIRUBIN >= 2X BASELINE IF BASELINE VALUE WAS ABNORMAL).
[1]SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.

FILE: ADLB5A.LIS, RUN: [redacted]20[redacted] 13:52; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:45
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADLB5.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.5　FINAL

＜資料番号 5.3.5.2-01：CT-9.5＞

表 2.7.4.7-217　アリピプラゾール IM デポ注射剤の用量を変更した被験者［日本人集団，二重盲検試験，二重盲検期（Phase D）］

CT-7.2.3R
Descriptive Statistics for Starting and Ending Dose Level of Aripiprazole/Placebo IM Depot by Titration Pattern
(Phase D Safety Sample)

			PHASE D TREATMENT					
			ARIP IMD (N=9)		PLACEBO (N=10)		TOTAL (N=19)	
PHASE	STARTING DOSE LEVEL	CHANGE	n	(%)	n	(%)	n	(%)
PHASE C	400 MG	NO CHANGE	6	(66.7)	10	(100.0)	16	(84.2)
		DECREASED	3	(33.3)	0	(0.0)	3	(15.8)
PHASE D	400 MG	NO CHANGE	6	(66.7)	8	(80.0)	14	(73.7)
		DECREASED	0	(0.0)	2	(20.0)	2	(10.5)
	300 MG	NO CHANGE	3	(33.3)	0	(0.0)	3	(15.8)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS TREATED IN PHASE D.

FILE: ADEX2AD.LIS, RUN: [redacted]20[redacted] 09:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 09:44
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J3¥ADEX2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-7.2.3　FINAL

＜資料番号 5.3.5.3-01：CT-7.2.3R＞

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	気管支炎	0 (0.0)	3 (2.4)	3 (2.3)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	4 (1.6)	5 (1.9)
	蜂巣炎	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	胃腸炎	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	ウイルス性胃腸炎	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (1.2)	3 (1.1)
	麦粒腫	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	インフルエンザ	0 (0.0)	3 (2.4)	3 (2.3)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	4 (1.6)	5 (1.9)
	喉頭炎	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	鼻咽頭炎	2 (22.2)	8 (6.5)	10 (7.6)	6 (60.0)	7 (5.7)	13 (9.8)	8 (42.1)	15 (6.1)	23 (8.7)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	外耳炎	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	中耳炎	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	咽頭炎	1 (11.1)	0 (0.0)	1 (0.8)	1 (10.0)	1 (0.8)	2 (1.5)	2 (10.5)	1 (0.4)	3 (1.1)
	レンサ球菌性咽頭炎	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (1.2)	3 (1.1)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.R　FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
感染症および寄生虫症	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	副鼻腔炎	0 (0.0)	5 (4.1)	5 (3.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	6 (2.4)	6 (2.3)
	須毛瘡	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	足部白癬	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	歯膿瘍	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	トリコモナス症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	上気道感染	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	6 (4.9)	6 (4.5)	0 (0.0)	10 (4.1)	10 (3.8)
	尿路感染	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	6 (2.4)	6 (2.3)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	歯感染	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (1.2)	3 (1.1)
	無症候性細菌尿	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	クラミジア感染	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	真菌性口腔咽頭炎	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	気道感染	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.R　FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
血液およびリンパ系障害	貧血	1 (11.1)	2 (1.6)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	2 (0.8)	3 (1.1)
	白血球減少症	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	好中球減少症	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
内分泌障害	高プロラクチン血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
代謝および栄養障害	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	高血糖	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	食欲亢進	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	5 (2.0)	5 (1.9)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	食欲減退	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	激越	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	5 (2.0)	5 (1.9)
	不安	1 (11.1)	8 (6.5)	9 (6.8)	2 (20.0)	4 (3.3)	6 (4.5)	3 (15.8)	12 (4.9)	15 (5.7)
	無感情	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)

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表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
精神障害	双極１型障害	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	8 (6.5)	8 (6.0)	0 (0.0)	10 (4.1)	10 (3.8)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	抑うつ気分	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	2 (0.8)	3 (1.1)
	うつ病	1 (11.1)	3 (2.4)	4 (3.0)	0 (0.0)	3 (2.4)	3 (2.3)	1 (5.3)	6 (2.4)	7 (2.6)
	軽躁	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	初期不眠症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	不眠症	0 (0.0)	10 (8.1)	10 (7.6)	1 (10.0)	9 (7.3)	10 (7.5)	1 (5.3)	19 (7.7)	20 (7.5)
	易刺激性	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	リビドー減退	0 (0.0)	3 (2.4)	3 (2.3)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	4 (1.6)	5 (1.9)
	躁病	1 (11.1)	2 (1.6)	3 (2.3)	3 (30.0)	11 (8.9)	14 (10.5)	4 (21.1)	13 (5.3)	17 (6.4)
	中期不眠症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	悪夢	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	パニック発作	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	精神運動制止遅滞	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	落ち着きのなさ	1 (11.1)	5 (4.1)	6 (4.5)	0 (0.0)	5 (4.1)	5 (3.8)	1 (5.3)	10 (4.1)	11 (4.2)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	社会逃避行動	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	夢遊症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	自殺企図	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.2.R　FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
精神障害	感情不安定	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	ディスフェミア	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	双極性障害	0 (0.0)	5 (4.1)	5 (3.8)	0 (0.0)	5 (4.1)	5 (3.8)	0 (0.0)	10 (4.1)	10 (3.8)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
神経系障害	アカシジア	0 (0.0)	28 (22.8)	28 (21.2)	2 (20.0)	15 (12.2)	17 (12.8)	2 (10.5)	43 (17.5)	45 (17.0)
	運動緩慢	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	注意力障害	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	浮動性めまい	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	2 (0.8)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	ジスキネジア	0 (0.0)	2 (1.6)	2 (1.5)	2 (20.0)	0 (0.0)	2 (1.5)	2 (10.5)	2 (0.8)	4 (1.5)
	錐体外路障害	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	4 (1.6)	4 (1.5)
	頭痛	0 (0.0)	4 (3.3)	4 (3.0)	2 (20.0)	7 (5.7)	9 (6.8)	2 (10.5)	11 (4.5)	13 (4.9)
	過眠症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	感覚鈍麻	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	嗜眠	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	錯感覚	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	パーキンソニズム	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	精神運動亢進	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.R　FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
神経系障害	坐骨神経痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	鎮静	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	傾眠	0 (0.0)	6 (4.9)	6 (4.5)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	7 (2.8)	7 (2.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	遅発性ジスキネジア	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	一過性脳虚血発作	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	振戦	0 (0.0)	3 (2.4)	3 (2.3)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	4 (1.6)	5 (1.9)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	脳損傷	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
眼障害	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	羞明	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	霧視	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	3 (1.1)
耳および迷路障害	耳鳴	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
心臓障害	心房細動	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	第一度房室ブロック	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	徐脈	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	心肺停止	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.R　FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
血管障害	本態性高血圧症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	高血圧	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	4 (1.6)	4 (1.5)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	呼吸不全	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	アレルギー性副鼻腔炎	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	気道うっ血	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	口腔咽頭痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
胃腸障害	腹部膨満	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	上腹部痛	0 (0.0)	2 (1.6)	2 (1.5)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	2 (0.8)	3 (1.1)
	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	便秘	1 (11.1)	3 (2.4)	4 (3.0)	1 (10.0)	3 (2.4)	4 (3.0)	2 (10.5)	6 (2.4)	8 (3.0)
	齲歯	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
	下痢	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	3 (2.4)	4 (3.0)	1 (5.3)	4 (1.6)	5 (1.9)
	口内乾燥	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	7 (2.8)	7 (2.6)
	消化不良	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	5 (2.0)	5 (1.9)

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.2.R FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
胃腸障害	食中毒	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	1 (0.4)	2 (0.8)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	悪心	0 (0.0)	3 (2.4)	3 (2.3)	2 (20.0)	4 (3.3)	6 (4.5)	2 (10.5)	7 (2.8)	9 (3.4)
	口腔内不快感	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	流涎過多	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	6 (2.4)	6 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	舌腫脹	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	歯痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	4 (1.6)	4 (1.5)
	嘔吐	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	4 (1.6)	4 (1.5)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	痔出血	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
肝胆道系障害	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	皮膚炎	1 (11.1)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	1 (0.4)	2 (0.8)
	接触性皮膚炎	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)

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表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
皮膚および皮下組織障害	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	寝汗	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	粃糠疹	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	発疹	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
筋骨格系および結合組織障害	関節痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	4 (1.6)	4 (1.5)
	関節炎	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	背部痛	1 (11.1)	2 (1.6)	3 (2.3)	1 (10.0)	3 (2.4)	4 (3.0)	2 (10.5)	5 (2.0)	7 (2.6)
	筋肉内出血	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	筋痙縮	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	筋骨格痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	頚部痛	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	4 (1.6)	4 (1.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.R　FINAL

表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
筋骨格系および結合組織障害	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	肩回旋筋腱板症候群	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	開口障害	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	筋骨格硬直	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	1 (0.8)	2 (1.5)	1 (5.3)	2 (0.8)	3 (1.1)
	筋浮腫	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
腎および尿路障害	排尿困難	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	緊張性膀胱	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	腎結石症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
生殖系および乳房障害	子宮頚部嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	射精遅延	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	月経過多	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
生殖系および乳房障害	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	卵巣嚢胞	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	性機能不全	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	勃起不全	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (1.2)	3 (1.1)
一般・全身障害および投与部位の状態	無力症	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	疲労	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	5 (4.1)	5 (3.8)	0 (0.0)	9 (3.7)	9 (3.4)
	注射部位疼痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	末梢性浮腫	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	不活発	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	非心臓性胸痛	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
臨床検査	アラニンアミノトランスフェラーゼ増加	0 (0.0)	1 (0.8)	1 (0.8)	2 (20.0)	0 (0.0)	2 (1.5)	2 (10.5)	1 (0.4)	3 (1.1)

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表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
臨床検査	アスパラギン酸アミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	2 (20.0)	0 (0.0)	2 (1.5)	2 (10.5)	0 (0.0)	2 (0.8)
	血中クレアチンホスホキナーゼ増加	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	4 (1.6)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	血中インスリン増加	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (1.2)	3 (1.1)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	血圧上昇	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (1.2)	3 (1.1)
	心電図ＳＴ部分下降	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	5 (4.1)	6 (4.5)	1 (5.3)	5 (2.0)	6 (2.3)
	体重増加	1 (11.1)	30 (24.4)	31 (23.5)	3 (30.0)	21 (17.1)	24 (18.0)	4 (21.1)	51 (20.7)	55 (20.8)
	肝機能検査値上昇	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	足骨折	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	裂傷	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)

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表 2.7.4.7-218　有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.2.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
傷害、中毒および処置合併症	挫傷	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	胸部損傷	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	歯牙破折	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	処置による疼痛	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	5 (2.0)	5 (1.9)
	脊柱損傷	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	注射に伴う反応	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	外傷後頸部症候群	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
社会環境	個人衛生不良	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
TOTAL1)		6 (66.7)	95 (77.2)	101 (76.5)	8 (80.0)	99 (80.5)	107 (80.5)	14 (73.7)	194 (78.9)	208 (78.5)

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＜資料番号 5.3.5.3-01：CT-8.2.2.R より作成＞

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	気管支炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)
	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	麦粒腫	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	喉頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	2 (22.2)	0 (0.0)	0 (0.0)	7 (5.7)	1 (0.8)	0 (0.0)	9 (6.8)	1 (0.8)	0 (0.0)
	精巣炎	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)
	外耳炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	咽頭炎	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	乳房蜂巣炎	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)
	気管支炎	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	蜂巣炎	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)
	結膜炎	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	胃腸炎	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)
	ウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	麦粒腫	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)
	インフルエンザ	0 (0.0)	1 (10.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)
	喉頭炎	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)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	鼻咽頭炎	5 (50.0)	1 (10.0)	0 (0.0)	7 (5.7)	0 (0.0)	0 (0.0)	12 (9.0)	1 (0.8)	0 (0.0)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	外耳炎	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)
	中耳炎	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)
	咽頭炎	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	レンサ球菌性咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	気管支炎	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	3 (1.2)	0 (0.0)	2 (0.8)	3 (1.1)	0 (0.0)
	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	結膜炎	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)
	麦粒腫	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	インフルエンザ	0 (0.0)	1 (5.3)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	2 (0.8)	3 (1.1)	0 (0.0)
	喉頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	鼻咽頭炎	7 (36.8)	1 (5.3)	0 (0.0)	14 (5.7)	1 (0.4)	0 (0.0)	21 (7.9)	2 (0.8)	0 (0.0)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	外耳炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	咽頭炎	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)
	レンサ球菌性咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	肺炎	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)
	鼻炎	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)
	副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	3 (2.4)	0 (0.0)	2 (1.5)	3 (2.3)	0 (0.0)
	須毛瘡	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	歯膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	トリコモナス症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	無症候性細菌尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	クラミジア感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	真菌性口腔咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	須毛瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	歯膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	トリコモナス症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	3 (2.4)	0 (0.0)	3 (2.3)	3 (2.3)	0 (0.0)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	歯感染	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	無症候性細菌尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	クラミジア感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	真菌性口腔咽頭炎	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)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	口腔ヘルペス	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	3 (1.2)	0 (0.0)	3 (1.1)	3 (1.1)	0 (0.0)
	須毛瘡	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	歯膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)
	トリコモナス症	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.4)	4 (1.6)	0 (0.0)	6 (2.3)	4 (1.5)	0 (0.0)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	1 (0.4)	0 (0.0)	5 (1.9)	1 (0.4)	0 (0.0)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	歯感染	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)
	無症候性細菌尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	クラミジア感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	真菌性口腔咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	口腔ヘルペス	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
血液およびリンパ系障害	貧血	1 (11.1)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
	白血球減少症	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	好中球減少症	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
内分泌障害	高プロラクチン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	２型糖尿病	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)
精神障害	感情障害	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)
	攻撃性	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)
	激越	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
血液およびリンパ系障害	貧血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白血球減少症	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)
	好中球減少症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
内分泌障害	高プロラクチン血症	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
代謝および栄養障害	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	激越	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.6)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
血液およびリンパ系障害	貧血	1 (5.3)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)
	白血球減少症	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	好中球減少症	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
内分泌障害	高プロラクチン血症	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
代謝および栄養障害	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	0 (0.0)	0 (0.0)	5 (1.9)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	高脂血症	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	激越	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	2 (0.8)	0 (0.0)	3 (1.1)	2 (0.8)	0 (0.0)

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FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	不安	1 (11.1)	0 (0.0)	0 (0.0)	4 (3.3)	4 (3.3)	0 (0.0)	5 (3.8)	4 (3.0)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	うつ病	1 (11.1)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	軽躁	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	初期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.1)	4 (3.3)	1 (0.8)	5 (3.8)	4 (3.0)	1 (0.8)
	易刺激性	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	リビドー減退	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	1 (0.8)	1 (0.8)
	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	精神運動制止遅滞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	落ち着きのなさ	0 (0.0)	1 (11.1)	0 (0.0)	2 (1.6)	3 (2.4)	0 (0.0)	2 (1.5)	4 (3.0)	0 (0.0)
	睡眠障害	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)
	社会逃避行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	不安	2 (20.0)	0 (0.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	5 (3.8)	1 (0.8)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	4 (3.3)	2 (1.6)	2 (1.5)	4 (3.0)	2 (1.5)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)
	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)
	初期不眠症	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)
	不眠症	0 (0.0)	0 (0.0)	1 (10.0)	7 (5.7)	2 (1.6)	0 (0.0)	7 (5.3)	2 (1.5)	1 (0.8)
	易刺激性	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)
	リビドー減退	1 (10.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	2 (20.0)	1 (10.0)	0 (0.0)	6 (4.9)	5 (4.1)	0 (0.0)	8 (6.0)	6 (4.5)
	中期不眠症	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)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	悪夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	精神運動制止遅滞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	1 (0.8)	0 (0.0)	4 (3.0)	1 (0.8)	0 (0.0)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	社会逃避行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	不安	3 (15.8)	0 (0.0)	0 (0.0)	7 (2.8)	5 (2.0)	0 (0.0)	10 (3.8)	5 (1.9)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	5 (2.0)	3 (1.2)	2 (0.8)	5 (1.9)	3 (1.1)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	1 (5.3)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)
	うつ病	1 (5.3)	0 (0.0)	0 (0.0)	3 (1.2)	3 (1.2)	0 (0.0)	4 (1.5)	3 (1.1)	0 (0.0)
	軽躁	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	初期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	0 (0.0)	1 (5.3)	12 (4.9)	6 (2.4)	1 (0.4)	12 (4.5)	6 (2.3)	2 (0.8)
	易刺激性	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	リビドー減退	1 (5.3)	0 (0.0)	0 (0.0)	4 (1.6)	0 (0.0)	0 (0.0)	5 (1.9)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	3 (15.8)	1 (5.3)	1 (0.4)	6 (2.4)	6 (2.4)	1 (0.4)	9 (3.4)	7 (2.6)
	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	悪夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	精神運動制止遅滞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	落ち着きのなさ	0 (0.0)	1 (5.3)	0 (0.0)	6 (2.4)	4 (1.6)	0 (0.0)	6 (2.3)	5 (1.9)	0 (0.0)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	社会逃避行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	夢遊症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情不安定	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	1 (0.8)	0 (0.0)	4 (3.0)	1 (0.8)
	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)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	0 (0.0)	0 (0.0)	0 (0.0)	16 (13.0)	11 (8.9)	1 (0.8)	16 (12.1)	11 (8.3)	1 (0.8)
	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	浮動性めまい	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)
	ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	頭痛	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	夢遊症	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)
	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	感情不安定	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	4 (3.3)	0 (0.0)	1 (0.8)	4 (3.0)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	2 (20.0)	0 (0.0)	0 (0.0)	9 (7.3)	6 (4.9)	0 (0.0)	11 (8.3)	6 (4.5)	0 (0.0)
	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	浮動性めまい	1 (10.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	構語障害	0 (0.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	ジスキネジア	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	頭痛	2 (20.0)	0 (0.0)	0 (0.0)	4 (3.3)	3 (2.4)	0 (0.0)	6 (4.5)	3 (2.3)	0 (0.0)
	過眠症	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)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	夢遊症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	自殺企図	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	感情不安定	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	5 (2.0)	0 (0.0)	5 (1.9)	5 (1.9)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	2 (10.5)	0 (0.0)	0 (0.0)	25 (10.2)	17 (6.9)	1 (0.4)	27 (10.2)	17 (6.4)	1 (0.4)
	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	浮動性めまい	1 (5.3)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)
	構語障害	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	ジスキネジア	2 (10.5)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	4 (1.5)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)
	頭痛	2 (10.5)	0 (0.0)	0 (0.0)	7 (2.8)	4 (1.6)	0 (0.0)	9 (3.4)	4 (1.5)	0 (0.0)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
神経系障害	片頭痛	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)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	精神運動亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	2 (1.6)	0 (0.0)	4 (3.0)	2 (1.5)	0 (0.0)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	一過性脳虚血発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	振戦	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脳損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
眼障害	眼痛	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)
	羞明	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
神経系障害	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	精神運動亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	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)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	一過性脳虚血発作	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)
	振戦	1 (10.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	脳損傷	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)
眼障害	眼痛	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	羞明	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
神経系障害	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	精神運動亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	2 (0.8)	0 (0.0)	5 (1.9)	2 (0.8)	0 (0.0)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	一過性脳虚血発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	振戦	1 (5.3)	0 (0.0)	0 (0.0)	3 (1.2)	1 (0.4)	0 (0.0)	4 (1.5)	1 (0.4)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	脳損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
眼障害	眼痛	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	羞明	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
心臓障害	心房細動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	第一度房室ブロック	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	心肺停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
血管障害	本態性高血圧症	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)
	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)
	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)
	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	アレルギー性副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	口腔咽頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
胃腸障害	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	腹痛	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)
	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
心臓障害	心房細動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	第一度房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	心肺停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	本態性高血圧症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)
呼吸器、胸郭および縦隔障害	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)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	アレルギー性副鼻腔炎	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)
	気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	口腔咽頭痛	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)
胃腸障害	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	上腹部痛	0 (0.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
心臓障害	心房細動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	第一度房室ブロック	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	心肺停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
血管障害	本態性高血圧症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	アレルギー性副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	口腔咽頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
胃腸障害	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	上腹部痛	0 (0.0)	1 (5.3)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
胃腸障害	潰瘍性大腸炎	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)
	便秘	1 (11.1)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	下痢	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.6)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	食中毒	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉痛	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)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	口腔内不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痔出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	便秘	1 (10.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	齲歯	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	下痢	1 (10.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	食中毒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	歯肉痛	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	悪心	1 (10.0)	1 (10.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	4 (3.0)	2 (1.5)	0 (0.0)
	口腔内不快感	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)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	舌腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	痔出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	便秘	2 (10.5)	0 (0.0)	0 (0.0)	6 (2.4)	0 (0.0)	0 (0.0)	8 (3.0)	0 (0.0)	0 (0.0)
	齲歯	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	下痢	1 (5.3)	0 (0.0)	0 (0.0)	4 (1.6)	0 (0.0)	0 (0.0)	5 (1.9)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	4 (1.6)	0 (0.0)	3 (1.1)	4 (1.5)	0 (0.0)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	0 (0.0)	0 (0.0)	5 (1.9)	0 (0.0)	0 (0.0)
	食中毒	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	歯肉痛	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	悪心	1 (5.3)	1 (5.3)	0 (0.0)	5 (2.0)	2 (0.8)	0 (0.0)	6 (2.3)	3 (1.1)	0 (0.0)
	口腔内不快感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	1 (0.4)	0 (0.0)	5 (1.9)	1 (0.4)	0 (0.0)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	舌腫脹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)	0 (0.0)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	1 (0.4)	0 (0.0)	3 (1.1)	1 (0.4)	0 (0.0)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	痔出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
肝胆道系障害	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)	0 (0.0)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	皮膚炎	1 (11.1)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	接触性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	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)
	多汗症	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)
	寝汗	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	粃糠疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
筋骨格系および結合組織障害	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)
	背部痛	1 (11.1)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
	筋肉内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
肝胆道系障害	脂肪肝	0 (0.0)	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)
	接触性皮膚炎	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	湿疹	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	紅斑	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	寝汗	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	粃糠疹	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)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	発疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
筋骨格系および結合組織障害	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)
	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)
	背部痛	1 (10.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	筋肉内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
肝胆道系障害	脂肪肝	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	皮膚炎	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	接触性皮膚炎	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	湿疹	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	紅斑	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	寝汗	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	粃糠疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	発疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
筋骨格系および結合組織障害	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	3 (1.2)	0 (0.0)	1 (0.4)	3 (1.1)	0 (0.0)
	関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)
	背部痛	2 (10.5)	0 (0.0)	0 (0.0)	4 (1.6)	1 (0.4)	0 (0.0)	6 (2.3)	1 (0.4)	0 (0.0)
	筋肉内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)											
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
筋骨格系および結合組織障害	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	筋攣縮	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)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	筋肉痛	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)
	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	四肢痛	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)
	顎痛	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)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肩回旋筋腱板症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	筋浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
腎および尿路障害	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)
	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	腎結石症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
筋骨格系および結合組織障害	筋痙縮	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)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	筋骨格痛	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)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	頚部痛	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	肩回旋筋腱板症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	開口障害	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)
	筋骨格硬直	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	筋浮腫	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)
腎および尿路障害	排尿困難	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎結石症	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)

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
筋骨格系および結合組織障害	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	頚部痛	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.6)	0 (0.0)	0 (0.0)	4 (1.5)	0 (0.0)	0 (0.0)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	肩回旋筋腱板症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	筋骨格硬直	0 (0.0)	1 (5.3)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)
	筋浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
腎および尿路障害	排尿困難	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	腎結石症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)

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CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
生殖系および乳房障害	子宮頚部嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経困難症	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)
	射精遅延	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	射精障害	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)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	無力症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	疲労	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
生殖系および乳房障害	子宮頚部嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	月経困難症	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	射精遅延	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	射精障害	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
一般・全身障害および投与部位の状態	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)
	疲労	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	2 (1.6)	0 (0.0)	3 (2.3)	2 (1.5)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
生殖系および乳房障害	子宮頚部嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	月経困難症	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	射精遅延	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	射精障害	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)
一般・全身障害および投与部位の状態	無力症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	疲労	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.4)	3 (1.2)	0 (0.0)	6 (2.3)	3 (1.1)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
一般・全身障害および投与部位の状態	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	注射部位そう痒感	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)
	倦怠感	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)
	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
臨床検査	アラニンアミノトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	アスパラギン酸アミノトランスフェラーゼ増加	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)
	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)	3 (2.4)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	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)
	血中インスリン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	血中カリウム減少	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)
	血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	心電図ＳＴ部分下降	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
一般・全身障害および投与部位の状態	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	倦怠感	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	末梢性浮腫	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)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	非心臓性胸痛	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)
臨床検査	アラニンアミノトランスフェラーゼ増加	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	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 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	血中インスリン増加	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	心電図ＳＴ部分下降	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
一般・全身障害および投与部位の状態	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	倦怠感	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
臨床検査	アラニンアミノトランスフェラーゼ増加	2 (10.5)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (10.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	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)	4 (1.6)	0 (0.0)	0 (0.0)	4 (1.5)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	血中インスリン増加	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)
	心電図ＳＴ部分下降	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
臨床検査	グリコヘモグロビン増加	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)
	体重減少	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)
	体重増加	1 (11.1)	0 (0.0)	0 (0.0)	23 (18.7)	7 (5.7)	0 (0.0)	24 (18.2)	7 (5.3)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	節足動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)
	橈骨骨折	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)
	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	胸部損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	処置による疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	3 (2.4)	0 (0.0)	1 (0.8)	3 (2.3)	0 (0.0)
	脊柱損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
臨床検査	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	体重減少	1 (10.0)	0 (0.0)	0 (0.0)	5 (4.1)	0 (0.0)	0 (0.0)	6 (4.5)	0 (0.0)	0 (0.0)
	体重増加	2 (20.0)	1 (10.0)	0 (0.0)	16 (13.0)	5 (4.1)	0 (0.0)	18 (13.5)	6 (4.5)	0 (0.0)
	肝機能検査値上昇	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	節足動物咬傷	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)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	足骨折	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)
	裂傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	挫傷	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)
	胸部損傷	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)
	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)	0 (0.0)
	処置による疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	脊柱損傷	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)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.2.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
臨床検査	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	体重減少	1 (5.3)	0 (0.0)	0 (0.0)	5 (2.0)	0 (0.0)	0 (0.0)	6 (2.3)	0 (0.0)	0 (0.0)
	体重増加	3 (15.8)	1 (5.3)	0 (0.0)	39 (15.9)	12 (4.9)	0 (0.0)	42 (15.8)	13 (4.9)	0 (0.0)
	肝機能検査値上昇	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	節足動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	裂傷	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	胸部損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	処置による疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	4 (1.6)	0 (0.0)	1 (0.4)	4 (1.5)	0 (0.0)
	脊柱損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
社会環境	個人衛生不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
TOTAL1)		4 (44.4)	2 (22.2)	0 (0.0)	40 (32.5)	47 (38.2)	8 (6.5)	44 (33.3)	49 (37.1)	8 (6.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
社会環境	個人衛生不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		3 (30.0)	4 (40.0)	1 (10.0)	36 (29.3)	49 (39.8)	14 (11.4)	39 (29.3)	53 (39.8)	15 (11.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.2.3.R

