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）

2.7.4 臨床的安全性

大塚製薬株式会社

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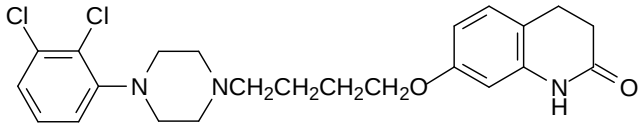
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略号一覧

略号	定義
AIMS	Abnormal Involuntary Movement Scale　異常不随意運動評価尺度
ALP	Alkaline phosphatase　アルカリホスファターゼ
ALT	Alanine aminotransferase　アラニンアミノトランスフェラーゼ
ANCOVA	Analysis of covariance　共分散分析
AST	Aspartate aminotransferase　アスパラギン酸アミノトランスフェラーゼ
BAS	Barnes Akathisia Rating Scale　Barnes　アカシジア評価尺度
BMI	Body mass index　肥満指数
BUN	Blood urea nitrogen　血液尿素窒素
C-CASA	Columbia Classification Algorithm of Suicide Assessment　自殺評価のためのコロンビア分類アルゴリズム
C-SSRS	Columbia-Suicide Severity Rating Scale　コロンビア自殺評価スケール
CGI-BP-S	Clinical Global Impression - Bipolar Version-Severity
CPK	Creatine phosphokinase　クレアチンホスホキナーゼ
DIEPSS	Drug Induced Extra-Pyramidal Symptoms Scale　薬原性錐体外路症状評価尺度
HDL	High-density lipoprotein　高比重リポ蛋白
HbA1c	Glycosylated hemoglobin　グリコシル化ヘモグロビン
IM	Intramuscular　筋肉内
LDH	Lactate (lactic acid) dehydrogenase　乳酸脱水素酵素
LDL	Low-density lipoprotein　低比重リポ蛋白
LOCF	Last observation carried forward　最終観測値をそれ以降の値に外挿する方法
MADRS	Montgomery Åsberg Depression Rating Scale
MedDRA	Medical Dictionary for Regulatory Activities　ICH 国際医薬用語集
OC	Observed cases　観察された症例
PBRER	Periodic benefit-risk evaluation report　定期的ベネフィット・リスク評価報告
QTc	Corrected QT interval　心拍数補正 QT
QTcB	QT interval corrected for heart rate using Bazett’s formula　Bazett 式による補正 QT
QTcF	QT interval corrected for heart rate using Fridericia’s formula　Fridericia 式による補正 QT
QTcN	QT interval corrected for heart rate using FDA Neuropharmacological Division formula　FDA の神経薬理部門により推奨された式で補正した QT
SAS	Simpson-Angus Scale　Simpson-Angus の錐体外路症状評価尺度
SD	Standard deviation　標準偏差
SOC	System organ class　器官別大分類
TSH	Thyroid-stimulating hormone　甲状腺刺激ホルモン
VAS	Visual Analogue Scale　視覚的アナログ尺度
YMRS	Young-Mania Rating Scale　ヤング躁病評価尺度
hCG	Human chorionic gonadotropin　ヒト絨毛性ゴナドトロピン
pH	Potential of hydrogen
γ-GTP	γ-glutamyl transpeptidase　γ-グルタミルトランスペプチダーゼ

名称（由来）	構造式
アリピプラゾール（JAN） OPC-14597	

2.7.4　臨床的安全性

臨床的安全性の概要では，成人双極 I 型障害患者を対象とした気分エピソードの再発防止のための維持療法（以下，双極 I 型障害患者の維持療法）でのアリピプラゾール IM デポ注射剤の安全性を評価した。安全性の評価は，双極 I 型障害患者を対象として実施した国際共同，第 III 相試験（日本を含む）である 31-08-250 試験（二重盲検試験）及びその継続試験である 31-08-252 試験（国際共同，日本を含む，長期投与試験）の結果を主要な安全性データとした。いずれの試験も評価資料とした。

2.7.4.1　医薬品への曝露

2.7.4.1.1　総括的安全性評価計画及び安全性試験の記述

2.7.4.1.1.1　安全性評価方法及び解析計画

(1)　全般的情報

双極 I 型障害患者を対象として実施したアリピプラゾール IM デポ注射剤の試験は，合計 2 試験である。すなわち，52 週間投与，多施設共同，無作為化，二重盲検，プラセボ対照試験の 31-08-250 試験（以下，二重盲検試験），及び 31-08-250 試験の継続試験として実施した，52 週間投与，多施設共同，無作為化，非盲検試験の 31-08-252 試験（以下，長期投与試験）である。いずれも国際共同治験として実施し，日本人被験者を含んでいる。安全性評価に使用した 2 試験の一覧を表 2.7.4.1.1-1 に示した。

二重盲検試験は，アリピプラゾール IM デポ注射剤投与により，8 週間以上安定状態を維持した双極 I 型障害患者を対象とした，無作為化，二重盲検，プラセボ対照の，有効性，安全性及び忍容性を評価するための試験である。本治験は，スクリーニング期に続き，4 つの投与期から構成された。すなわち，アリピプラゾール錠剤切り替え期［以下，錠剤切り替え期（Phase A）］（必要に応じて設定），アリピプラゾール錠剤安定期［以下，錠剤安定期（Phase B）］，アリピプラゾール IM デポ注射剤安定期［以下，IM デポ剤安定期（Phase C）］，及び二重盲検期［以下，二重盲検期（Phase D）］である。被験者は錠剤安定期に続いて，8 週間以上アリピプラゾール IM デポ注射剤を単盲検で投与され，二重盲検期でアリピプラゾール IM デポ注射剤又はプラセボに割り付けられ，治験薬を 52 週間投与された（「2.7.4.1.1.2(1) 二重盲検試験」参照）。

長期投与試験は，二重盲検試験と類似した投与期の構成になっており，スクリーニング期（必要に応じて設定）に続き，錠剤切り替え期（必要に応じて設定）［以下，錠剤切り替え期（Phase A）］，錠剤安定期［以下，錠剤安定期（Phase B）］及び非盲検の IM デポ剤維持治療期［以下，IM デポ剤維持治療期（Phase C）］で構成された（「2.7.4.1.1.2(2) 長期投与試験」参照）。

双極 I 型障害患者でのアリピプラゾール IM デポ注射剤の安全性及び忍容性を評価するための主要なデータは，二重盲検試験の二重盲検期（Phase D）のデータである。また，長期での安全性評価のために，長期投与試験の IM デポ剤維持治療期（Phase C）のデータも主要なデータと位置付けた。そのほか，主要データを支持するためのデータとして，二重盲検試験の IM デポ剤安定期（Phase C）のデータも使用した。

各臨床試験で実施した安全性評価項目を表 2.7.4.1.1-1 に示した。安全性評価方法は「2.7.4.1.1.3 安全性評価方法」に示した。

本概要中で示した試験ごとの安全性解析は，各試験の総括報告書で示した解析計画に基づいて実施した。本概要中で示したデータの主な解析方法は「2.7.4.1.1.4 安全性成績の解析方法」に示した。また，臨床的安全性の概要を作成するための解析出力はすべて 5 部に添付した（資料番号 5.3.5.1-01，5.3.5.2-01，5.3.5.3-01）。

表 2.7.4.1.1-1　　双極 I 型障害患者を対象とした安全性評価試験の概要

試験の種類 試験番号 （実施国） 添付資料番号 ［資料の取扱い］	試験デザイン	投与量，用法 （安全性解析対象例数）	投与期間 （投与回数）	安全性評価項目
第 III 相 31-08-250 国際共同 （カナダ，日本，韓国，ポーランド，ルーマニア，台湾，アメリカ） 103 施設 5.3.5.1-01 評価資料	無作為化 二重盲検 プラセボ対照 2 群並行群間 ［スクリーニング及びその後の 4 つの治療期（Phase A～D）から構成される］	Phase A，B[a]： アリピプラゾール錠剤 10-30 mg/日（Phase A：466 例，Phase B：632 例） Phase C[b]： アリピプラゾール IM デポ注射剤 400 mg 又は 300 mg を 4 週間ごと投与。 Week1-2 はアリピプラゾール錠剤 10-20 mg/日と一緒に投与（425 例） Phase D[c]： アリピプラゾール IM デポ注射剤 400 mg 又は 300 mg を 4 週間ごと，又はプラセボ注射剤を 4 週間ごとに投与（IM デポ群：132 例，プラセボ群：133 例）	Phase A：4～6 週間 Phase B：2～8 週間 Phase C：12～28 週間（3～7 回投与） Phase D：52 週間（13 回投与）	有害事象，臨床検査，バイタルサイン（血圧，心拍数，体温），体重，BMI，ウエスト周囲径，12 誘導心電図，錐体外路症状評価尺度［DIEPSS（日本人のみ），AIMS，BAS，SAS（日本人以外）］，コロンビア自殺リスク評価尺度（C-SSRS），注射部位反応，注射部位疼痛自己評価（VAS）
第 III 相 31-08-252 国際共同 （カナダ，日本，韓国，ポーランド，ルーマニア，台湾，アメリカ，マレーシア，フランス，ハンガリー） 145 施設 5.3.5.2-01 評価資料	非盲検	Phase A，B[d]： アリピプラゾール錠剤 10-30 mg/日（Phase A：498 例，Phase B：540 例） Phase C[e]： アリピプラゾール IM デポ注射剤 400 mg 又は 300 mg を 4 週間ごとに投与。 Week1-2 はアリピプラゾール錠剤 6-20 mg/日と一緒に投与（464 例）	Phase A：4～6 週間 Phase B：4～12 週間 Phase C：52 週間（13 回投与）	有害事象，臨床検査，バイタルサイン（血圧，心拍数，体温），体重，BMI，ウエスト周囲径，12 誘導心電図，錐体外路症状評価尺度［DIEPSS（日本人のみ），AIMS，BAS，SAS（日本人以外）］，コロンビア自殺リスク評価尺度（C-SSRS），注射部位反応，注射部位疼痛自己評価（VAS）

31-08-250 試験：Phase A：錠剤切り替え期，Phase B：錠剤安定期，Phase C：IM デポ剤安定期，Phase D：二重盲検期

31-08-252 試験：Phase A：錠剤切り替え期，Phase B：錠剤安定期，Phase C：IM デポ剤維持治療期

[a]：Phase A ではアリピプラゾール錠剤 5～30 mg/日を投与した。Phase B ではアリピプラゾール錠剤 15～30 mg/日を投与した。忍容性に応じて 10 mg/日に減量可能であったが，Phase C に進むまでに 15 mg/日以上とすることとした。

[b]: IM デポ注射剤は忍容性が認められない場合，300 mg への減量 1 回と 400 mg への増量 1 回が許容された。錠剤の初回用量は，Phase B の最終用量に基づき決定することとした（Phase B の最終用量が 15 mg/日，又は 20 mg/日の場合は 10 mg/日，20 mg/日超 30 mg/日以下の場合は 15 mg/日）。Phase C の最初の 2 週間であれば治験責任医師等の判断で最大 20 mg/日，最小 10 mg/日まで 5 mg ずつの用量の増減を可能とした。

[c]: Phase D の開始用量は，Phase C の最終用量とした。アリピプラゾール IM デポ注射剤の開始用量が 400 mg（又はプラセボ注射剤）の被験者は，300 mg（又はプラセボ注射剤）への減量 1 回と 400 mg（又はプラセボ注射剤）への増量 1 回が許容された。アリピプラゾール IM デポ注射剤の開始用量が 300 mg（又はプラセボ注射剤）の被験者は，400 mg（又はプラセボ注射剤）への増量 1 回と 300 mg（又はプラセボ注射剤）への減量 1 回が許容された。

[d]: Phase A ではアリピプラゾール錠剤 5～30 mg/日を投与した。Phase B ではアリピプラゾール錠剤を日本は 12～30 mg/日，日本以外は 15～30 mg/日を投与した。忍容性に応じて日本は 6 mg/日，日本以外は 10 mg/日に減量可能であったが，Phase C に進むまでに日本は 12 mg/日，日本以外は 15 mg/日以上とすることとした。

[e]: 必要に応じて何度でもアリピプラゾール IM デポ注射剤の用量を 300 mg 又は 400 mg に柔軟に調整できた。錠剤の初回用量は，Phase B の最終用量に基づき決定することとした（Phase B の最終用量が日本で 12 mg/日の場合は 6 mg/日，12 mg/日超 30 mg/日以下の場合は 12 mg/日，日本以外で 15 mg/日，又は 20 mg/日の場合は 10 mg/日，20 mg/日超 30 mg/日以下の場合は 15 mg/日）。Phase C の最初の 2 週間はいつでも，治験責任医師等の判断で最大用量を日本は 18 mg/日，日本以外は 20 mg/日，最小用量を日本は 6 mg/日，日本以外は 10 mg/日として，補助的な経口剤の用量に対する変更を日本では 6 mg ずつ，日本以外では 5 mg ずつ増減可能とした。