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
社会環境	個人衛生不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
TOTAL1)		7 (36.8)	6 (31.6)	1 (5.3)	76 (30.9)	96 (39.0)	22 (8.9)	83 (31.3)	102 (38.5)	23 (8.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	鼻咽頭炎	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)
	鼻炎	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)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
血液およびリンパ系障害	貧血	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	白血球減少症	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	好中球減少症	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
代謝および栄養障害	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	激越	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	不安	1 (11.1)	0 (0.0)	0 (0.0)	2 (1.6)	3 (2.4)	0 (0.0)	3 (2.3)	3 (2.3)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23BC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	鼻咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血液およびリンパ系障害	貧血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白血球減少症	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)
	好中球減少症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
代謝および栄養障害	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
精神障害	激越	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)
	不安	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
感染症および寄生虫症	鼻咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
血液およびリンパ系障害	貧血	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	白血球減少症	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	好中球減少症	1 (5.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
代謝および栄養障害	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	0 (0.0)	0 (0.0)	5 (1.9)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
精神障害	激越	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)
	不安	1 (5.3)	0 (0.0)	0 (0.0)	3 (1.2)	4 (1.6)	0 (0.0)	4 (1.5)	4 (1.5)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	双極１型障害	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)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	1 (11.1)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	初期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.6)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)
	リビドー減退	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.6)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)
	睡眠障害	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)
	夢遊症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	0 (0.0)	0 (0.0)	0 (0.0)	15 (12.2)	11 (8.9)	1 (0.8)	15 (11.4)	11 (8.3)	1 (0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	双極１型障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	初期不眠症	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)
	不眠症	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	2 (1.6)	0 (0.0)	4 (3.0)	2 (1.5)	0 (0.0)
	リビドー減退	1 (10.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	1 (10.0)	1 (10.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	3 (2.3)	1 (0.8)
	中期不眠症	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)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	1 (0.8)	0 (0.0)	4 (3.0)	1 (0.8)	0 (0.0)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	夢遊症	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)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	2 (20.0)	0 (0.0)	0 (0.0)	9 (7.3)	6 (4.9)	0 (0.0)	11 (8.3)	6 (4.5)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
精神障害	双極１型障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	うつ病	1 (5.3)	0 (0.0)	0 (0.0)	3 (1.2)	1 (0.4)	0 (0.0)	4 (1.5)	1 (0.4)	0 (0.0)
	初期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.4)	4 (1.6)	0 (0.0)	6 (2.3)	4 (1.5)	0 (0.0)
	リビドー減退	1 (5.3)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	0 (0.0)	4 (1.5)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	1 (5.3)	1 (5.3)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	3 (1.1)	1 (0.4)
	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.4)	3 (1.2)	0 (0.0)	6 (2.3)	3 (1.1)	0 (0.0)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	夢遊症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	2 (10.5)	0 (0.0)	0 (0.0)	24 (9.8)	17 (6.9)	1 (0.4)	26 (9.8)	17 (6.4)	1 (0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
神経系障害	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	浮動性めまい	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	頭痛	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)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	片頭痛	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)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	2 (1.6)	0 (0.0)	3 (2.3)	2 (1.5)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	振戦	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	羞明	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.3.3.R FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
神経系障害	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	ジスキネジア	2 (20.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	過眠症	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)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	1 (10.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
眼障害	羞明	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
神経系障害	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	浮動性めまい	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	ジスキネジア	2 (10.5)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	4 (1.5)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)
	頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.6)	2 (0.8)	0 (0.0)	4 (1.5)	2 (0.8)	0 (0.0)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	振戦	1 (5.3)	0 (0.0)	0 (0.0)	3 (1.2)	1 (0.4)	0 (0.0)	4 (1.5)	1 (0.4)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
眼障害	羞明	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
耳および迷路障害	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
心臓障害	第一度房室ブロック	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
血管障害	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
胃腸障害	便秘	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	多汗症	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)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
耳および迷路障害	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	第一度房室ブロック	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)
胃腸障害	便秘	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.6)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	悪心	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	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)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
耳および迷路障害	耳鳴	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
心臓障害	第一度房室ブロック	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
血管障害	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)	1 (0.4)	2 (0.8)	0 (0.0)
胃腸障害	便秘	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	0 (0.0)	0 (0.0)	3 (1.1)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	3 (1.2)	0 (0.0)	2 (0.8)	3 (1.1)	0 (0.0)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	悪心	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)	2 (0.8)	1 (0.4)	0 (0.0)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	1 (0.4)	0 (0.0)	5 (1.9)	1 (0.4)	0 (0.0)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	皮膚炎	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
皮膚および皮下組織障害	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)	0 (0.0)
筋骨格系および結合組織障害	筋攣縮	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)
	筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	顎痛	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)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
生殖系および乳房障害	射精遅延	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
皮膚および皮下組織障害	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
筋骨格系および結合組織障害	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	筋骨格痛	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)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	開口障害	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)
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
生殖系および乳房障害	射精遅延	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
皮膚および皮下組織障害	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
筋骨格系および結合組織障害	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	筋骨格痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
生殖系および乳房障害	射精遅延	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
生殖系および乳房障害	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	疲労	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.4)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)
	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	注射部位そう痒感	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)
	倦怠感	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)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
臨床検査	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)	2 (1.6)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	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)
	血中インスリン増加	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)
	グリコヘモグロビン増加	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)
	体重減少	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)
	体重増加	1 (11.1)	0 (0.0)	0 (0.0)	22 (17.9)	7 (5.7)	0 (0.0)	23 (17.4)	7 (5.3)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23BC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
生殖系および乳房障害	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	疲労	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.6)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)
	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	倦怠感	1 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
臨床検査	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)
	血中インスリン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.3)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)
	体重増加	1 (10.0)	0 (0.0)	0 (0.0)	15 (12.2)	5 (4.1)	0 (0.0)	16 (12.0)	5 (3.8)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23BC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
生殖系および乳房障害	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	疲労	0 (0.0)	0 (0.0)	0 (0.0)	5 (2.0)	3 (1.2)	0 (0.0)	5 (1.9)	3 (1.1)	0 (0.0)
	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	倦怠感	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
臨床検査	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)	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)
	血中インスリン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)	1 (0.4)	1 (0.4)	0 (0.0)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.6)	0 (0.0)	0 (0.0)	4 (1.5)	0 (0.0)	0 (0.0)
	体重増加	2 (10.5)	0 (0.0)	0 (0.0)	37 (15.0)	12 (4.9)	0 (0.0)	39 (14.7)	12 (4.5)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)								
		JPN (N=9)			NON-JPN (N=123)			TOTAL (N=132)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
傷害、中毒および処置合併症	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
TOTAL1)		5 (55.6)	0 (0.0)	0 (0.0)	46 (37.4)	30 (24.4)	1 (0.8)	51 (38.6)	30 (22.7)	1 (0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23BC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		PLACEBO (N=133)								
		JPN (N=10)			NON-JPN (N=123)			TOTAL (N=133)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
傷害、中毒および処置合併症	挫傷	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)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		2 (20.0)	1 (10.0)	1 (10.0)	35 (28.5)	25 (20.3)	3 (2.4)	37 (27.8)	26 (19.5)	4 (3.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23BC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

表 2.7.4.7-219　重症度別有害事象及び副作用［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.3.3.R

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Phase D by System Organ Class, MedDRA Preferred Term and Severity by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		TOTAL (N=265)								
		JPN (N=19)			NON-JPN (N=246)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %	MILD n %	MOD n %	SEV n %
傷害、中毒および処置合併症	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
	注射に伴う反応	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)
TOTAL1)		7 (36.8)	1 (5.3)	1 (5.3)	81 (32.9)	55 (22.4)	4 (1.6)	88 (33.2)	56 (21.1)	5 (1.9)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23BC.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3.R　FINAL

＜資料番号 5.3.5.3-01：CT-8.2.3.R，CT-8.3.3.R より作成＞

表 2.7.4.7-220　重篤な有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.5.2.R

Incidence of Serious Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
感染症および寄生虫症	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	双極１型障害	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	5 (2.0)	5 (1.9)
	軽躁	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	躁病	1 (11.1)	1 (0.8)	2 (1.5)	3 (30.0)	7 (5.7)	10 (7.5)	4 (21.1)	8 (3.3)	12 (4.5)
	自殺企図	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	感情不安定	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	双極性障害	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	4 (1.6)	4 (1.5)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
神経系障害	アカシジア	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	一過性脳虚血発作	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	脳損傷	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
心臓障害	心房細動	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	心肺停止	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AD.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.5.2.R FINAL

表 2.7.4.7-220　重篤な有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

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CT-8.5.2.R

Incidence of Serious Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	呼吸不全	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	痔出血	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
生殖系および乳房障害	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
傷害、中毒および処置合併症	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
TOTAL1)		2 (22.2)	8 (6.5)	10 (7.6)	3 (30.0)	22 (17.9)	25 (18.8)	5 (26.3)	30 (12.2)	35 (13.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AD.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.5.2.R　FINAL

＜資料番号 5.3.5.3-01：CT-8.5.2.R より作成＞

表 2.7.4.7-221　投与中止に至った有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.6.2.R

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase D
by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN) (Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
	不安	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	双極１型障害	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	8 (6.5)	8 (6.0)	0 (0.0)	10 (4.1)	10 (3.8)
	抑うつ気分	0 (0.0)	1 (0.8)	1 (0.8)	1 (10.0)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
	うつ病	1 (11.1)	3 (2.4)	4 (3.0)	0 (0.0)	3 (2.4)	3 (2.3)	1 (5.3)	6 (2.4)	7 (2.6)
	躁病	1 (11.1)	2 (1.6)	3 (2.3)	2 (20.0)	9 (7.3)	11 (8.3)	3 (15.8)	11 (4.5)	14 (5.3)
	自殺企図	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (0.8)	2 (0.8)
	感情不安定	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.4)
	双極性障害	0 (0.0)	5 (4.1)	5 (3.8)	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	9 (3.7)	9 (3.4)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	2 (0.8)
神経系障害	アカシジア	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.8)
	傾眠	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
血管障害	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	1 (0.4)
呼吸器、胸郭および縦隔障害	呼吸不全	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AE.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.6.2.R FINAL

表 2.7.4.7-221　投与中止に至った有害事象［日本，日本以外，二重盲検試験，二重盲検期（Phase D）］

CT-8.6.2.R

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase D
by System Organ Class and MedDRA Preferred Term by Region (JPN vs Non-JPN) (Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	JPN (N=9) n %	NON-JPN (N=123) n %	TOTAL (N=132) n %	JPN (N=10) n %	NON-JPN (N=123) n %	TOTAL (N=133) n %	JPN (N=19) n %	NON-JPN (N=246) n %	TOTAL (N=265) n %
臨床検査	体重増加	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
TOTAL1)		3 (33.3)	20 (16.3)	23 (17.4)	3 (30.0)	31 (25.2)	34 (25.6)	6 (31.6)	51 (20.7)	57 (21.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE23AE.LIS, RUN: [redacted]20[redacted] 11:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE23.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.2.R　FINAL

＜資料番号 5.3.5.3-01：CT-8.6.2.R より作成＞

表 2.7.4.7-222　最も新しい気分エピソード別アリピプラゾール IM デポ注射剤の曝露状況［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-7.2.1.2
Extent of Exposure to Trial Medication by Injection Dose - Aripiprazole IM Depot in Phase C
by Most Recent Episode in Japan (Phase C Enrolled Sample)

		MOST RECENT EPISODE											
		MANIC N=(39)						HYPOMANIC N=(7)					
		INJECTION DOSE						INJECTION DOSE					
		TOTAL		400 MG		300 MG		TOTAL		400 MG		300 MG	
PHASE	INJECTION	Ne	(%)1)	n	(%)2)	n	(%)2)	Ne	(%)1)	n	(%)2)	n	(%)2)
PHASE C	1ST INJECTION	39	(100.0)	38	(97.4)	1	(2.6)	7	(100.0)	7	(100.0)	0	(0.0)
	2ND INJECTION	39	(100.0)	33	(84.6)	6	(15.4)	6	(85.7)	5	(83.3)	1	(16.7)
	3RD INJECTION	37	(94.9)	29	(78.4)	8	(21.6)	6	(85.7)	4	(66.7)	2	(33.3)
	4TH INJECTION	36	(92.3)	28	(77.8)	8	(22.2)	5	(71.4)	4	(80.0)	1	(20.0)
	5TH INJECTION	36	(92.3)	27	(75.0)	9	(25.0)	5	(71.4)	4	(80.0)	1	(20.0)
	6TH INJECTION	36	(92.3)	26	(72.2)	10	(27.8)	4	(57.1)	4	(100.0)	0	(0.0)
	7TH INJECTION	35	(89.7)	26	(74.3)	9	(25.7)	4	(57.1)	4	(100.0)	0	(0.0)
	8TH INJECTION	26	(66.7)	20	(76.9)	6	(23.1)	4	(57.1)	4	(100.0)	0	(0.0)
	9TH INJECTION	25	(64.1)	19	(76.0)	6	(24.0)	4	(57.1)	4	(100.0)	0	(0.0)
	10TH INJECTION	25	(64.1)	17	(68.0)	8	(32.0)	4	(57.1)	4	(100.0)	0	(0.0)
	11TH INJECTION	24	(61.5)	16	(66.7)	8	(33.3)	4	(57.1)	4	(100.0)	0	(0.0)
	12TH INJECTION	23	(59.0)	16	(69.6)	7	(30.4)	4	(57.1)	4	(100.0)	0	(0.0)
	13TH INJECTION	23	(59.0)	16	(69.6)	7	(30.4)	4	(57.1)	4	(100.0)	0	(0.0)

1)DENOMINATOR FOR TOTAL GROUP IS NUMBER OF SUBJECTS ENROLLED IN PHASE C.
2)DENOMINATOR FOR 300 AND 400 MG GROUPS - NUMBER OF SUBJECTS IN TOTAL GROUP (Ne).

FILE: ADEX22AB.LIS, RUN: [redacted]20[redacted] 16:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:33
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADEX22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-7.2.1.2　FINAL

表 2.7.4.7-222　最も新しい気分エピソード別アリピプラゾール IM デポ注射剤の曝露状況［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-7.2.1.2
Extent of Exposure to Trial Medication by Injection Dose - Aripiprazole IM Depot in Phase C
by Most Recent Episode in Japan (Phase C Enrolled Sample)

		MOST RECENT EPISODE											
		MIXED N=(4)						DEPRESSIVE N=(25)					
		INJECTION DOSE						INJECTION DOSE					
		TOTAL		400 MG		300 MG		TOTAL		400 MG		300 MG	
PHASE	INJECTION	Ne	(%)1)	n	(%)2)	n	(%)2)	Ne	(%)1)	n	(%)2)	n	(%)2)
PHASE C	1ST INJECTION	4	(100.0)	4	(100.0)	0	(0.0)	25	(100.0)	25	(100.0)	0	(0.0)
	2ND INJECTION	3	(75.0)	3	(100.0)	0	(0.0)	24	(96.0)	21	(87.5)	3	(12.5)
	3RD INJECTION	3	(75.0)	2	(66.7)	1	(33.3)	22	(88.0)	18	(81.8)	4	(18.2)
	4TH INJECTION	3	(75.0)	2	(66.7)	1	(33.3)	22	(88.0)	17	(77.3)	5	(22.7)
	5TH INJECTION	3	(75.0)	2	(66.7)	1	(33.3)	22	(88.0)	16	(72.7)	6	(27.3)
	6TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	22	(88.0)	16	(72.7)	6	(27.3)
	7TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	22	(88.0)	16	(72.7)	6	(27.3)
	8TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	21	(84.0)	15	(71.4)	6	(28.6)
	9TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	21	(84.0)	15	(71.4)	6	(28.6)
	10TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	19	(76.0)	15	(78.9)	4	(21.1)
	11TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	19	(76.0)	15	(78.9)	4	(21.1)
	12TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	19	(76.0)	15	(78.9)	4	(21.1)
	13TH INJECTION	2	(50.0)	1	(50.0)	1	(50.0)	19	(76.0)	15	(78.9)	4	(21.1)

1)DENOMINATOR FOR TOTAL GROUP IS NUMBER OF SUBJECTS ENROLLED IN PHASE C.
2)DENOMINATOR FOR 300 AND 400 MG GROUPS - NUMBER OF SUBJECTS IN TOTAL GROUP (Ne).

FILE: ADEX22AB.LIS, RUN: [redacted]20[redacted] 16:20; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:33
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADEX22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-7.2.1.2　FINAL

表 2.7.4.7-222　最も新しい気分エピソード別アリピプラゾール IM デポ注射剤の曝露状況［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-7.2.1.2
Extent of Exposure to Trial Medication by Injection Dose - Aripiprazole IM Depot in Phase C
by Most Recent Episode in Japan (Phase C Enrolled Sample)

		MOST RECENT EPISODE					
		TOTAL N=(75)					
		INJECTION DOSE					
		TOTAL		400 MG		300 MG	
PHASE	INJECTION	Ne	(%)1)	n	(%)2)	n	(%)2)
PHASE C	1ST INJECTION	75	(100.0)	74	(98.7)	1	(1.3)
	2ND INJECTION	72	(96.0)	62	(86.1)	10	(13.9)
	3RD INJECTION	68	(90.7)	53	(77.9)	15	(22.1)
	4TH INJECTION	66	(88.0)	51	(77.3)	15	(22.7)
	5TH INJECTION	66	(88.0)	49	(74.2)	17	(25.8)
	6TH INJECTION	64	(85.3)	47	(73.4)	17	(26.6)
	7TH INJECTION	63	(84.0)	47	(74.6)	16	(25.4)
	8TH INJECTION	53	(70.7)	40	(75.5)	13	(24.5)
	9TH INJECTION	52	(69.3)	39	(75.0)	13	(25.0)
	10TH INJECTION	50	(66.7)	37	(74.0)	13	(26.0)
	11TH INJECTION	49	(65.3)	36	(73.5)	13	(26.5)
	12TH INJECTION	48	(64.0)	36	(75.0)	12	(25.0)
	13TH INJECTION	48	(64.0)	36	(75.0)	12	(25.0)

1)DENOMINATOR FOR TOTAL GROUP IS NUMBER OF SUBJECTS ENROLLED IN PHASE C.
2)DENOMINATOR FOR 300 AND 400 MG GROUPS - NUMBER OF SUBJECTS IN TOTAL GROUP (Ne).

FILE: ADEX22AB.LIS, RUN: [redacted]2C[redacted] 16:20; ANALYSIS DATASET CREATED: [redacted]2C[redacted] 13:33
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADEX22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-7.2.1.2　FINAL

＜資料番号 5.3.5.3-01：CT-7.2.1.2＞

表 2.7.4.7-223　アリピプラゾール IM デポ注射剤の用量を変更した被験者［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-7.2.3.1
Descriptive Statistics for Starting and Ending Dose Level of Aripiprazole IM Depot in Phase C
by Region (JAPAN/NON-JAPAN) (Phase C Enrolled Sample)

		REGION					
		JAPAN (N=75)		NON-JAPAN (N=389)		TOTAL (N=464)	
STARTING DOSE LEVEL	CHANGE	n	(%)	n	(%)	n	(%)
400 MG	NO CHANGE	50	(66.7)	284	(73.0)	334	(72.0)
	DECREASED	23	(30.7)	94	(24.2)	117	(25.2)
	DECREASED-INCREASED	1	(1.3)	10	(2.6)	11	(2.4)
300 MG	NO CHANGE	1	(1.3)	1	(0.3)	2	(0.4)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED PHASE C.

FILE: ADEX21AD.LIS, RUN: [redacted]20[redacted] 15:10; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:33
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADEX21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-7.2.3.1　FINAL

＜資料番号 5.3.5.3-01：CT-7.2.3.1＞

表 2.7.4.7-224　IMデポ剤維持治療期（Phase C）の錠剤開始投与量［日本人集団，長期投与試験］

ITEM		MANIC	DEPRESSIVE	TOTAL
STARTING DOSE (MG/DAY)	N	40	25	65
	MEAN	8.9	8.4	8.7
	SD	3.0	3.0	3.0
	MEDIAN	6.0	6.0	6.0
	MIN	6.0	6.0	6.0
	MAX	12.0	12.0	12.0

表 2.7.4.7-224　IMデポ剤維持治療期（Phase C）の錠剤開始投与量［日本人集団，長期投与試験］

ITEM		MANIC (N=40) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=65) n	(%)
STARTING DOSE (MG/DAY)	<6	0	(0.0)	0	(0.0)	0	(0.0)
	6	21	(52.5)	15	(60.0)	36	(55.4)
	12	19	(47.5)	10	(40.0)	29	(44.6)
	18	0	(0.0)	0	(0.0)	0	(0.0)
	>18	0	(0.0)	0	(0.0)	0	(0.0)

＜資料番号5.3.5.3-01：31-08-252 Table 5.3.5.3-6＞

表 2.7.4.7-225　錠剤安定期（Phase B）の錠剤各投与量別，最も新しい気分エピソード別の錠剤安定期（Phase B）記述統計量［日本人集団，長期投与試験］

Table 5.3.5.3-xx Trial Medication - Aripiprazole Tablets in Phase B
by Most Recent Episode in Japan (Phase B Safety Sample)

ITEM		MANIC	DEPRESSIVE	TOTAL
ENDING DOSE (MG/DAY)	N	46	26	72
	MEAN	17.7	14.8	16.7
	SD	6.7	4.9	6.2
	MEDIAN	12.0	12.0	12.0
	MIN	12.0	6.0	6.0
	MAX	30.0	30.0	30.0
STARTING DOSE (MG/DAY)	N	46	26	72
	MEAN	17.1	13.8	15.9
	SD	6.3	3.3	5.6
	MEDIAN	12.0	12.0	12.0
	MIN	12.0	12.0	12.0
	MAX	30.0	24.0	30.0
MAXIMUM DOSE (MG/DAY)	N	46	26	72
	MEAN	17.7	15.5	16.9
	SD	6.7	5.4	6.3
	MEDIAN	12.0	12.0	12.0
	MIN	12.0	12.0	12.0
	MAX	30.0	30.0	30.0
MOST FREQUENT DOSE (MG/DAY)	N	46	26	72
	MEAN	17.6	14.3	16.4
	SD	6.6	3.4	5.9
	MEDIAN	12.0	12.0	12.0
	MIN	12.0	12.0	12.0
	MAX	30.0	24.0	30.0
AVERAGE DAILY DOSE (MG)	N	46	26	72
	MEAN	17.2	14.1	16.1
	SD	6.4	3.4	5.6
	MEDIAN	12.0	12.0	12.0
	MIN	9.4	10.6	9.4
	MAX	30.0	24.0	30.0
DURATION OF TRIAL MEDICATION IN PHASE B (DAY)	N	46	26	72
	MEAN	29.6	30.1	29.8
	SD	9.7	8.7	9.3
	MEDIAN	28.0	28.0	28.0
	MIN	11.0	21.0	11.0
	MAX	70.0	68.0	70.0

表 2.7.4.7-225　錠剤安定期（Phase B）の錠剤各投与量別，最も新しい気分エピソード別の錠剤安定期（Phase B）記述統計量［日本人集団，長期投与試験］

Table 5.3.5.3-xx Trial Medication - Aripiprazole Tablets in Phase B
by Most Recent Episode in Japan (Phase B Safety Sample)

ITEM		MANIC (N=46) n	(%)	DEPRESSIVE (N=26) n	(%)	TOTAL (N=72) n	(%)
ENDING DOSE (MG/DAY)	<12	0	(0.0)	1	(3.8)	1	(1.4)
	12	24	(52.2)	15	(57.7)	39	(54.2)
	18	5	(10.9)	8	(30.8)	13	(18.1)
	24	12	(26.1)	1	(3.8)	13	(18.1)
	30	5	(10.9)	1	(3.8)	6	(8.3)
	>30	0	(0.0)	0	(0.0)	0	(0.0)
STARTING DOSE (MG/DAY)	<12	0	(0.0)	0	(0.0)	0	(0.0)
	12	25	(54.3)	19	(73.1)	44	(61.1)
	18	7	(15.2)	6	(23.1)	13	(18.1)
	24	10	(21.7)	1	(3.8)	11	(15.3)
	30	4	(8.7)	0	(0.0)	4	(5.6)
	>30	0	(0.0)	0	(0.0)	0	(0.0)
MAXIMUM DOSE (MG/DAY)	<12	0	(0.0)	0	(0.0)	0	(0.0)
	12	24	(52.2)	16	(61.5)	40	(55.6)
	18	5	(10.9)	7	(26.9)	12	(16.7)
	24	12	(26.1)	1	(3.8)	13	(18.1)
	30	5	(10.9)	2	(7.7)	7	(9.7)
	>30	0	(0.0)	0	(0.0)	0	(0.0)
MOST FREQUENT DOSE (MG/DAY)	<12	0	(0.0)	0	(0.0)	0	(0.0)
	12	24	(52.2)	17	(65.4)	41	(56.9)
	18	6	(13.0)	8	(30.8)	14	(19.4)
	24	11	(23.9)	1	(3.8)	12	(16.7)
	30	5	(10.9)	0	(0.0)	5	(6.9)
	>30	0	(0.0)	0	(0.0)	0	(0.0)
AVERAGE DAILY DOSE (MG)	<12	4	(8.7)	3	(11.5)	7	(9.7)
	12 - <18	22	(47.8)	17	(65.4)	39	(54.2)
	18 - <24	7	(15.2)	5	(19.2)	12	(16.7)
	24 - <30	9	(19.6)	1	(3.8)	10	(13.9)
	>=30	4	(8.7)	0	(0.0)	4	(5.6)
DURATION OF TRIAL MEDICATION IN PHASE B (DAY)	<=28	32	(69.6)	22	(84.6)	54	(75.0)
	29 - 42	11	(23.9)	3	(11.5)	14	(19.4)
	43 - 56	2	(4.3)	0	(0.0)	2	(2.8)
	57 - 70	1	(2.2)	1	(3.8)	2	(2.8)
	71 - 84	0	(0.0)	0	(0.0)	0	(0.0)
	>=85	0	(0.0)	0	(0.0)	0	(0.0)

＜資料番号5.3.5.3-01：31-08-252 Table 5.3.5.3-11＞

表 2.7.4.7-226　人口統計学的特性［日本，日本以外，長期投与試験，全集団］

CT-3.1.1.1
Demographic Characteristics by Region (JAPAN/NON-JAPAN)
(Enrolled Sample)

DEMOGRAPHIC CHARACTERISTICS		PHASE A JAPAN (N=39)	PHASE A NON-JAPAN (N=462)	PHASE A TOTAL (N=501)	PHASE B JAPAN (N=72)	PHASE B NON-JAPAN (N=483)	PHASE B TOTAL (N=555)	PHASE C JAPAN (N=75)	PHASE C NON-JAPAN (N=389)	PHASE C TOTAL (N=464)	TOTAL JAPAN (N=92)	TOTAL NON-JAPAN (N=656)	TOTAL TOTAL (N=748)
AGE (YEARS)	N	39	462	501	72	483	555	75	389	464	92	656	748
	MEAN	47.9	40.8	41.3	44.5	40.5	41.0	43.9	40.6	41.1	45.1	40.5	41.1
	SD	10.6	12.4	12.4	10.7	12.3	12.2	10.2	12.0	11.8	10.6	12.1	12.0
	MEDIAN	48.0	42.0	43.0	44.5	41.0	42.0	43.0	41.0	41.0	44.5	41.0	42.0
	MIN	29.0	18.0	18.0	21.0	18.0	18.0	21.0	18.0	18.0	21.0	18.0	18.0
	MAX	66.0	65.0	66.0	65.0	66.0	66.0	65.0	66.0	66.0	66.0	66.0	66.0
WEIGHT (KG)	N	39	462	501	72	481	553	75	389	464	92	656	748
	MEAN	65.7	87.8	86.0	67.4	89.5	86.6	67.7	90.2	86.6	67.5	89.1	86.5
	SD	12.1	23.2	23.3	12.9	24.1	24.1	13.7	24.8	24.8	13.6	23.9	24.0
	MEDIAN	67.0	83.6	82.2	66.5	85.2	83.1	67.3	86.8	83.9	67.5	85.0	83.0
	MIN	42.6	43.5	42.6	43.8	45.0	43.8	43.4	45.0	43.4	42.6	43.5	42.6
	MAX	92.0	191.8	191.8	102.8	189.1	189.1	101.4	187.3	187.3	102.8	191.8	191.8
HEIGHT (CM)	N	39	462	501	72	483	555	75	389	464	92	656	748
	MEAN	162.1	169.3	168.7	164.0	169.7	169.0	164.0	169.9	168.9	163.8	169.7	169.0
	SD	7.7	10.3	10.3	8.9	10.3	10.3	9.3	10.1	10.2	9.2	10.1	10.1
	MEDIAN	162.0	168.0	168.0	163.0	169.0	168.0	163.0	169.0	168.0	163.0	169.0	168.0
	MIN	146.0	130.0	130.0	146.0	130.0	130.0	146.0	141.0	141.0	146.0	130.0	130.0
	MAX	178.0	196.0	196.0	185.0	196.0	196.0	185.0	196.0	196.0	185.0	196.0	196.0

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE A, B, C AND THE TRIAL PERIOD ARE INCLUDED RESPECTIVELY.
AGE, WEIGHT AND BMI REPRESENT VALUES AT BASELINE OF PHASE A, B, C AND THE TRIAL PERIOD RESPECTIVELY.

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表 2.7.4.7-226　人口統計学的特性［日本，日本以外，長期投与試験，全集団］

CT-3.1.1.1
Demographic Characteristics by Region (JAPAN/NON-JAPAN)
(Enrolled Sample)

DEMOGRAPHIC CHARACTERISTICS		PHASE A JAPAN (N=39)	PHASE A NON-JAPAN (N=462)	PHASE A TOTAL (N=501)	PHASE B JAPAN (N=72)	PHASE B NON-JAPAN (N=483)	PHASE B TOTAL (N=555)	PHASE C JAPAN (N=75)	PHASE C NON-JAPAN (N=389)	PHASE C TOTAL (N=464)	TOTAL JAPAN (N=92)	TOTAL NON-JAPAN (N=656)	TOTAL TOTAL (N=748)
BODY MASS INDEX (kg/m2)	N	39	462	501	72	481	553	75	389	464	92	656	748
	MEAN	25.0	30.6	30.1	25.0	31.0	30.2	25.0	31.2	30.2	25.1	30.9	30.2
	SD	4.3	7.5	7.4	4.0	7.7	7.6	4.1	7.9	7.7	4.2	7.7	7.6
	MEDIAN	25.3	29.1	28.7	24.9	29.3	28.5	24.6	29.4	28.6	25.0	29.3	28.5
	MIN	17.5	16.7	16.7	17.2	17.5	17.2	16.9	17.9	16.9	17.5	16.7	16.7
	MAX	35.6	64.1	64.1	36.7	62.6	62.6	35.6	67.4	67.4	36.2	67.4	67.4

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE A, B, C AND THE TRIAL PERIOD ARE INCLUDED RESPECTIVELY.
AGE, WEIGHT AND BMI REPRESENT VALUES AT BASELINE OF PHASE A, B, C AND THE TRIAL PERIOD RESPECTIVELY.