(2)　安全性に関する補足情報

アリピプラゾール経口錠剤及び他の剤型の安全性及び忍容性は双極 I 型障害患者を含む複数の疾患患者で検討され，多くの知見が得られている。治験期間中及び製造販売後に得られたアリピプラゾール経口錠剤及び他の剤型での情報及び経験は，統合失調症を効能・効果としたアリピプラゾール IM デポ注射剤の添付文書に含まれている。アリピプラゾール IM デポ注射剤の製造販売後に得られた情報は，「2.7.4.6 市販後データ」に示した。

2.7.4.1.1.2　安全性評価に用いた臨床試験の概要

(1)　二重盲検試験（31-08-250 試験）

二重盲検試験は，主に躁病エピソードを発症している双極 I 型障害患者を対象として，アリピプラゾール錠剤で気分症状の安定が確認された被験者に対して，アリピプラゾール IM デポ注射剤で 8 週間以上安定状態を維持した後，アリピプラゾール IM デポ注射剤 400 mg（開始用量が 400 mg の場合，300 mg に減量し，また 400 mg に戻すことが 1 回可能，開始用量が 300 mg の場合，400 mg に増量し，また 300 mg に戻すことが 1 回可能）又はプラセボを 4 週間に 1 回 52 週間投与し，アリピプラゾール IM デポ注射剤の有効性，安全性及び忍容性を検討した国際共同第 III 相試験である。試験デザインの概要を図 2.7.4.1.1-1 に示した。二重盲検試験はアリピプラゾール IM デポ注射剤の投与に入る前に，忍容性と反応性を確立するため，アリピプラゾール錠剤が投与された。なお，本治験を完了した被験者［二重盲検期（Phase D）の Week 52 まで継続した被験者］は，非盲検の長期投与試験（31-08-252）へ移行を可能とした。

なお，二重盲検試験では統計解析計画書（資料番号 5.3.5.1-01, Section16.1.9）に規定したとおり，主要評価項目と主な副次的有効性評価項目について中間解析を行った。試験の目的が達成されたと中間解析によって示された場合，試験を早期に終了することができたが，中間解析で群間に有意差が認められなかったため，試験の早期終了を勧告されなかった。試験は最後まで継続された。

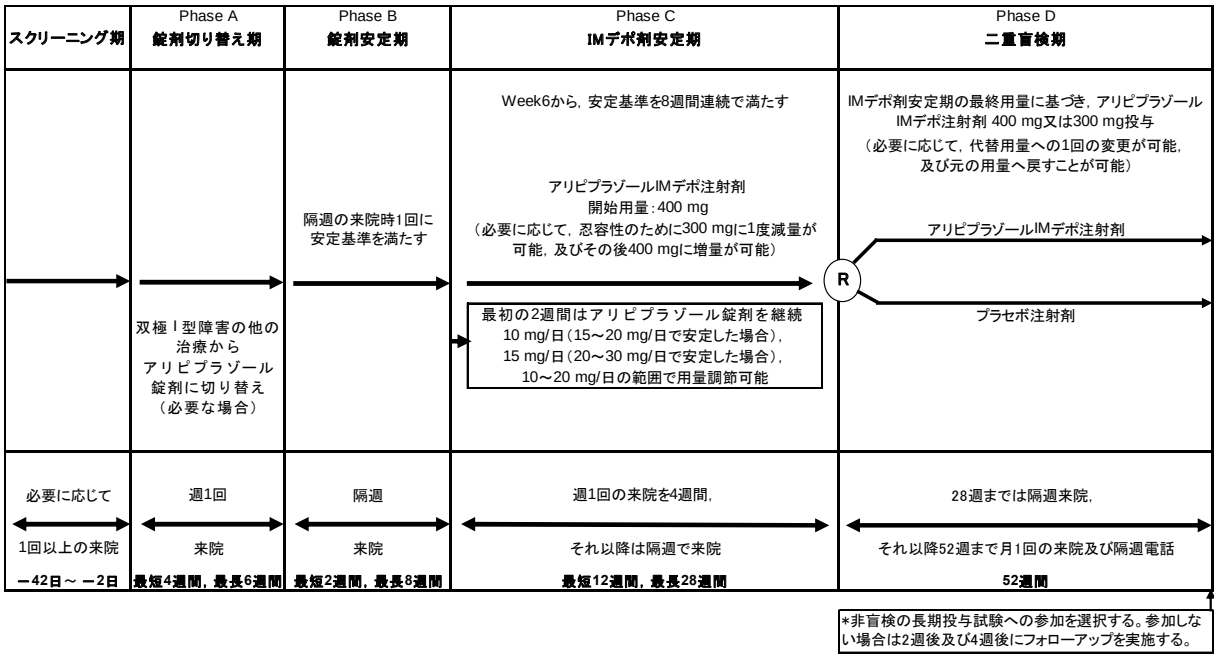


図 2.7.4.1.1-1　　31-08-250 試験の治験デザイン概要

R：無作為化
＜資料番号 5.3.5.1-01：Figure 9.1-1 より作成＞

二重盲検試験は，以下に示す 4 つの投与期から構成される。

(a)　錠剤切り替え期（Phase A）

投与期間は 4～6 週間である。週 1 回の来院を通じて，他の抗精神病薬からアリピプラゾール錠の単剤（目標用量：15 mg/日）へ切り替えた。

スクリーニング時点でアリピプラゾールの用量が 30 mg/日以下であれば，直接 Phase B の錠剤安定期へ進んだ。

(b)　錠剤安定期（Phase B）

投与期間は 2～8 週間である。アリピプラゾール錠剤 15～30 mg/日の範囲の単剤を投与した。

(c)　IM デポ剤安定期（Phase C）

投与期間は 12～28 週間である。錠剤安定期に 2 週間（隔週の来院で 1 回），安定基準（2.7.6.1.1.1 参照）を満たした被験者が移行した。アリピプラゾール IM デポ注射剤 400 mg を 4 週間に 1 回，臀部筋肉内に投与した。忍容性が認められない場合，300 mg へ減量 1 回と 400 mg へ増量 1 回が許容された。最初の 2 週間は，血中濃度を維持するためアリピプラゾール錠剤 10～20 mg/日の投与も継続した。錠剤の初回用量は，錠剤安定期（Phase B）の最終用量に基づき決定した。

(d)　二重盲検期（Phase D）

投与期間は 52 週間である。IM デポ剤安定期に 8 週以上連続（隔週の来院で 4 回連続）して，安定基準（2.7.6.1.1.1 参照）を満たした被験者が移行した。アリピプラゾール IM デポ注射剤

（400 mg 又は 300 mg）又はプラセボ注射剤を 4 週間に 1 回，臀部筋肉内に投与した。二重盲検期（Phase D）の開始用量は，IM デポ剤安定期（Phase C）のアリピプラゾール IM デポ注射剤の最終用量とした。アリピプラゾール IM デポ注射剤の開始用量が 400 mg（又はプラセボ注射剤）の被験者は，300 mg（又はプラセボ注射剤）へ減量 1 回と 400 mg（又はプラセボ注射剤）へ増量 1 回が許容された。アリピプラゾール IM デポ注射剤の開始用量が 300 mg（又はプラセボ注射剤）の被験者は，400 mg（又はプラセボ注射剤）へ増量 1 回と 300 mg（又はプラセボ注射剤）へ減量 1 回が許容された。

(2) 長期投与試験（31-08-252 試験）

長期投与試験は，二重盲検試験から移行する双極 I 型障害患者（継続例），及び治験責任医師が双極 I 型障害に対する長期的な治療が必要と判断し，有用性が期待できる双極 I 型障害患者（新規例）を対象として，アリピプラゾール錠剤で 4 週間以上安定状態を維持した後（新規例のみ），アリピプラゾール IM デポ注射剤 400 mg（開始用量が 400 mg の場合，300 mg に減量し，また 400 mg に戻すことが可能，開始用量が 300 mg の場合，400 mg に増量し，また 300 mg に戻すことが可能）を 4 週間に 1 回 52 週間投与し，双極 I 型障害維持療法に対するアリピプラゾール IM デポ注射剤の有効性，安全性及び忍容性を検討した非盲検試験である。試験デザインの概要を図 2.7.4.1.1-2 に示した。

なお，総合機構からの「長期投与試験において，直近の気分エピソードが躁病以外の日本人患者も組み入れ，直前の気分エピソードが躁病以外の患者に対する本薬の維持療法のデータを積極的に収集すること」との助言により，IM デポ剤維持治療期（Phase C）に直前の気分エピソードが躁病の患者及び躁病以外の患者を組み入れることとした。最終的には直前の気分エピソードが躁病の患者 50 例（軽躁病 7 例及び混合性エピソード 4 例を含む），躁病以外の患者 25 例となった。

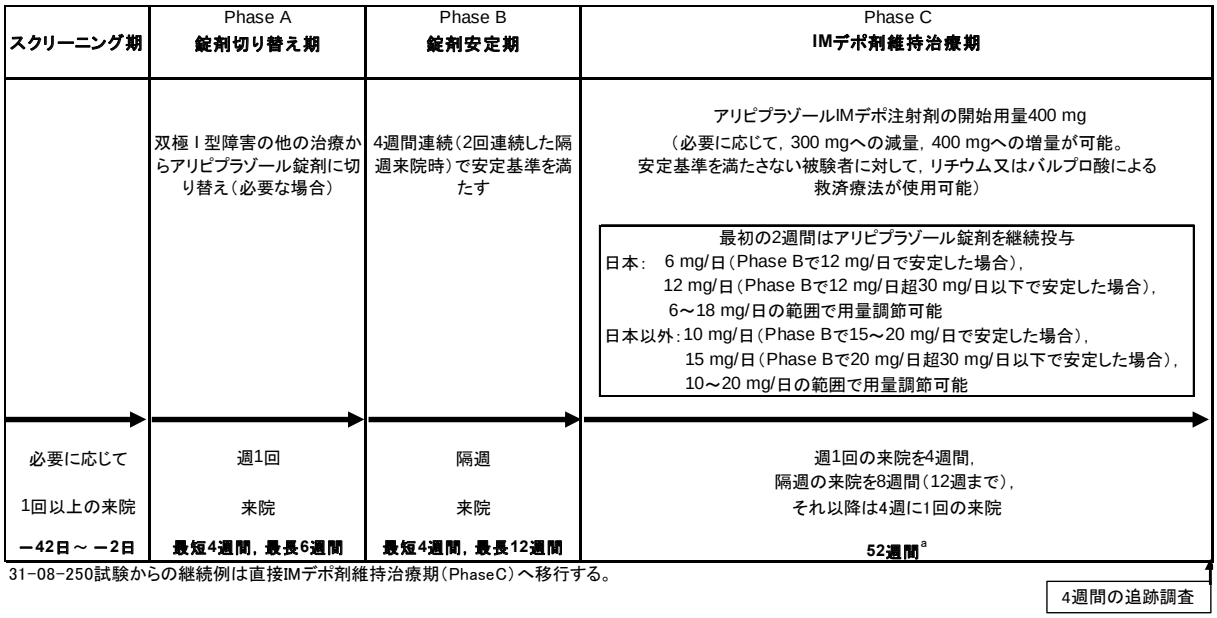


図 2.7.4.1.1-2　　31-08-252 試験の治験デザイン概要

[a]：2015 年 2 月 4 日改訂（日本用：2015 年 6 月 11 日改訂）の治験計画書で，31-08-250 試験からの継続例は 52 週間から 28 週間に短縮された（新規例は除く）。最終投与は 24 週。24 週を超えた被験者は，治験責任医師の裁量に基づき，次回の予定来院日を最終投与にするか，又は中止時来院とした。

＜資料番号 5.3.5.2-01：Figure 9.1-1 より作成＞

長期投与試験では，以下に示す 3 つの投与期から構成される。ただし，31-08-250 試験からの継続例は直接 IM デポ剤維持治療期（Phase C）から開始した。