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表 2.7.4.7-226　人口統計学的特性［日本，日本以外，長期投与試験，全集団］

CT-3.1.1.1
Demographic Characteristics by Region (JAPAN/NON-JAPAN)
(Enrolled Sample)

DEMOGRAPHIC CHARACTERISTICS		PHASE A			PHASE B			PHASE C		
		JAPAN (N=39) n (%)	NON-JAPAN (N=462) n (%)	TOTAL (N=501) n (%)	JAPAN (N=72) n (%)	NON-JAPAN (N=483) n (%)	TOTAL (N=555) n (%)	JAPAN (N=75) n (%)	NON-JAPAN (N=389) n (%)	TOTAL (N=464) n (%)
AGE (YEARS)1	< 45	14 (35.9)	263 (56.9)	277 (55.3)	36 (50.0)	281 (58.2)	317 (57.1)	41 (54.7)	230 (59.1)	271 (58.4)
	>= 45	25 (64.1)	199 (43.1)	224 (44.7)	36 (50.0)	202 (41.8)	238 (42.9)	34 (45.3)	159 (40.9)	193 (41.6)
BMI (kg/m2)1	<18.5	3 (7.7)	4 (0.9)	7 (1.4)	3 (4.2)	4 (0.8)	7 (1.3)	3 (4.0)	6 (1.5)	9 (1.9)
	18.5 - <25	16 (41.0)	105 (22.7)	121 (24.2)	33 (45.8)	95 (19.7)	128 (23.1)	37 (49.3)	74 (19.0)	111 (23.9)
	25 - <30	17 (43.6)	144 (31.2)	161 (32.1)	30 (41.7)	162 (33.5)	192 (34.6)	27 (36.0)	125 (32.1)	152 (32.8)
	>=30	3 (7.7)	209 (45.2)	212 (42.3)	6 (8.3)	220 (45.5)	226 (40.7)	8 (10.7)	184 (47.3)	192 (41.4)
BMI (kg/m2)1	<= 28	33 (84.6)	197 (42.6)	230 (45.9)	60 (83.3)	192 (39.8)	252 (45.4)	58 (77.3)	150 (38.6)	208 (44.8)
	> 28	6 (15.4)	265 (57.4)	271 (54.1)	12 (16.7)	289 (59.8)	301 (54.2)	17 (22.7)	239 (61.4)	256 (55.2)
RACE1)	WHITE	0 (0.0)	319 (69.0)	319 (63.7)	0 (0.0)	338 (70.0)	338 (60.9)	0 (0.0)	255 (65.6)	255 (55.0)
	BLACK OR AFRICAN AMERICAN	0 (0.0)	111 (24.0)	111 (22.2)	0 (0.0)	117 (24.2)	117 (21.1)	0 (0.0)	104 (26.7)	104 (22.4)
	AMERICAN INDIAN OR ALASKA NATIVE	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)	2 (0.4)
	ASIAN	39(100.0)	18 (3.9)	57 (11.4)	72(100.0)	15 (3.1)	87 (15.7)	75(100.0)	19 (4.9)	94 (20.3)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	3 (0.6)	3 (0.5)	0 (0.0)	2 (0.5)	2 (0.4)
	OTHER	0 (0.0)	10 (2.2)	10 (2.0)	0 (0.0)	9 (1.9)	9 (1.6)	0 (0.0)	7 (1.8)	7 (1.5)
ETHNICITY1)	HISPANIC OR LATINO	0 (0.0)	39 (8.4)	39 (7.8)	0 (0.0)	45 (9.3)	45 (8.1)	0 (0.0)	29 (7.5)	29 (6.3)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE A, B, C AND TOTAL TRIAL PERIOD ARE INCLUDED RESPECTIVELY.
1)PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL ENROLLED SAMPLE IN THE CORESPONDING PHASE OR IN THE TRIAL PERIOD.

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表 2.7.4.7-226　人口統計学的特性［日本，日本以外，長期投与試験，全集団］

CT-3.1.1.1
Demographic Characteristics by Region (JAPAN/NON-JAPAN)
(Enrolled Sample)

		TOTAL					
DEMOGRAPHIC CHARACTE-RISTICS		JAPAN (N=92)		NON-JAPAN (N=656)		TOTAL (N=748)	
		n	(%)	n	(%)	n	(%)
AGE (YEARS)1	< 45	46	(50.0)	387	(59.0)	433	(57.9)
	>= 45	46	(50.0)	269	(41.0)	315	(42.1)
BMI (kg/m2)1	<18.5	4	(4.3)	5	(0.8)	9	(1.2)
	18.5 - <25	42	(45.7)	142	(21.6)	184	(24.6)
	25 - <30	37	(40.2)	208	(31.7)	245	(32.8)
	>=30	9	(9.8)	301	(45.9)	310	(41.4)
BMI (kg/m2)1	<= 28	73	(79.3)	271	(41.3)	344	(46.0)
	> 28	19	(20.7)	385	(58.7)	404	(54.0)
RACE1)	WHITE	0	(0.0)	440	(67.1)	440	(58.8)
	BLACK OR AFRICAN AMERICAN	0	(0.0)	171	(26.1)	171	(22.9)
	AMERICAN INDIAN OR ALASKA NATIVE	0	(0.0)	3	(0.5)	3	(0.4)
	ASIAN	92	(100.0)	25	(3.8)	117	(15.6)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	(0.0)	3	(0.5)	3	(0.4)
	OTHER	0	(0.0)	14	(2.1)	14	(1.9)
ETHNICITY1)	HISPANIC OR LATINO	0	(0.0)	60	(9.1)	60	(8.0)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE A, B, C AND TOTAL TRIAL PERIOD ARE INCLUDED RESPECTIVELY.
1)PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL ENROLLED SAMPLE IN THE CORESPONDING PHASE OR IN THE TRIAL PERIOD.

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表 2.7.4.7-226　人口統計学的特性［日本，日本以外，長期投与試験，全集団］

CT-3.1.1.1
Demographic Characteristics by Region (JAPAN/NON-JAPAN)
(Enrolled Sample)

DEMOGRAPHIC CHARACTERISTICS		PHASE A JAPAN (N=39) n (%)	PHASE A NON-JAPAN (N=462) n (%)	PHASE A TOTAL (N=501) n (%)	PHASE B JAPAN (N=72) n (%)	PHASE B NON-JAPAN (N=483) n (%)	PHASE B TOTAL (N=555) n (%)	PHASE C JAPAN (N=75) n (%)	PHASE C NON-JAPAN (N=389) n (%)	PHASE C TOTAL (N=464) n (%)
ETHNICITY1)	NOT HISPANIC OR LATINO	39 (100.0)	422 (91.3)	461 (92.0)	72 (100.0)	438 (90.7)	510 (91.9)	75 (100.0)	360 (92.5)	435 (93.8)
	UNKNOWN	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
REGION1)	NORTH AMERICA	0 (0.0)	409 (88.5)	409 (81.6)	0 (0.0)	427 (88.4)	427 (76.9)	0 (0.0)	325 (83.5)	325 (70.0)
	EUROPE	0 (0.0)	38 (8.2)	38 (7.6)	0 (0.0)	45 (9.3)	45 (8.1)	0 (0.0)	47 (12.1)	47 (10.1)
	JAPAN	39 (100.0)	0 (0.0)	39 (7.8)	72 (100.0)	0 (0.0)	72 (13.0)	75 (100.0)	0 (0.0)	75 (16.2)
	OTHER ASIAN COUNTRIES	0 (0.0)	15 (3.2)	15 (3.0)	0 (0.0)	11 (2.3)	11 (2.0)	0 (0.0)	17 (4.4)	17 (3.7)
AGE (YEARS)1	18 - 64	36 (92.3)	457 (98.9)	493 (98.4)	70 (97.2)	477 (98.8)	547 (98.6)	73 (97.3)	385 (99.0)	458 (98.7)
	65 - 84	3 (7.7)	5 (1.1)	8 (1.6)	2 (2.8)	6 (1.2)	8 (1.4)	2 (2.7)	4 (1.0)	6 (1.3)
SEX1)	MALE	13 (33.3)	178 (38.5)	191 (38.1)	35 (48.6)	188 (38.9)	223 (40.2)	36 (48.0)	160 (41.1)	196 (42.2)
	FEMALE	26 (66.7)	284 (61.5)	310 (61.9)	37 (51.4)	295 (61.1)	332 (59.8)	39 (52.0)	229 (58.9)	268 (57.8)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE A, B, C AND TOTAL TRIAL PERIOD ARE INCLUDED RESPECTIVELY.
1)PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL ENROLLED SAMPLE IN THE CORESPONDING PHASE OR IN THE TRIAL PERIOD.

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表 2.7.4.7-226　人口統計学的特性［日本，日本以外，長期投与試験，全集団］

CT-3.1.1.1
Demographic Characteristics by Region (JAPAN/NON-JAPAN)
(Enrolled Sample)

DEMOGRAPHIC CHARACTERISTICS		TOTAL JAPAN (N=92) n (%)	TOTAL NON-JAPAN (N=656) n (%)	TOTAL TOTAL (N=748) n (%)
ETHNICITY1)	NOT HISPANIC OR LATINO	92 (100.0)	595 (90.7)	687 (91.8)
	UNKNOWN	0 (0.0)	1 (0.2)	1 (0.1)
REGION1)	NORTH AMERICA	0 (0.0)	577 (88.0)	577 (77.1)
	EUROPE	0 (0.0)	57 (8.7)	57 (7.6)
	JAPAN	92 (100.0)	0 (0.0)	92 (12.3)
	OTHER ASIAN COUNTRIES	0 (0.0)	22 (3.4)	22 (2.9)
AGE (YEARS)1	18 - 64	89 (96.7)	650 (99.1)	739 (98.8)
	65 - 84	3 (3.3)	6 (0.9)	9 (1.2)
SEX1)	MALE	43 (46.7)	258 (39.3)	301 (40.2)
	FEMALE	49 (53.3)	398 (60.7)	447 (59.8)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE A, B, C AND TOTAL TRIAL PERIOD ARE INCLUDED RESPECTIVELY.
1)PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL ENROLLED SAMPLE IN THE CORESPONDING PHASE OR IN THE TRIAL PERIOD.

FILE: ADDM21A.LIS, RUN: [redacted]20[redacted] 14:55
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADDM21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-3.1.1.1　FINAL

＜資料番号 5.3.5.3-01：CT-3.1.1.1＞

表 2.7.4.7-227　他の基準値の特性［日本，日本以外，長期投与試験，全集団］

CT-3.2.1.1
Baseline Disease Severity by Region (JAPAN/NON-JAPAN) (Enrolled Sample)

BASELINE CHARACTERISTICS		JAPAN PHASE B (N=72)	JAPAN PHASE C (N=75)	NON-JAPAN PHASE B (N=483)	NON-JAPAN PHASE C (N=389)	TOTAL PHASE B (N=555)	TOTAL PHASE C (N=464)
YMRS TOTAL SCORE	N	72	75	483	389	555	464
	MEAN	2.2	0.8	6.5	2.6	5.9	2.3
	SD	4.8	1.6	7.0	3.0	6.9	2.9
	MEDIAN	0.5	0.0	4.0	2.0	4.0	1.0
	MIN	0	0	0	0	0	0
	MAX	27	10	36	12	36	12
MADRS TOTAL SCORE	N	72	75	483	389	555	464
	MEAN	4.6	3.6	8.1	3.2	7.7	3.2
	SD	4.7	3.9	7.9	3.0	7.6	3.2
	MEDIAN	3.0	2.0	6.0	2.0	6.0	2.0
	MIN	0	0	0	0	0	0
	MAX	18	12	48	13	48	13
MADRS SUICIDAL THOUGHTS SCORE	N	72	75	483	389	555	464
	MEAN	0.1	0.1	0.1	0.0	0.1	0.0
	SD	0.3	0.4	0.4	0.2	0.4	0.2
	MEDIAN	0.0	0.0	0.0	0.0	0.0	0.0
	MIN	0	0	0	0	0	0
	MAX	2	2	4	2	4	2
CGI-BP SEVERITY - MANIA	N	72	75	483	389	555	464
	MEAN	1.4	1.2	2.2	1.6	2.1	1.5
	SD	0.9	0.5	1.2	0.8	1.2	0.8

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B AND C ARE INCLUDED RESPECTIVELY.

FILE: ADDM21C.LIS, RUN: [redacted]20[redacted] 14:55; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:13
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADDM21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-3.2.1.1　FINAL

表 2.7.4.7-227　他の基準値の特性［日本，日本以外，長期投与試験，全集団］

CT-3.2.1.1
Baseline Disease Severity by Region (JAPAN/NON-JAPAN) (Enrolled Sample)

BASELINE CHARACTERISTICS		JAPAN PHASE B (N=72)	JAPAN PHASE C (N=75)	NON-JAPAN PHASE B (N=483)	NON-JAPAN PHASE C (N=389)	TOTAL PHASE B (N=555)	TOTAL PHASE C (N=464)
CGI-BP SEVERITY - MANIA	MEDIAN	1.0	1.0	2.0	1.0	2.0	1.0
	MIN	1	1	1	1	1	1
	MAX	5	4	6	4	6	4
CGI-BP SEVERITY - DEPRESSION	N	72	75	483	389	555	464
	MEAN	1.8	1.7	2.2	1.6	2.1	1.6
	SD	0.9	0.8	1.2	0.8	1.1	0.8
	MEDIAN	1.5	1.0	2.0	1.0	2.0	1.0
	MIN	1	1	1	1	1	1
	MAX	4	4	7	4	7	4
CGI-BP SEVERITY - OVERALL	N	72	75	483	389	555	464
	MEAN	1.9	1.7	2.6	1.8	2.5	1.7
	SD	1.0	0.8	1.2	0.8	1.2	0.8
	MEDIAN	2.0	1.0	2.0	2.0	2.0	2.0
	MIN	1	1	1	1	1	1
	MAX	5	4	6	4	6	4
CGI-BP CHANGE FROM PRECEDING PHASE - MANIA	N		75		387		462
	MEAN		3.5		2.8		2.9
	SD		1.0		1.2		1.2
	MEDIAN		4.0		3.0		3.0
	MIN		1		1		1
	MAX		4		5		5

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B AND C ARE INCLUDED RESPECTIVELY.

FILE: ADDM21C.LIS, RUN: [redacted]20[redacted] 14:55; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:13
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADDM21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-3.2.1.1　FINAL

表 2.7.4.7-227　他の基準値の特性［日本，日本以外，長期投与試験，全集団］

CT-3.2.1.1
Baseline Disease Severity by Region (JAPAN/NON-JAPAN) (Enrolled Sample)

BASELINE CHARACTERISTICS		JAPAN PHASE C (N=75)	NON-JAPAN PHASE C (N=389)	TOTAL PHASE C (N=464)
CGI-BP CHANGE FROM PRECEDING PHASE - DEPRESSION	N	75	389	464
	MEAN	3.7	2.9	3.0
	SD	0.9	1.2	1.2
	MEDIAN	4.0	3.0	3.0
	MIN	1	1	1
	MAX	5	5	5
CGI-BP CHANGE FROM PRECEDING PHASE - OVERALL	N	75	389	464
	MEAN	3.7	2.8	2.9
	SD	0.9	1.1	1.2
	MEDIAN	4.0	3.0	3.0
	MIN	1	1	1
	MAX	5	5	5

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B AND C ARE INCLUDED RESPECTIVELY.

FILE: ADDM21C.LIS, RUN: [redacted]20[redacted] 14:55; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:13
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADDM21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-3.2.1.1　FINAL

表 2.7.4.7-227　他の基準値の特性［日本，日本以外，長期投与試験，全集団］

CT-3.2.1.1
Baseline Disease Severity by Region (JAPAN/NON-JAPAN) (Enrolled Sample)

BASELINE CHARACTERISTICS		JAPAN PHASE B (N=72) n	(%)	NON-JAPAN PHASE B (N=483) n	(%)	TOTAL PHASE B (N=555) n	(%)
C-SSRS ACTIVE SUICIDAL IDEATION WITH SOME INTENT TO ACT WITHOUT SPECIFIC PLAN	N	72	(100.0)	483	(100.0)	555	(100.0)
	Y	0	(0.0)	0	(0.0)	0	(0.0)
C-SSRS ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	N	72	(100.0)	483	(100.0)	555	(100.0)
	Y	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B AND C ARE INCLUDED RESPECTIVELY.

FILE: ADDM21C.LIS, RUN: [redacted]20[redacted] 14:55; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:13
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADDM21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-3.2.1.1　FINAL

表 2.7.4.7-227　他の基準値の特性［日本，日本以外，長期投与試験，全集団］

CT-3.2.1.1
Baseline Disease Severity by Region (JAPAN/NON-JAPAN) (Enrolled Sample)

BASELINE CHARACTERISTICS		JAPAN PHASE C (N=75) n	(%)	NON-JAPAN PHASE C (N=389) n	(%)	TOTAL PHASE C (N=464) n	(%)
C-SSRS ACTIVE SUICIDAL IDEATION WITH SOME INTENT TO ACT WITHOUT SPECIFIC PLAN	N	75	(100.0)	389	(100.0)	464	(100.0)
	Y	0	(0.0)	0	(0.0)	0	(0.0)
C-SSRS ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	N	75	(100.0)	389	(100.0)	464	(100.0)
	Y	0	(0.0)	0	(0.0)	0	(0.0)
OUTPATIENT STATUS	Y	75	(100.0)	389	(100.0)	464	(100.0)
	N	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B AND C ARE INCLUDED RESPECTIVELY.

FILE: ADDM21C.LIS, RUN: [redacted]20[redacted] 14:55; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:13
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADDM21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-3.2.1.1　FINAL
＜資料番号 5.3.5.3-01：CT-3.2.1.1＞

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	気管支炎	1	(1.3)	10	(2.6)	11	(2.4)
	蜂巣炎	0	(0.0)	2	(0.5)	2	(0.4)
	膀胱炎	2	(2.7)	1	(0.3)	3	(0.6)
	耳感染	0	(0.0)	4	(1.0)	4	(0.9)
	毛包炎	0	(0.0)	1	(0.3)	1	(0.2)
	せつ	0	(0.0)	1	(0.3)	1	(0.2)
	胃腸炎	1	(1.3)	0	(0.0)	1	(0.2)
	ウイルス性胃腸炎	0	(0.0)	11	(2.8)	11	(2.4)
	歯肉炎	1	(1.3)	0	(0.0)	1	(0.2)
	単純ヘルペス	0	(0.0)	1	(0.3)	1	(0.2)
	帯状疱疹	1	(1.3)	0	(0.0)	1	(0.2)
	麦粒腫	1	(1.3)	1	(0.3)	2	(0.4)
	感染	1	(1.3)	0	(0.0)	1	(0.2)
	インフルエンザ	1	(1.3)	7	(1.8)	8	(1.7)
	腎感染	0	(0.0)	1	(0.3)	1	(0.2)
	限局性感染	0	(0.0)	1	(0.3)	1	(0.2)
	下気道感染	0	(0.0)	1	(0.3)	1	(0.2)
	鼻咽頭炎	29	(38.7)	27	(6.9)	56	(12.1)
	外耳炎	0	(0.0)	1	(0.3)	1	(0.2)
	中耳炎	0	(0.0)	1	(0.3)	1	(0.2)
	歯周炎	1	(1.3)	0	(0.0)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	咽頭炎	6	(8.0)	0	(0.0)	6	(1.3)
	レンサ球菌性咽頭炎	0	(0.0)	2	(0.5)	2	(0.4)
	毛巣嚢胞	0	(0.0)	1	(0.3)	1	(0.2)
	肺炎	0	(0.0)	1	(0.3)	1	(0.2)
	マイコプラズマ性肺炎	1	(1.3)	0	(0.0)	1	(0.2)
	腎盂腎炎	0	(0.0)	1	(0.3)	1	(0.2)
	鼻炎	0	(0.0)	1	(0.3)	1	(0.2)
	副鼻腔炎	0	(0.0)	6	(1.5)	6	(1.3)
	皮下組織膿瘍	0	(0.0)	1	(0.3)	1	(0.2)
	歯膿瘍	0	(0.0)	4	(1.0)	4	(0.9)
	上気道感染	1	(1.3)	23	(5.9)	24	(5.2)
	尿路感染	1	(1.3)	10	(2.6)	11	(2.4)
	ウイルス性上気道感染	0	(0.0)	1	(0.3)	1	(0.2)
	歯感染	0	(0.0)	3	(0.8)	3	(0.6)
	白癬感染	0	(0.0)	1	(0.3)	1	(0.2)
	ダニ皮膚炎	0	(0.0)	3	(0.8)	3	(0.6)
	外陰腟真菌感染	0	(0.0)	1	(0.3)	1	(0.2)
	口腔ヘルペス	1	(1.3)	0	(0.0)	1	(0.2)
	ノロウイルス性胃腸炎	0	(0.0)	1	(0.3)	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）	基底細胞癌	0	(0.0)	1	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
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）	乳癌	0	(0.0)	1	(0.3)	1	(0.2)
	脂肪腫	1	(1.3)	0	(0.0)	1	(0.2)
	皮膚の新生物	0	(0.0)	1	(0.3)	1	(0.2)
	扁平上皮癌	0	(0.0)	1	(0.3)	1	(0.2)
	子宮平滑筋腫	0	(0.0)	1	(0.3)	1	(0.2)
	肛門性器疣贅	1	(1.3)	0	(0.0)	1	(0.2)
血液およびリンパ系障害	貧血	0	(0.0)	1	(0.3)	1	(0.2)
免疫系障害	動物アレルギー	0	(0.0)	1	(0.3)	1	(0.2)
	食物アレルギー	0	(0.0)	1	(0.3)	1	(0.2)
	季節性アレルギー	1	(1.3)	3	(0.8)	4	(0.9)
内分泌障害	高プロラクチン血症	0	(0.0)	3	(0.8)	3	(0.6)
	甲状腺機能低下症	0	(0.0)	2	(0.5)	2	(0.4)
代謝および栄養障害	糖尿病	1	(1.3)	4	(1.0)	5	(1.1)
	コントロール不良の糖尿病	0	(0.0)	2	(0.5)	2	(0.4)
	体液貯留	0	(0.0)	1	(0.3)	1	(0.2)
	耐糖能障害	0	(0.0)	1	(0.3)	1	(0.2)
	痛風	0	(0.0)	1	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)		NON-JAPAN (N=389)		TOTAL (N=464)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
代謝および栄養障害	高血糖	0	(0.0)	2	(0.5)	2	(0.4)
	低カリウム血症	0	(0.0)	1	(0.3)	1	(0.2)
	食欲亢進	1	(1.3)	15	(3.9)	16	(3.4)
	肥満	1	(1.3)	1	(0.3)	2	(0.4)
	食欲減退	1	(1.3)	6	(1.5)	7	(1.5)
	高脂血症	0	(0.0)	2	(0.5)	2	(0.4)
	過小食	1	(1.3)	0	(0.0)	1	(0.2)
	２型糖尿病	0	(0.0)	3	(0.8)	3	(0.6)
精神障害	異常な夢	0	(0.0)	6	(1.5)	6	(1.3)
	急性ストレス反応	1	(1.3)	0	(0.0)	1	(0.2)
	攻撃性	0	(0.0)	1	(0.3)	1	(0.2)
	激越	0	(0.0)	8	(2.1)	8	(1.7)
	広場恐怖症	0	(0.0)	1	(0.3)	1	(0.2)
	不安	10	(13.3)	36	(9.3)	46	(9.9)
	無感情	0	(0.0)	1	(0.3)	1	(0.2)
	注意喚起行動	1	(1.3)	0	(0.0)	1	(0.2)
	双極１型障害	14	(18.7)	4	(1.0)	18	(3.9)
	情動鈍麻	0	(0.0)	1	(0.3)	1	(0.2)
	歯ぎしり	0	(0.0)	3	(0.8)	3	(0.6)
	抑うつ気分	1	(1.3)	1	(0.3)	2	(0.4)
	うつ病	3	(4.0)	23	(5.9)	26	(5.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)		NON-JAPAN (N=389)		TOTAL (N=464)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
精神障害	不快気分	0	(0.0)	1	(0.3)	1	(0.2)
	感情の貧困	0	(0.0)	2	(0.5)	2	(0.4)
	軽躁	1	(1.3)	1	(0.3)	2	(0.4)
	衝動行為	0	(0.0)	1	(0.3)	1	(0.2)
	初期不眠症	0	(0.0)	1	(0.3)	1	(0.2)
	不眠症	11	(14.7)	40	(10.3)	51	(11.0)
	故意の自傷行為	0	(0.0)	1	(0.3)	1	(0.2)
	易刺激性	0	(0.0)	4	(1.0)	4	(0.9)
	リビドー減退	0	(0.0)	3	(0.8)	3	(0.6)
	躁病	0	(0.0)	4	(1.0)	4	(0.9)
	気分変化	0	(0.0)	2	(0.5)	2	(0.4)
	神経過敏	0	(0.0)	2	(0.5)	2	(0.4)
	悪夢	0	(0.0)	2	(0.5)	2	(0.4)
	パニック発作	0	(0.0)	1	(0.3)	1	(0.2)
	妄想症	0	(0.0)	1	(0.3)	1	(0.2)
	落ち着きのなさ	1	(1.3)	22	(5.7)	23	(5.0)
	睡眠障害	0	(0.0)	2	(0.5)	2	(0.4)
	社会逃避行動	0	(0.0)	1	(0.3)	1	(0.2)
	自殺念慮	1	(1.3)	8	(2.1)	9	(1.9)
	自殺企図	2	(2.7)	1	(0.3)	3	(0.6)
	抑うつ症状	1	(1.3)	2	(0.5)	3	(0.6)
	双極性障害	0	(0.0)	4	(1.0)	4	(0.9)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
精神障害	大うつ病	0	(0.0)	1	(0.3)	1	(0.2)
	異常行動	0	(0.0)	1	(0.3)	1	(0.2)
	自傷行動	0	(0.0)	3	(0.8)	3	(0.6)
	早朝覚醒型不眠症	0	(0.0)	1	(0.3)	1	(0.2)
神経系障害	アカシジア	14	(18.7)	54	(13.9)	68	(14.7)
	失語症	0	(0.0)	1	(0.3)	1	(0.2)
	自律神経失調	1	(1.3)	0	(0.0)	1	(0.2)
	運動緩慢	1	(1.3)	2	(0.5)	3	(0.6)
	注意力障害	0	(0.0)	3	(0.8)	3	(0.6)
	浮動性めまい	1	(1.3)	9	(2.3)	10	(2.2)
	体位性めまい	2	(2.7)	3	(0.8)	5	(1.1)
	よだれ	0	(0.0)	2	(0.5)	2	(0.4)
	構語障害	0	(0.0)	1	(0.3)	1	(0.2)
	味覚異常	1	(1.3)	0	(0.0)	1	(0.2)
	ジスキネジア	3	(4.0)	5	(1.3)	8	(1.7)
	ジストニア	1	(1.3)	3	(0.8)	4	(0.9)
	錐体外路障害	0	(0.0)	12	(3.1)	12	(2.6)
	頭痛	7	(9.3)	22	(5.7)	29	(6.3)
	運動過多	0	(0.0)	1	(0.3)	1	(0.2)
	過眠症	0	(0.0)	2	(0.5)	2	(0.4)
	感覚鈍麻	1	(1.3)	1	(0.3)	2	(0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)		NON-JAPAN (N=389)		TOTAL (N=464)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
神経系障害	企図振戦	0	(0.0)	2	(0.5)	2	(0.4)
	嗜眠	0	(0.0)	4	(1.0)	4	(0.9)
	精神的機能障害	0	(0.0)	1	(0.3)	1	(0.2)
	片頭痛	0	(0.0)	3	(0.8)	3	(0.6)
	錯感覚	0	(0.0)	1	(0.3)	1	(0.2)
	パーキンソニズム	1	(1.3)	4	(1.0)	5	(1.1)
	坐骨神経痛	0	(0.0)	2	(0.5)	2	(0.4)
	鎮静	1	(1.3)	16	(4.1)	17	(3.7)
	感覚障害	0	(0.0)	1	(0.3)	1	(0.2)
	副鼻腔炎に伴う頭痛	0	(0.0)	1	(0.3)	1	(0.2)
	傾眠	2	(2.7)	18	(4.6)	20	(4.3)
	失神	0	(0.0)	1	(0.3)	1	(0.2)
	遅発性ジスキネジア	0	(0.0)	3	(0.8)	3	(0.6)
	振戦	3	(4.0)	25	(6.4)	28	(6.0)
	眉間反射異常	0	(0.0)	1	(0.3)	1	(0.2)
	下肢静止不能症候群	0	(0.0)	4	(1.0)	4	(0.9)
	微細運動機能障害	0	(0.0)	1	(0.3)	1	(0.2)
眼障害	眼瞼痙攣	0	(0.0)	4	(1.0)	4	(0.9)
	糖尿病性白内障	1	(1.3)	0	(0.0)	1	(0.2)
	霧視	0	(0.0)	2	(0.5)	2	(0.4)
	注視麻痺	0	(0.0)	1	(0.3)	1	(0.2)