(a)　錠剤切り替え期（Phase A）

投与期間は 4～6 週間である。週 1 回の来院を通じて，他の抗精神病薬からアリピプラゾール錠の単剤（目標用量：15 mg/日）へ切り替えた。

(b)　錠剤安定期（Phase B）

投与期間は 4～12 週間である。アリピプラゾール錠剤 15～30 mg/日の範囲の単剤を投与した。

(c)　IM デポ剤維持治療期（Phase C）

投与期間は 52 週間である。錠剤安定期に 4 週間連続（隔週の来院 2 回連続）して，安定基準（2.7.6.1.1.1 参照）を満たした被験者が移行した。アリピプラゾール IM デポ注射剤（初回用量 400 mg）を 4 週間に 1 回，52 週間，臀部筋肉内に投与した。忍容性が認められない場合，300 mg へ減量が可能であり，IM デポ剤維持治療期間中は，300 mg 又は 400 mg の用量範囲で，アリピプラゾール IM デポ注射剤の増量及び減量が適宜許容された。IM デポ剤維持治療期開始後 2 週間は，必要な血漿中アリピプラゾール濃度を維持するため，アリピプラゾール錠剤 10～20 mg/日（日本 6～18 mg/日）を投与した。IM デポ剤維持治療期間中に気分症状の安定/維持の基準（2.7.6.1.1.1 参照）を満たさない被験者には，医師判断に基づいて救済療法を行った。

2.7.4.1.1.3　安全性評価方法

本申請のために実施した二重盲検試験及び長期投与試験で用いられた主な安全性評価方法を記載した。なお，詳細な方法は個々の試験の治験総括報告書に記載しているため，本項では安全性評価方法の概略を記載した。

(1)　有害事象

二重盲検試験及び長期試験共に，同意取得以降に発現した事象を有害事象とした。本概要では，アリピプラゾール IM デポ注射剤投与後に発現した有害事象を主として提示した。

(a)　定義

治験薬との関連の有無の判断に関わらず，治験参加中に患者又は被験者に発現したあらゆる好ましくない医学上のできごと。

(b)　重症度

重症度は次の 3 段階とした。

- 軽　度（Mild）：不快感を覚えるが，日常生活に支障ない。
- 中等度（Moderate）：日常生活に制限，又は影響がある程度に不快である。
- 高　度（Severe）：仕事や日常生活を行うことができない。

(c)　治験薬との関連性

有害事象と治験薬の因果関係は以下の基準で判定した。関連性があると判断された有害事象を副作用とした。

- 関連性がある（Related）
  - 関連性は明らかにあり（Definite）：治験薬と有害事象との間に合理的な因果関係がある，又は事象が治験薬の投与中止と関係しており，収集されたすべての臨床情報を元にした事象に対する治験責任医師の評価が「明らかに関連あり」である場合。
  - 関連性は多分あり（Probable）：治験薬と有害事象との間に合理的な因果関係がある。事象が治験薬の投与中止と関係している場合がある，又は収集されたすべての臨床情報を元にした事象に対する治験責任医師の評価が「多分関連あり」である場合。
  - 関連性はあるかもしれない（Possible）：治験薬と有害事象との間に合理的な因果関係がある。治験薬の投与中止はない，又は不明で，収集されたすべての臨床情報を元にした事象に対する治験責任医師の評価が「関連があるかもしれない」である場合。
- 関連性はない（Unrelated）
  - 関連性は多分ない（Not Likely）：治験薬の投与に時間的な関連性はあるが，収集した臨床情報を元に治験責任医師が治験薬と事象の間に合理的な因果関係はないと考えた場合。
  - 関連性はない（Not Related）：収集した臨床情報を元に治験責任医師が治験薬と事象の

間に時間的関連性や因果関係はないと考えた場合。

(d) 転帰

転帰は次の 6 分類とした。

- 回復（Recovered/Resolved）
- 軽快（回復途上）（Recovering/Resolving）
- 未回復（Not recovered/Not resolved）
- 回復したが後遺症あり（Recovered/Resolved with sequelae）
- 死亡（Fatal）
- 不明（Unknown）

(e) 重篤な有害事象

重篤な有害事象の定義は次のとおりとした。

- 死亡に至るもの
- 生命を脅かすもの（すなわち，事象の発現により被験者に差し迫った死の危険があると治験責任又は分担医師が判断するもの）。発現した事象がより重度であれば，死亡につながるかもしれないという事象は含まない。
- 治療のため入院又は入院期間の延長が必要となるもの
  注： 事前に予定されていた入院（観察，薬の変更，又は安定化目的を含む）は重篤な有害事象とはみなされない。ただし，精神障害を理由とした入院を含む，その他すべての入院について重篤な有害事象フォームに記入する必要がある。心理社会的な入院（例，ホームレス又は避難所の必要性といった被験者の精神状態に関係ないもの）又は患者が以前の抗精神病療法から経口アリピプラゾールに安全に切り替えられるようにモニターする目的の予防入院（入院患者病棟への入院を含む）は重篤な有害事象として報告しない。
- 永続的又は顕著な障害・機能不全に陥るもの
- 先天異常を来すもの
- 被験者を危機にさらしたり，上記のいずれかの転帰に至らぬように内科的又は外科的処置を必要とするような医学的に問題となる事象を，適切な医学的判断に基づき重篤とする。この例としては，救急室又は自宅で集中治療を必要とするアレルギー性気管支痙攣，入院に至らないものの血液障害又は痙攣を来した場合，薬物依存症又は薬物乱用などが挙げられる。

(f) 臨床検査

以下の臨床検査を実施した。実施時期は，治験実施計画書で規定された内容に準じた。測定は中央検査機関で実施した。二重盲検試験は盲検性維持のため，プロラクチンのデータの入手は開鍵後とした。

- 血液学的検査：赤血球数，白血球数，白血球分画（好中球，好酸球，好塩基球，単球，リ

ンパ球），血小板数，ヘモグロビン，ヘマトクリット値

- 生化学的検査：AST，ALT，ALP，LDH，γ-GTP，総蛋白，総ビリルビン，コレステロール（総コレステロール，LDL，HDL），トリグリセリド，BUN，クレアチニン，尿酸，CPK，Na，K，Cl，Ca，P，Mg，重炭酸塩，血糖，$HbA1_c$[a]，インスリン，プロラクチン[b]，アルブミン
- 尿検査：蛋白，糖，ケトン体，潜血，pH，比重，顕微鏡検査（尿検査のいずれかが陰性でない場合に実施）
- その他の検査：TSH，尿中薬物検査，尿による妊娠検査，血清 β-hCG，血中アルコール値

[a]：空腹時血糖が 125 mg/dL 以上，又は尿糖が陽性の被験者は，$HbA1_c$ を追加で測定する。被験者の血糖値が 125 mg/dL 以上だが，空腹時血糖値ではない場合，$HbA1_c$ を検査する前に空腹時血糖検査を実施して値が 125 mg/dL 以上であることを確認することとした。

[b]：二重盲検試験では，プロラクチン濃度は，IM デポ剤安定期（Phase C）終了/二重盲検期（Phase D）ベースライン及び二重盲検期（Phase D）終了の来院日にのみ測定した。長期投与試験では，錠剤安定期（Phase B）終了/IM デポ剤維持治療期（Phase C）ベースライン及び IM デポ剤維持治療期（Phase C）終了の来院日にのみ測定した。

(g) バイタルサイン（血圧，心拍数，体温）及び体重

以下の項目を測定した。実施時期は，治験実施計画書で規定された内容に準じた。

- 収縮期血圧及び拡張期血圧
- 心拍数
- 体温

(h) 体重，BMI，ウエスト周囲径

体重, ウエスト周囲径を測定した。BMI は, スクリーニング時の身長と来院時の体重から kg/m^2 の形式で計算した。実施時期は，治験実施計画書で規定された内容に準じた。

(i) 心電図検査

12 誘導心電図検査を実施した。実施時期は，治験実施計画書で規定された内容に準じた。治験実施医療機関の定める方法に従って，12 誘導心電図検査を実施し，検査結果の判読は中央心電図解析機関が行った。

(j) SAS

SAS は錐体外路症状を評価する尺度である。日本人を除いた被験者を対象に，治験実施計画書で規定された時期に準じて SAS を用いて錐体外路症状に関する下記の 10 項目について，1～5 の 5 段階で評価した。

1．歩行（Gait）2．腕落下（Arm Dropping）3．肩懸振（Shoulder Shaking）
4．肘硬直（Elbow Rigidity）5．手首硬直（Wrist Rigidity）
6．頭落下（Head Rotation）7．眉間叩打（Glabella Tap）8．振戦（Tremor）9．流涎（Salivation）
10．アカシジア（Akathisia）

(k)　AIMS

AIMS は異常不随意運動を評価する目的で作られた評価尺度である。治験実施計画書で規定された時期に準じて AIMS を評価した。「表情筋」，「口唇と口周辺部」，「顎」，「舌」，「上肢（腕，手首，手，指）」，「下肢（脚，膝，踵，足趾）」，「頚・肩・腰」の 7 部位における異常不随意運動の重症度及び 3 項目の総合判定を「0. なし」～「4. 高度」で，歯の状態における「最近の歯および/又は義歯の問題」を「あり」，「なし」で，「患者は義歯を使用しているか」を「している」，「していない」で評価した。

(l)　BAS

BAS はアカシジアを評価する尺度である。治験実施計画書で規定された時期に準じて BAS を評価した。アカシジアの「客観症状」，「主観症状－内的不穏の自覚の程度」，「主観症状－内的不穏に関連した苦痛」を 0（苦痛なし）～3（重度）の 4 段階，「アカシジアの包括的臨床評価」を 0（なし）～5（重度のアカシジア）の 6 段階で評価した。

(m)　DIEPSS

DIEPSS は錐体外路症状を評価する尺度である。日本人を対象に，治験実施計画書で規定された時期に準じ，DIEPSS を用いて錐体外路症状に関する下記の 9 項目について，0（なし，正常）～4（重度）で評価した。

1. 歩行　2. 動作緩慢　3. 流涎　4. 筋強剛　5. 振戦　6. アカシジア
7. ジストニア　8. ジスキネジア　9. 概括重症度

(n)　C-SSRS

C-SSRS はベースライン前の自殺関連事象及び自殺念慮の既往と，前回の治験診察時以降の自殺傾向を評価する尺度である。治験実施計画書で規定された時期に準じて実施した。治験薬投与開始時には，ベースライン評価（自殺関連事象及び自殺念慮の既往の評価）を行い，それ以降は前回の治験診察時以降の評価を行った。

(o)　注射部位反応

治験実施計画書で規定された時期に準じて実施し，評価時の直近の注射部位の発赤，腫脹，硬結，疼痛を，それぞれ次の程度で評価した。穿針に伴う疼痛は評価の対象にしないこととした。

0：なし，1：軽度，2：中等度，3：高度

（疼痛の評価の場合，0：なし，1：軽度；わずかに痛い，2：中等度；痛いが我慢できる，3：高度；我慢できない痛み）

結果が 2 又は 3 の場合は，その後の来院日で消失（スコア 0「なし」）になるまで，継続的に評価した。

(p)　注射部位疼痛自己評価（VAS）

注射部位の疼痛を評価するため VAS を用いた。治験実施計画書で規定された回数に準じ，

100 mm VAS を用いて評価した。患者は評価時直近の注射部位の疼痛の程度を 0（No pain）～100（Unbearably painful）で評価し，0 端からの長さ（mm）を測定した。

2.7.4.1.1.4　安全性成績の解析方法

(1)　データセットの構成

本申請のための試験では，データ統合及び併合解析は行わず，試験ごとに結果を示した。ただし，添付文書に利用するため有害事象については二重盲検試験と長期投与試験のデータを統合して使用した。

本概要で示す主要なデータは，二重盲検試験の二重盲検期（Phase D）のデータである。そのほか，主要データを支持するためのデータとして，二重盲検試験の IM デポ剤安定期（Phase C）及び長期投与試験の IM デポ剤維持治療期（Phase C）のデータも示した。

表 2.7.4.1.1-2　　二重盲検試験及び長期投与試験のデータセットの構成

データセット		対象及び試験番号		投与期間	安全性解析対象例数	
					IM デポ群	プラセボ群
二重盲検試験	二重盲検期（Phase D）	双極 I 型障害	31-08-250	52 週 [a]	132	133
	IM デポ剤安定期（Phase C）			12～28 週 [b]	425[c]	－
長期投与試験 IM デポ剤維持治療期（Phase C）		双極 I 型障害	31-08-252	52 週 [d]	464	－

[a]：二重盲検期（Phase D）の投与期間。13 回目のアリピプラゾール IM デポ注射剤投与 4 週後までを投与期間とした。

[b]：IM デポ剤安定期（Phase C）の投与期間。

[c]：安全性解析対象集団

[d]：IM デポ剤維持治療期（Phase C）の投与期間。13 回目のアリピプラゾール IM デポ注射剤投与 4 週後までを投与期間とした。ただし，20[redacted]年[redacted]月[redacted]日（日本版：20[redacted]年[redacted]月[redacted]日）付の治験計画書改訂により，31-08-250 試験からの継続例は最短 28 週間（7 回投与）。