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表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
眼障害	瞬目過多	0	(0.0)	2	(0.5)	2	(0.4)
耳および迷路障害	耳痛	0	(0.0)	1	(0.3)	1	(0.2)
	回転性めまい	1	(1.3)	1	(0.3)	2	(0.4)
心臓障害	急性心筋梗塞	0	(0.0)	1	(0.3)	1	(0.2)
	徐脈	0	(0.0)	1	(0.3)	1	(0.2)
	心停止	0	(0.0)	1	(0.3)	1	(0.2)
	心筋梗塞	0	(0.0)	1	(0.3)	1	(0.2)
	動悸	0	(0.0)	1	(0.3)	1	(0.2)
	プリンツメタル狭心症	0	(0.0)	1	(0.3)	1	(0.2)
	頻脈	0	(0.0)	4	(1.0)	4	(0.9)
血管障害	本態性高血圧症	0	(0.0)	1	(0.3)	1	(0.2)
	潮紅	0	(0.0)	1	(0.3)	1	(0.2)
	血腫	0	(0.0)	1	(0.3)	1	(0.2)
	高血圧	0	(0.0)	4	(1.0)	4	(0.9)
	起立性低血圧	3	(4.0)	2	(0.5)	5	(1.1)
呼吸器、胸郭および縦隔障害	喘息	0	(0.0)	1	(0.3)	1	(0.2)
	慢性閉塞性肺疾患	0	(0.0)	1	(0.3)	1	(0.2)
	咳嗽	0	(0.0)	7	(1.8)	7	(1.5)

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表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1	(1.3)	0	(0.0)	1	(0.2)
	呼吸困難	0	(0.0)	1	(0.3)	1	(0.2)
	鼻出血	0	(0.0)	2	(0.5)	2	(0.4)
	しゃっくり	0	(0.0)	1	(0.3)	1	(0.2)
	低酸素症	0	(0.0)	1	(0.3)	1	(0.2)
	肺障害	0	(0.0)	1	(0.3)	1	(0.2)
	鼻閉	0	(0.0)	3	(0.8)	3	(0.6)
	鼻乾燥	0	(0.0)	1	(0.3)	1	(0.2)
	胸膜炎	0	(0.0)	1	(0.3)	1	(0.2)
	鼻漏	1	(1.3)	1	(0.3)	2	(0.4)
	咽喉絞扼感	1	(1.3)	0	(0.0)	1	(0.2)
	アレルギー性副鼻腔炎	0	(0.0)	2	(0.5)	2	(0.4)
	上気道の炎症	1	(1.3)	0	(0.0)	1	(0.2)
	口腔咽頭痛	2	(2.7)	3	(0.8)	5	(1.1)
	咽頭反射亢進	0	(0.0)	1	(0.3)	1	(0.2)
胃腸障害	腹部不快感	3	(4.0)	1	(0.3)	4	(0.9)
	腹部膨満	0	(0.0)	1	(0.3)	1	(0.2)
	腹痛	0	(0.0)	6	(1.5)	6	(1.3)
	上腹部痛	3	(4.0)	2	(0.5)	5	(1.1)
	慢性胃炎	1	(1.3)	0	(0.0)	1	(0.2)
	便秘	4	(5.3)	6	(1.5)	10	(2.2)

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表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
胃腸障害	齲歯	4	(5.3)	1	(0.3)	5	(1.1)
	下痢	7	(9.3)	14	(3.6)	21	(4.5)
	口内乾燥	1	(1.3)	7	(1.8)	8	(1.7)
	消化不良	0	(0.0)	3	(0.8)	3	(0.6)
	嚥下障害	0	(0.0)	2	(0.5)	2	(0.4)
	腸炎	1	(1.3)	0	(0.0)	1	(0.2)
	胃炎	1	(1.3)	1	(0.3)	2	(0.4)
	胃食道逆流性疾患	0	(0.0)	1	(0.3)	1	(0.2)
	消化器痛	0	(0.0)	1	(0.3)	1	(0.2)
	血便排泄	0	(0.0)	1	(0.3)	1	(0.2)
	痔核	0	(0.0)	1	(0.3)	1	(0.2)
	過敏性腸症候群	0	(0.0)	1	(0.3)	1	(0.2)
	悪心	4	(5.3)	11	(2.8)	15	(3.2)
	歯周病	1	(1.3)	0	(0.0)	1	(0.2)
	流涎過多	1	(1.3)	13	(3.3)	14	(3.0)
	歯の知覚過敏	0	(0.0)	1	(0.3)	1	(0.2)
	口内炎	1	(1.3)	0	(0.0)	1	(0.2)
	舌障害	0	(0.0)	2	(0.5)	2	(0.4)
	歯の脱落	0	(0.0)	1	(0.3)	1	(0.2)
	歯痛	2	(2.7)	13	(3.3)	15	(3.2)
	嘔吐	3	(4.0)	9	(2.3)	12	(2.6)
	心窩部不快感	0	(0.0)	1	(0.3)	1	(0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
胃腸障害	口の錯感覚	0	(0.0)	1	(0.3)	1	(0.2)
肝胆道系障害	胆嚢炎	0	(0.0)	1	(0.3)	1	(0.2)
	急性胆嚢炎	0	(0.0)	1	(0.3)	1	(0.2)
	肝炎	0	(0.0)	1	(0.3)	1	(0.2)
	高ビリルビン血症	1	(1.3)	0	(0.0)	1	(0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	0	(0.0)	1	(0.3)	1	(0.2)
	水疱	0	(0.0)	1	(0.3)	1	(0.2)
	皮膚炎	0	(0.0)	1	(0.3)	1	(0.2)
	ざ瘡様皮膚炎	0	(0.0)	1	(0.3)	1	(0.2)
	接触性皮膚炎	0	(0.0)	1	(0.3)	1	(0.2)
	皮膚乾燥	0	(0.0)	2	(0.5)	2	(0.4)
	斑状出血	0	(0.0)	1	(0.3)	1	(0.2)
	湿疹	2	(2.7)	1	(0.3)	3	(0.6)
	紅斑	1	(1.3)	0	(0.0)	1	(0.2)
	多汗症	1	(1.3)	3	(0.8)	4	(0.9)
	嵌入爪	0	(0.0)	1	(0.3)	1	(0.2)
	寝汗	0	(0.0)	1	(0.3)	1	(0.2)
	光線過敏性反応	0	(0.0)	1	(0.3)	1	(0.2)
	そう痒症	3	(4.0)	2	(0.5)	5	(1.1)
	乾癬	0	(0.0)	1	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
皮膚および皮下組織障害	発疹	3	(4.0)	6	(1.5)	9	(1.9)
	斑状皮疹	0	(0.0)	1	(0.3)	1	(0.2)
	斑状丘疹状皮疹	0	(0.0)	1	(0.3)	1	(0.2)
	そう痒性皮疹	0	(0.0)	1	(0.3)	1	(0.2)
	脂漏性皮膚炎	1	(1.3)	0	(0.0)	1	(0.2)
	蕁麻疹	1	(1.3)	2	(0.5)	3	(0.6)
筋骨格系および結合組織障害	関節痛	2	(2.7)	9	(2.3)	11	(2.4)
	背部痛	4	(5.3)	11	(2.8)	15	(3.2)
	外骨腫	0	(0.0)	1	(0.3)	1	(0.2)
	肩径部痛	1	(1.3)	0	(0.0)	1	(0.2)
	関節硬直	0	(0.0)	1	(0.3)	1	(0.2)
	筋萎縮	1	(1.3)	0	(0.0)	1	(0.2)
	筋固縮	0	(0.0)	1	(0.3)	1	(0.2)
	筋痙縮	0	(0.0)	4	(1.0)	4	(0.9)
	筋攣縮	0	(0.0)	2	(0.5)	2	(0.4)
	筋骨格痛	2	(2.7)	2	(0.5)	4	(0.9)
	筋肉痛	1	(1.3)	3	(0.8)	4	(0.9)
	頚部痛	0	(0.0)	1	(0.3)	1	(0.2)
	骨端症	0	(0.0)	1	(0.3)	1	(0.2)
	骨壊死	0	(0.0)	1	(0.3)	1	(0.2)
	四肢痛	1	(1.3)	9	(2.3)	10	(2.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
筋骨格系および結合組織障害	滑液嚢腫	1	(1.3)	0	(0.0)	1	(0.2)
	顎関節症候群	0	(0.0)	1	(0.3)	1	(0.2)
	腱炎	0	(0.0)	1	(0.3)	1	(0.2)
	開口障害	0	(0.0)	1	(0.3)	1	(0.2)
	筋緊張	0	(0.0)	1	(0.3)	1	(0.2)
	椎間板突出	0	(0.0)	1	(0.3)	1	(0.2)
	筋骨格硬直	1	(1.3)	7	(1.8)	8	(1.7)
	項部硬直	0	(0.0)	1	(0.3)	1	(0.2)
	椎間板障害	1	(1.3)	0	(0.0)	1	(0.2)
	関節過伸展	0	(0.0)	1	(0.3)	1	(0.2)
	関節不安定	0	(0.0)	1	(0.3)	1	(0.2)
腎および尿路障害	血尿	0	(0.0)	1	(0.3)	1	(0.2)
	尿意切迫	0	(0.0)	1	(0.3)	1	(0.2)
	腎結石症	0	(0.0)	2	(0.5)	2	(0.4)
	夜間頻尿	0	(0.0)	1	(0.3)	1	(0.2)
	頻尿	1	(1.3)	1	(0.3)	2	(0.4)
	蛋白尿	0	(0.0)	1	(0.3)	1	(0.2)
	尿失禁	1	(1.3)	0	(0.0)	1	(0.2)
	尿管結石症	1	(1.3)	1	(0.3)	2	(0.4)
生殖系および乳房障害	無月経	0	(0.0)	1	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
生殖系および乳房障害	良性前立腺肥大症	0	(0.0)	1	(0.3)	1	(0.2)
	性器発疹	0	(0.0)	1	(0.3)	1	(0.2)
	月経障害	0	(0.0)	1	(0.3)	1	(0.2)
	月経遅延	0	(0.0)	1	(0.3)	1	(0.2)
	不規則月経	1	(1.3)	0	(0.0)	1	(0.2)
	不正子宮出血	0	(0.0)	1	(0.3)	1	(0.2)
	卵巣嚢胞	0	(0.0)	1	(0.3)	1	(0.2)
	性機能不全	0	(0.0)	1	(0.3)	1	(0.2)
	外陰腟乾燥	0	(0.0)	1	(0.3)	1	(0.2)
	勃起不全	0	(0.0)	6	(1.5)	6	(1.3)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1	(1.3)	0	(0.0)	1	(0.2)
一般・全身障害および投与部位の状態	無菌膿瘍	0	(0.0)	1	(0.3)	1	(0.2)
	無力症	0	(0.0)	4	(1.0)	4	(0.9)
	胸部不快感	0	(0.0)	1	(0.3)	1	(0.2)
	胸痛	0	(0.0)	4	(1.0)	4	(0.9)
	嚢胞	0	(0.0)	1	(0.3)	1	(0.2)
	疲労	0	(0.0)	20	(5.1)	20	(4.3)
	異常感	0	(0.0)	1	(0.3)	1	(0.2)
	歩行障害	0	(0.0)	1	(0.3)	1	(0.2)
	インフルエンザ様疾患	1	(1.3)	2	(0.5)	3	(0.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
一般・全身障害および投与部位の状態	注射部位内出血	0	(0.0)	2	(0.5)	2	(0.4)
	注射部位紅斑	0	(0.0)	1	(0.3)	1	(0.2)
	注射部位硬結	0	(0.0)	1	(0.3)	1	(0.2)
	注射部位腫瘤	0	(0.0)	2	(0.5)	2	(0.4)
	注射部位疼痛	10	(13.3)	24	(6.2)	34	(7.3)
	倦怠感	3	(4.0)	0	(0.0)	3	(0.6)
	末梢性浮腫	0	(0.0)	2	(0.5)	2	(0.4)
	疼痛	0	(0.0)	1	(0.3)	1	(0.2)
	発熱	1	(1.3)	4	(1.0)	5	(1.1)
	口渇	0	(0.0)	1	(0.3)	1	(0.2)
	注射部位腫脹	1	(1.3)	3	(0.8)	4	(0.9)
	小結節	0	(0.0)	1	(0.3)	1	(0.2)
	非心臓性胸痛	0	(0.0)	2	(0.5)	2	(0.4)
臨床検査	アラニンアミノトランスフェラーゼ増加	2	(2.7)	1	(0.3)	3	(0.6)
	アスパラギン酸アミノトランスフェラーゼ増加	2	(2.7)	1	(0.3)	3	(0.6)
	血中コレステロール増加	0	(0.0)	2	(0.5)	2	(0.4)
	血中クレアチンホスホキナーゼ増加	2	(2.7)	3	(0.8)	5	(1.1)
	血中ブドウ糖増加	2	(2.7)	2	(0.5)	4	(0.9)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
臨床検査	血圧低下	2	(2.7)	0	(0.0)	2	(0.4)
	血圧上昇	2	(2.7)	2	(0.5)	4	(0.9)
	血中プロラクチン減少	1	(1.3)	0	(0.0)	1	(0.2)
	血中プロラクチン増加	0	(0.0)	1	(0.3)	1	(0.2)
	血中トリグリセリド増加	0	(0.0)	1	(0.3)	1	(0.2)
	血中尿酸増加	1	(1.3)	0	(0.0)	1	(0.2)
	心雑音	0	(0.0)	1	(0.3)	1	(0.2)
	γ－グルタミルトランスフェラーゼ増加	1	(1.3)	1	(0.3)	2	(0.4)
	尿中ブドウ糖陽性	1	(1.3)	0	(0.0)	1	(0.2)
	グリコヘモグロビン増加	1	(1.3)	0	(0.0)	1	(0.2)
	尿中血陽性	1	(1.3)	0	(0.0)	1	(0.2)
	心拍数増加	1	(1.3)	2	(0.5)	3	(0.6)
	体重減少	4	(5.3)	9	(2.3)	13	(2.8)
	体重増加	12	(16.0)	50	(12.9)	62	(13.4)
	尿中白血球陽性	2	(2.7)	0	(0.0)	2	(0.4)
	起立血圧上昇	0	(0.0)	1	(0.3)	1	(0.2)
	肝酵素上昇	1	(1.3)	0	(0.0)	1	(0.2)
	ビタミンD減少	0	(0.0)	1	(0.3)	1	(0.2)
	ヘリコバクター検査陽性	0	(0.0)	1	(0.3)	1	(0.2)
	肝機能検査値上昇	0	(0.0)	1	(0.3)	1	(0.2)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

表 2.7.4.7-228　有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)		NON-JAPAN (N=389)		TOTAL (N=464)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
傷害、中毒および処置合併症	足関節部骨折	0	(0.0)	1	(0.3)	1	(0.2)
	節足動物咬傷	0	(0.0)	2	(0.5)	2	(0.4)
	凍瘡	1	(1.3)	0	(0.0)	1	(0.2)
	転倒	0	(0.0)	2	(0.5)	2	(0.4)
	裂傷	1	(1.3)	3	(0.8)	4	(0.9)
	靭帯捻挫	2	(2.7)	7	(1.8)	9	(1.9)
	ストレス骨折	0	(0.0)	1	(0.3)	1	(0.2)
	肉離れ	0	(0.0)	2	(0.5)	2	(0.4)
	挫傷	1	(1.3)	0	(0.0)	1	(0.2)
	関節損傷	1	(1.3)	0	(0.0)	1	(0.2)
	四肢損傷	0	(0.0)	1	(0.3)	1	(0.2)
	胸部損傷	0	(0.0)	2	(0.5)	2	(0.4)
	歯牙破折	1	(1.3)	1	(0.3)	2	(0.4)
	処置による疼痛	1	(1.3)	6	(1.5)	7	(1.5)
	皮膚擦過傷	0	(0.0)	1	(0.3)	1	(0.2)
TOTAL1)		71	(94.7)	303	(77.9)	374	(80.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.1　FINAL

＜資料番号 5.3.5.3-01：CT-8.2.2.1.1＞

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	気管支炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	5 (1.3)	5 (1.3)	0 (0.0)	10 (2.6)
	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	膀胱炎	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.0)
	毛包炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	せつ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	胃腸炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)	6 (1.5)	0 (0.0)	11 (2.8)
	歯肉炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	単純ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	帯状疱疹	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	感染	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	2 (0.5)	4 (1.0)	1 (0.3)	7 (1.8)
	腎感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	下気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	鼻咽頭炎	26 (34.7)	3 (4.0)	0 (0.0)	29 (38.7)	11 (2.8)	16 (4.1)	0 (0.0)	27 (6.9)
	外耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	歯周炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	6 (8.0)	0 (0.0)	0 (0.0)	6 (8.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	気管支炎	6 (1.3)	5 (1.1)	0 (0.0)	11 (2.4)
	蜂巣炎	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	膀胱炎	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	耳感染	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	毛包炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	せつ	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	胃腸炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ウイルス性胃腸炎	5 (1.1)	6 (1.3)	0 (0.0)	11 (2.4)
	歯肉炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	単純ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	帯状疱疹	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	麦粒腫	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	感染	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	インフルエンザ	2 (0.4)	5 (1.1)	1 (0.2)	8 (1.7)
	腎感染	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	限局性感染	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	下気道感染	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻咽頭炎	37 (8.0)	19 (4.1)	0 (0.0)	56 (12.1)
	外耳炎	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	中耳炎	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	歯周炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	咽頭炎	6 (1.3)	0 (0.0)	0 (0.0)	6 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	レンサ球菌性咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	毛巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	マイコプラズマ性肺炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎盂腎炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)	2 (0.5)	0 (0.0)	6 (1.5)
	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	歯膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	1 (0.3)	4 (1.0)
	上気道感染	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	15 (3.9)	7 (1.8)	1 (0.3)	23 (5.9)
	尿路感染	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	5 (1.3)	5 (1.3)	0 (0.0)	10 (2.6)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	歯感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	3 (0.8)
	白癬感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	外陰腟真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	口腔ヘルペス	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ノロウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (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）	基底細胞癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	レンサ球菌性咽頭炎	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	毛巣嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	肺炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	マイコプラズマ性肺炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	腎盂腎炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鼻炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	副鼻腔炎	4 (0.9)	2 (0.4)	0 (0.0)	6 (1.3)
	皮下組織膿瘍	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	歯膿瘍	2 (0.4)	1 (0.2)	1 (0.2)	4 (0.9)
	上気道感染	16 (3.4)	7 (1.5)	1 (0.2)	24 (5.2)
	尿路感染	6 (1.3)	5 (1.1)	0 (0.0)	11 (2.4)
	ウイルス性上気道感染	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	歯感染	0 (0.0)	3 (0.6)	0 (0.0)	3 (0.6)
	白癬感染	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	ダニ皮膚炎	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	外陰腟真菌感染	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	口腔ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ノロウイルス性胃腸炎	0 (0.0)	1 (0.2)	0 (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）	基底細胞癌	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
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）	乳癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	脂肪腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚の新生物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	扁平上皮癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	子宮平滑筋腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	肛門性器疣贅	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血液およびリンパ系障害	貧血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
免疫系障害	動物アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	食物アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	季節性アレルギー	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
内分泌障害	高プロラクチン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	甲状腺機能低下症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
代謝および栄養障害	糖尿病	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (0.5)	1 (0.3)	1 (0.3)	4 (1.0)
	コントロール不良の糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	体液貯留	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
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）	乳癌	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	脂肪腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	皮膚の新生物	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	扁平上皮癌	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	子宮平滑筋腫	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	肛門性器疣贅	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
血液およびリンパ系障害	貧血	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
免疫系障害	動物アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	食物アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	季節性アレルギー	2 (0.4)	2 (0.4)	0 (0.0)	4 (0.9)
内分泌障害	高プロラクチン血症	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	甲状腺機能低下症	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
代謝および栄養障害	糖尿病	3 (0.6)	1 (0.2)	1 (0.2)	5 (1.1)
	コントロール不良の糖尿病	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	体液貯留	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
代謝および栄養障害	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	痛風	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	低カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	食欲亢進	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	10 (2.6)	4 (1.0)	1 (0.3)	15 (3.9)
	肥満	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	食欲減退	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	4 (1.0)	2 (0.5)	0 (0.0)	6 (1.5)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	過小食	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
精神障害	異常な夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)	2 (0.5)	0 (0.0)	6 (1.5)
	急性ストレス反応	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	激越	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)	3 (0.8)	0 (0.0)	8 (2.1)
	広場恐怖症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	不安	7 (9.3)	3 (4.0)	0 (0.0)	10 (13.3)	15 (3.9)	20 (5.1)	1 (0.3)	36 (9.3)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	注意喚起行動	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	10 (13.3)	3 (4.0)	1 (1.3)	14 (18.7)	0 (0.0)	3 (0.8)	1 (0.3)	4 (1.0)
	情動鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
代謝および栄養障害	耐糖能障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	痛風	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	高血糖	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	低カリウム血症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	食欲亢進	11 (2.4)	4 (0.9)	1 (0.2)	16 (3.4)
	肥満	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	食欲減退	5 (1.1)	2 (0.4)	0 (0.0)	7 (1.5)
	高脂血症	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	過小食	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	２型糖尿病	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
精神障害	異常な夢	4 (0.9)	2 (0.4)	0 (0.0)	6 (1.3)
	急性ストレス反応	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	攻撃性	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	激越	5 (1.1)	3 (0.6)	0 (0.0)	8 (1.7)
	広場恐怖症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	不安	22 (4.7)	23 (5.0)	1 (0.2)	46 (9.9)
	無感情	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	注意喚起行動	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	双極１型障害	10 (2.2)	6 (1.3)	2 (0.4)	18 (3.9)
	情動鈍麻	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	歯ぎしり	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
精神障害	抑うつ気分	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	うつ病	0 (0.0)	3 (4.0)	0 (0.0)	3 (4.0)	9 (2.3)	13 (3.3)	1 (0.3)	23 (5.9)
	不快気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	感情の貧困	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	軽躁	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	衝動行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	初期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	不眠症	8 (10.7)	3 (4.0)	0 (0.0)	11 (14.7)	24 (6.2)	15 (3.9)	1 (0.3)	40 (10.3)
	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	易刺激性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	3 (0.8)	0 (0.0)	4 (1.0)
	リビドー減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	3 (0.8)
	躁病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	3 (0.8)	4 (1.0)
	気分変化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	悪夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)
	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	妄想症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	落ち着きのなさ	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	12 (3.1)	10 (2.6)	0 (0.0)	22 (5.7)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	社会逃避行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	自殺念慮	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	4 (1.0)	2 (0.5)	2 (0.5)	8 (2.1)
	自殺企図	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
精神障害	抑うつ気分	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	うつ病	9 (1.9)	16 (3.4)	1 (0.2)	26 (5.6)
	不快気分	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	感情の貧困	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	軽躁	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	衝動行為	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	初期不眠症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	不眠症	32 (6.9)	18 (3.9)	1 (0.2)	51 (11.0)
	故意の自傷行為	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	易刺激性	1 (0.2)	3 (0.6)	0 (0.0)	4 (0.9)
	リビドー減退	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	躁病	1 (0.2)	0 (0.0)	3 (0.6)	4 (0.9)
	気分変化	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	神経過敏	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	悪夢	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	パニック発作	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	妄想症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	落ち着きのなさ	13 (2.8)	10 (2.2)	0 (0.0)	23 (5.0)
	睡眠障害	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	自殺念慮	5 (1.1)	2 (0.4)	2 (0.4)	9 (1.9)
	自殺企図	2 (0.4)	0 (0.0)	1 (0.2)	3 (0.6)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
精神障害	抑うつ症状	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	1 (0.3)	4 (1.0)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	異常行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	自傷行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	3 (0.8)
	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
神経系障害	アカシジア	10 (13.3)	4 (5.3)	0 (0.0)	14 (18.7)	35 (9.0)	18 (4.6)	1 (0.3)	54 (13.9)
	失語症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	自律神経失調	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動緩慢	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	浮動性めまい	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	6 (1.5)	3 (0.8)	0 (0.0)	9 (2.3)
	体位性めまい	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)
	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	味覚異常	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	3 (0.8)	2 (0.5)	0 (0.0)	5 (1.3)
	ジストニア	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.8)	4 (1.0)	1 (0.3)	12 (3.1)
	頭痛	7 (9.3)	0 (0.0)	0 (0.0)	7 (9.3)	10 (2.6)	12 (3.1)	0 (0.0)	22 (5.7)
	運動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
精神障害	抑うつ症状	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	双極性障害	0 (0.0)	3 (0.6)	1 (0.2)	4 (0.9)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	異常行動	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	自傷行動	0 (0.0)	3 (0.6)	0 (0.0)	3 (0.6)
	早朝覚醒型不眠症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
神経系障害	アカシジア	45 (9.7)	22 (4.7)	1 (0.2)	68 (14.7)
	失語症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	自律神経失調	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	運動緩慢	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	注意力障害	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	浮動性めまい	7 (1.5)	3 (0.6)	0 (0.0)	10 (2.2)
	体位性めまい	5 (1.1)	0 (0.0)	0 (0.0)	5 (1.1)
	よだれ	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	構語障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	味覚異常	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ジスキネジア	6 (1.3)	2 (0.4)	0 (0.0)	8 (1.7)
	ジストニア	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	錐体外路障害	7 (1.5)	4 (0.9)	1 (0.2)	12 (2.6)
	頭痛	17 (3.7)	12 (2.6)	0 (0.0)	29 (6.3)
	運動過多	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
神経系障害	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	感覚鈍麻	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	企図振戦	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	1 (0.3)	4 (1.0)
	精神的機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	3 (0.8)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	パーキンソニズム	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.0)
	坐骨神経痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	鎮静	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	4 (1.0)	10 (2.6)	2 (0.5)	16 (4.1)
	感覚障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	副鼻腔炎に伴う頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	傾眠	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	11 (2.8)	6 (1.5)	1 (0.3)	18 (4.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	遅発性ジスキネジア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	1 (0.3)	3 (0.8)
	振戦	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	22 (5.7)	2 (0.5)	1 (0.3)	25 (6.4)
	眉間反射異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.0)
	微細運動機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
眼障害	眼瞼痙攣	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)	0 (0.0)	0 (0.0)	4 (1.0)
	糖尿病性白内障	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
神経系障害	過眠症	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	感覚鈍麻	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	企図振戦	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	嗜眠	2 (0.4)	1 (0.2)	1 (0.2)	4 (0.9)
	精神的機能障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	片頭痛	0 (0.0)	2 (0.4)	1 (0.2)	3 (0.6)
	錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	パーキンソニズム	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	坐骨神経痛	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	鎮静	4 (0.9)	11 (2.4)	2 (0.4)	17 (3.7)
	感覚障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔炎に伴う頭痛	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	傾眠	13 (2.8)	6 (1.3)	1 (0.2)	20 (4.3)
	失神	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	遅発性ジスキネジア	1 (0.2)	1 (0.2)	1 (0.2)	3 (0.6)
	振戦	25 (5.4)	2 (0.4)	1 (0.2)	28 (6.0)
	眉間反射異常	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	下肢静止不能症候群	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	微細運動機能障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
眼障害	眼瞼痙攣	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	糖尿病性白内障	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
眼障害	霧視	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	注視麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	瞬目過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
耳および迷路障害	耳痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	回転性めまい	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
心臓障害	急性心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	動悸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	プリンツメタル狭心症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)	0 (0.0)	0 (0.0)	4 (1.0)
血管障害	本態性高血圧症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	潮紅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.0)
	起立性低血圧	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
眼障害	霧視	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	注視麻痺	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	瞬目過多	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
耳および迷路障害	耳痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	回転性めまい	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
心臓障害	急性心筋梗塞	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	徐脈	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心停止	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	心筋梗塞	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	動悸	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	頻脈	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
血管障害	本態性高血圧症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	潮紅	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	高血圧	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	起立性低血圧	5 (1.1)	0 (0.0)	0 (0.0)	5 (1.1)