(2)　解析の方法

本概要で提示した安全性データの解析は，総括報告書作成のための解析計画に基づいて安全性の解析を実施した。ただし，日本人と日本人以外の安全性データを比較するための解析は，本概要作成のために実施した。また，有害事象のうち，初回発現時期別，持続期間別，及び転帰別の解析は本概要作成のために実施した。

以下に，双極 I 型障害患者でのアリピプラゾール IM デポ注射剤の安全性及び忍容性を評価するための主要なデータである，二重盲検試験の二重盲検期（Phase D）での主な解析方法を示した。二重盲検試験の二重盲検期（Phase D）での「ベースライン」は，IM デポ剤安定期（Phase C）の最終測定時を意味する。

(a) 有害事象

表 2.7.4.1.1-2 に示したデータセットを用いて，治験薬投与後に発現した有害事象及び副作用（因果関係があると判断された有害事象）の発現割合を投与群別に集計した。発現例数及び発現割合の集計に際しては，同一被験者で同一事象が 2 回以上発現した場合は 1 例として集計した。複数の有害事象を発現した被験者は，器官別大分類別の集計及び有害事象全体の集計では 1 例として合計した。また，重症度別の集計では最も重い重症度を有害事象の集計対象とした。なお，性別特異的な事象の発現割合は性別を考慮して算出した。

有害事象の読替えには MedDRA Version 19.0 を使用し，和訳の際も同じバージョンの MedDRA を使用した。

有害事象の集計は次に示した区別で実施した。

- 器官別大分類別及び基本語別
- 重症度別
- 初回発現時期別
- 持続期間別
- 転帰別
- 重篤な有害事象，治験薬投与中止に至った有害事象の器官別大分類別及び基本語別

二重盲検試験の二重盲検期（Phase D）では，以下の層別項目で有害事象の層別解析を実施した。

- 人口統計学的及び他の特性
  年齢別（45 歳未満，45 歳以上），性別，BMI カテゴリ別（28 kg/m^2 以下，28 kg/m^2 超），地域別（全体，米国，米国以外），人種別（白人，黒人/アフリカ系アメリカ人，アジア人，その他），民族（ヒスパニック系/ラテン系，ヒスパニック系/ラテン系以外）

また，以下の有害事象では，本概要作成のために，日本人，日本以外の層別解析を実施した。

- 器官別大分類別及び基本語別（副作用も）
- 重症度別（副作用も）
- 重篤な有害事象，治験薬投与中止に至った有害事象の器官別大分類別及び基本語別

長期投与試験では，総括報告書作成のための解析で計画した項目に加えて，以下の層別項目で有害事象の層別解析を実施した。

- 気分エピソード

更に，アリピプラゾール IM デポ注射剤投与時に留意が必要な有害事象として下記の事象に着目し，以下に示したカテゴリごとに個別有害事象の発現頻度を求めた。

- 錐体外路系有害事象
- 体重
- 脂質代謝
- 糖代謝関連

- 白血球異常
- 起立性障害
- QT 間隔延長
- プロラクチン
- 自殺
- 注射部位反応

各カテゴリで着目する個別有害事象は，各カテゴリの特徴を反映するような有害事象を MedDRA 基本語から定義した。定義は表 2.7.4.7-1 に記載した。

(b) 臨床検査

臨床検査の各項目（血液学的検査項目，生化学的検査項目，尿検査項目）について次に示した解析を実施した。なお，集計の対象は安全性解析対象例のうち，ベースラインの測定値と投与後の測定値がある被験者とした。

- 実測値及びベースラインからの変化量の記述統計量を求めた（血液学的検査項目，生化学的検査項目，尿検査項目）。
- 表 2.7.4.7-2 に示した基準に従い，投与後の値について臨床的に重要な変動を示した被験者の割合を求めた。
- 糖脂質代謝関連パラメータ及びプロラクチンの値を基準に基づいてカテゴリ化し，投与後の値が投与前から変化した被験者の割合を求めた。
- 以下の Hy's Law の基準すべてに該当する被験者をリストした。
  - ベースラインの値が基準値内であった場合は, ALT 又は AST が基準値上限の 3 倍以上。ベースラインの値が基準値内になかった場合は，ALT 又は AST がベースライン値の 3 倍以上。
  - ベースラインの値が基準値内であった場合は，総ビリルビンが基準値上限の 2 倍以上。ベースラインの値が基準値内になかった場合は，総ビリルビンがベースライン値の 2 倍以上。

(c) バイタルサイン（血圧，心拍数，体温），BMI，ウエスト周囲径

バイタルサインの各項目（血圧，心拍数，体温），BMI，ウエスト周囲径について次に示した解析を実施した。なお，集計の対象は安全性解析対象例のうち，ベースラインの測定値と投与後の測定値がある被験者とした。

- 実測値及びベースラインからの変化量の記述統計量を求めた。
- バイタルサインの各項目（血圧，心拍数，体温）について表 2.7.4.7-3 に示した基準に従い，投与後の値について臨床的に重要な変動を示した被験者の割合を求めた。

(d) 体重

体重について，次に示した解析を実施した。なお，集計の対象は安全性解析対象例のうち，

ベースラインの測定値と投与後の測定値がある被験者とした。

- 実測値及びベースラインからの変化量の記述統計量を求めた。
- 臨床的に重要な体重の増加又は減少（ベースラインから 7%以上の増加又は減少）が認められた被験者の割合を求めた。
- 下記に示す BMI カテゴリ別に, 体重の実測値及びベースラインからの変化量の記述統計量, 及び臨床的に重要な体重の増加又は減少（ベースラインから 7%以上の増加又は減少）が認められた被験者の割合を求めた。
  - 23 kg/m^2 未満
  - 23 kg/m^2 以上 27.0 kg/m^2 以下
  - 27.0 kg/m^2 超

(e) 心電図検査

12 誘導心電図検査結果について，次に示した解析を実施した。なお，集計の対象は安全性解析対象例のうち，ベースラインの測定値と投与後の測定値がある被験者とした。

- 各パラメータの実測値及びベースラインからの変化量の記述統計量を求めた。なお，QTc 間隔は，Bazett による補正後の値（$QTcB = QT/RR^{0.5}$），Fridericia による補正後の値（$QTcF = QT/RR^{0.33}$）及び FDA’s Neuropharmacological Division による補正後の値（$QTcN = QT/RR^{0.37}$）とした。
- QTc 間隔について次のカテゴリで分類し，被験者の割合を求めた。
  - 最悪時の QTcB，QTcF，及び QTcN：
    450 msec 超，480 msec 超，500 msec 超
  - 最悪時の QTcB，QTcF，及び QTcN についてベースラインの値からの変化量：
    30 msec 以上 60 msec 未満，60 msec 以上

(f) SAS，AIMS，BAS，DIEPSS

次に示した解析を実施した。なお，集計の対象は安全性解析対象例のうち，ベースラインの評点と投与後の評点がある被験者とした。

- 各合計スコアのの実測値及びベースラインからの変化量の記述統計量を求めた。

(g) 注射部位疼痛自己評価［Visual analog scale (VAS)］

注射部位疼痛自己評価（VAS）について，下記に示した解析を実施した。なお，集計の対象は安全性解析対象例のうち，ベースラインの測定値と投与後の測定値がある被験者とした。

- 各時期の実測値及びベースラインからの変化量の記述統計量を示した。

2.7.4.1.2 全般的な曝露状況

2.7.4.1.2.1 二重盲検試験での曝露状況

二重盲検試験の IM デポ剤安定期（Phase C）では，アリピプラゾール IM デポ注射剤 400 mg を

4 週間に 1 回，12～28 週間，計 3～7 回投与した。忍容性が認められない場合は 300 mg への減量 1 回と 400 mg への増量 1 回が可能であった。IM デポ剤安定期（Phase C）開始後 2 週間はアリピプラゾール錠剤の投与も継続した。錠剤の初回用量は，錠剤安定期（Phase B）の最終用量［錠剤安定期（Phase B）の最終用量が 15 mg/日，又は 20 mg/日の場合は 10 mg/日，20 mg/日超 30 mg/日以下の場合は 15 mg/日］に基づき決定し，IM デポ剤安定期（Phase C）の開始後 2 週間であれば治験責任医師等の判断で最大 20 mg/日，最小 10 mg/日まで 5 mg ずつの用量の増減を可能とした。

二重盲検期（Phase D）では，アリピプラゾール IM デポ注射剤（400 mg 又は 300 mg）又はプラセボ注射剤を 4 週間に 1 回，52 週間，計 13 回投与することとした。二重盲検期（Phase D）の開始用量は，IM デポ剤安定期（Phase C）の最終用量とした。アリピプラゾール IM デポ注射剤の開始用量が 400 mg（又はプラセボ注射剤）の被験者は，300 mg（又はプラセボ注射剤）への減量 1 回と 400 mg（又はプラセボ注射剤）への増量 1 回が可能であった。アリピプラゾール IM デポ注射剤の開始用量が 300 mg（又はプラセボ注射剤）の被験者は，400 mg（又はプラセボ注射剤）への増量 1 回と 300 mg（又はプラセボ注射剤）への減量 1 回が可能であった。

なお，二重盲検試験で使用したアリピプラゾール錠剤の曝露量を表 2.7.4.7-6～表 2.7.4.7-8 に示した。

(1) 二重盲検期（Phase D）

二重盲検期（Phase D）のアリピプラゾール IM デポ注射剤の曝露状況を表 2.7.4.1.2-1 に，各投与までの平均期間を表 2.7.4.7-9 に，投与量を変更した被験者の割合を表 2.7.4.7-10 にそれぞれ示した。

二重盲検期では，265 例（IM デポ群 132 例，プラセボ群 133 例）にアリピプラゾール IM デポ注射剤又はプラセボ注射剤が 4 週間に 1 回投与された。

IM デポ群 132 例中，開始用量が 400 mg であった被験者は 113 例，300 mg であった被験者は 19 例であった。開始用量が 400 mg であった被験者 113 例のうち 103 例，300 mg であった 19 例のうち 18 例の被験者が二重盲検期間中に用量変更を実施しなかった。また，400 mg で開始した 113 例のうち，300 mg に減量したのは 10 例であった。この 10 例のうち 2 例は，再度 400 mg に増量した。プラセボ群でもほとんどの被験者が用量変更を実施しなかった。

初回投与から最終投与までの期間（中央値）は，IM デポ群では 311.5 日間，プラセボ群では 143.0 日間であった。

アリピプラゾール IM デポ注射剤及びプラセボ注射剤を 7 回以上投与したのは，IM デポ群で 61.7%（82/133 例）及びプラセボ群で 48.9%（65/133 例）であり，13 回以上の投与は，IM デポ群で 48.9%（65/133 例）及びプラセボ群で 30.8%（41/133 例）であった。

表 2.7.4.1.2-1　　二重盲検試験での二重盲検期（Phase D）の治験薬の曝露状況

	IMデポ群 (133例)			プラセボ群 (133例)		
	400 mg	300 mg	計	400 mg	300 mg	計
	例数 (%)[a]	例数 (%)[a]	対象例数 (%)[b]	例数 (%)[a]	例数 (%)[a]	対象例数 (%)[b]
1回目	113 (85.6)	19 (14.4)	132 (99.2)	118 (88.7)	15 (11.3)	133 (100.0)
2回目	97 (80.8)	23 (19.2)	120 (90.2)	97 (87.4)	14 (12.6)	111 (83.5)
3回目	87 (82.9)	18 (17.1)	105 (78.9)	85 (87.6)	12 (12.4)	97 (72.9)
4回目	81 (81.8)	18 (18.2)	99 (74.4)	75 (86.2)	12 (13.8)	87 (65.4)
5回目	71 (81.6)	16 (18.4)	87 (65.4)	69 (85.2)	12 (14.8)	81 (60.9)
6回目	69 (81.2)	16 (18.8)	85 (63.9)	61 (84.7)	11 (15.3)	72 (54.1)
7回目	66 (80.5)	16 (19.5)	82 (61.7)	54 (83.1)	11 (16.9)	65 (48.9)
8回目	64 (82.1)	14 (17.9)	78 (58.6)	47 (82.5)	10 (17.5)	57 (42.9)
9回目	60 (82.2)	13 (17.8)	73 (54.9)	44 (83.0)	9 (17.0)	53 (39.8)
10回目	58 (82.9)	12 (17.1)	70 (52.6)	42 (82.4)	9 (17.6)	51 (38.3)
11回目	56 (81.2)	13 (18.8)	69 (51.9)	40 (81.6)	9 (18.4)	49 (36.8)
12回目	56 (82.4)	12 (17.6)	68 (51.1)	38 (82.6)	8 (17.4)	46 (34.6)
13回目	55 (84.6)	10 (15.4)	65 (48.9)	33 (80.5)	8 (19.5)	41 (30.8)
最終投与	106 (80.3)	26 (19.7)	132 (99.2)	116 (87.2)	17 (12.8)	133 (100.0)

[a]：分母は，各投与群での各投与回数の計の被験者数

[b]：分母は，IM デポ群又はプラセボ群に無作為に割付けられた被験者数

＜資料番号 5.3.5.1-01：CT-7.2.1 より作成＞

(2)　IM デポ剤安定期（Phase C）

IM デポ剤安定期（Phase C）のアリピプラゾール IM デポ注射剤の曝露状況を表 2.7.4.1.2-2 に，各投与までの平均期間を表 2.7.4.7-11 に，投与量を変更した被験者の割合を表 2.7.4.7-12 にそれぞれ示した。

IM デポ剤安定期（Phase C）では 425 例の被験者にアリピプラゾール IM デポ注射剤が投与された。全被験者が開始用量を 400 mg として投与を開始し，忍容性に問題がある場合は，1 回のみ 300 mg に減量することが可能であった。300 mg に減量した場合は，1 回のみ 400 mg に増量することが可能であった。IM デポ剤安定期では 425 例のうち 366 例の被験者が用量を変更しなかった。また，59 例が 300 mg に減量し，このうち 8 例が再度 400 mg に増量した。

IM デポ剤安定期（Phase C）では，12～28 週間の投与期間で，4 週間ごとに 3～7 回投与することとした。82.8%（352/425 例）の被験者が 3 回以上投与された。

IM デポ剤安定期（Phase C）では，最初の 2 週間はアリピプラゾール錠剤の投与も継続した（図 2.7.4.1.1-1 参照）。IM デポ剤安定期（Phase C）でアリピプラゾール錠剤を併用していた被験者は，423 例であった［99.5%，423/425 例，1 日平均用量 ± SD = 12.1 ± 3.0 mg］（表 2.7.4.7-6）。

表 2.7.4.1.2-2　二重盲検試験での IM デポ剤安定期（Phase C）の治験薬の曝露状況

	400 mg	300 mg	計
	例数 (%)[a]	例数 (%)[a]	対象例数 (%)[b]
1回目	425 (100.0)	0 (0.0)	425 (100.0)
2回目	337 (89.4)	40 (10.6)	377 (88.7)
3回目	307 (87.2)	45 (12.8)	352 (82.8)
4回目	88 (83.8)	17 (16.2)	105 (24.7)
5回目	58 (86.6)	9 (13.4)	67 (15.8)
6回目	32 (88.9)	4 (11.1)	36 (8.5)
7回目	7 (87.5)	1 (12.5)	8 (1.9)
最終投与	374 (88.0)	51 (12.0)	425 (100.0)

[a]：分母は，各投与群での各投与回数の計の被験者数
[b]：分母は，IM デポ剤安定期（Phase C）に移行した被験者数
＜資料番号 5.3.5.1-01：CT-20.2.1 より作成＞

2.7.4.1.2.2　長期投与試験での曝露状況

IM デポ剤維持治療期（Phase C）では，アリピプラゾール IM デポ注射剤 400 mg を 52 週間の投与期間で，4 週間ごとに合計 13 回投与することとした。ただし，20[redacted] 年 [redacted] 月 [redacted] 日（日本版：20[redacted] 年 [redacted] 月 [redacted] 日）付の治験計画書改訂により，31-08-250 試験からの継続例は最短 28 週間（7 回投与）とした。必要に応じて何度でもアリピプラゾール IM デポ注射剤の用量を 300 mg 又は 400 mg に柔軟に調節可能であった。新規被験者については全員，及び継続例については医師の判断により IM デポ剤維持治療期（Phase C）の投与開始後 2 週間はアリピプラゾール錠剤の投与も継続した。錠剤の初期用量は，錠剤安定期（Phase B）の最終用量に基づき決定することとした［錠剤安定期（Phase B）の最終用量が日本で 12 mg/日の場合は 6 mg/日，12 mg/日超 30 mg/日以下の場合は 12 mg/日，日本以外で 15 mg/日，又は 20 mg/日の場合は 10 mg/日，20 mg/日超 30 mg/日以下の場合は 15 mg/日］。治験責任医師等の判断で最大用量を日本は 18 mg/日，日本以外は 20 mg/日，最小用量を日本は 6 mg/日，日本以外は 10 mg/日とした。補助的な経口剤の用量に対する変更は日本では 6 mg ずつ，日本以外では 5 mg ずつ増減可能とした。なお，31-08-250 試験からの継続例には，治験責任医師の裁量に基づき IM デポ剤維持治療期（Phase C）の最初の 2 週間はアリピプラゾール錠剤投与を行った。

IM デポ剤維持治療期（Phase C）のアリピプラゾール IM デポ注射剤の曝露状況を表 2.7.4.1.2-3 に，投与までの平均期間を表 2.7.4.7-13 に，投与量を変更した被験者の割合を表 2.7.4.7-14 にそれぞれ示した。また，長期投与試験で使用したアリピプラゾール錠剤の曝露量を表 2.7.4.7-15 に示した。

IM デポ剤維持治療期（Phase C）では 464 例の被験者にアリピプラゾール IM デポ注射剤が投与された。アリピプラゾール IM デポ注射剤の用量は，必要に応じて何度でも 300 mg 又は 400 mg に柔軟に調節できた。開始用量が 300 mg であった被験者 2 例のうち 2 例，400 mg であった 462 例のうち 334 例の被験者が用量を変更しなかった。また，400 mg で開始した 462 例のうち，300 mg に減量後増量しなかった被験者は 117 例で，再度 400 mg に増量した被験者は 11 例であった。

IM デポ剤維持治療期（Phase C）では，76.1%（353/464 例）の被験者が 7 回以上投与され，48.1%

（223/464 例）の被験者が 13 回以上アリピプラゾール IM デポ注射剤を投与された。

IM デポ剤維持治療期（Phase C）では，最初の 2 週間はアリピプラゾール錠剤の投与も継続した（図 2.7.4.1.1-2 参照）。IM デポ剤維持治療期（Phase C）でアリピプラゾール錠剤を併用していた被験者は，新規例で 378 例（99.7%，378/379），継続例で 1 例（1.2%，1/85）であった［全例で 81.7%（379/464 例），1 日平均用量 ± SD = 10.7 ± 2.8 mg］（表 2.7.4.7-15）。

表 2.7.4.1.2-3　　長期投与試験での IM デポ剤維持治療期（Phase C）の治験薬の曝露状況

	新規例 (379例)			継続例 (85例)			全体 (464例)		
	計	400 mg	300 mg	計	400 mg	300 mg	計	400 mg	300 mg
	対象例数 (%)[a]	例数 (%)[b]	例数 (%)[b]	対象例数 (%)[a]	例数 (%)[b]	例数 (%)[b]	対象例数 (%)[a]	例数 (%)[b]	例数 (%)[b]
1回目	379 (100.0)	378 (99.7)	1 (0.3)	85 (100.0)	84 (98.8)	1 (1.2)	464 (100.0)	462 (99.6)	2 (0.4)
2回目	355 (93.7)	319 (89.9)	36 (10.1)	80 (94.1)	73 (91.3)	7 (8.8)	435 (93.8)	392 (90.1)	43 (9.9)
3回目	346 (91.3)	289 (83.5)	57 (16.5)	76 (89.4)	66 (86.8)	10 (13.2)	422 (90.9)	355 (84.1)	67 (15.9)
4回目	327 (86.3)	264 (80.7)	63 (19.3)	75 (88.2)	65 (86.7)	10 (13.3)	402 (86.6)	329 (81.8)	73 (18.2)
5回目	313 (82.6)	243 (77.6)	70 (22.4)	74 (87.1)	64 (86.5)	10 (13.5)	387 (83.4)	307 (79.3)	80 (20.7)
6回目	294 (77.6)	227 (77.2)	67 (22.8)	72 (84.7)	61 (84.7)	11 (15.3)	366 (78.9)	288 (78.7)	78 (21.3)
7回目	282 (74.4)	217 (77.0)	65 (23.0)	71 (83.5)	60 (84.5)	11 (15.5)	353 (76.1)	277 (78.5)	76 (21.5)
8回目	268 (70.7)	203 (75.7)	65 (24.3)	27 (31.8)	23 (85.2)	4 (14.8)	295 (63.6)	226 (76.6)	69 (23.4)
9回目	259 (68.3)	195 (75.3)	64 (24.7)	25 (29.4)	21 (84.0)	4 (16.0)	284 (61.2)	216 (76.1)	68 (23.9)
10回目	245 (64.6)	185 (75.5)	60 (24.5)	19 (22.4)	16 (84.2)	3 (15.8)	264 (56.9)	201 (76.1)	63 (23.9)
11回目	236 (62.3)	176 (74.6)	60 (25.4)	19 (22.4)	16 (84.2)	3 (15.8)	255 (55.0)	192 (75.3)	63 (24.7)
12回目	232 (61.2)	172 (74.1)	60 (25.9)	15 (17.6)	13 (86.7)	2 (13.3)	247 (53.2)	185 (74.9)	62 (25.1)
13回目	210 (55.4)	155 (73.8)	55 (26.2)	13 (15.3)	12 (92.3)	1 (7.7)	223 (48.1)	167 (74.9)	56 (25.1)

[a]：分母は，IM デポ剤維持治療期（Phase C）に割付けられた被験者数

[b]：分母は，各投与回数の計の被験者数

＜資料番号 5.3.5.2-01：Table 12.1-1 より作成＞

2.7.4.1.2.3　被験者の内訳

(1)　二重盲検試験

(a)　二重盲検試験に組み入れられたすべての被験者の内訳

二重盲検試験での被験者の内訳を表 2.7.4.7-16 に，中止例の内訳を表 2.7.4.1.2-4 に示した。

1175 例の患者にスクリーニング検査を実施し，このうち 444 例がスクリーニング不適格となった。組み入れられた 731 例のうち 466 例が錠剤切り替え期（Phase A）に移行し，直接錠剤安定期（Phase B）に移行した 265 例を含めると，合計 632 例が錠剤安定期（Phase B）に移行した。このうち 425 例が IM デポ剤安定期（Phase C）に移行し，266 例が二重盲検期（Phase D）に移行し，IM デポ群 133 例，プラセボ群 133 例に割付けられた。

IM デポ剤安定期（Phase C）では 425 例に 1 回以上アリピプラゾール IM デポ注射剤が投与され，全例が安全性解析対象となった。二重盲検期（Phase D）では 266 例のうち 265 例に 1 回以上アリピプラゾール IM デポ注射剤が投与され，全例が安全性解析対象となった。

錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤安定期（Phase C），二重盲検期（Phase D）の全体で最も多かった中止理由は，被験者による同意撤回（21.3%，156/731 例）であった。

表 2.7.4.1.2-4　　二重盲検試験での中止例の内訳（全 Phase，治験に組入れられた被験者）

被験者の内訳	錠剤切り替え期（Phase A）(466例) 例数 (%)[a]	錠剤安定期（Phase B）(632例) 例数 (%)[a]	IMデポ剤安定期（Phase C）(425例) 例数 (%)[a]	二重盲検期（Phase D）(266例) 例数 (%)[a]	計 (731例) 例数 (%)[a]
登録例	466 (100.0)	632 (100.0)	425 (100.0)	266 (100.0)	731 (100.0)
中止例	99 (21.2)	207 (32.8)	159 (37.4)	164 (61.7)	629 (86.0)
追跡不可能	16 (3.4)	44 (7.0)	21 (4.9)	13 (4.9)	94 (12.9)
有害事象[b]	33 (7.1)	63 (10.0)	37 (8.7)	0 (0.0)	133 (18.2)
治験依頼者による中止	0 (0.0)	0 (0.0)	1 (0.2)	4 (1.5)	5 (0.7)
中止基準に抵触	10 (2.1)	41 (6.5)	26 (6.1)	11 (4.1)	88 (12.0)
治験責任医師等による中止	3 (0.6)	2 (0.3)	6 (1.4)	0 (0.0)	11 (1.5)
被験者による同意撤回	32 (6.9)	45 (7.1)	56 (13.2)	23 (8.6)	156 (21.3)
治験実施計画書からの逸脱	3 (0.6)	0 (0.0)	5 (1.2)	2 (0.8)	10 (1.4)
効果不十分	2 (0.4)	12 (1.9)	7 (1.6)	0 (0.0)	21 (2.9)
有害事象（関連する気分エピソードの再発なし）[c]	0 (0.0)	0 (0.0)	0 (0.0)	8 (3.0)	8 (1.1)
気分エピソードの再発（関連する有害事象あり）[c]	0 (0.0)	0 (0.0)	0 (0.0)	49 (18.4)	49 (6.7)
気分エピソードの再発（関連する有害事象なし）[c]	0 (0.0)	0 (0.0)	0 (0.0)	54 (20.3)	54 (7.4)
中間解析結果に基づき治験依頼者による中止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[a]：%は当該投与期又は投与群の対象例数に基づく