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FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	慢性閉塞性肺疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.0)	3 (0.8)	0 (0.0)	7 (1.8)
	咽喉乾燥	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	しゃっくり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	低酸素症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	肺障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	鼻閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	鼻乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	胸膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	鼻漏	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	咽喉絞扼感	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	アレルギー性副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	上気道の炎症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔咽頭痛	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	咽頭反射亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
胃腸障害	腹部不快感	2 (2.7)	1 (1.3)	0 (0.0)	3 (4.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	腹部膨満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	慢性閉塞性肺疾患	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	咳嗽	4 (0.9)	3 (0.6)	0 (0.0)	7 (1.5)
	咽喉乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	呼吸困難	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	鼻出血	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	しゃっくり	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	低酸素症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	肺障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鼻閉	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	鼻乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	胸膜炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鼻漏	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	咽喉絞扼感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アレルギー性副鼻腔炎	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	上気道の炎症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	口腔咽頭痛	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	咽頭反射亢進	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
胃腸障害	腹部不快感	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	腹部膨満	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
胃腸障害	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	4 (1.0)	0 (0.0)	6 (1.5)
	上腹部痛	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	慢性胃炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)	4 (1.0)	2 (0.5)	0 (0.0)	6 (1.5)
	齲歯	3 (4.0)	1 (1.3)	0 (0.0)	4 (5.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	下痢	7 (9.3)	0 (0.0)	0 (0.0)	7 (9.3)	12 (3.1)	2 (0.5)	0 (0.0)	14 (3.6)
	口内乾燥	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	6 (1.5)	1 (0.3)	0 (0.0)	7 (1.8)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	腸炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	消化器痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	過敏性腸症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	悪心	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)	8 (2.1)	2 (0.5)	1 (0.3)	11 (2.8)
	歯周病	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	11 (2.8)	2 (0.5)	0 (0.0)	13 (3.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	口内炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
胃腸障害	腹痛	2 (0.4)	4 (0.9)	0 (0.0)	6 (1.3)
	上腹部痛	5 (1.1)	0 (0.0)	0 (0.0)	5 (1.1)
	慢性胃炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	便秘	8 (1.7)	2 (0.4)	0 (0.0)	10 (2.2)
	齲歯	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	下痢	19 (4.1)	2 (0.4)	0 (0.0)	21 (4.5)
	口内乾燥	7 (1.5)	1 (0.2)	0 (0.0)	8 (1.7)
	消化不良	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	嚥下障害	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	腸炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	胃炎	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	胃食道逆流性疾患	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	消化器痛	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	血便排泄	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	痔核	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	過敏性腸症候群	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	悪心	12 (2.6)	2 (0.4)	1 (0.2)	15 (3.2)
	歯周病	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	流涎過多	12 (2.6)	2 (0.4)	0 (0.0)	14 (3.0)
	歯の知覚過敏	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	口内炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	舌障害	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
胃腸障害	歯の脱落	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	歯痛	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	8 (2.1)	5 (1.3)	0 (0.0)	13 (3.3)
	嘔吐	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	9 (2.3)	0 (0.0)	0 (0.0)	9 (2.3)
	心窩部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	口の錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
肝胆道系障害	胆嚢炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	急性胆嚢炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	高ビリルビン血症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	嚢胞性ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	ざ瘡様皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	接触性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	斑状出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	湿疹	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	紅斑	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)
	嵌入爪	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
胃腸障害	歯の脱落	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	歯痛	10 (2.2)	5 (1.1)	0 (0.0)	15 (3.2)
	嘔吐	12 (2.6)	0 (0.0)	0 (0.0)	12 (2.6)
	心窩部不快感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	口の錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
肝胆道系障害	胆嚢炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	急性胆嚢炎	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	肝炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	高ビリルビン血症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	水疱	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ざ瘡様皮膚炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	接触性皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	皮膚乾燥	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	斑状出血	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	湿疹	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	紅斑	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	多汗症	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	嵌入爪	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害	寝汗	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	光線過敏性反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	そう痒症	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	乾癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	発疹	2 (2.7)	1 (1.3)	0 (0.0)	3 (4.0)	5 (1.3)	1 (0.3)	0 (0.0)	6 (1.5)
	斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	斑状丘疹状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	そう痒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	脂漏性皮膚炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蕁麻疹	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
筋骨格系および結合組織障害	関節痛	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	2 (0.5)	6 (1.5)	1 (0.3)	9 (2.3)
	背部痛	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)	10 (2.6)	1 (0.3)	0 (0.0)	11 (2.8)
	外骨腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	鼡径部痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	筋萎縮	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	2 (0.5)	0 (0.0)	4 (1.0)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	筋骨格痛	1 (1.3)	1 (1.3)	0 (0.0)	2 (2.7)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害	寝汗	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	光線過敏性反応	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	そう痒症	5 (1.1)	0 (0.0)	0 (0.0)	5 (1.1)
	乾癬	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	発疹	7 (1.5)	2 (0.4)	0 (0.0)	9 (1.9)
	斑状皮疹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	斑状丘疹状皮疹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	そう痒性皮疹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	脂漏性皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	蕁麻疹	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
筋骨格系および結合組織障害	関節痛	4 (0.9)	6 (1.3)	1 (0.2)	11 (2.4)
	背部痛	14 (3.0)	1 (0.2)	0 (0.0)	15 (3.2)
	外骨腫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鼡径部痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	関節硬直	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	筋萎縮	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋固縮	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋痙縮	2 (0.4)	2 (0.4)	0 (0.0)	4 (0.9)
	筋攣縮	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	筋骨格痛	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
筋骨格系および結合組織障害	筋肉痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	2 (0.5)	3 (0.8)
	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	骨端症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	骨壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	四肢痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	9 (2.3)	0 (0.0)	0 (0.0)	9 (2.3)
	滑液嚢腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	腱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	筋緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	椎間板突出	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	筋骨格硬直	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	5 (1.3)	2 (0.5)	0 (0.0)	7 (1.8)
	項部硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	椎間板障害	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節過伸展	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	関節不安定	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
腎および尿路障害	血尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	尿意切迫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	腎結石症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.5)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
筋骨格系および結合組織障害	筋肉痛	2 (0.4)	0 (0.0)	2 (0.4)	4 (0.9)
	頚部痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	骨端症	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	骨壊死	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	四肢痛	10 (2.2)	0 (0.0)	0 (0.0)	10 (2.2)
	滑液嚢腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	顎関節症候群	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腱炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	開口障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	筋緊張	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	椎間板突出	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋骨格硬直	6 (1.3)	2 (0.4)	0 (0.0)	8 (1.7)
	項部硬直	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	椎間板障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	関節過伸展	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	関節不安定	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
腎および尿路障害	血尿	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	尿意切迫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腎結石症	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.4)
	夜間頻尿	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
腎および尿路障害	頻尿	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	蛋白尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	尿失禁	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿管結石症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
生殖系および乳房障害	無月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	良性前立腺肥大症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	性器発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	月経遅延	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	不規則月経	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	性機能不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	外陰腟乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.3)	1 (0.3)	0 (0.0)	6 (1.5)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	無菌膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
腎および尿路障害	頻尿	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	蛋白尿	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	尿失禁	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	尿管結石症	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
生殖系および乳房障害	無月経	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	良性前立腺肥大症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	性器発疹	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	月経障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	月経遅延	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	不正子宮出血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	卵巣嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	性機能不全	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	外陰腟乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	勃起不全	5 (1.1)	1 (0.2)	0 (0.0)	6 (1.3)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
一般・全身障害および投与部位の状態	無菌膿瘍	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.0)
	胸部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	胸痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	2 (0.5)	4 (1.0)
	嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	疲労	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (3.3)	7 (1.8)	0 (0.0)	20 (5.1)
	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	インフルエンザ様疾患	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	注射部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	注射部位紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	注射部位硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	注射部位腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	注射部位疼痛	9 (12.0)	1 (1.3)	0 (0.0)	10 (13.3)	20 (5.1)	4 (1.0)	0 (0.0)	24 (6.2)
	倦怠感	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	発熱	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	4 (1.0)	0 (0.0)	0 (0.0)	4 (1.0)
	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	注射部位腫脹	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)
	小結節	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態	無力症	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	胸部不快感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	胸痛	0 (0.0)	2 (0.4)	2 (0.4)	4 (0.9)
	嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	疲労	13 (2.8)	7 (1.5)	0 (0.0)	20 (4.3)
	異常感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	歩行障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	インフルエンザ様疾患	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	注射部位内出血	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	注射部位紅斑	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位腫瘤	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	注射部位疼痛	29 (6.3)	5 (1.1)	0 (0.0)	34 (7.3)
	倦怠感	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	末梢性浮腫	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	疼痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	発熱	5 (1.1)	0 (0.0)	0 (0.0)	5 (1.1)
	口渇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位腫脹	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	小結節	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	非心臓性胸痛	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
臨床検査	アラニンアミノトランスフェラーゼ増加	1 (1.3)	1 (1.3)	0 (0.0)	2 (2.7)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	血中コレステロール増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	血中クレアチンホスホキナーゼ増加	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)
	血中ブドウ糖増加	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	血圧低下	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	血中プロラクチン減少	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	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)	1 (0.3)	0 (0.0)	1 (0.3)
	血中尿酸増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心雑音	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	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 (1.3)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	尿中ブドウ糖陽性	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	グリコヘモグロビン増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	体重減少	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)	2 (0.5)	7 (1.8)	0 (0.0)	9 (2.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
臨床検査	アラニンアミノトランスフェラーゼ増加	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	血中コレステロール増加	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	血中クレアチンホスホキナーゼ増加	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	血中ブドウ糖増加	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	血圧低下	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	血圧上昇	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
	血中プロラクチン減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中プロラクチン増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中トリグリセリド増加	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	血中尿酸増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心雑音	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	γ－グルタミルトランスフェラーゼ増加	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	尿中ブドウ糖陽性	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	グリコヘモグロビン増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	尿中血陽性	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心拍数増加	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	体重減少	6 (1.3)	7 (1.5)	0 (0.0)	13 (2.8)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
臨床検査	体重増加	11 (14.7)	1 (1.3)	0 (0.0)	12 (16.0)	27 (6.9)	19 (4.9)	4 (1.0)	50 (12.9)
	尿中白血球陽性	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	肝酵素上昇	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ビタミンＤ減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	ヘリコバクター検査陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
傷害、中毒および処置合併症	足関節部骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	節足動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)
	凍瘡	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	裂傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	2 (0.5)	0 (0.0)	3 (0.8)
	靱帯捻挫	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)	4 (1.0)	3 (0.8)	0 (0.0)	7 (1.8)
	ストレス骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)
	肉離れ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	挫傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)
	胸部損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)
	歯牙破折	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
臨床検査	体重増加	38 (8.2)	20 (4.3)	4 (0.9)	62 (13.4)
	尿中白血球陽性	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	起立血圧上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	肝酵素上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ビタミンＤ減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ヘリコバクター検査陽性	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	肝機能検査値上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症	足関節部骨折	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	節足動物咬傷	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	凍瘡	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	転倒	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	裂傷	2 (0.4)	2 (0.4)	0 (0.0)	4 (0.9)
	靱帯捻挫	6 (1.3)	3 (0.6)	0 (0.0)	9 (1.9)
	ストレス骨折	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	肉離れ	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	挫傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	関節損傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢損傷	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	胸部損傷	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	歯牙破折	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)				NON-JAPAN (N=389)			
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MILD n (%)	MOD n (%)	SEV n (%)	TOTAL n (%)	MILD n (%)	MOD n (%)	SEV n (%)	TOTAL n (%)
傷害、中毒および処置合併症	処置による疼痛	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)	2 (0.5)	4 (1.0)	0 (0.0)	6 (1.5)
	皮膚擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

表 2.7.4.7-229　重症度別有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.1

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		TOTAL (N=464)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症	処置による疼痛	2 (0.4)	4 (0.9)	1 (0.2)	7 (1.5)
	皮膚擦過傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6AAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.1　FINAL

＜資料番号 5.3.5.3-01：CT-8.2.3.1＞

表 2.7.4.7-230　重篤な有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.5.2.1

Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	腎感染	0	(0.0)	1	(0.3)	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）	乳癌	0	(0.0)	1	(0.3)	1	(0.2)
内分泌障害	高プロラクチン血症	0	(0.0)	1	(0.3)	1	(0.2)
代謝および栄養障害	糖尿病	0	(0.0)	1	(0.3)	1	(0.2)
	コントロール不良の糖尿病	0	(0.0)	1	(0.3)	1	(0.2)
	肥満	0	(0.0)	1	(0.3)	1	(0.2)
精神障害	攻撃性	0	(0.0)	1	(0.3)	1	(0.2)
	双極１型障害	2	(2.7)	2	(0.5)	4	(0.9)
	躁病	0	(0.0)	3	(0.8)	3	(0.6)
	社会逃避行動	0	(0.0)	1	(0.3)	1	(0.2)
	自殺念慮	0	(0.0)	4	(1.0)	4	(0.9)
	自殺企図	0	(0.0)	1	(0.3)	1	(0.2)
	双極性障害	0	(0.0)	2	(0.5)	2	(0.4)
	大うつ病	0	(0.0)	1	(0.3)	1	(0.2)
神経系障害	傾眠	0	(0.0)	1	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6ADB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.5.2.1　FINAL

表 2.7.4.7-230　重篤な有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.5.2.1

Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
神経系障害	遅発性ジスキネジア	0	(0.0)	1	(0.3)	1	(0.2)
心臓障害	急性心筋梗塞	0	(0.0)	1	(0.3)	1	(0.2)
	心停止	0	(0.0)	1	(0.3)	1	(0.2)
	心筋梗塞	0	(0.0)	1	(0.3)	1	(0.2)
	プリンツメタル狭心症	0	(0.0)	1	(0.3)	1	(0.2)
呼吸器、胸郭および縦隔障害	呼吸困難	0	(0.0)	1	(0.3)	1	(0.2)
肝胆道系障害	急性胆嚢炎	0	(0.0)	1	(0.3)	1	(0.2)
一般・全身障害および投与部位の状態	胸痛	0	(0.0)	2	(0.5)	2	(0.4)
傷害、中毒および処置合併症	節足動物咬傷	0	(0.0)	1	(0.3)	1	(0.2)
TOTAL1)		2	(2.7)	28	(7.2)	30	(6.5)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6ADB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.5.2.1　FINAL

＜資料番号 5.3.5.3-01：CT-8.5.2.1＞

表 2.7.4.7-231　投与中止に至った有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.6.2.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	ウイルス性胃腸炎	0	(0.0)	1	(0.3)	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）	乳癌	0	(0.0)	1	(0.3)	1	(0.2)
内分泌障害	高プロラクチン血症	0	(0.0)	1	(0.3)	1	(0.2)
代謝および栄養障害	糖尿病	1	(1.3)	0	(0.0)	1	(0.2)
	コントロール不良の糖尿病	0	(0.0)	2	(0.5)	2	(0.4)
	食欲亢進	0	(0.0)	1	(0.3)	1	(0.2)
精神障害	不安	0	(0.0)	1	(0.3)	1	(0.2)
	双極１型障害	3	(4.0)	1	(0.3)	4	(0.9)
	歯ぎしり	0	(0.0)	1	(0.3)	1	(0.2)
	うつ病	0	(0.0)	3	(0.8)	3	(0.6)
	不眠症	0	(0.0)	2	(0.5)	2	(0.4)
	躁病	0	(0.0)	3	(0.8)	3	(0.6)
	落ち着きのなさ	0	(0.0)	2	(0.5)	2	(0.4)
	社会逃避行動	0	(0.0)	1	(0.3)	1	(0.2)
	自殺念慮	0	(0.0)	3	(0.8)	3	(0.6)
	双極性障害	0	(0.0)	2	(0.5)	2	(0.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6AEB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.2.1　FINAL

表 2.7.4.7-231　投与中止に至った有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.6.2.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

		JAPAN (N=75)		NON-JAPAN (N=389)		TOTAL (N=464)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
精神障害	大うつ病	0	(0.0)	1	(0.3)	1	(0.2)
神経系障害	アカシジア	0	(0.0)	3	(0.8)	3	(0.6)
	錐体外路障害	0	(0.0)	2	(0.5)	2	(0.4)
	嗜眠	0	(0.0)	1	(0.3)	1	(0.2)
	パーキンソニズム	0	(0.0)	1	(0.3)	1	(0.2)
	鎮静	0	(0.0)	1	(0.3)	1	(0.2)
	傾眠	0	(0.0)	2	(0.5)	2	(0.4)
	遅発性ジスキネジア	0	(0.0)	2	(0.5)	2	(0.4)
	振戦	0	(0.0)	2	(0.5)	2	(0.4)
心臓障害	プリンツメタル狭心症	0	(0.0)	1	(0.3)	1	(0.2)
呼吸器、胸郭および縦隔障害	咽頭反射亢進	0	(0.0)	1	(0.3)	1	(0.2)
筋骨格系および結合組織障害	筋萎縮	1	(1.3)	0	(0.0)	1	(0.2)
一般・全身障害および投与部位の状態	無力症	0	(0.0)	1	(0.3)	1	(0.2)
	疲労	0	(0.0)	1	(0.3)	1	(0.2)
臨床検査	体重増加	1	(1.3)	6	(1.5)	7	(1.5)
	肝機能検査値上昇	0	(0.0)	1	(0.3)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.2.1　FINAL

表 2.7.4.7-231　投与中止に至った有害事象［日本，日本以外，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.6.2.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=75) n	(%)	NON-JAPAN (N=389) n	(%)	TOTAL (N=464) n	(%)
TOTAL1)		6	(8.0)	41	(10.5)	47	(10.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.6.2.1 FINAL

＜資料番号 5.3.5.3-01：CT-8.6.2.1＞

表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MANIC (N=50) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=75) n	(%)
感染症および寄生虫症	気管支炎	0	(0.0)	1	(4.0)	1	(1.3)
	膀胱炎	2	(4.0)	0	(0.0)	2	(2.7)
	胃腸炎	1	(2.0)	0	(0.0)	1	(1.3)
	歯肉炎	1	(2.0)	0	(0.0)	1	(1.3)
	帯状疱疹	1	(2.0)	0	(0.0)	1	(1.3)
	麦粒腫	0	(0.0)	1	(4.0)	1	(1.3)
	感染	1	(2.0)	0	(0.0)	1	(1.3)
	インフルエンザ	0	(0.0)	1	(4.0)	1	(1.3)
	鼻咽頭炎	19	(38.0)	10	(40.0)	29	(38.7)
	歯周炎	1	(2.0)	0	(0.0)	1	(1.3)
	咽頭炎	4	(8.0)	2	(8.0)	6	(8.0)
	マイコプラズマ性肺炎	1	(2.0)	0	(0.0)	1	(1.3)
	上気道感染	1	(2.0)	0	(0.0)	1	(1.3)
	尿路感染	0	(0.0)	1	(4.0)	1	(1.3)
	口腔ヘルペス	0	(0.0)	1	(4.0)	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）	脂肪腫	0	(0.0)	1	(4.0)	1	(1.3)
	肛門性器疣贅	1	(2.0)	0	(0.0)	1	(1.3)
免疫系障害	季節性アレルギー	1	(2.0)	0	(0.0)	1	(1.3)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.3　FINAL

表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MANIC (N=50) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=75) n	(%)
代謝および栄養障害	糖尿病	1	(2.0)	0	(0.0)	1	(1.3)
	食欲亢進	0	(0.0)	1	(4.0)	1	(1.3)
	肥満	1	(2.0)	0	(0.0)	1	(1.3)
	食欲減退	0	(0.0)	1	(4.0)	1	(1.3)
	過小食	1	(2.0)	0	(0.0)	1	(1.3)
精神障害	急性ストレス反応	1	(2.0)	0	(0.0)	1	(1.3)
	不安	7	(14.0)	3	(12.0)	10	(13.3)
	注意喚起行動	0	(0.0)	1	(4.0)	1	(1.3)
	双極１型障害	7	(14.0)	7	(28.0)	14	(18.7)
	抑うつ気分	1	(2.0)	0	(0.0)	1	(1.3)
	うつ病	3	(6.0)	0	(0.0)	3	(4.0)
	軽躁	1	(2.0)	0	(0.0)	1	(1.3)
	不眠症	6	(12.0)	5	(20.0)	11	(14.7)
	落ち着きのなさ	1	(2.0)	0	(0.0)	1	(1.3)
	自殺念慮	1	(2.0)	0	(0.0)	1	(1.3)
	自殺企図	1	(2.0)	1	(4.0)	2	(2.7)
	抑うつ症状	1	(2.0)	0	(0.0)	1	(1.3)
神経系障害	アカシジア	9	(18.0)	5	(20.0)	14	(18.7)
	自律神経失調	0	(0.0)	1	(4.0)	1	(1.3)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.3　FINAL

表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MANIC (N=50) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=75) n	(%)
神経系障害	運動緩慢	1	(2.0)	0	(0.0)	1	(1.3)
	浮動性めまい	1	(2.0)	0	(0.0)	1	(1.3)
	体位性めまい	2	(4.0)	0	(0.0)	2	(2.7)
	味覚異常	0	(0.0)	1	(4.0)	1	(1.3)
	ジスキネジア	2	(4.0)	1	(4.0)	3	(4.0)
	ジストニア	1	(2.0)	0	(0.0)	1	(1.3)
	頭痛	7	(14.0)	0	(0.0)	7	(9.3)
	感覚鈍麻	0	(0.0)	1	(4.0)	1	(1.3)
	パーキンソニズム	1	(2.0)	0	(0.0)	1	(1.3)
	鎮静	1	(2.0)	0	(0.0)	1	(1.3)
	傾眠	2	(4.0)	0	(0.0)	2	(2.7)
	振戦	3	(6.0)	0	(0.0)	3	(4.0)
眼障害	糖尿病性白内障	1	(2.0)	0	(0.0)	1	(1.3)
耳および迷路障害	回転性めまい	1	(2.0)	0	(0.0)	1	(1.3)
血管障害	起立性低血圧	2	(4.0)	1	(4.0)	3	(4.0)
呼吸器、胸郭および縦隔障害	咽喉乾燥	0	(0.0)	1	(4.0)	1	(1.3)
	鼻漏	1	(2.0)	0	(0.0)	1	(1.3)
	咽喉絞扼感	1	(2.0)	0	(0.0)	1	(1.3)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.3　FINAL

表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MANIC (N=50) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=75) n	(%)
呼吸器、胸郭および縦隔障害	上気道の炎症	1	(2.0)	0	(0.0)	1	(1.3)
	口腔咽頭痛	1	(2.0)	1	(4.0)	2	(2.7)
胃腸障害	腹部不快感	3	(6.0)	0	(0.0)	3	(4.0)
	上腹部痛	3	(6.0)	0	(0.0)	3	(4.0)
	慢性胃炎	1	(2.0)	0	(0.0)	1	(1.3)
	便秘	4	(8.0)	0	(0.0)	4	(5.3)
	齲歯	1	(2.0)	3	(12.0)	4	(5.3)
	下痢	4	(8.0)	3	(12.0)	7	(9.3)
	口内乾燥	1	(2.0)	0	(0.0)	1	(1.3)
	腸炎	0	(0.0)	1	(4.0)	1	(1.3)
	胃炎	0	(0.0)	1	(4.0)	1	(1.3)
	悪心	3	(6.0)	1	(4.0)	4	(5.3)
	歯周病	0	(0.0)	1	(4.0)	1	(1.3)
	流涎過多	1	(2.0)	0	(0.0)	1	(1.3)
	口内炎	1	(2.0)	0	(0.0)	1	(1.3)
	歯痛	2	(4.0)	0	(0.0)	2	(2.7)
	嘔吐	2	(4.0)	1	(4.0)	3	(4.0)
肝胆道系障害	高ビリルビン血症	1	(2.0)	0	(0.0)	1	(1.3)
皮膚および皮下組織障害	湿疹	1	(2.0)	1	(4.0)	2	(2.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.3　FINAL

表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MANIC (N=50) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=75) n	(%)
皮膚および皮下組織障害	紅斑	1	(2.0)	0	(0.0)	1	(1.3)
	多汗症	0	(0.0)	1	(4.0)	1	(1.3)
	そう痒症	2	(4.0)	1	(4.0)	3	(4.0)
	発疹	2	(4.0)	1	(4.0)	3	(4.0)
	脂漏性皮膚炎	0	(0.0)	1	(4.0)	1	(1.3)
	蕁麻疹	1	(2.0)	0	(0.0)	1	(1.3)
筋骨格系および結合組織障害	関節痛	1	(2.0)	1	(4.0)	2	(2.7)
	背部痛	2	(4.0)	2	(8.0)	4	(5.3)
	胤径部痛	1	(2.0)	0	(0.0)	1	(1.3)
	筋萎縮	1	(2.0)	0	(0.0)	1	(1.3)
	筋骨格痛	2	(4.0)	0	(0.0)	2	(2.7)
	筋肉痛	1	(2.0)	0	(0.0)	1	(1.3)
	四肢痛	1	(2.0)	0	(0.0)	1	(1.3)
	滑液嚢腫	0	(0.0)	1	(4.0)	1	(1.3)
	筋骨格硬直	1	(2.0)	0	(0.0)	1	(1.3)
	椎間板障害	1	(2.0)	0	(0.0)	1	(1.3)
腎および尿路障害	頻尿	0	(0.0)	1	(4.0)	1	(1.3)
	尿失禁	1	(2.0)	0	(0.0)	1	(1.3)
	尿管結石症	1	(2.0)	0	(0.0)	1	(1.3)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)		DEPRESSIVE (N=25)		TOTAL (N=75)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
生殖系および乳房障害	不規則月経	1	(2.0)	0	(0.0)	1	(1.3)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1	(2.0)	0	(0.0)	1	(1.3)
一般・全身障害および投与部位の状態	インフルエンザ様疾患	1	(2.0)	0	(0.0)	1	(1.3)
	注射部位疼痛	4	(8.0)	6	(24.0)	10	(13.3)
	倦怠感	0	(0.0)	3	(12.0)	3	(4.0)
	発熱	1	(2.0)	0	(0.0)	1	(1.3)
	注射部位腫脹	1	(2.0)	0	(0.0)	1	(1.3)
臨床検査	アラニンアミノトランスフェラーゼ増加	1	(2.0)	1	(4.0)	2	(2.7)
	アスパラギン酸アミノトランスフェラーゼ増加	1	(2.0)	1	(4.0)	2	(2.7)
	血中クレアチンホスホキナーゼ増加	1	(2.0)	1	(4.0)	2	(2.7)
	血中ブドウ糖増加	2	(4.0)	0	(0.0)	2	(2.7)
	血圧低下	2	(4.0)	0	(0.0)	2	(2.7)
	血圧上昇	1	(2.0)	1	(4.0)	2	(2.7)
	血中プロラクチン減少	1	(2.0)	0	(0.0)	1	(1.3)
	血中尿酸増加	1	(2.0)	0	(0.0)	1	(1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE8AAB.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.3　FINAL

表 2.7.4.7-232　最も新しい気分エピソード別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)		DEPRESSIVE (N=25)		TOTAL (N=75)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
臨床検査	γ－グルタミルトランスフェラーゼ増加	0	(0.0)	1	(4.0)	1	(1.3)
	尿中ブドウ糖陽性	1	(2.0)	0	(0.0)	1	(1.3)
	グリコヘモグロビン増加	1	(2.0)	0	(0.0)	1	(1.3)
	尿中血陽性	1	(2.0)	0	(0.0)	1	(1.3)
	心拍数増加	0	(0.0)	1	(4.0)	1	(1.3)
	体重減少	2	(4.0)	2	(8.0)	4	(5.3)
	体重増加	10	(20.0)	2	(8.0)	12	(16.0)
	尿中白血球陽性	1	(2.0)	1	(4.0)	2	(2.7)
	肝酵素上昇	0	(0.0)	1	(4.0)	1	(1.3)
傷害、中毒および処置合併症	凍瘡	1	(2.0)	0	(0.0)	1	(1.3)
	裂傷	0	(0.0)	1	(4.0)	1	(1.3)
	靭帯捻挫	1	(2.0)	1	(4.0)	2	(2.7)
	挫傷	0	(0.0)	1	(4.0)	1	(1.3)
	関節損傷	0	(0.0)	1	(4.0)	1	(1.3)
	歯牙破折	1	(2.0)	0	(0.0)	1	(1.3)
	処置による疼痛	1	(2.0)	0	(0.0)	1	(1.3)
TOTAL1)		46	(92.0)	25	(100.0)	71	(94.7)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1.3　FINAL