[b]：錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤安定期（Phase C）

[c]：二重盲検期（Phase D）

＜資料番号 5.3.5.1-01：CT-2.1 より作成＞

(b) 二重盲検期（Phase D）での内訳

二重盲検期（Phase D）での被験者の内訳を表 2.7.4.7-17 に，中止例の内訳を表 2.7.4.1.2-5 に示した。

二重盲検期（Phase D）では 266 例のうち 133 例が IM デポ群に，133 例がプラセボ群に割り付けられた。IM デポ群では 133 例のうち 132 例に 1 回以上アリピプラゾール IM デポ注射剤が投与され，全例が安全性解析対象となった。プラセボ群では 133 例全例に 1 回以上プラセボが投与され，全例が安全性解析対象となった。

二重盲検期（Phase D）で IM デポ群又はプラセボ群に割り付けられた 266 例のうち，102 例（38.3%）が二重盲検期（Phase D）を完了した。各群での内訳は，IM デポ群 64 例（48.1%），プラセボ群 38 例（28.6%）である。

二重盲検期（Phase D）で中止した被験者の割合は，プラセボ群 71.4%（95/133 例），IM デポ群 51.9%（69/133 例）であり，プラセボ群で高かった。

二重盲検期（Phase D）の全体で最も多かった中止理由は，関連する有害事象のない気分エピソードの再発（20.3%，54/266 例）であった（プラセボ群 14.3%，19/133 例，IM デポ群 26.3%，35/133 例）。

なお，二重盲検試験では，二重盲検期（Phase D）で被験者が基準を満たす気分エピソードが再発した場合は中止することがあらかじめ設定されていた。

表 2.7.4.1.2-5　二重盲検期（Phase D）での中止例の内訳（無作為割付された被験者）

	二重盲検期（Phase D）		
	IMデポ群 (133例)	プラセボ群 (133例)	計 (266例)
被験者の内訳	例数 (%)[a]	例数 (%)[a]	例数 (%)[a]
登録例	133 (100.0)	133 (100.0)	266 (100.0)
中止例	69 (51.9)	95 (71.4)	164 (61.7)
追跡不可能	8 (6.0)	5 (3.8)	13 (4.9)
有害事象[b]	0 (0.0)	0 (0.0)	0 (0.0)
治験依頼者による中止	1 (0.8)	3 (2.3)	4 (1.5)
中止基準に抵触	4 (3.0)	7 (5.3)	11 (4.1)
治験責任医師等による中止	0 (0.0)	0 (0.0)	0 (0.0)
被験者による同意撤回	13 (9.8)	10 (7.5)	23 (8.6)
治験実施計画書からの逸脱	1 (0.8)	1 (0.8)	2 (0.8)
効果不十分	0 (0.0)	0 (0.0)	0 (0.0)
有害事象（関連する気分エピソードの再発なし）[c]	7 (5.3)	1 (0.8)	8 (3.0)
気分エピソードの再発（関連する有害事象あり）[c]	16 (12.0)	33 (24.8)	49 (18.4)
気分エピソードの再発（関連する有害事象なし）[c]	19 (14.3)	35 (26.3)	54 (20.3)
中間解析結果に基づき治験依頼者による中止	0 (0.0)	0 (0.0)	0 (0.0)

[a]：%は当該投与期又は投与群の対象例数に基づく

[b]：錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤安定期（Phase C）

[c]：二重盲検期（Phase D）

＜資料番号 5.3.5.1-01：CT-2.2 より作成＞

(c) IM デポ剤安定期（Phase C）での被験者の内訳

IM デポ剤安定期（Phase C）での被験者の内訳は表 2.7.4.7-16 に，中止例の内訳は表 2.7.4.1.2-4 に示した。

IM デポ剤安定期（Phase C）では 425 例に 1 回以上アリピプラゾール IM デポ注射剤が投与され，266 例が二重盲検期（Phase D）に移行し，159 例が治験の中止に至った。IM デポ剤安定期（Phase C）で最も多かった中止理由は，被験者による同意撤回（13.2%，56/425 例）であった。

(2) 長期投与試験

(a) 長期投与試験に組み入れられたすべての被験者の内訳

長期投与試験での被験者の内訳を表 2.7.4.7-18 に，中止例の内訳を表 2.7.4.1.2-6 に示した。

新規例では 958 例の患者にスクリーニング検査を実施し，663 例が組み入れられた。このうち錠剤安定期（Phase B）に移行した 555 例のうち IM デポ剤維持治療期（Phase C）に移行したのは 379 例であった。31-08-250 試験から直接 IM デポ剤維持治療期（Phase C）に参加した継続例は 85 例であり，試験全体では 464 例が IM デポ剤維持治療期（Phase C）にて治験薬投与を受けた。このうち 52 週目の投与を完了した被験者は 62.7%（291/464 例）であった。

IM デポ剤維持治療期（Phase C）では 464 例に 1 回以上アリピプラゾール IM デポ注射剤が投与され，全例が安全性解析対象となった。

錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤維持治療期（Phase C）を含む全体で最も多かった中止理由は，有害事象（17.4%，130/748 例）であった。

表 2.7.4.1.2-6　　長期投与試験での中止理由（全 Phase，組入れられた被験者）

被験者の内訳	錠剤切り替え期（Phase A）(501例) 例数 (%)[a]	錠剤安定期（Phase B）(555例) 例数 (%)[a]	IM デポ剤維持治療期（Phase C）(464例) 例数 (%)[a]	計 (748例) 例数 (%)[a]
登録例	501 (100.0)	555 (100.0)	464 (100.0)	748 (100.0)
中止例	108 (21.6)	176 (31.7)	173 (37.3)	457 (61.1)
追跡不可能	21 (4.2)	32 (5.8)	29 (6.3)	82 (11.0)
有害事象	41 (8.2)	41 (7.4)	48 (10.3)	130 (17.4)
治験依頼者による中止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
中止基準に抵触	12 (2.4)	42 (7.6)	33 (7.1)	87 (11.6)
治験責任医師等による中止	4 (0.8)	1 (0.2)	2 (0.4)	7 (0.9)
被験者による同意撤回	23 (4.6)	43 (7.7)	53 (11.4)	119 (15.9)
治験実施計画書からの逸脱	4 (0.8)	2 (0.4)	5 (1.1)	11 (1.5)
効果不十分	3 (0.6)	15 (2.7)	3 (0.6)	21 (2.8)

[a]：%は当該投与期又は投与群の対象例数に基づく

162 例の被験者がスクリーニング期から直接錠剤安定期（Phase B）に移行した。

＜資料番号 5.3.5.2-01：CT-2.1 より作成＞

(b) IM デポ剤維持治療期（Phase C）

IM デポ剤維持治療期（Phase C）では移行した 464 例のうち 291 例（62.7%）が IM デポ剤維

持治療期（Phase C）を完了した（表 2.7.4.7-18 参照）。

IM デポ剤維持治療期（Phase C）で最も多かった中止理由は，被験者による同意撤回（11.4%，53/464 例）であった（表 2.7.4.1.2-6）。

2.7.4.1.3　治験対象集団の人口統計学的特性及びその他の基準値の特性

2.7.4.1.3.1　二重盲検試験

(1)　二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）での人口統計学的特性を表 2.7.4.1.3-1 に，他の基準値の特性を表 2.7.4.1.3-2 に示した。

IM デポ群の 133 例では，年齢 40.6 ± 10.8 歳（平均値 ± SD，以下同様）で，男性 37.6%（50 例），女性 62.4%（83 例）であり，人種は白人 52.6%（70 例），アジア人 14.3%（19 例）であった。最高年齢は 65 歳（1 例）であった。プラセボ群の 133 例では，年齢 40.6 ± 11.2 歳で，男性 47.4%（63 例），女性 52.6%（70 例），人種は白人 55.6%（74 例），アジア人 13.5%（18 例）であった。最高年齢は 66 歳（65 歳以上 1 例）であった。IM デポ群とプラセボ群で人口統計学的特性は類似していた。

IM デポ群 133 例の他の基準値の特性は，体重 89.3 ± 24.1 kg であり，地域は日本 6.8%（9 例），北米 77.4%（103 例）であった。登録前の罹病期間は 12.1 ± 9.2 年，躁病エピソードの初回診断時の年齢は 25.2 ± 10.3 歳，過去 12 ヵ月での気分エピソードの数は 2.2 ± 1.2 回，気分エピソードのための入院回数は 3.5 ± 3.9 回であった。また，YMRS 合計スコアは 2.9 ± 3.5，MADRS 合計スコアは 3.0 ± 3.4，CGI-BP-S（躁病）スコアは 1.5 ± 0.7 であった。プラセボ群では体重 89.2 ± 22.6 kg であり，地域は日本 7.5%（10 例），北米 76.7%（102 例）であった。登録前の罹病期間は 13.6 ± 9.8 年，躁病エピソードの初回診断時の年齢は 24.8 ± 9.9 歳，過去 12 ヵ月での気分エピソードの数は 2.2 ± 1.1 回，気分エピソードのための入院回数は 3.5 ± 4.1 回であった。また，YMRS 合計スコアは 2.6 ± 3.0，MADRS 合計スコアは 2.4 ± 3.4，CGI-BP-S（躁病）スコアは 1.4 ± 0.6 であった。IM デポ群とプラセボ群で他の基準値の特性は類似していた。

表 2.7.4.1.3-1　　二重盲検試験の二重盲検期（Phase D）での人口統計学的特性
（無作為割付された被験者）

	二重盲検期（Phase D）		
特性	IMデポ群 (133例)	プラセボ群 (133例)	計 (266例)
性別［例数(%)］			
男性	50 (37.6%)	63 (47.4%)	113 (42.5%)
女性	83 (62.4%)	70 (52.6%)	153 (57.5%)
人種［例数(%)］			
白人	70 (52.6%)	74 (55.6%)	144 (54.1%)
黒人/アフリカ系アメリカ人	40 (30.1%)	35 (26.3%)	75 (28.2%)
アメリカインディアン又はアラスカ先住民	1 (0.8%)	1 (0.8%)	2 (0.8%)
アジア人	19 (14.3%)	18 (13.5%)	37 (13.9%)
その他	3 (2.3%)	5 (3.8%)	8 (3.0%)
民族［例数(%)］			
ヒスパニック系/ラテン系	8 (6.0%)	11 (8.3%)	19 (7.1%)
ヒスパニック系/ラテン系以外	125 (94.0%)	122 (91.7%)	247 (92.9%)
年齢（歳）			
例数	133	133	266
平均値 (SD)	40.6 (10.8)	40.6 (11.2)	40.6 (11.0)
範囲	21.0, 65.0	19.0, 66.0	19.0, 66.0
体重（kg）			
例数	133	133	266
平均値 (SD)	89.3 (24.1)	89.2 (22.6)	89.2 (23.3)
範囲	40.9, 197.1	49.0, 155.6	40.9, 197.1
身長（cm）			
例数	133	133	266
平均値 (SD)	168.4 (10.3)	170.7 (9.6)	169.6 (10.0)
範囲	145.0, 198.0	148.0, 193.0	145.0, 198.0
BMI (kg/m^2)			
例数	133	133	266
平均値 (SD)	31.4 (7.7)	30.5 (7.0)	30.9 (7.3)
範囲	17.5, 72.4	18.7, 55.1	17.5, 72.4
地域［例数(%)］			
北米	103 (77.4%)	102 (76.7%)	205 (77.1%)
ヨーロッパ	12 (9.0%)	13 (9.8%)	25 (9.4%)
日本	9 (6.8%)	10 (7.5%)	19 (7.1%)
その他のアジア	9 (6.8%)	8 (6.0%)	17 (6.4%)
IMデポ剤安定期（Phase C）のIMデポ注射剤の最終用量［例数(%)］			
300 mg	19 (14.3%)	16 (12.0%)	35 (13.2%)
400 mg	114 (85.7%)	117 (88.0%)	231 (86.8%)