＜資料番号 5.3.5.3-01：CT-8.2.2.1.3＞

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)				DEPRESSIVE (N=25)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	気管支炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	膀胱炎	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉炎	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	帯状疱疹	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	感染	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	1 (4.0)
	鼻咽頭炎	16 (32.0)	3 (6.0)	0 (0.0)	19 (38.0)	10 (40.0)	0 (0.0)	0 (0.0)	10 (40.0)
	歯周炎	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	4 (8.0)	0 (0.0)	0 (0.0)	4 (8.0)	2 (8.0)	0 (0.0)	0 (0.0)	2 (8.0)
	マイコプラズマ性肺炎	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
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）	脂肪腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	肛門性器疣贅	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	季節性アレルギー	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	気管支炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	膀胱炎	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	胃腸炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	歯肉炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	帯状疱疹	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	麦粒腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	感染	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	インフルエンザ	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	鼻咽頭炎	26 (34.7)	3 (4.0)	0 (0.0)	29 (38.7)
	歯周炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	咽頭炎	6 (8.0)	0 (0.0)	0 (0.0)	6 (8.0)
	マイコプラズマ性肺炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	上気道感染	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	尿路感染	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	口腔ヘルペス	1 (1.3)	0 (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）	脂肪腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	肛門性器疣贅	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
免疫系障害	季節性アレルギー	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)				DEPRESSIVE (N=25)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
代謝および栄養障害	糖尿病	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	肥満	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	過小食	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	急性ストレス反応	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	7 (14.0)	0 (0.0)	0 (0.0)	7 (14.0)	0 (0.0)	3 (12.0)	0 (0.0)	3 (12.0)
	注意喚起行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	双極１型障害	5 (10.0)	1 (2.0)	1 (2.0)	7 (14.0)	5 (20.0)	2 (8.0)	0 (0.0)	7 (28.0)
	抑うつ気分	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	0 (0.0)	3 (6.0)	0 (0.0)	3 (6.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	3 (6.0)	3 (6.0)	0 (0.0)	6 (12.0)	5 (20.0)	0 (0.0)	0 (0.0)	5 (20.0)
	落ち着きのなさ	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺企図	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	抑うつ症状	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	6 (12.0)	3 (6.0)	0 (0.0)	9 (18.0)	4 (16.0)	1 (4.0)	0 (0.0)	5 (20.0)
	自律神経失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	運動緩慢	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
代謝および栄養障害	糖尿病	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	食欲亢進	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	肥満	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	食欲減退	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	過小食	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
精神障害	急性ストレス反応	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	不安	7 (9.3)	3 (4.0)	0 (0.0)	10 (13.3)
	注意喚起行動	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	双極１型障害	10 (13.3)	3 (4.0)	1 (1.3)	14 (18.7)
	抑うつ気分	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	うつ病	0 (0.0)	3 (4.0)	0 (0.0)	3 (4.0)
	軽躁	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	不眠症	8 (10.7)	3 (4.0)	0 (0.0)	11 (14.7)
	落ち着きのなさ	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	自殺念慮	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	自殺企図	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	抑うつ症状	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
神経系障害	アカシジア	10 (13.3)	4 (5.3)	0 (0.0)	14 (18.7)
	自律神経失調	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	運動緩慢	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)				DEPRESSIVE (N=25)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
神経系障害	浮動性めまい	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	味覚異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	ジスキネジア	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	ジストニア	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	7 (14.0)	0 (0.0)	0 (0.0)	7 (14.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	パーキンソニズム	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	3 (6.0)	0 (0.0)	0 (0.0)	3 (6.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	糖尿病性白内障	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	回転性めまい	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	起立性低血圧	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
呼吸器、胸郭および縦隔障害	咽喉乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	鼻漏	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉絞扼感	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE8AAC.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
神経系障害	浮動性めまい	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	体位性めまい	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	味覚異常	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	ジスキネジア	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
	ジストニア	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	頭痛	7 (9.3)	0 (0.0)	0 (0.0)	7 (9.3)
	感覚鈍麻	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	パーキンソニズム	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	鎮静	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	傾眠	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	振戦	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
眼障害	糖尿病性白内障	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
耳および迷路障害	回転性めまい	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
血管障害	起立性低血圧	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	鼻漏	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	咽喉絞扼感	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)								DEPRESSIVE (N=25)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
呼吸器、胸郭および縦隔障害	上気道の炎症	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口腔咽頭痛	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
胃腸障害	腹部不快感	2	(4.0)	1	(2.0)	0	(0.0)	3	(6.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上腹部痛	3	(6.0)	0	(0.0)	0	(0.0)	3	(6.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	慢性胃炎	0	(0.0)	1	(2.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	4	(8.0)	0	(0.0)	0	(0.0)	4	(8.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	齲歯	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	2	(8.0)	1	(4.0)	0	(0.0)	3	(12.0)
	下痢	4	(8.0)	0	(0.0)	0	(0.0)	4	(8.0)	3	(12.0)	0	(0.0)	0	(0.0)	3	(12.0)
	口内乾燥	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	胃炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	悪心	3	(6.0)	0	(0.0)	0	(0.0)	3	(6.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	歯周病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	流涎過多	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内炎	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯痛	2	(4.0)	0	(0.0)	0	(0.0)	2	(4.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	嘔吐	2	(4.0)	0	(0.0)	0	(0.0)	2	(4.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
肝胆道系障害	高ビリルビン血症	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
呼吸器、胸郭および縦隔障害	上気道の炎症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	口腔咽頭痛	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
胃腸障害	腹部不快感	2 (2.7)	1 (1.3)	0 (0.0)	3 (4.0)
	上腹部痛	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
	慢性胃炎	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	便秘	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)
	齲歯	3 (4.0)	1 (1.3)	0 (0.0)	4 (5.3)
	下痢	7 (9.3)	0 (0.0)	0 (0.0)	7 (9.3)
	口内乾燥	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	腸炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	胃炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	悪心	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)
	歯周病	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	流涎過多	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	口内炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	歯痛	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	嘔吐	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
肝胆道系障害	高ビリルビン血症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)								DEPRESSIVE (N=25)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
皮膚および皮下組織障害	湿疹	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	紅斑	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	多汗症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	そう痒症	2	(4.0)	0	(0.0)	0	(0.0)	2	(4.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	発疹	2	(4.0)	0	(0.0)	0	(0.0)	2	(4.0)	0	(0.0)	1	(4.0)	0	(0.0)	1	(4.0)
	脂漏性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	蕁麻疹	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
筋骨格系および結合組織障害	関節痛	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	背部痛	2	(4.0)	0	(0.0)	0	(0.0)	2	(4.0)	2	(8.0)	0	(0.0)	0	(0.0)	2	(8.0)
	胤径部痛	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	1	(2.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	1	(2.0)	1	(2.0)	0	(0.0)	2	(4.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢痛	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	滑液嚢腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	筋骨格硬直	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	椎間板障害	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
腎および尿路障害	頻尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(4.0)
	尿失禁	1	(2.0)	0	(0.0)	0	(0.0)	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害	湿疹	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	紅斑	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	多汗症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	そう痒症	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
	発疹	2 (2.7)	1 (1.3)	0 (0.0)	3 (4.0)
	脂漏性皮膚炎	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	蕁麻疹	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
筋骨格系および結合組織障害	関節痛	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	背部痛	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)
	鼠径部痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	筋萎縮	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
	筋骨格痛	1 (1.3)	1 (1.3)	0 (0.0)	2 (2.7)
	筋肉痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	四肢痛	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	滑液嚢腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	筋骨格硬直	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	椎間板障害	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
腎および尿路障害	頻尿	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	尿失禁	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE8AAC.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)				DEPRESSIVE (N=25)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
腎および尿路障害	尿管結石症	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
生殖系および乳房障害	不規則月経	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
一般・全身障害および投与部位の状態	インフルエンザ様疾患	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	3 (6.0)	1 (2.0)	0 (0.0)	4 (8.0)	6 (24.0)	0 (0.0)	0 (0.0)	6 (24.0)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (12.0)	0 (0.0)	0 (0.0)	3 (12.0)
	発熱	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
臨床検査	アラニンアミノトランスフェラーゼ増加	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	アスパラギン酸アミノトランスフェラーゼ増加	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	血中クレアチンホスホキナーゼ増加	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	血中ブドウ糖増加	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE8AAC.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
腎および尿路障害	尿管結石症	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
生殖系および乳房障害	不規則月経	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
一般・全身障害および投与部位の状態	インフルエンザ様疾患	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	注射部位疼痛	9 (12.0)	1 (1.3)	0 (0.0)	10 (13.3)
	倦怠感	3 (4.0)	0 (0.0)	0 (0.0)	3 (4.0)
	発熱	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	注射部位腫脹	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
臨床検査	アラニンアミノトランスフェラーゼ増加	1 (1.3)	1 (1.3)	0 (0.0)	2 (2.7)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	血中クレアチンホスホキナーゼ増加	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	血中ブドウ糖増加	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	血圧低下	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE8AAC.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)				DEPRESSIVE (N=25)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
臨床検査	血圧上昇	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	血中プロラクチン減少	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中尿酸増加	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	尿中ブドウ糖陽性	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	グリコヘモグロビン増加	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	体重減少	2 (4.0)	0 (0.0)	0 (0.0)	2 (4.0)	2 (8.0)	0 (0.0)	0 (0.0)	2 (8.0)
	体重増加	9 (18.0)	1 (2.0)	0 (0.0)	10 (20.0)	2 (8.0)	0 (0.0)	0 (0.0)	2 (8.0)
	尿中白血球陽性	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	肝酵素上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
傷害、中毒および処置合併症	凍瘡	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	靱帯捻挫	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	関節損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.0)	0 (0.0)	0 (0.0)	1 (4.0)
	歯牙破折	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	0 (0.0)	0 (0.0)	1 (2.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE8AAC.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

表 2.7.4.7-233　最も新しい気分エピソード別重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.2.3.3

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
臨床検査	血圧上昇	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	血中プロラクチン減少	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	血中尿酸増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	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 (1.3)
	尿中ブドウ糖陽性	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	グリコヘモグロビン増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	尿中血陽性	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	心拍数増加	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	体重減少	4 (5.3)	0 (0.0)	0 (0.0)	4 (5.3)
	体重増加	11 (14.7)	1 (1.3)	0 (0.0)	12 (16.0)
	尿中白血球陽性	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	肝酵素上昇	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
傷害、中毒および処置合併症	凍瘡	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	裂傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	靱帯捻挫	2 (2.7)	0 (0.0)	0 (0.0)	2 (2.7)
	挫傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	関節損傷	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	歯牙破折	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
	処置による疼痛	0 (0.0)	0 (0.0)	1 (1.3)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE8AAC.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3.3　FINAL

＜資料番号 5.3.5.3-01：CT-8.2.3.3＞

表 2.7.4.7-234　最も新しい気分エピソード別重篤な有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.5.2.3
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)		DEPRESSIVE (N=25)		TOTAL (N=75)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
精神障害	**双極１型障害**	2	(4.0)	0	(0.0)	2	(2.7)
TOTAL1)		2	(4.0)	0	(0.0)	2	(2.7)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE8ADB.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.5.2.3　FINAL

＜資料番号 5.3.5.3-01：CT-8.5.2.3＞

表 2.7.4.7-235　最も新しい気分エピソード別投与中止に至った有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.6.2.3

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class and MedDRA Preferred Term by Most Recent Episode in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MANIC (N=50) n	(%)	DEPRESSIVE (N=25) n	(%)	TOTAL (N=75) n	(%)
代謝および栄養障害	糖尿病	1	(2.0)	0	(0.0)	1	(1.3)
精神障害	双極１型障害	1	(2.0)	2	(8.0)	3	(4.0)
筋骨格系および結合組織障害	筋萎縮	1	(2.0)	0	(0.0)	1	(1.3)
臨床検査	体重増加	1	(2.0)	0	(0.0)	1	(1.3)
TOTAL1)		4	(8.0)	2	(8.0)	6	(8.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE8AEB.LIS, RUN: [redacted]20[redacted] 11:01; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-8.6.2.3 FINAL

＜資料番号 5.3.5.3-01：CT-8.6.2.3＞

表 2.7.4.7-236　最も新しい気分エピソード別重症度別投与中止に至った重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.6.3.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		MANIC (N=50)				DEPRESSIVE (N=25)			
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MILD n (%)	MOD n (%)	SEV n (%)	TOTAL n (%)	MILD n (%)	MOD n (%)	SEV n (%)	TOTAL n (%)
代謝および栄養障害	糖尿病	1 (2.0)	0 (0.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	双極１型障害	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	2 (8.0)	0 (0.0)	2 (8.0)
筋骨格系および結合組織障害	筋萎縮	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
臨床検査	体重増加	0 (0.0)	1 (2.0)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.6.3.3　FINAL

表 2.7.4.7-236　最も新しい気分エピソード別重症度別投与中止に至った重症度別有害事象［日本，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-8.6.3.3
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class, MedDRA Preferred Term and Severity by Most Recent Episode in Japan (Phase C Safety Sample)

		TOTAL (N=75)			
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	MILD n (%)	MOD n (%)	SEV n (%)	TOTAL n (%)
代謝および栄養障害	糖尿病	1 (1.3)	0 (0.0)	0 (0.0)	1 (1.3)
精神障害	双極１型障害	0 (0.0)	3 (4.0)	0 (0.0)	3 (4.0)
筋骨格系および結合組織障害	筋萎縮	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)
臨床検査	体重増加	0 (0.0)	1 (1.3)	0 (0.0)	1 (1.3)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE8.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.6.3.3　FINAL
＜資料番号 5.3.5.3-01：CT-8.6.3.3＞

表 2.7.4.7-237　錠剤安定期（PhaseB）の錠剤各投与量別，最も新しい気分エピソード別の重症度別有害事象［日本人集団，長期投与試験，IMデポ剤維持治療期（Phase C）］

Table 5.3.5.3-xx Treatment-emergent Adverse Events in Phase C by Severity by Trial Medication - Aripiprazole Tablets in Phase B by Most Recent Episode in Japan (De Novo and Phase C Safety Sample)

		MANIC (N=40)								DEPRESSIVE (N=25)							
			MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL
ITEM		N	n	(%)	n	(%)	n	(%)	n	(%)	N	n	(%)	n	(%)	n	(%)	n	(%)
ENDING DOSE (MG/DAY)	<12	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
	12	21	9	(42.9)	10	(47.6)	1	(4.8)	20	(95.2)	15	10	(66.7)	5	(33.3)	0	(0.0)	15	(100.0)
	18	5	3	(60.0)	2	(40.0)	0	(0.0)	5	(100.0)	8	7	(87.5)	1	(12.5)	0	(0.0)	8	(100.0)
	24	10	6	(60.0)	3	(30.0)	1	(10.0)	10	(100.0)	1	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
	30	4	3	(75.0)	1	(25.0)	0	(0.0)	4	(100.0)	1	0	(0.0)	1	(100.0)	0	(0.0)	1	(100.0)
	>30	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
STARTING DOSE (MG/DAY)	<12	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
	12	21	9	(42.9)	10	(47.6)	1	(4.8)	20	(95.2)	18	11	(61.1)	7	(38.9)	0	(0.0)	18	(100.0)
	18	6	3	(50.0)	3	(50.0)	0	(0.0)	6	(100.0)	6	6	(100.0)	0	(0.0)	0	(0.0)	6	(100.0)
	24	10	6	(60.0)	3	(30.0)	1	(10.0)	10	(100.0)	1	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
	30	3	3	(100.0)	0	(0.0)	0	(0.0)	3	(100.0)	0	0	(---)	0	(---)	0	(---)	0	(---)
	>30	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
MAXIMUM DOSE (MG/DAY)	<12	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
	12	21	9	(42.9)	10	(47.6)	1	(4.8)	20	(95.2)	15	10	(66.7)	5	(33.3)	0	(0.0)	15	(100.0)
	18	5	3	(60.0)	2	(40.0)	0	(0.0)	5	(100.0)	7	6	(85.7)	1	(14.3)	0	(0.0)	7	(100.0)
	24	10	6	(60.0)	3	(30.0)	1	(10.0)	10	(100.0)	1	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
	30	4	3	(75.0)	1	(25.0)	0	(0.0)	4	(100.0)	2	1	(50.0)	1	(50.0)	0	(0.0)	2	(100.0)
	>30	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
MOST FREQUENT DOSE (MG/DAY)	<12	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
	12	21	9	(42.9)	10	(47.6)	1	(4.8)	20	(95.2)	16	10	(62.5)	6	(37.5)	0	(0.0)	16	(100.0)
	18	5	3	(60.0)	2	(40.0)	0	(0.0)	5	(100.0)	8	7	(87.5)	1	(12.5)	0	(0.0)	8	(100.0)
	24	10	6	(60.0)	3	(30.0)	1	(10.0)	10	(100.0)	1	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
	30	4	3	(75.0)	1	(25.0)	0	(0.0)	4	(100.0)	0	0	(---)	0	(---)	0	(---)	0	(---)
	>30	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
AVERAGE DAILY DOSE (MG)	<12	3	1	(33.3)	1	(33.3)	1	(33.3)	3	(100.0)	2	1	(50.0)	1	(50.0)	0	(0.0)	2	(100.0)
	12 - <18	20	8	(40.0)	11	(55.0)	0	(0.0)	19	(95.0)	17	11	(64.7)	6	(35.3)	0	(0.0)	17	(100.0)
	18 - <24	5	3	(60.0)	1	(20.0)	1	(20.0)	5	(100.0)	5	5	(100.0)	0	(0.0)	0	(0.0)	5	(100.0)
	24 - <30	9	6	(66.7)	3	(33.3)	0	(0.0)	9	(100.0)	1	1	(100.0)	0	(0.0)	0	(0.0)	1	(100.0)
	>=30	3	3	(100.0)	0	(0.0)	0	(0.0)	3	(100.0)	0	0	(---)	0	(---)	0	(---)	0	(---)
DURATION OF TRIAL MEDICATION IN PHASE B (DAY)	<=28	28	15	(53.6)	11	(39.3)	1	(3.6)	27	(96.4)	21	16	(76.2)	5	(23.8)	0	(0.0)	21	(100.0)
	29 - 42	10	5	(50.0)	4	(40.0)	1	(10.0)	10	(100.0)	3	2	(66.7)	1	(33.3)	0	(0.0)	3	(100.0)
	43 - 56	2	1	(50.0)	1	(50.0)	0	(0.0)	2	(100.0)	0	0	(---)	0	(---)	0	(---)	0	(---)
	57 - 70	0	0	(---)	0	(---)	0	(---)	0	(---)	1	0	(0.0)	1	(100.0)	0	(0.0)	1	(100.0)
	71 - 84	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)
	>=85	0	0	(---)	0	(---)	0	(---)	0	(---)	0	0	(---)	0	(---)	0	(---)	0	(---)

表 2.7.4.7-237　錠剤安定期（PhaseB）の錠剤各投与量別，最も新しい気分エピソード別の重症度別有害事象［日本人集団，長期投与試験，IMデポ剤維持治療期（Phase C）］

Table 5.3.5.3-xx Treatment-emergent Adverse Events in Phase C by Severity by Trial Medication - Aripiprazole Tablets in Phase B by Most Recent Episode in Japan (De Novo and Phase C Safety Sample)

ITEM		TOTAL (N=65) N	MILD n (%)	MOD n (%)	SEV n (%)	TOTAL n (%)
ENDING DOSE (MG/DAY)	<12	0	0 (---)	0 (---)	0 (---)	0 (---)
	12	36	19 (52.8)	15 (41.7)	1 (2.8)	35 (97.2)
	18	13	10 (76.9)	3 (23.1)	0 (0.0)	13 (100.0)
	24	11	7 (63.6)	3 (27.3)	1 (9.1)	11 (100.0)
	30	5	3 (60.0)	2 (40.0)	0 (0.0)	5 (100.0)
	>30	0	0 (---)	0 (---)	0 (---)	0 (---)
STARTING DOSE (MG/DAY)	<12	0	0 (---)	0 (---)	0 (---)	0 (---)
	12	39	20 (51.3)	17 (43.6)	1 (2.6)	38 (97.4)
	18	12	9 (75.0)	3 (25.0)	0 (0.0)	12 (100.0)
	24	11	7 (63.6)	3 (27.3)	1 (9.1)	11 (100.0)
	30	3	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
	>30	0	0 (---)	0 (---)	0 (---)	0 (---)
MAXIMUM DOSE (MG/DAY)	<12	0	0 (---)	0 (---)	0 (---)	0 (---)
	12	36	19 (52.8)	15 (41.7)	1 (2.8)	35 (97.2)
	18	12	9 (75.0)	3 (25.0)	0 (0.0)	12 (100.0)
	24	11	7 (63.6)	3 (27.3)	1 (9.1)	11 (100.0)
	30	6	4 (66.7)	2 (33.3)	0 (0.0)	6 (100.0)
	>30	0	0 (---)	0 (---)	0 (---)	0 (---)
MOST FREQUENT DOSE (MG/DAY)	<12	0	0 (---)	0 (---)	0 (---)	0 (---)
	12	37	19 (51.4)	16 (43.2)	1 (2.7)	36 (97.3)
	18	13	10 (76.9)	3 (23.1)	0 (0.0)	13 (100.0)
	24	11	7 (63.6)	3 (27.3)	1 (9.1)	11 (100.0)
	30	4	3 (75.0)	1 (25.0)	0 (0.0)	4 (100.0)
	>30	0	0 (---)	0 (---)	0 (---)	0 (---)
AVERAGE DAILY DOSE (MG)	<12	5	2 (40.0)	2 (40.0)	1 (20.0)	5 (100.0)
	12 - <18	37	19 (51.4)	17 (45.9)	0 (0.0)	36 (97.3)
	18 - <24	10	8 (80.0)	1 (10.0)	1 (10.0)	10 (100.0)
	24 - <30	10	7 (70.0)	3 (30.0)	0 (0.0)	10 (100.0)
	>=30	3	3 (100.0)	0 (0.0)	0 (0.0)	3 (100.0)
DURATION OF TRIAL MEDICATION IN PHASE B (DAY)	<=28	49	31 (63.3)	16 (32.7)	1 (2.0)	48 (98.0)
	29 - 42	13	7 (53.8)	5 (38.5)	1 (7.7)	13 (100.0)
	43 - 56	2	1 (50.0)	1 (50.0)	0 (0.0)	2 (100.0)
	57 - 70	1	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	71 - 84	0	0 (---)	0 (---)	0 (---)	0 (---)
	>=85	0	0 (---)	0 (---)	0 (---)	0 (---)

＜資料番号5.3.5.3-01：31-08-252 Table 5.3.5.3-10＞

表 2.7.4.7-238　錠剤安定期（PhaseB）の錠剤最終投与量別の重篤な有害事象［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

5.3.5.3.XX
Incidence of Serious Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
by Ending Dose in Phase B in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	12 mg (N=36) n	(%)	18 mg (N=13) n	(%)	24 mg (N=11) n	(%)	30 mg (N=5) n	(%)	TOTAL (N=65) n	(%)
精神障害	双極１型障害	2	(5.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(3.1)
TOTAL1)		2	(5.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(3.1)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAEAADB.LIS, RUN: [redacted]20[redacted] 10:14; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAEA.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3.XX　FINAL
＜資料番号 5.3.5.3-01：31-08-252 Table 5.3.5.3-1＞

表 2.7.4.7-239　錠剤安定期（PhaseB）の錠剤最終投与量別の投与中止に至った有害事象［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

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5.3.5.3.XX
Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product in Phase C
by System Organ Class and MedDRA Preferred Term by Ending Dose in Phase B in Japan (Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	12 mg (N=36) n	(%)	18 mg (N=13) n	(%)	24 mg (N=11) n	(%)	30 mg (N=5) n	(%)	TOTAL (N=65) n	(%)
代謝および栄養障害	糖尿病	0	(0.0)	0	(0.0)	1	(9.1)	0	(0.0)	1	(1.5)
精神障害	双極１型障害	3	(8.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(4.6)
筋骨格系および結合組織障害	筋萎縮	0	(0.0)	0	(0.0)	1	(9.1)	0	(0.0)	1	(1.5)
臨床検査	体重増加	1	(2.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.5)
TOTAL1)		4	(11.1)	0	(0.0)	2	(18.2)	0	(0.0)	6	(9.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAEA.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 5.3.5.3.XX FINAL
＜資料番号 5.3.5.3-01：31-08-252 Table 5.3.5.3-2＞

表 2.7.4.7-240　有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
感染症および寄生虫症	細菌性膣症	0	(0.0)	2	(0.4)	2	(0.4)
	気管支炎	0	(0.0)	4	(0.9)	4	(0.7)
	蜂巣炎	0	(0.0)	1	(0.2)	1	(0.2)
	ブドウ球菌性蜂巣炎	0	(0.0)	1	(0.2)	1	(0.2)
	胃腸炎	0	(0.0)	3	(0.6)	3	(0.6)
	ウイルス性胃腸炎	0	(0.0)	2	(0.4)	2	(0.4)
	帯状疱疹	1	(1.4)	0	(0.0)	1	(0.2)
	麦粒腫	1	(1.4)	0	(0.0)	1	(0.2)
	インフルエンザ	1	(1.4)	2	(0.4)	3	(0.6)
	乳腺炎	0	(0.0)	1	(0.2)	1	(0.2)
	鼻咽頭炎	5	(6.9)	10	(2.1)	15	(2.8)
	歯周炎	1	(1.4)	0	(0.0)	1	(0.2)
	レンサ球菌性咽頭炎	0	(0.0)	1	(0.2)	1	(0.2)
	副鼻腔炎	0	(0.0)	4	(0.9)	4	(0.7)
	上気道感染	1	(1.4)	9	(1.9)	10	(1.9)
	尿路感染	0	(0.0)	6	(1.3)	6	(1.1)
	ウイルス性上気道感染	0	(0.0)	1	(0.2)	1	(0.2)
	歯感染	0	(0.0)	2	(0.4)	2	(0.4)
	感染性腸炎	1	(1.4)	0	(0.0)	1	(0.2)
	肺感染	0	(0.0)	1	(0.2)	1	(0.2)
	外陰膣真菌感染	0	(0.0)	1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
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FILE: ADAE6BAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.2.1　FINAL

CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
感染症および寄生虫症	ウイルス性消化管感染	0	(0.0)	1	(0.2)	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）	腎細胞癌	0	(0.0)	1	(0.2)	1	(0.2)
免疫系障害	季節性アレルギー	0	(0.0)	1	(0.2)	1	(0.2)
内分泌障害	高プロラクチン血症	0	(0.0)	2	(0.4)	2	(0.4)
	甲状腺機能亢進症	0	(0.0)	1	(0.2)	1	(0.2)
	甲状腺機能低下症	0	(0.0)	1	(0.2)	1	(0.2)
代謝および栄養障害	脱水	0	(0.0)	1	(0.2)	1	(0.2)
	糖尿病	1	(1.4)	0	(0.0)	1	(0.2)
	コントロール不良の糖尿病	0	(0.0)	1	(0.2)	1	(0.2)
	高尿酸血症	0	(0.0)	1	(0.2)	1	(0.2)
	食欲亢進	1	(1.4)	18	(3.8)	19	(3.5)
	食欲減退	0	(0.0)	8	(1.7)	8	(1.5)
	過小食	1	(1.4)	0	(0.0)	1	(0.2)
	２型糖尿病	0	(0.0)	1	(0.2)	1	(0.2)
精神障害	異常な夢	0	(0.0)	3	(0.6)	3	(0.6)
	激越	0	(0.0)	16	(3.4)	16	(3.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2.1　FINAL

表 2.7.4.7-240　有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
精神障害	不安	3	(4.2)	25	(5.3)	28	(5.2)
	双極１型障害	3	(4.2)	0	(0.0)	3	(0.6)
	歯ぎしり	0	(0.0)	3	(0.6)	3	(0.6)
	抑うつ気分	0	(0.0)	3	(0.6)	3	(0.6)
	うつ病	1	(1.4)	5	(1.1)	6	(1.1)
	解離	0	(0.0)	1	(0.2)	1	(0.2)
	感情の貧困	0	(0.0)	1	(0.2)	1	(0.2)
	幻覚	0	(0.0)	1	(0.2)	1	(0.2)
	幻聴	0	(0.0)	1	(0.2)	1	(0.2)
	幻視	0	(0.0)	1	(0.2)	1	(0.2)
	覚醒時幻覚	0	(0.0)	1	(0.2)	1	(0.2)
	軽躁	1	(1.4)	0	(0.0)	1	(0.2)
	初期不眠症	0	(0.0)	2	(0.4)	2	(0.4)
	不眠症	3	(4.2)	27	(5.8)	30	(5.6)
	易刺激性	0	(0.0)	4	(0.9)	4	(0.7)
	リビドー減退	0	(0.0)	5	(1.1)	5	(0.9)
	中期不眠症	0	(0.0)	1	(0.2)	1	(0.2)
	早漏	0	(0.0)	1	(0.2)	1	(0.2)
	落ち着きのなさ	1	(1.4)	24	(5.1)	25	(4.6)
	睡眠障害	1	(1.4)	2	(0.4)	3	(0.6)
	自殺念慮	0	(0.0)	3	(0.6)	3	(0.6)
	自殺企図	0	(0.0)	1	(0.2)	1	(0.2)

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CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
精神障害	抑うつ症状	0	(0.0)	1	(0.2)	1	(0.2)
	大うつ病	0	(0.0)	1	(0.2)	1	(0.2)
	消極的思考	0	(0.0)	1	(0.2)	1	(0.2)
	精神活動過多	0	(0.0)	1	(0.2)	1	(0.2)
	短時間睡眠	0	(0.0)	1	(0.2)	1	(0.2)
	早朝覚醒型不眠症	0	(0.0)	2	(0.4)	2	(0.4)
	持続性抑うつ障害	0	(0.0)	1	(0.2)	1	(0.2)
神経系障害	アカシジア	5	(6.9)	73	(15.6)	78	(14.4)
	健忘	0	(0.0)	1	(0.2)	1	(0.2)
	運動緩慢	1	(1.4)	2	(0.4)	3	(0.6)
	歯車様固縮	0	(0.0)	1	(0.2)	1	(0.2)
	注意力障害	0	(0.0)	1	(0.2)	1	(0.2)
	浮動性めまい	2	(2.8)	7	(1.5)	9	(1.7)
	体位性めまい	1	(1.4)	4	(0.9)	5	(0.9)
	よだれ	0	(0.0)	1	(0.2)	1	(0.2)
	ジスキネジア	0	(0.0)	3	(0.6)	3	(0.6)
	ジストニア	1	(1.4)	4	(0.9)	5	(0.9)
	錐体外路障害	1	(1.4)	9	(1.9)	10	(1.9)
	頭痛	1	(1.4)	9	(1.9)	10	(1.9)
	知覚過敏	0	(0.0)	1	(0.2)	1	(0.2)
	感覚鈍麻	0	(0.0)	1	(0.2)	1	(0.2)

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CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
神経系障害	嗜眠	0	(0.0)	2	(0.4)	2	(0.4)
	意識消失	0	(0.0)	1	(0.2)	1	(0.2)
	片頭痛	0	(0.0)	2	(0.4)	2	(0.4)
	不随意性筋収縮	0	(0.0)	1	(0.2)	1	(0.2)
	錯感覚	0	(0.0)	2	(0.4)	2	(0.4)
	精神運動亢進	0	(0.0)	1	(0.2)	1	(0.2)
	鎮静	0	(0.0)	17	(3.6)	17	(3.1)
	傾眠	1	(1.4)	17	(3.6)	18	(3.3)
	失神	0	(0.0)	3	(0.6)	3	(0.6)
	振戦	4	(5.6)	6	(1.3)	10	(1.9)
	下肢静止不能症候群	0	(0.0)	2	(0.4)	2	(0.4)
眼障害	眼瞼痙攣	0	(0.0)	5	(1.1)	5	(0.9)
	糖尿病性白内障	1	(1.4)	0	(0.0)	1	(0.2)
	眼充血	0	(0.0)	1	(0.2)	1	(0.2)
	霧視	0	(0.0)	1	(0.2)	1	(0.2)
	瞬目過多	0	(0.0)	1	(0.2)	1	(0.2)
耳および迷路障害	耳鳴	0	(0.0)	1	(0.2)	1	(0.2)
心臓障害	動悸	0	(0.0)	1	(0.2)	1	(0.2)

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
血管障害	高血圧	0	(0.0)	3	(0.6)	3	(0.6)
呼吸器、胸郭および縦隔障害	慢性閉塞性肺疾患	0	(0.0)	1	(0.2)	1	(0.2)
	咳嗽	0	(0.0)	2	(0.4)	2	(0.4)
	咽喉乾燥	1	(1.4)	0	(0.0)	1	(0.2)
	しゃっくり	0	(0.0)	2	(0.4)	2	(0.4)
	咽喉絞扼感	0	(0.0)	1	(0.2)	1	(0.2)
	アレルギー性副鼻腔炎	0	(0.0)	1	(0.2)	1	(0.2)
	気道うっ血	0	(0.0)	1	(0.2)	1	(0.2)
	口腔咽頭痛	1	(1.4)	3	(0.6)	4	(0.7)
胃腸障害	腹部膨満	1	(1.4)	1	(0.2)	2	(0.4)
	腹痛	0	(0.0)	1	(0.2)	1	(0.2)
	上腹部痛	1	(1.4)	2	(0.4)	3	(0.6)
	便秘	2	(2.8)	5	(1.1)	7	(1.3)
	下痢	1	(1.4)	10	(2.1)	11	(2.0)
	口内乾燥	0	(0.0)	8	(1.7)	8	(1.5)
	十二指腸炎	0	(0.0)	1	(0.2)	1	(0.2)
	消化不良	0	(0.0)	1	(0.2)	1	(0.2)
	鼓腸	0	(0.0)	1	(0.2)	1	(0.2)
	胃炎	0	(0.0)	2	(0.4)	2	(0.4)
	胃食道逆流性疾患	0	(0.0)	3	(0.6)	3	(0.6)

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SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
胃腸障害	歯肉痛	0	(0.0)	1	(0.2)	1	(0.2)
	悪心	1	(1.4)	7	(1.5)	8	(1.5)
	口腔内痛	0	(0.0)	1	(0.2)	1	(0.2)
	流涎過多	0	(0.0)	10	(2.1)	10	(1.9)
	歯の知覚過敏	0	(0.0)	1	(0.2)	1	(0.2)
	舌腫脹	0	(0.0)	1	(0.2)	1	(0.2)
	舌障害	0	(0.0)	4	(0.9)	4	(0.7)
	歯痛	0	(0.0)	3	(0.6)	3	(0.6)
	嘔吐	0	(0.0)	6	(1.3)	6	(1.1)
	口の錯感覚	0	(0.0)	1	(0.2)	1	(0.2)
	好酸球性食道炎	0	(0.0)	1	(0.2)	1	(0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	0	(0.0)	1	(0.2)	1	(0.2)
	脱毛症	0	(0.0)	1	(0.2)	1	(0.2)
	水疱	0	(0.0)	1	(0.2)	1	(0.2)
	接触性皮膚炎	1	(1.4)	0	(0.0)	1	(0.2)
	皮膚乾燥	0	(0.0)	1	(0.2)	1	(0.2)
	湿疹	1	(1.4)	0	(0.0)	1	(0.2)
	多汗症	1	(1.4)	0	(0.0)	1	(0.2)
	そう痒症	0	(0.0)	1	(0.2)	1	(0.2)
	乾癬	0	(0.0)	1	(0.2)	1	(0.2)
	発疹	0	(0.0)	1	(0.2)	1	(0.2)

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
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SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
皮膚および皮下組織障害	丘疹性皮疹	0	(0.0)	1	(0.2)	1	(0.2)
	蕁麻疹	0	(0.0)	1	(0.2)	1	(0.2)
筋骨格系および結合組織障害	関節痛	0	(0.0)	3	(0.6)	3	(0.6)
	背部痛	0	(0.0)	5	(1.1)	5	(0.9)
	関節硬直	0	(0.0)	2	(0.4)	2	(0.4)
	関節腫脹	0	(0.0)	1	(0.2)	1	(0.2)
	筋固縮	0	(0.0)	1	(0.2)	1	(0.2)
	筋痙縮	0	(0.0)	3	(0.6)	3	(0.6)
	筋攣縮	0	(0.0)	5	(1.1)	5	(0.9)
	筋肉痛	0	(0.0)	6	(1.3)	6	(1.1)
	頚部痛	0	(0.0)	2	(0.4)	2	(0.4)
	変形性関節症	0	(0.0)	1	(0.2)	1	(0.2)
	四肢痛	0	(0.0)	2	(0.4)	2	(0.4)
	関節周囲炎	1	(1.4)	0	(0.0)	1	(0.2)
	腱炎	0	(0.0)	2	(0.4)	2	(0.4)
	開口障害	0	(0.0)	1	(0.2)	1	(0.2)
	筋緊張	0	(0.0)	2	(0.4)	2	(0.4)
	筋骨格硬直	0	(0.0)	1	(0.2)	1	(0.2)
	四肢不快感	0	(0.0)	1	(0.2)	1	(0.2)
腎および尿路障害	頻尿	0	(0.0)	1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6BAB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.2.1　FINAL

表 2.7.4.7-240　有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
腎および尿路障害	腎臓痛	0	(0.0)	1	(0.2)	1	(0.2)
	排尿躊躇	0	(0.0)	1	(0.2)	1	(0.2)
生殖系および乳房障害	無月経	0	(0.0)	1	(0.2)	1	(0.2)
	射精遅延	0	(0.0)	1	(0.2)	1	(0.2)
	乳汁漏出症	0	(0.0)	1	(0.2)	1	(0.2)
	不正子宮出血	1	(1.4)	0	(0.0)	1	(0.2)
	性機能不全	0	(0.0)	1	(0.2)	1	(0.2)
	外陰腟乾燥	0	(0.0)	1	(0.2)	1	(0.2)
	勃起不全	0	(0.0)	3	(0.6)	3	(0.6)
一般・全身障害および投与部位の状態	無力症	0	(0.0)	1	(0.2)	1	(0.2)
	胸痛	0	(0.0)	1	(0.2)	1	(0.2)
	疲労	1	(1.4)	19	(4.1)	20	(3.7)
	異常感	0	(0.0)	2	(0.4)	2	(0.4)
	びくびく感	0	(0.0)	1	(0.2)	1	(0.2)
	末梢性浮腫	0	(0.0)	1	(0.2)	1	(0.2)
	疼痛	0	(0.0)	1	(0.2)	1	(0.2)
	発熱	0	(0.0)	5	(1.1)	5	(0.9)
	口渇	0	(0.0)	1	(0.2)	1	(0.2)
	末梢腫脹	0	(0.0)	1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2.1　FINAL

表 2.7.4.7-240　有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
臨床検査	アラニンアミノトランスフェラーゼ増加	1	(1.4)	2	(0.4)	3	(0.6)
	アスパラギン酸アミノトランスフェラーゼ増加	1	(1.4)	0	(0.0)	1	(0.2)
	血中コレステロール増加	0	(0.0)	1	(0.2)	1	(0.2)
	血中クレアチンホスホキナーゼ増加	1	(1.4)	0	(0.0)	1	(0.2)
	血中ブドウ糖増加	0	(0.0)	2	(0.4)	2	(0.4)
	血圧低下	0	(0.0)	1	(0.2)	1	(0.2)
	血圧上昇	0	(0.0)	1	(0.2)	1	(0.2)
	血中プロラクチン減少	1	(1.4)	0	(0.0)	1	(0.2)
	血中甲状腺刺激ホルモン増加	0	(0.0)	1	(0.2)	1	(0.2)
	心電図異常	0	(0.0)	1	(0.2)	1	(0.2)
	心電図ＱＴ延長	0	(0.0)	1	(0.2)	1	(0.2)
	γ－グルタミルトランスフェラーゼ増加	1	(1.4)	2	(0.4)	3	(0.6)
	グリコヘモグロビン増加	0	(0.0)	1	(0.2)	1	(0.2)
	心拍数減少	0	(0.0)	1	(0.2)	1	(0.2)
	心拍数増加	0	(0.0)	1	(0.2)	1	(0.2)
	ＨＩＶ検査陽性	0	(0.0)	1	(0.2)	1	(0.2)
	体重減少	1	(1.4)	2	(0.4)	3	(0.6)
	体重増加	2	(2.8)	16	(3.4)	18	(3.3)

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SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2.1　FINAL

表 2.7.4.7-240　有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.2.1
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
臨床検査	起立血圧上昇	0	(0.0)	1	(0.2)	1	(0.2)
	肝酵素上昇	0	(0.0)	1	(0.2)	1	(0.2)
	尿検査異常	0	(0.0)	1	(0.2)	1	(0.2)
傷害、中毒および処置合併症	鎖骨骨折	1	(1.4)	0	(0.0)	1	(0.2)
	転倒	0	(0.0)	1	(0.2)	1	(0.2)
	前腕骨折	1	(1.4)	0	(0.0)	1	(0.2)
	手骨折	1	(1.4)	0	(0.0)	1	(0.2)
	裂傷	0	(0.0)	2	(0.4)	2	(0.4)
	靭帯捻挫	0	(0.0)	1	(0.2)	1	(0.2)
	交通事故	0	(0.0)	1	(0.2)	1	(0.2)
	軟部組織損傷	0	(0.0)	1	(0.2)	1	(0.2)
	肉離れ	0	(0.0)	2	(0.4)	2	(0.4)
	挫傷	0	(0.0)	1	(0.2)	1	(0.2)
	熱傷	0	(0.0)	1	(0.2)	1	(0.2)
	歯牙破折	0	(0.0)	2	(0.4)	2	(0.4)
	処置による疼痛	0	(0.0)	1	(0.2)	1	(0.2)
	各種物質毒性	0	(0.0)	1	(0.2)	1	(0.2)
TOTAL1)		35	(48.6)	276	(59.0)	311	(57.6)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2.1　FINAL

＜資料番号 5.3.5.3-01：CT-21.2.2.1＞

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)								NON-JAPAN (N=468)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
感染症および寄生虫症	細菌性膣症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.4)
	気管支炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	3	(0.6)	0	(0.0)	4	(0.9)
	蜂巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	ブドウ球菌性蜂巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	胃腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	0	(0.0)	3	(0.6)
	ウイルス性胃腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	2	(0.4)
	帯状疱疹	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	麦粒腫	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	インフルエンザ	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.4)
	乳腺炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	鼻咽頭炎	5	(6.9)	0	(0.0)	0	(0.0)	5	(6.9)	3	(0.6)	7	(1.5)	0	(0.0)	10	(2.1)
	歯周炎	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	レンサ球菌性咽頭炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	副鼻腔炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	1	(0.2)	4	(0.9)
	上気道感染	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	8	(1.7)	1	(0.2)	0	(0.0)	9	(1.9)
	尿路感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.1)	1	(0.2)	0	(0.0)	6	(1.3)
	ウイルス性上気道感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	歯感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	感染性腸炎	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肺感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	外陰膣真菌感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	ウイルス性消化管感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
感染症および寄生虫症	細菌性膣症	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	気管支炎	1 (0.2)	3 (0.6)	0 (0.0)	4 (0.7)
	蜂巣炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	ブドウ球菌性蜂巣炎	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	胃腸炎	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	ウイルス性胃腸炎	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	帯状疱疹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	麦粒腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	インフルエンザ	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	乳腺炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鼻咽頭炎	8 (1.5)	7 (1.3)	0 (0.0)	15 (2.8)
	歯周炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	レンサ球菌性咽頭炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	副鼻腔炎	2 (0.4)	1 (0.2)	1 (0.2)	4 (0.7)
	上気道感染	9 (1.7)	1 (0.2)	0 (0.0)	10 (1.9)
	尿路感染	5 (0.9)	1 (0.2)	0 (0.0)	6 (1.1)
	ウイルス性上気道感染	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	歯感染	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	感染性腸炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	肺感染	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	外陰膣真菌感染	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ウイルス性消化管感染	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)				NON-JAPAN (N=468)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
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）	腎細胞癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
免疫系障害	季節性アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
内分泌障害	高プロラクチン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	甲状腺機能亢進症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	甲状腺機能低下症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
代謝および栄養障害	脱水	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	糖尿病	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	高尿酸血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	食欲亢進	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	9 (1.9)	8 (1.7)	1 (0.2)	18 (3.8)
	食欲減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.3)	2 (0.4)	0 (0.0)	8 (1.7)
	過小食	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
精神障害	異常な夢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	激越	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (1.3)	10 (2.1)	0 (0.0)	16 (3.4)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
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）	腎細胞癌	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
免疫系障害	季節性アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
内分泌障害	高プロラクチン血症	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	甲状腺機能亢進症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	甲状腺機能低下症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
代謝および栄養障害	脱水	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	糖尿病	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	コントロール不良の糖尿病	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	高尿酸血症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	食欲亢進	10 (1.9)	8 (1.5)	1 (0.2)	19 (3.5)
	食欲減退	6 (1.1)	2 (0.4)	0 (0.0)	8 (1.5)
	過小食	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	２型糖尿病	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
精神障害	異常な夢	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	激越	6 (1.1)	10 (1.9)	0 (0.0)	16 (3.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)								NON-JAPAN (N=468)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
精神障害	不安	3	(4.2)	0	(0.0)	0	(0.0)	3	(4.2)	12	(2.6)	12	(2.6)	1	(0.2)	25	(5.3)
	双極１型障害	1	(1.4)	2	(2.8)	0	(0.0)	3	(4.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	0	(0.0)	3	(0.6)
	抑うつ気分	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.6)	0	(0.0)	3	(0.6)
	うつ病	0	(0.0)	1	(1.4)	0	(0.0)	1	(1.4)	2	(0.4)	3	(0.6)	0	(0.0)	5	(1.1)
	解離	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	感情の貧困	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	幻覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	幻聴	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	幻視	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	覚醒時幻覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	軽躁	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	初期不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.4)
	不眠症	2	(2.8)	1	(1.4)	0	(0.0)	3	(4.2)	12	(2.6)	15	(3.2)	0	(0.0)	27	(5.8)
	易刺激性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	1	(0.2)	4	(0.9)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	4	(0.9)	0	(0.0)	5	(1.1)
	中期不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	早漏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	落ち着きのなさ	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	14	(3.0)	10	(2.1)	0	(0.0)	24	(5.1)
	睡眠障害	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	2	(0.4)	0	(0.0)	0	(0.0)	2	(0.4)
	自殺念慮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	2	(0.4)	0	(0.0)	3	(0.6)
	自殺企図	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)							
		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)
精神障害	不安	15	(2.8)	12	(2.2)	1	(0.2)	28	(5.2)
	双極１型障害	1	(0.2)	2	(0.4)	0	(0.0)	3	(0.6)
	歯ぎしり	2	(0.4)	1	(0.2)	0	(0.0)	3	(0.6)
	抑うつ気分	0	(0.0)	3	(0.6)	0	(0.0)	3	(0.6)
	うつ病	2	(0.4)	4	(0.7)	0	(0.0)	6	(1.1)
	解離	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	感情の貧困	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	幻覚	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	幻聴	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	幻視	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	覚醒時幻覚	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	軽躁	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	初期不眠症	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.4)
	不眠症	14	(2.6)	16	(3.0)	0	(0.0)	30	(5.6)
	易刺激性	2	(0.4)	1	(0.2)	1	(0.2)	4	(0.7)
	リビドー減退	1	(0.2)	4	(0.7)	0	(0.0)	5	(0.9)
	中期不眠症	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	早漏	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	落ち着きのなさ	15	(2.8)	10	(1.9)	0	(0.0)	25	(4.6)
	睡眠障害	3	(0.6)	0	(0.0)	0	(0.0)	3	(0.6)
	自殺念慮	1	(0.2)	2	(0.4)	0	(0.0)	3	(0.6)
	自殺企図	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)

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表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

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by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)								NON-JAPAN (N=468)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
精神障害	抑うつ症状	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	大うつ病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	消極的思考	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	精神活動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	短時間睡眠	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	早朝覚醒型不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	持続性抑うつ障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
神経系障害	アカシジア	3	(4.2)	2	(2.8)	0	(0.0)	5	(6.9)	37	(7.9)	31	(6.6)	5	(1.1)	73	(15.6)
	健忘	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	運動緩慢	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	歯車様固縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	注意力障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	浮動性めまい	2	(2.8)	0	(0.0)	0	(0.0)	2	(2.8)	7	(1.5)	0	(0.0)	0	(0.0)	7	(1.5)
	体位性めまい	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	4	(0.9)	0	(0.0)	0	(0.0)	4	(0.9)
	よだれ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	2	(0.4)	0	(0.0)	3	(0.6)
	ジストニア	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	3	(0.6)	0	(0.0)	1	(0.2)	4	(0.9)
	錐体外路障害	0	(0.0)	1	(1.4)	0	(0.0)	1	(1.4)	5	(1.1)	4	(0.9)	0	(0.0)	9	(1.9)
	頭痛	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	8	(1.7)	0	(0.0)	1	(0.2)	9	(1.9)
	知覚過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	感覚鈍麻	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
精神障害	抑うつ症状	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	大うつ病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	消極的思考	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	精神活動過多	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	短時間睡眠	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	早朝覚醒型不眠症	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	持続性抑うつ障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
神経系障害	アカシジア	40 (7.4)	33 (6.1)	5 (0.9)	78 (14.4)
	健忘	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	運動緩慢	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	歯車様固縮	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注意力障害	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	浮動性めまい	9 (1.7)	0 (0.0)	0 (0.0)	9 (1.7)
	体位性めまい	5 (0.9)	0 (0.0)	0 (0.0)	5 (0.9)
	よだれ	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ジスキネジア	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	ジストニア	4 (0.7)	0 (0.0)	1 (0.2)	5 (0.9)
	錐体外路障害	5 (0.9)	5 (0.9)	0 (0.0)	10 (1.9)
	頭痛	9 (1.7)	0 (0.0)	1 (0.2)	10 (1.9)
	知覚過敏	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	感覚鈍麻	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)								NON-JAPAN (N=468)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
神経系障害	嗜眠	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	意識消失	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	片頭痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	不随意性筋収縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	2	(0.4)
	精神運動亢進	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	鎮静	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	8	(1.7)	9	(1.9)	0	(0.0)	17	(3.6)
	傾眠	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	11	(2.4)	5	(1.1)	1	(0.2)	17	(3.6)
	失神	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	2	(0.4)	0	(0.0)	3	(0.6)
	振戦	4	(5.6)	0	(0.0)	0	(0.0)	4	(5.6)	6	(1.3)	0	(0.0)	0	(0.0)	6	(1.3)
	下肢静止不能症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
眼障害	眼瞼痙攣	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.1)	0	(0.0)	0	(0.0)	5	(1.1)
	糖尿病性白内障	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	眼充血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	霧視	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	瞬目過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
耳および迷路障害	耳鳴	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
心臓障害	動悸	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
神経系障害	嗜眠	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	意識消失	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	片頭痛	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	不随意性筋収縮	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	錯感覚	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	精神運動亢進	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鎮静	8 (1.5)	9 (1.7)	0 (0.0)	17 (3.1)
	傾眠	12 (2.2)	5 (0.9)	1 (0.2)	18 (3.3)
	失神	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	振戦	10 (1.9)	0 (0.0)	0 (0.0)	10 (1.9)
	下肢静止不能症候群	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
眼障害	眼瞼痙攣	5 (0.9)	0 (0.0)	0 (0.0)	5 (0.9)
	糖尿病性白内障	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	眼充血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	霧視	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	瞬目過多	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
耳および迷路障害	耳鳴	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
心臓障害	動悸	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)				NON-JAPAN (N=468)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
血管障害	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
呼吸器、胸郭および縦隔障害	慢性閉塞性肺疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	咽喉乾燥	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	咽喉絞扼感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アレルギー性副鼻腔炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	口腔咽頭痛	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
胃腸障害	腹部膨満	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	上腹部痛	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	便秘	2 (2.8)	0 (0.0)	0 (0.0)	2 (2.8)	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	下痢	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	8 (1.7)	2 (0.4)	0 (0.0)	10 (2.1)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.1)	3 (0.6)	0 (0.0)	8 (1.7)
	十二指腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鼓腸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
血管障害	高血圧	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
呼吸器、胸郭および縦隔障害	慢性閉塞性肺疾患	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	咳嗽	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	咽喉乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	しゃっくり	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	咽喉絞扼感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アレルギー性副鼻腔炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	気道うっ血	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	口腔咽頭痛	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.7)
胃腸障害	腹部膨満	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	腹痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	上腹部痛	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	便秘	6 (1.1)	1 (0.2)	0 (0.0)	7 (1.3)
	下痢	9 (1.7)	2 (0.4)	0 (0.0)	11 (2.0)
	口内乾燥	5 (0.9)	3 (0.6)	0 (0.0)	8 (1.5)
	十二指腸炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	消化不良	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鼓腸	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	胃炎	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)

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表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)				NON-JAPAN (N=468)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
胃腸障害	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)	0 (0.0)	3 (0.6)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	悪心	0 (0.0)	1 (1.4)	0 (0.0)	1 (1.4)	5 (1.1)	2 (0.4)	0 (0.0)	7 (1.5)
	口腔内痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (1.5)	3 (0.6)	0 (0.0)	10 (2.1)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	舌腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	舌障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	歯痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)	2 (0.4)	0 (0.0)	6 (1.3)
	口の錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	好酸球性食道炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	脱毛症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	接触性皮膚炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	湿疹	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	乾癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
胃腸障害	胃食道逆流性疾患	0 (0.0)	3 (0.6)	0 (0.0)	3 (0.6)
	歯肉痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	悪心	5 (0.9)	3 (0.6)	0 (0.0)	8 (1.5)
	口腔内痛	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	流涎過多	7 (1.3)	3 (0.6)	0 (0.0)	10 (1.9)
	歯の知覚過敏	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	舌腫脹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	舌障害	4 (0.7)	0 (0.0)	0 (0.0)	4 (0.7)
	歯痛	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	嘔吐	4 (0.7)	2 (0.4)	0 (0.0)	6 (1.1)
	口の錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	好酸球性食道炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	脱毛症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	水疱	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	接触性皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	皮膚乾燥	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	湿疹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	多汗症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	そう痒症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	乾癬	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)				NON-JAPAN (N=468)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	丘疹性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	蕁麻疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
筋骨格系および結合組織障害	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	1 (0.2)	3 (0.6)
	背部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	関節硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	関節腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	筋固縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋痙縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	1 (0.2)	3 (0.6)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)	2 (0.4)	1 (0.2)	6 (1.3)
	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	変形性関節症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	関節周囲炎	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	筋緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
皮膚および皮下組織障害	発疹	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	丘疹性皮疹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	蕁麻疹	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
筋骨格系および結合組織障害	関節痛	0 (0.0)	2 (0.4)	1 (0.2)	3 (0.6)
	背部痛	4 (0.7)	1 (0.2)	0 (0.0)	5 (0.9)
	関節硬直	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	関節腫脹	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	筋固縮	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋痙縮	0 (0.0)	2 (0.4)	1 (0.2)	3 (0.6)
	筋攣縮	4 (0.7)	1 (0.2)	0 (0.0)	5 (0.9)
	筋肉痛	3 (0.6)	2 (0.4)	1 (0.2)	6 (1.1)
	頚部痛	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	変形性関節症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢痛	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	関節周囲炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腱炎	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	開口障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	筋緊張	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	筋骨格硬直	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢不快感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)								NON-JAPAN (N=468)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
腎および尿路障害	頻尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	腎臓痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	排尿躊躇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
生殖系および乳房障害	無月経	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	射精遅延	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	乳汁漏出症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	不正子宮出血	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	性機能不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	外陰腟乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	勃起不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	0	(0.0)	3	(0.6)
一般・全身障害および投与部位の状態	無力症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	胸痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	疲労	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	11	(2.4)	8	(1.7)	0	(0.0)	19	(4.1)
	異常感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	2	(0.4)
	びくびく感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	末梢性浮腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	発熱	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.1)	0	(0.0)	0	(0.0)	5	(1.1)
	口渇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
腎および尿路障害	頻尿	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腎臓痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	排尿躊躇	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
生殖系および乳房障害	無月経	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	射精遅延	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	乳汁漏出症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	不正子宮出血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	性機能不全	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	外陰腟乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	勃起不全	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
一般・全身障害および投与部位の状態	無力症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	胸痛	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	疲労	12 (2.2)	8 (1.5)	0 (0.0)	20 (3.7)
	異常感	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	びくびく感	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	末梢性浮腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	疼痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	発熱	5 (0.9)	0 (0.0)	0 (0.0)	5 (0.9)
	口渇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)				NON-JAPAN (N=468)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態	末梢腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
臨床検査	アラニンアミノトランスフェラーゼ増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	アスパラギン酸アミノトランスフェラーゼ増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中コレステロール増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	血中クレアチンホスホキナーゼ増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	血圧低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中プロラクチン減少	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中甲状腺刺激ホルモン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	心電図異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心電図ＱＴ延長	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	γ－グルタミルトランスフェラーゼ増加	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	心拍数減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
一般・全身障害および投与部位の状態	末梢腫脹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
臨床検査	アラニンアミノトランスフェラーゼ増加	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	アスパラギン酸アミノトランスフェラーゼ増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中コレステロール増加	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	血中クレアチンホスホキナーゼ増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中ブドウ糖増加	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	血圧低下	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血圧上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中プロラクチン減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中甲状腺刺激ホルモン増加	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	心電図異常	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心電図ＱＴ延長	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	γ－グルタミルトランスフェラーゼ増加	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	グリコヘモグロビン増加	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	心拍数減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)								NON-JAPAN (N=468)							
		MILD		MOD		SEV		TOTAL		MILD		MOD		SEV		TOTAL	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
臨床検査	心拍数増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	ＨＩＶ検査陽性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	体重減少	1	(1.4)	0	(0.0)	0	(0.0)	1	(1.4)	2	(0.4)	0	(0.0)	0	(0.0)	2	(0.4)
	体重増加	2	(2.8)	0	(0.0)	0	(0.0)	2	(2.8)	10	(2.1)	5	(1.1)	1	(0.2)	16	(3.4)
	起立血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	肝酵素上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	尿検査異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
傷害、中毒および処置合併症	鎖骨骨折	0	(0.0)	0	(0.0)	1	(1.4)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	転倒	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	前腕骨折	0	(0.0)	0	(0.0)	1	(1.4)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	手骨折	0	(0.0)	0	(0.0)	1	(1.4)	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	裂傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	靱帯捻挫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	交通事故	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	軟部組織損傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	肉離れ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	挫傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	熱傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	歯牙破折	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.4)
	処置による疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
臨床検査	心拍数増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ＨＩＶ検査陽性	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	体重減少	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	体重増加	12 (2.2)	5 (0.9)	1 (0.2)	18 (3.3)
	起立血圧上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	肝酵素上昇	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	尿検査異常	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症	鎖骨骨折	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	転倒	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	前腕骨折	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	手骨折	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	裂傷	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	靱帯捻挫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	交通事故	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	軟部組織損傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	肉離れ	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	挫傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	熱傷	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	歯牙破折	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	処置による疼痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)				NON-JAPAN (N=468)			
		MILD	MOD	SEV	TOTAL	MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症	各種物質毒性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

表 2.7.4.7-241　重症度別有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.2.3.1
Incidence of Treatment-emergent Adverse Events by System Organ Class, MedDRA Preferred Term and Severity
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		TOTAL (N=540)			
		MILD	MOD	SEV	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n (%)	n (%)	n (%)	n (%)
傷害、中毒および処置合併症	各種物質毒性	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.