＜資料番号 5.3.5.1-01：CT-3.1.2 より作成＞

表 2.7.4.1.3-2　　二重盲検試験の二重盲検期（Phase D）での他の基準値の特性
（無作為割付された被験者）

特性	二重盲検期（Phase D） IMデポ群 (133例)	プラセボ群 (133例)	計 (266例)
躁病エピソードの初回診断時の年齢			
例数	133	133	266
平均値 (SD)	25.2 (10.3)	24.8 (9.9)	25.0 (10.1)
範囲	10, 60	7, 59	7, 60
過去12ヵ月での気分エピソードの数			
例数	133	133	266
平均値 (SD)	2.2 (1.2)	2.2 (1.1)	2.2 (1.2)
範囲	0, 8	1, 7	0, 8
登録前の罹病期間（年）			
例数	133	133	266
平均値 (SD)	12.1 (9.2)	13.6 (9.8)	12.9 (9.5)
範囲	1, 39	0, 39	0, 39
気分エピソードのための入院回数			
例数	133	133	266
平均値 (SD)	3.5 (3.9)	3.5 (4.1)	3.5 (4.0)
範囲	0, 20	0, 19	0, 20
YMRS合計スコア[a]			
例数	133	133	266
平均値 (SD)	2.9 (3.5)	2.6 (3.0)	2.8 (3.3)
範囲	0, 12	0, 12	0, 12
MADRS合計スコア[a]			
例数	133	133	266
平均値 (SD)	3.0 (3.4)	2.4 (3.4)	2.7 (3.4)
範囲	0, 12	0, 12	0, 12
CGI-BP-S（躁病）スコア[a]			
例数	133	133	266
平均値 (SD)	1.5 (0.7)	1.4 (0.6)	1.5 (0.7)
範囲	1, 4	1, 3	1, 4

[a] 二重盲検期（Phase D）のベースライン値

＜資料番号 5.3.5.1-01：CT-3.2.2 より作成＞

(2)　IM デポ剤安定期（Phase C）

IM デポ剤安定期（Phase C）での人口統計学的特性を表 2.7.4.1.3-3 に，他の基準値の特性を表 2.7.4.7-19 にそれぞれ示した。

IM デポ剤安定期（Phase C）の 425 例では，年齢 40.3 ± 11.3 歳（平均値 ± SD，以下同様）で，男性 39.8%（169 例），女性 60.2%（256 例）であり，人種は白人 55.5%（236 例），アジア人 12.9%（55 例）であった。最高年齢は 66 歳（65 歳以上 2 例）であった。

IM デポ剤安定期（Phase C）の 425 例での他の特性は，体重 87.7 ± 22.4 kg であり，地域は日本 6.6%（28 例），北米 80.2%（341 例）であった。YMRS 合計スコアは 5.8 ± 4.1，MADRS 合計スコアは 3.7 ± 4.1，CGI-BP-S（躁病）スコアは 2.0 ± 0.8 であった。

表 2.7.4.1.3-3　二重盲検試験の IM デポ剤安定期（Phase C）での人口統計学的特性（組み入れられた被験者）

特性	IMデポ剤安定期（Phase C）(425例)
性別［例数(%)］	
男性	169 (39.8%)
女性	256 (60.2%)
人種［例数(%)］	
白人	236 (55.5%)
黒人/アフリカ系アメリカ人	118 (27.8%)
アメリカインディアン又はアラスカ先住民	3 (0.7%)
アジア人	55 (12.9%)
その他	12 (2.8%)
不明	1 (0.2%)
民族［例数(%)］	
ヒスパニック系/ラテン系	31 (7.3%)
ヒスパニック系/ラテン系以外	394 (92.7%)
不明	0 (0.0%)
年齢（歳）	
例数	425
平均値 (SD)	40.3 (11.3)
範囲	18.0, 66.0
体重（kg）	
例数	425
平均値 (SD)	87.7 (22.4)
範囲	38.8, 188.4
身長（cm）	
例数	425
平均値 (SD)	169.0 (9.5)
範囲	145.0, 198.0
BMI (kg/m^2)	
例数	425
平均値 (SD)	30.6 (7.2)
範囲	16.6, 69.2
地域［例数(%)］	
北米	341 (80.2%)
ヨーロッパ	32 (7.5%)
日本	28 (6.6%)
その他のアジア	24 (5.6%)

＜資料番号 5.3.5.1-01：CT-3.1.1 より作成＞

2.7.4.1.3.2　長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）の人口統計学的特性及び他の基準値の特性を表 2.7.4.7-20 及び表 2.7.4.7-21 にそれぞれ示した。

IM デポ剤維持治療期（Phase C）の 464 例では，年齢 41.1 ± 11.8 歳（平均値 ± SD，以下同様）で，男性 42.2%（196 例），女性 57.8%（268 例）であり，人種は白人 55.0%（255 例），アジア

人 20.3%（94 例）であった。最高年齢は 66 歳であった。他の特性は，体重 86.6 ± 24.8 kg であり，地域は日本 16.2%（75 例），北米 70.0%（325 例）であった。登録前の罹病期間は 11.9 ± 9.5 年，躁病エピソードの初回診断時の年齢は 25.0 ± 10.4 歳，過去 12 ヵ月での気分エピソードの数は 2.1 ± 1.7 回，気分エピソードのための入院回数は 2.5 ± 3.2 回であった。また，YMRS 合計スコアは 2.3 ± 2.9，MADRS 合計スコアは 3.2 ± 3.2，CGI-BP-S（躁病）スコアは 1.5 ± 0.8 であった。

IM デポ剤維持治療期（Phase C）の 464 例では，全例が外来患者であった（資料番号 5.3.5.3-01 CT-3.2.1.1 参照）。

2.7.4.1.4　併用薬使用状況

2.7.4.1.4.1　二重盲検試験

(1)　二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）の 266 例で，何らかの併用薬を使用していた被験者は，207 例（77.8%）であった。IM デポ群では 133 例のうち 103 例（77.4%）が，プラセボ群では 133 例のうち 104 例（78.2%）が使用していた。最も使用されていた薬剤は，精神抑制薬（抗精神病薬，抗うつ薬，抗不安薬，睡眠薬，その他）で，IM デポ群では 54 例（40.6%），プラセボ群では 50 例（37.6%）と，同程度の被験者が使用していた（資料番号 5.3.5.1-01，CT-4.2.4 参照）

ベンゾジアゼピン系薬剤の服用は，激越，不安，不眠など急性の AE 治療を管理を目的とする場合は許容されていたことから，二重盲検期（Phase D）でのベンゾジアゼピン系薬剤の使用状況を表 2.7.4.1.4-1 に示した。また，抗コリン性抗パーキンソン薬の併用が許容されていたことから，抗コリン薬の使用状況を表 2.7.4.7-22 に示した。

ベンゾジアゼピン系薬剤は，IM デポ群で 27.8%（37/133 例），プラセボ群で 24.1%（32/133 例）が使用しており，抗コリン薬は，IM デポ群で 18.0%（24/133 例），プラセボ群で 14.3%（19/133 例）が使用していた。IM デポ群とプラセボ群でベンゾジアゼピン系薬剤又は抗コリン薬の使用割合に臨床的に意味のある違いはなかった。

使用されていたベンゾジアゼピン系薬剤の 1 日平均用量は，IM デポ群の 28 例で 1.16 ± 0.75 mg，プラセボ群の 24 例で 1.44 ± 1.23 mg であり，抗コリン薬の 1 日平均用量は，IM デポ群の 23 例で 1.72 ± 1.06 mg（平均値 ± 標準偏差，以下同様），プラセボ群の 17 例で 1.68 ± 0.91 mg であった。

表 2.7.4.1.4-1　　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［二重盲検期（Phase D）］

併用薬	投与群	対象例数[a]	例数 (%)[b]	1日平均用量 (mg)[d] 対象例数[c]	平均値(SD)	中央値
抗コリン薬	IMデポ群	133	24 (18.0)	132	0.22 (0.70)	0.00
	プラセボ群	133	19 (14.3)	131	0.12 (0.42)	0.00
	計	266	43 (16.2)	263	0.17 (0.58)	0.00
ベンゾジアゼピン系薬剤	IMデポ群	133	37 (27.8)	124	0.05 (0.14)	0.00
	プラセボ群	133	32 (24.1)	125	0.05 (0.17)	0.00
	計	266	69 (25.9)	249	0.05 (0.16)	0.00

[a]：二重盲検期（PhaseD）に割り付けられた被験者数
[b]：二重盲検期（PhaseD）に併用薬を使用した被験者数：%の分母は二重盲検期（PhaseD）に割り付けられた被験者数
[c]：二重盲検期（PhaseD）に割り付けられた被験者のうち，当該併用薬を使用しなかった又は当該併用薬を使用し1日用量が得られた被験者数
[d]：1 日平均用量（mg） = 使用した合計用量(mg)/登録から Phase 終了までの日数；当該併用薬を使用しなかった被験者は 0 とした
＜資料番号 5.3.5.1-01：CT-4.4.1.1 より作成＞

(2)　IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）の 425 例では，338 例（79.5%）の被験者が併用薬を使用していた。最も使用されていた薬剤は，精神抑制薬（抗精神病薬，抗うつ薬，抗不安薬，睡眠薬，その他）で，187 例（44.0%）が使用していた（資料番号 5.3.5.1-01，CT-17.3 参照）。

2.7.4.1.4.2　長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）464 例で，何らかの併用薬を使用していた被験者は，381 例（82.1%）であった。最も使用されていた薬剤は，精神抑制薬（抗精神病薬，抗うつ薬，抗不安薬，睡眠薬，その他）で，185 例（39.9%）が使用していた（資料番号 5.3.5.2-01，CT-4.2.3 参照）。

長期投与試験でもベンゾジアゼピン系薬剤の服用は，激越，不安，不眠など急性の AE の治療を目的とする場合は許容されていたことから，IM デポ剤維持治療期（Phase C）のベンゾジアゼピン系薬剤の使用状況を表 2.7.4.7-23 に，また，抗コリン性抗パーキンソン薬の併用が許容されていたことから，抗コリン薬の使用状況を表 2.7.4.7-24 に示した。

また，救済治療薬の使用状況を表 2.7.4.7-25 に示した。

ベンゾジアゼピン系薬剤は，26.7%（124/464 例）が使用しており，抗コリン薬は，16.4%（76/464 例）が使用していた。

使用されていたベンゾジアゼピン系薬剤の 1 日平均用量は 77 例で 1.40 ± 1.32 mg であり，抗コリン薬の 1 日平均用量は，70 例で 2.00 ± 1.06 mg（平均値 ± 標準偏差，以下同様）であった。

IM デポ剤維持治療期（Phase C）では救済治療薬として気分安定薬及び抗痙攣薬のうちリチウムとバルプロ酸のみ救済治療薬として服用可能であった。IM デポ剤維持治療期（Phase C）ではリチウムを使用した被験者は 6.0%（28/464 例）で，その平均使用日数は 147.86 日であった。バル

プロ酸を使用した被験者は 7.8%（36/464 例）で，その平均使用日数は 113.69 日であった。

2.7.4.2　有害事象

2.7.4.2.1　有害事象の解析

有害事象の読替えには MedDRA Version 19.0 を使用し，和訳の際も同じバージョンの MedDRA を使用した。

本申請の評価資料とした試験の統合データでの全有害事象及び全副作用を表 に示し，各試験で発現した有害事象及び副作用の要約を以下に示した。

(1)　二重盲検試験で発現した有害事象の要約

(a)　二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）で発現した有害事象の要約を表 2.7.4.2.1-1 に示した。

二重盲検期（Phase D）での安全性解析対象は IM デポ群で 132 例，プラセボ群で 133 例であった。有害事象の発現割合は，IM デポ群で 76.5%（101/132 例），プラセボ群で 80.5%（107/133 例）であり，治験薬と関連性があると判断された有害事象（副作用）の発現割合は，IM デポ群が 62.1%（82/132 例），プラセボ群が 50.4%（67/133 例）であった。

重篤な有害事象の発現割合は，IM デポ群で 7.6%（10/132 例），プラセボ群で 18.8%（25/133 例）であった。このうち IM デポ群の 1 例で死亡が認められた。死亡に至った有害事象は，脳損傷，呼吸不全の計 2 件で，治験薬との関連性はなしであった（表 2.7.4.7-27）。投与中止に至った有害事象の発現割合は IM デポ群で 17.4%（23/132 例），プラセボ群で 25.6%（34/133 例）であった。

副作用の発現割合は IM デポ群で約 12%高かったものの，有害事象，重篤な有害事象，及び投与中止に至った有害事象の発現割合は，IM デポ群でプラセボ群と比較して 4%～11%程度低かった。

表 2.7.4.2.1-1　有害事象の要約［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］（安全性解析対象集団）