FILE: ADAE6BAC.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-21.2.3.1　FINAL

＜資料番号 5.3.5.3-01：CT-21.2.3.1＞

表 2.7.4.7-242　重篤な有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.5.2.1
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
感染症および寄生虫症	ブドウ球菌性蜂巣炎	0	(0.0)	1	(0.2)	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）	腎細胞癌	0	(0.0)	1	(0.2)	1	(0.2)
内分泌障害	高プロラクチン血症	0	(0.0)	1	(0.2)	1	(0.2)
	甲状腺機能低下症	0	(0.0)	1	(0.2)	1	(0.2)
代謝および栄養障害	コントロール不良の糖尿病	0	(0.0)	1	(0.2)	1	(0.2)
精神障害	自殺企図	0	(0.0)	1	(0.2)	1	(0.2)
	大うつ病	0	(0.0)	1	(0.2)	1	(0.2)
神経系障害	意識消失	0	(0.0)	1	(0.2)	1	(0.2)
胃腸障害	十二指腸炎	0	(0.0)	1	(0.2)	1	(0.2)
	胃炎	0	(0.0)	1	(0.2)	1	(0.2)
	好酸球性食道炎	0	(0.0)	1	(0.2)	1	(0.2)
生殖系および乳房障害	乳汁漏出症	0	(0.0)	1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6BDB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.5.2.1　FINAL

表 2.7.4.7-242　重篤な有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.5.2.1
Incidence of Serious Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
傷害、中毒および処置合併症	鎖骨骨折	1	(1.4)	0	(0.0)	1	(0.2)
	前腕骨折	1	(1.4)	0	(0.0)	1	(0.2)
	手骨折	1	(1.4)	0	(0.0)	1	(0.2)
	熱傷	0	(0.0)	1	(0.2)	1	(0.2)
	各種物質毒性	0	(0.0)	1	(0.2)	1	(0.2)
TOTAL1)		1	(1.4)	10	(2.1)	11	(2.0)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

表 2.7.4.7-243　アリピプラゾール IM デポ注射剤の投与遵守状況［二重盲検試験，二重盲検期（Phase D）］

SMED-1.1
Summary of Investigational Medicinal Product (IM Depot Aripiprazole or Placebo) in Phase C and Phase D
(Phase D Randomized Sample)

					NON-COMPLIANT									
									> 182 DAYS SINCE FIRST PHASE C INJECTION		> 350 DAYS SINCE FIRST PHASE D INJECTION		< 26 DAYS BETWEEN INJECTIONS	
PHASE	PHASE D TREATMENT	N	COMPLIANT n	(%)	ANY REASON n	(%)	MISSED INJECTION n	(%)	n	(%)	n	(%)	n	(%)
PHASE C	ARIP IMD	133	127	(95.5)	6	(4.5)	6	(4.5)	0	(0.0)			0	(0.0)
	PLACEBO	133	130	(97.7)	3	(2.3)	3	(2.3)	0	(0.0)			0	(0.0)
PHASE D	ARIP IMD	133	131	(98.5)	2	(1.5)	2	(1.5)			0	(0.0)	0	(0.0)
	PLACEBO	133	132	(99.2)	1	(0.8)	1	(0.8)			0	(0.0)	0	(0.0)

FILE: ADEX3AB.LIS, RUN: [redacted]20[redacted] 10:59; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:55
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADEX3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　SMED-1.1　FINAL

＜資料番号 5.3.5.1-01：SMED-1.1 より作成＞

表 2.7.4.7-244　アリピプラゾール IM デポ注射剤の投与遵守状況［二重盲検試験，IM デポ剤安定期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-250

SMED-1.2
Summary of Investigational Medicinal Product (IM Depot Aripiprazole) in Phase C (Enrolled Sample)

				NON-COMPLIANT							
		COMPLIANT		ANY REASON		MISSED INJECTION		> 182 DAYS SINCE FIRST PHASE C INJECTION		< 26 DAYS BETWEEN INJECTIONS	
PHASE	N	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
PHASE C	425	415	(97.6)	10	(2.4)	10	(2.4)	0	(0.0)	0	(0.0)

FILE: ADEX3AC.LIS, RUN: [redacted]20[redacted] 10:59; ANALYSIS DATASET CREATED: [redacted]20[redacted] 16:55
PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADEX3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 SMED-1.2 FINAL

＜資料番号 5.3.5.1-01：SMED-1.2 より作成＞

表 2.7.4.7-245　投与中止に至った有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.6.2.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
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）	腎細胞癌	0	(0.0)	1	(0.2)	1	(0.2)
内分泌障害	甲状腺機能亢進症	0	(0.0)	1	(0.2)	1	(0.2)
代謝および栄養障害	食欲亢進	0	(0.0)	2	(0.4)	2	(0.4)
精神障害	激越	0	(0.0)	2	(0.4)	2	(0.4)
	不安	0	(0.0)	4	(0.9)	4	(0.7)
	双極１型障害	2	(2.8)	0	(0.0)	2	(0.4)
	抑うつ気分	0	(0.0)	3	(0.6)	3	(0.6)
	うつ病	1	(1.4)	1	(0.2)	2	(0.4)
	幻聴	0	(0.0)	1	(0.2)	1	(0.2)
	幻視	0	(0.0)	1	(0.2)	1	(0.2)
	不眠症	1	(1.4)	1	(0.2)	2	(0.4)
	易刺激性	0	(0.0)	2	(0.4)	2	(0.4)
	落ち着きのなさ	0	(0.0)	2	(0.4)	2	(0.4)
	自殺念慮	0	(0.0)	1	(0.2)	1	(0.2)
	大うつ病	0	(0.0)	1	(0.2)	1	(0.2)
神経系障害	アカシジア	0	(0.0)	5	(1.1)	5	(0.9)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6BEB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.2.1　FINAL

表 2.7.4.7-245　投与中止に至った有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.6.2.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	JAPAN (N=72) n	(%)	NON-JAPAN (N=468) n	(%)	TOTAL (N=540) n	(%)
神経系障害	ジストニア	0	(0.0)	1	(0.2)	1	(0.2)
	錐体外路障害	1	(1.4)	1	(0.2)	2	(0.4)
	鎮静	0	(0.0)	2	(0.4)	2	(0.4)
	傾眠	0	(0.0)	1	(0.2)	1	(0.2)
胃腸障害	悪心	0	(0.0)	1	(0.2)	1	(0.2)
	嘔吐	0	(0.0)	1	(0.2)	1	(0.2)
皮膚および皮下組織障害	発疹	0	(0.0)	1	(0.2)	1	(0.2)
	蕁麻疹	0	(0.0)	1	(0.2)	1	(0.2)
筋骨格系および結合組織障害	筋攣縮	0	(0.0)	1	(0.2)	1	(0.2)
一般・全身障害および投与部位の状態	胸痛	0	(0.0)	1	(0.2)	1	(0.2)
	疲労	0	(0.0)	1	(0.2)	1	(0.2)
臨床検査	血圧上昇	0	(0.0)	1	(0.2)	1	(0.2)
	心電図異常	0	(0.0)	1	(0.2)	1	(0.2)
	心拍数増加	0	(0.0)	1	(0.2)	1	(0.2)
傷害、中毒および処置合併症	熱傷	0	(0.0)	1	(0.2)	1	(0.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY.
SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6BEB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.2.1　FINAL

表 2.7.4.7-245　投与中止に至った有害事象［日本，日本以外，長期投与試験，錠剤安定期（PhaseB）］

CT-21.6.2.1

Incidence of Treatment-emergent Adverse Events Resulting in Discontinuation of Investigational Medicinal Product by System Organ Class and MedDRA Preferred Term by Region (JAPAN/NON-JAPAN) (Phase B Safety Sample)

		JAPAN (N=72)		NON-JAPAN (N=468)		TOTAL (N=540)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)
TOTAL1)		4	(5.6)	35	(7.5)	39	(7.2)

NOTE: A TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS AN ADVERSE EVENT THAT STARTED AFTER START OF TRIAL DRUG TREATMENT; OR IF THE EVENT WAS CONTINUOUS FROM BASELINE AND WAS SERIOUS, TRIAL DRUG RELATED, OR RESULTED IN DEATH, DISCONTINUATION, INTERRUPTION OR REDUCTION OF TRIAL THERAPY. SUBJECTS ARE COUNTED ONCE, PER TERM, FOR THE MOST SEVERE OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA (VERSION 19.0) PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE6BEB.LIS, RUN: [redacted]20[redacted] 10:41; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J4¥ADAE6.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.6.2.1　FINAL

＜資料番号 5.3.5.3-01：CT-21.6.2.1＞

表 2.7.4.7-246　アリピプラゾール IM デポ注射剤の投与遵守状況［長期投与試験，IM デポ剤維持治療期（Phase C）］

OPC14597 1 OF 1
PROTOCOL 31-08-252

SMED-1.2
Summary of Investigational Medicinal Product (IM Depot Aripiprazole) in Phase C (Enrolled Sample)

ENROLLMENT SOURCE	N	COMPLIANT n	COMPLIANT (%)	NON-COMPLIANT: ANY REASON n	ANY REASON (%)	MISSED INJECTION n	MISSED INJECTION (%)	> 350 DAYS SINCE FIRST PHASE C INJECTION n	> 350 DAYS SINCE FIRST PHASE C INJECTION (%)	< 26 DAYS BETWEEN INJECTIONS n	< 26 DAYS BETWEEN INJECTIONS (%)
DE NOVO	379	371	(97.9)	8	(2.1)	4	(1.1)	0	(0.0)	2	(0.5)
ROLLOVER	85	84	(98.8)	1	(1.2)	1	(1.2)	0	(0.0)	0	(0.0)
TOTAL	464	455	(98.1)	9	(1.9)	5	(1.1)	0	(0.0)	2	(0.4)

FILE: ADEX3AB.LIS, RUN: [redacted]20[redacted] 11:48; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:54
PROGRAM: K:\OPC14597\P3108252\PROGRAM.DEV\ADEX3.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　SMED-1.2　FINAL
＜資料番号 5.3.5.2-01：SMED-1.2 より作成＞

表 2.7.4.7-247　重篤な有害事象一覧表［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 6-12MG	[redacted]	6[redacted]/[redacted]/[redacted]	胃潰瘍*/GASTRIC ULCER	胃腸障害	20[redacted]-10-21	同年*-11-28 15:00	18	SEVERE
				双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-10-29 14:10	翌年*-03-03 11:10	26	SEVERE
		[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-04-01 13:00	同年*-06-17 13:15	5	MODERATE
PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/[redacted]/[redacted]	鎖骨骨折*/RIGHT CLAVICLE DISTAL FRACTURE	傷害、中毒および処置合併症	20[redacted]-03-21 14:10	同年*-04-22 15:00	31	SEVERE
				手骨折*/RIGHT THIRD AND FORTH METACARPAL BONE FRACTURE	傷害、中毒および処置合併症	20[redacted]-03-21 14:10	同年*-04-22 15:00	31	SEVERE
				前腕骨折*/RIGHT RADIUS ULNA DISTAL FRACTURE	傷害、中毒および処置合併症	20[redacted]-03-21 14:10	同年*-04-22 15:00	31	SEVERE
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	20[redacted]-05-12	同年*-06-12 14:00	40	MODERATE
		[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-07-15 14:00	同年*-10-08 14:45	80	SEVERE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 15:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J3¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-247　重篤な有害事象一覧表［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-9.2
Listing of Serious Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS CRITERIA	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 6-12MG	[redacted]	6[redacted]/[redacted]	胃潰瘍*/GASTRIC ULCER	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG INTERRUPTED	RECOVERED/ RESOLVED
				双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED
PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/[redacted]	鎖骨骨折*/RIGHT CLAVICLE DISTAL FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				手骨折*/RIGHT THIRD AND FORTH METACARPAL BONE FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				前腕骨折*/RIGHT RADIUS ULNA DISTAL FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
PHASE C	ARIP IMD 400/300MG	[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.LIS, RUN: [redacted]20[redacted] 15:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J3¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.2　FINAL

＜資料番号 5.3.5.3-01：31-08-252 CT-9.2＞

表 2.7.4.7-248　投与中止に至った有害事象一覧表［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE A	ARIP 6-12MG	[redacted]	4[redacted]/[redacted]	不眠症*/INSOMNIA AGGRAVATED	精神障害	20[redacted]-02-09 09:00	同年*-03-13 10:30	-4	MILD
				浮動性めまい*/DIZZINESS	神経系障害	20[redacted]-02-22 13:00	同年*-03-04 09:00	10	MILD
				嘔吐*/VOMITING	胃腸障害	20[redacted]-03-09 12:00	同年*-03-11 09:00	25	MILD
		[redacted]	6[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-10-29 14:10	翌年*-03-03 11:10	26	SEVERE
		[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-07-07 09:00	同年*-09-11 09:15	40	MODERATE
PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/[redacted]	糖尿病*/DIABETES MELLITUS AGGRAVATED	代謝および栄養障害	20[redacted]-01-24 10:08	ONGOING	29	MILD
		[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-08-14	同年*-10-28	17	MODERATE
		[redacted]	5[redacted]/[redacted]	うつ病*/RELAPSE OF DEPRESSION	精神障害	20[redacted]-04-05	同年*-07-17	17	MODERATE
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	20[redacted]-04-05	同年*-05-09	17	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 15:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J3¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-248　投与中止に至った有害事象一覧表［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE A	ARIP 6-12MG	[redacted]	4[redacted]/[redacted]/[redacted]	不眠症*/INSOMNIA AGGRAVATED	精神障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				浮動性めまい*/DIZZINESS	神経系障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				嘔吐*/VOMITING	胃腸障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	YES	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE B	ARIP 12-30MG	[redacted]	3[redacted]/[redacted]/[redacted]	糖尿病*/DIABETES MELLITUS AGGRAVATED	代謝および栄養障害	NO	POSSIBLE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]/[redacted]	うつ病*/RELAPSE OF DEPRESSION	精神障害	NO	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME	神経系障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 15:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J3¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

表 2.7.4.7-248　投与中止に至った有害事象一覧表［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	START DATE/TIME	END DATE/TIME	TRIAL DAY3)	SEVERITY
PHASE B	ARIP 12-30MG	[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-11-27 18:00	翌年*-01-21	30	MODERATE
		[redacted]	3[redacted]/[redacted]/[redacted]	不眠症*/INSOMNIA AGGRAVATED	精神障害	20[redacted]-01-04	ONGOING	8	MODERATE
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-12-28	翌年*-02-17 10:00	52	MODERATE
		[redacted]	5[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	20[redacted]-05-12	同年*-06-12 14:00	40	MODERATE
		[redacted]	5[redacted]/[redacted]/[redacted]	筋萎縮*/MUSCLE ATROPHY	筋骨格系および結合組織障害	20[redacted]-10-08 09:30	同年*-11-05 10:00	169	MODERATE
		[redacted]	5[redacted]/[redacted]/[redacted]	体重増加*/WEIGHT GAIN	臨床検査	20[redacted]-04-24 14:00	ONGOING	72	MODERATE
		[redacted]	3[redacted]/[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	20[redacted]-09-02 09:55	同年*-10-28 15:56	224	MODERATE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
 ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 15:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J3¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-248　投与中止に至った有害事象一覧表［日本人集団，長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-9.3
Listing of Discontinuations Due to Adverse Events by Phase (Enrolled Sample)

PHASE	TREATMENT	SUBJECT ID1)	AGE/SEX/RACE	AE(MedDRA PT2) / VERBATIM TERM)	SYSTEM ORGAN CLASS	SERIOUS	TRIAL DRUG CAUSALITY	ACTION TAKEN	OUTCOME
PHASE B	ARIP 12-30MG	[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/[redacted]	不眠症*/INSOMNIA AGGRAVATED	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERING/ RESOLVING
PHASE C	ARIP IMD 400/300MG	[redacted]	3[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]	双極１型障害*/WORSENING OF THE BIPOLAR I DISORDER	精神障害	YES	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]	筋萎縮*/MUSCLE ATROPHY	筋骨格系および結合組織障害	NO	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/[redacted]	体重増加*/WEIGHT GAIN	臨床検査	NO	UNRELATED	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	3[redacted]/[redacted]	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	NO	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
ASTERISK AFTER THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1E.LIS, RUN: [redacted]20[redacted] 15:03; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J3¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.3　FINAL

＜資料番号 5.3.5.3-01：31-08-252 CT-9.3＞

表 2.7.4.7-249 20■年■月■日～20■年■月■日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
計	892	308
感染症および寄生虫症	11	7
菌血症	1	0
感染	0	2
インフルエンザ	0	1
口腔ヘルペス	1	0
肺炎	4	2
細菌性肺炎	0	1
腰筋膿瘍	1	0
尿路感染	3	1
創傷感染	1	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）	6	1
急性骨髄性白血病	1	0
脳の悪性新生物	1	0
白血病	0	1
肺の悪性新生物	1	0
悪性黒色腫	1	0
悪性新生物	1	0
精巣新生物	1	0
血液およびリンパ系障害	5	0
貧血	1	0
免疫性血小板減少性紫斑病	1	0
大赤血球症	1	0
好中球減少症	2	0
免疫系障害	2	1
過敏症	2	1
内分泌障害	4	0
高プロラクチン血症	2	0
下垂体炎	1	0
甲状腺機能低下症	1	0
代謝および栄養障害	20	5
異常体重増加	3	0
食欲減退	2	0
脱水	1	1
糖尿病	3	1
葉酸欠乏	1	0
高コレステロール血症	1	1
高血糖	3	0
低血糖	1	1
低カリウム血症	0	1
低ナトリウム血症	1	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
食欲亢進	1	0
肥満	1	0
２型糖尿病	1	0
水中毒	1	0
精神障害	221	129
異常行動	3	1
異常な夢	2	1
急性精神病	1	0
攻撃性	14	2
激越	5	7
怒り	3	0
不安	2	2
無感情	1	0
双極性障害	1	0
境界性パーソナリティ障害	1	0
カタトニー	4	1
コミュニケーション障害	1	0
自殺既遂	7	1
強迫性性行動	1	0
錯乱状態	3	0
反抗的行動	0	1
譫妄	3	0
妄想	6	5
依存	1	0
抑うつ気分	2	2
うつ病	3	1
希死念慮を有するうつ病	1	0
抑うつ症状	0	4
現実感消失	1	0
失見当識	1	0
解離性障害	1	0
解離性同一性障害	0	1
薬物乱用	0	1
ディスフェミア	0	1
摂食障害	2	0
感情的苦悩	1	0
感情の貧困	2	0
多幸気分	2	0
絶望感	1	0
自己否定気分	0	1
欲求不満耐性低下	1	0
ギャンブル障害	4	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
幻覚	4	6
幻聴	3	2
殺人念慮	1	0
敵意	1	4
性欲過剰	3	0
錯覚	1	0
せっかち	1	0
衝動制御障害	1	0
不相応な情動	1	0
不眠症	3	0
故意の自傷行為	4	0
易刺激性	3	1
大うつ病	1	0
躁病	5	5
精神障害	10	5
気分動揺	1	0
消極的思考	1	1
神経過敏	3	1
パニック発作	1	1
妄想症	5	1
精神的機能代償不全	4	0
精神症状	1	30
精神病性障害	16	10
精神病症状	0	1
落ち着きのなさ	9	0
統合失調感情障害	2	1
双極型統合失調感情障害	0	1
統合失調症	15	11
自傷念慮	0	1
不適切な性的行動	1	0
睡眠障害	5	0
ストレス	2	0
物質誘発性精神病性障害	1	0
自殺行為	2	2
自殺念慮	19	9
自殺企図	8	2
自殺恐怖	0	1
思考異常	2	1

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
神経系障害	137	18
アカシジア	12	1
健忘	3	0
病態失認	1	1
失語症	1	0
運動失調	1	0
平衡障害	1	0
脳損傷	0	1
脳血管発作	1	1
認知障害	2	0
昏睡	0	1
協調運動異常	1	0
認知症	1	0
意識レベルの低下	3	0
糖尿病性昏睡	1	0
浮動性めまい	5	0
よだれ	3	0
構語障害	1	0
ジスキネジア	2	0
ジストニア	3	0
錐体外路障害	8	1
顔面麻痺	1	0
出血性卒中	1	0
頭痛	6	1
水頭症	0	1
反射亢進	2	0
過眠症	1	0
運動低下	1	0
判断力低下	1	0
嗜眠	2	0
意識消失	2	0
記憶障害	2	0
運動障害	1	0
多発性硬化症	3	0
悪性症候群	9	2
錯感覚	2	0
麻痺	1	0
パーキンソニズム	6	0
睡眠の質低下	1	0
精神運動亢進	0	1
錐体路症候群	0	1
鎮静	3	2

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
痙攣発作	16	3
感覚消失	1	0
セロトニン症候群	2	0
傾眠	7	0
会話障害	1	0
昏迷	1	0
遅発性ジスキネジア	4	0
一過性脳虚血発作	2	0
振戦	8	0
刺激無反応	0	1
眼障害	10	1
眼瞼痙攣	1	0
眼運動障害	1	0
眼部腫脹	1	0
眼球回転発作	3	0
斜視	0	1
霧視	4	0
耳および迷路障害	1	1
聴覚障害	0	1
難聴	1	0
心臓障害	23	1
不整脈	1	0
心房細動	1	0
徐脈	2	0
左脚ブロック	1	0
心停止	2	0
心不全	2	0
心臓弁硬化症	1	0
心肺停止	1	0
心血管障害	1	0
期外収縮	0	1
ＱＴ延長症候群	1	0
心筋梗塞	3	0
心筋炎	1	0
動悸	2	0
拘束性心筋症	1	0
洞性徐脈	1	0
心室性期外収縮	1	0
心室壁運動低下	1	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
血管障害	4	3
動脈瘤	0	1
大動脈瘤	1	0
出血	0	1
高血圧	1	1
起立性高血圧	1	0
末梢循環不良	1	0
呼吸器、胸郭および縦隔障害	31	1
窒息	1	0
喘息	1	0
息詰まり	2	0
咳嗽	1	0
発声障害	1	0
呼吸困難	11	0
肺障害	1	0
鼻閉	1	0
口腔咽頭痛	1	0
胸水	2	0
誤嚥性肺炎	1	0
肺塞栓症	5	0
呼吸性アシドーシス	1	0
睡眠時無呼吸症候群	1	0
新生児一過性頻呼吸	1	1
胃腸障害	44	1
腹部膨満	1	0
アルコール性膵炎	1	0
便通不規則	1	0
口唇のひび割れ	1	0
潰瘍性大腸炎	1	0
便秘	3	0
下痢	3	0
消化不良	1	0
嚥下障害	2	0
食中毒	1	0
胃腸障害	1	0
吐血	2	0
腸閉塞	1	1
口唇腫脹	1	0
悪心	2	0
食道障害	1	0
食道破裂	1	0
口腔障害	1	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
膵臓障害	1	0
膵炎	1	0
直腸攣縮	1	0
流涎過多	1	0
小腸閉塞	1	0
小腸穿孔	1	0
舌腫脹	4	0
舌苔	1	0
舌の運動障害	1	0
歯の障害	1	0
歯の脱落	1	0
嘔吐	4	0
噴出性嘔吐	1	0
肝胆道系障害	8	4
胆管閉塞	1	0
薬物性肝障害	1	1
肝不全	1	0
肝機能異常	0	1
脂肪肝	1	0
肝炎	1	0
肝腫大	1	0
高ビリルビン血症	1	1
黄疸	0	1
非アルコール性脂肪性肝炎	1	0
皮膚および皮下組織障害	17	3
脱毛症	2	0
皮膚乾燥	1	0
紅斑	2	0
汗腺炎	1	0
多汗症	2	0
そう痒症	1	0
発疹	5	0
紅斑性皮疹	2	0
全身性皮疹	0	1
皮膚のたるみ	1	0
皮膚病変	0	1
蕁麻疹	0	1

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
筋骨格系および結合組織障害	30	3
関節痛	3	0
関節炎	1	0
背部痛	1	1
関節可動域低下	1	0
関節硬直	1	0
腰部脊柱管狭窄症	1	0
筋拘縮	2	0
筋痙縮	2	1
筋攣縮	2	0
筋力低下	1	1
筋骨格不快感	1	0
筋骨格痛	1	0
筋骨格硬直	3	0
変形性関節症	1	0
骨粗鬆症	1	0
四肢痛	1	0
姿勢異常	1	0
横紋筋融解症	6	0
腎および尿路障害	11	5
急性腎障害	1	2
排尿困難	1	0
尿路出血	1	0
頻尿	1	0
腎障害	0	1
腎不全	2	0
腎機能障害	0	1
尿失禁	3	1
尿閉	2	0
妊娠、産褥および周産期の状態	3	4
自然流産	2	1
早産児	1	1
早産	0	1
前期破水	0	1
生殖系および乳房障害	14	2
無月経	3	0
乳房圧痛	1	0
勃起不全	1	0
乳汁漏出症	1	0
女性化乳房	1	1
不妊症	1	0
陰唇肥大	1	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
男性性機能不全	1	0
月経過多	1	0
卵巣嚢胞	1	0
性機能不全	1	1
外陰部障害	1	0
先天性、家族性および遺伝性障害	2	1
頭蓋骨癒合症	0	1
先天性心臓疾患	1	0
陰嚢水瘤	1	0
一般・全身障害および投与部位の状態	90	16
医薬品副作用	1	0
有害事象	3	1
無力症	6	0
胸部不快感	1	0
胸痛	7	0
悪寒	1	0
随伴疾患悪化	1	0
状態悪化	3	3
嚢胞	1	0
死亡	4	3
疾患再発	9	2
薬効不十分	0	1
薬効欠如	9	1
薬物相互作用	2	0
新生児薬物離脱症候群	0	1
疲労	9	0
異常感	2	0
歩行障害	2	0
全身健康状態低下	1	0
宿酔	1	0
低体温	1	0
注射部位運動障害	1	0
倦怠感	9	0
多臓器機能不全症候群	1	1
疼痛	3	0
末梢腫脹	1	0
絶叫	1	0
不活発	1	0
症状再発	1	2
治療効果短縮	1	0
治療ノンレスポンダー	3	1
治療非遵守	4	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
臨床検査	71	2
アラニンアミノトランスフェラーゼ異常	1	0
アラニンアミノトランスフェラーゼ増加	2	0
アニオンギャップ増加	1	0
アスパラギン酸アミノトランスフェラーゼ増加	1	0
肝生検	1	0
血中重炭酸塩減少	1	0
血中ビリルビン増加	1	0
血中コレステロール増加	1	0
血中クレアチンホスホキナーゼ増加	4	0
血中ブドウ糖異常	1	0
血中ブドウ糖増加	3	0
血中マグネシウム増加	1	0
血圧異常	1	0
血圧低下	1	0
収縮期血圧上昇	1	0
血中プロラクチン減少	1	0
血中プロラクチン増加	2	0
血中トリグリセリド増加	1	0
血中尿素減少	1	0
心機能検査異常	1	0
心電図異常ＱＲＳ群	1	0
心電図ＱＴ延長	4	0
フィブリンＤダイマー増加	1	0
γ－グルタミルトランスフェラーゼ異常	1	0
糸球体濾過率増加	1	0
ヘマトクリット増加	1	0
心拍数減少	0	1
心拍数増加	2	0
心拍数不整	1	0
好中球数減少	2	0
総蛋白増加	1	0
精神医学的評価	0	1
洞調律	1	0
トランスアミナーゼ上昇	2	0
トロポニン増加	1	0
体重減少	3	0
体重増加	20	0
白血球数減少	2	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
傷害、中毒および処置合併症	31	18
偶発的過量投与	2	0
膀胱損傷	1	0
脳振盪	1	0
不適切な年齢の患者への薬剤投与	1	0
薬剤モニタリング手順実施上の誤り	1	0
処方過誤	1	0
暴力的事象への曝露	0	1
転倒	0	2
大腿骨頚部骨折	0	1
足骨折	0	1
消化管内異物	0	1
頭部損傷	0	2
熱疲労	0	1
熱射病	1	0
不適切な薬剤投与計画	1	0
誤用量投与	2	0
誤った投与期間	1	0
誤った投与経路	1	0
企図的過量投与	0	1
内臓損傷	1	0
下肢骨折	1	2
妊娠時の母体の曝露	2	1
多発骨折	1	0
適応外使用	3	0
過量投与	1	1
処方に基づく過少量投与	1	0
未承認の適応に対する製品使用	4	0
製品使用の問題	1	0
交通事故	1	2
陰嚢血腫	1	0
鎮静合併症	0	1
皮膚損傷	1	0
上肢骨折	0	1
外科および内科処置	78	59
気管内挿管	1	0
血液透析	1	0
入院	72	58
腸管手術	0	1
腎臓手術	1	0
外科手術	1	0
治療中断	2	0

表 2.7.4.7-249 20[redacted]年[redacted]月[redacted]日～20[redacted]年[redacted]月[redacted]日までに国内及び海外で報告された重篤な副作用

器官別大分類 基本語	自発報告（規制当局及び文献を含む）	市販後の非介入試験からの報告
社会環境	18	22
寝たきり	1	0
障害者	7	1
家庭内ストレス	0	1
殺人	1	0
入獄	1	0
日常活動における個人の自立の喪失	1	0
身体的暴行	3	0
個人衛生不良	1	0
患者による治療拒否	0	1
社会問題	1	3
社会的入院	0	15
物質使用	0	1
言語的虐待	1	0
車椅子使用者	1	0

MedDRA Version 21.0
＜資料番号5.3.6-01：Appendix 21.3より作成＞

エビリファイ持続性水懸筋注用 300 mg
エビリファイ持続性水懸筋注用 400 mg
エビリファイ持続性水懸筋注用 300 mg シリンジ
エビリファイ持続性水懸筋注用 400 mg シリンジ

第 2 部（モジュール 2）：CTD の概要（サマリー）

2.7.5 参考文献

大塚製薬株式会社

2.7.5　参考文献

2.7.5.1　2.7.1 章の文献

なし

2.7.5.2　2.7.2 章の文献

なし

2.7.5.3　2.7.3 章の文献

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2.7.5.4 2.7.4 章の文献

なし