	IMデポ剤安定期（Phase C）	二重盲検期（Phase D）	
		IMデポ群	プラセボ群
	例数 (%)[a]	例数 (%)[a]	例数 (%)[a]
対象例数	425	132	133
有害事象	291 (68.5)	101 (76.5)	107 (80.5)
副作用	238 (56.0)	82 (62.1)	67 (50.4)
高度の有害事象	28 (6.6)	8 (6.1)	15 (11.3)
重篤な有害事象	36 (8.5)	10 (7.6)	25 (18.8)
投与中止に至った有害事象	37 (8.7)	23 (17.4)	34 (25.6)
死亡	0 (0.0)	1 (0.8)	0 (0.0)

[a]：%の分母は治験薬を投与された被験者数

＜資料番号 5.3.5.1-01：CT-8.1，CT-8.3.1，CT-21.1，CT-21.3.1 より作成＞

(b)　IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）で発現した有害事象の要約を表 2.7.4.2.1-1 に示した。

IM デポ剤安定期（Phase C）での安全性解析対象は 425 例であった。有害事象の発現割合は 68.5%（291/425 例），副作用の発現割合は 56.0%（238/425 例）であった。重篤な有害事象の発現割合は 8.5%（36/425 例）で，死亡例は認められなかった。投与中止に至った有害事象の発現割合は 8.7%（37/425 例）であった。

なお，二重盲検試験では錠剤安定期（Phase B）で死亡例が 1 例に認められた。死亡に至った有害事象は，心筋梗塞で，治験薬との関連性はなしであった（表 2.7.4.7-27）。

(2)　長期投与試験で発現した有害事象の要約

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した有害事象の要約を表 2.7.4.2.1-2 に示した。

IM デポ剤維持治療期（Phase C）での安全性解析対象は 464 例であった。有害事象の発現割合は 80.6%（374/464 例），副作用の発現割合は 56.7%（263/464 例）であった。重篤な有害事象の発現割合は 6.5%（30/464 例）で，死亡例が 1 例に認められた。死亡に至った有害事象は，心停止で，治験薬との関連性はなしであった（表 2.7.4.7-28）。投与中止に至った有害事象の発現割合は 10.1%（47/464 例）であった。

表 2.7.4.2.1-2　　有害事象の要約[長期投与試験の IM デポ剤維持治療期（Phase C）]

	IM デポ剤維持治療期（Phase C）		
	新規例(379例)	継続例(85例)	計(464例)
	例数 (%)[a]	例数 (%)[a]	例数 (%)[a]
アリピプラゾール錠剤投与例	378 (99.7)	1 (1.2)	379 (81.7)
IMデポ注射剤投与例	379 (100.0)	85 (100.0)	464 (100.0)
有害事象	323 (85.2)	51 (60.0)	374 (80.6)
重篤な有害事象	27 (7.1)	3 (3.5)	30 (6.5)
副作用	237 (62.5)	26 (30.6)	263 (56.7)
高度の有害事象	39 (10.3)	2 (2.4)	41 (8.8)
投与中止に至った有害事象	44 (11.6)	3 (3.5)	47 (10.1)
死亡	1 (0.3)	0 (0.0)	1 (0.2)

a：%の分母は IM デポ剤維持治療期（Phase C）で治験薬を投与された被験者数

＜資料番号 5.3.5.2-01：Table 12.2.1-1，CT-8.3.1 より作成＞

2.7.4.2.1.1　比較的よく見られる有害事象

(1)　二重盲検試験の二重盲検期（Phase D）

(a)　器官別大分類別

二重盲検試験の二重盲検期（Phase D）で発現した器官別大分類別有害事象及び副作用を表 2.7.4.2.1-3 及び表 2.7.4.2.1-4 に示した。

器官別大分類別有害事象で発現割合が最も高かったのは，IM デポ群では神経系障害 35.6%（47/132 例），プラセボ群では精神障害 36.8%（49/133 例）であった。

IM デポ群での発現割合がプラセボ群より 5%以上高かったのは，神経系障害に分類される事象であった。

器官別大分類別副作用で発現割合が最も高かったのは，IM デポ群，プラセボ群のいずれも神経系障害であった。発現割合は，IM デポ群で 29.5%（39/132 例），プラセボ群で 18.0%（24/133 例）であった。

IM デポ群での発現割合がプラセボ群より 5%以上高かったのは，神経系障害に分類される事象であった。

表 2.7.4.2.1-3　　器官別大分類別有害事象[二重盲検試験の二重盲検期(Phase D)]

	IMデポ群 (132例)	プラセボ群 (133例)
器官別大分類	例数 (%)	例数 (%)
有害事象	101 (76.5)	107 (80.5)
血液およびリンパ系障害	3 (2.3)	1 (0.8)
心臓障害	4 (3.0)	0 (0.0)
耳および迷路障害	1 (0.8)	0 (0.0)
内分泌障害	0 (0.0)	1 (0.8)
眼障害	4 (3.0)	2 (1.5)
胃腸障害	18 (13.6)	26 (19.5)
一般・全身障害および投与部位の状態	9 (6.8)	8 (6.0)
肝胆道系障害	0 (0.0)	1 (0.8)
感染症および寄生虫症	39 (29.5)	35 (26.3)
傷害、中毒および処置合併症	11 (8.3)	6 (4.5)
臨床検査	35 (26.5)	38 (28.6)
代謝および栄養障害	6 (4.5)	5 (3.8)
筋骨格系および結合組織障害	10 (7.6)	18 (13.5)
神経系障害	47 (35.6)	35 (26.3)
精神障害	43 (32.6)	49 (36.8)
腎および尿路障害	2 (1.5)	2 (1.5)
生殖系および乳房障害	5 (3.8)	9 (6.8)
呼吸器、胸郭および縦隔障害	4 (3.0)	3 (2.3)
皮膚および皮下組織障害	7 (5.3)	7 (5.3)
社会環境	1 (0.8)	0 (0.0)
血管障害	1 (0.8)	4 (3.0)

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＜資料番号 5.3.5.1-01：CT-8.2.1 より作成＞

表 2.7.4.2.1-4　　器官別大分類別副作用［二重盲検試験の二重盲検期（Phase D）］

器官別大分類	IMデポ群 (132例) 例数 (%)	プラセボ群 (133例) 例数 (%)
副作用	82 (62.1)	67 (50.4)
血液およびリンパ系障害	1 (0.8)	1 (0.8)
心臓障害	1 (0.8)	0 (0.0)
耳および迷路障害	1 (0.8)	0 (0.0)
眼障害	4 (3.0)	1 (0.8)
胃腸障害	8 (6.1)	9 (6.8)
一般・全身障害および投与部位の状態	5 (3.8)	8 (6.0)
感染症および寄生虫症	1 (0.8)	2 (1.5)
傷害、中毒および処置合併症	2 (1.5)	0 (0.0)
臨床検査	32 (24.2)	27 (20.3)
代謝および栄養障害	4 (3.0)	2 (1.5)
筋骨格系および結合組織障害	2 (1.5)	4 (3.0)
神経系障害	39 (29.5)	24 (18.0)
精神障害	23 (17.4)	21 (15.8)
腎および尿路障害	0 (0.0)	1 (0.8)
生殖系および乳房障害	5 (3.8)	3 (2.3)
皮膚および皮下組織障害	1 (0.8)	3 (2.3)
血管障害	1 (0.8)	2 (1.5)

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＜資料番号 5.3.5.1-01：CT-8.3.1 より作成＞

(b)　基本語別

二重盲検試験の二重盲検期（Phase D）で発現した有害事象のうち，IM デポ群で 2%以上に発現し，かつ，プラセボ群より発現割合が高い有害事象を表 2.7.4.2.1-5 に，いずれかの群で 2%以上に発現した副作用を表 2.7.4.2.1-6 に，すべての有害事象及び副作用を表 2.7.4.7-29 及び表 2.7.4.7-30 に示した。

5%以上に発現した有害事象は，IM デポ群では，体重増加 23.5%（31/132 例），アカシジア 21.2%（28/132 例），不眠症 7.6%（10/132 例），不安 6.8%（9/132 例）であった。プラセボ群では，体重増加 18.0%（24/133 例），アカシジア 12.8%（17/133 例），不眠症 7.5%（10/133 例）であった。

IM デポ群で，発現割合が 5%以上かつプラセボ群と比較して発現割合が 2 倍以上の有害事象は認められなかった。IM デポ群で発現した有害事象のうち，発現割合がプラセボ群より 5%以上高かった有害事象は，体重増加，アカシジアであった。

表 2.7.4.2.1-5　　IM デポ群で 2%以上に発現し，かつ，プラセボ群より発現割合が高い有害事象［二重盲検試験の二重盲検期（Phase D）］

器官別大分類 基本語	IMデポ群 (132例) 例数 (%)	プラセボ群 (133例) 例数 (%)
有害事象	101 (76.5)	107 (80.5)
血液およびリンパ系障害		
貧血	3 (2.3)	0 (0.0)
眼障害		
霧視	3 (2.3)	0 (0.0)
胃腸障害		
便秘	4 (3.0)	4 (3.0)
口内乾燥	4 (3.0)	3 (2.3)
流涎過多	3 (2.3)	3 (2.3)
感染症および寄生虫症		
気管支炎	3 (2.3)	2 (1.5)
インフルエンザ	3 (2.3)	2 (1.5)
副鼻腔炎	5 (3.8)	1 (0.8)
尿路感染	4 (3.0)	2 (1.5)
傷害、中毒および処置合併症		
処置による疼痛	4 (3.0)	1 (0.8)
臨床検査		
血中クレアチンホスホキナーゼ増加	3 (2.3)	1 (0.8)
体重増加	31 (23.5)	24 (18.0)
代謝および栄養障害		
食欲亢進	4 (3.0)	1 (0.8)
神経系障害		
アカシジア	28 (21.2)	17 (12.8)
傾眠	6 (4.5)	1 (0.8)
振戦	3 (2.3)	2 (1.5)
精神障害		
不安	9 (6.8)	6 (4.5)
双極性障害	5 (3.8)	5 (3.8)
うつ病	4 (3.0)	3 (2.3)
不眠症	10 (7.6)	10 (7.5)
リビドー減退	3 (2.3)	2 (1.5)
落ち着きのなさ	6 (4.5)	5 (3.8)

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＜資料番号 5.3.5.1-01：CT-8.2.2，CT-8.2.4.2 より作成＞

5%以上に発現した副作用は，IM デポ群では，体重増加 22.7%（30/132 例），アカシジア 20.5%（27/132 例）であった。プラセボ群でも，体重増加 15.8%（21/133 例），アカシジア 12.8%（17/133 例）であった。

表 2.7.4.2.1-6　IM デポ群又はプラセボ群で 2%以上に発現した副作用［二重盲検試験の二重盲検期（Phase D）］

器官別大分類 基本語	IMデポ群 (132例) 例数 (%)	プラセボ群 (133例) 例数 (%)
副作用	82 (62.1)	67 (50.4)
眼障害		
霧視	3 (2.3)	0 (0.0)
胃腸障害		
口内乾燥	2 (1.5)	3 (2.3)
流涎過多	3 (2.3)	3 (2.3)
一般・全身障害および投与部位の状態		
疲労	4 (3.0)	4 (3.0)
臨床検査		
体重減少	0 (0.0)	4 (3.0)
体重増加	30 (22.7)	21 (15.8)
代謝および栄養障害		
食欲亢進	4 (3.0)	1 (0.8)
神経系障害		
アカシジア	27 (20.5)	17 (12.8)
傾眠	5 (3.8)	1 (0.8)
振戦	3 (2.3)	2 (1.5)
精神障害		
不安	6 (4.5)	2 (1.5)
うつ病	4 (3.0)	1 (0.8)
不眠症	4 (3.0)	6 (4.5)
躁病	1 (0.8)	4 (3.0)
落ち着きのなさ	4 (3.0)	5 (3.8)

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＜資料番号 5.3.5.1-01：CT-8.3.2 より作成＞

(c)　重症度別

二重盲検試験の二重盲検期（Phase D）で発現した重症度別有害事象及び副作用を表 2.7.4.7-31 及び表 2.7.4.7-32 に示した。

IM デポ群の重症度別有害事象の発現割合は，高度 6.1%（8/132 例），中等度 37.1%（49/132 例），軽度 33.3%（44/132 例）であり，プラセボ群では，高度 11.3%（15/133 例），中等度 39.8%（53/133 例），軽度 29.3%（39/133 例）であった（表 2.7.4.7-219 参照）。

IM デポ群で発現した高度な有害事象はいずれも 1 例で，心肺停止，筋肉内出血，筋浮腫，アカシジア，脳損傷，一過性脳虚血発作，双極性障害，双極 1 型障害，不眠症，躁病，自殺企図，喘息，呼吸不全であった。プラセボ群で発現した高度な有害事象は，躁病（6 例），双極性障害（4 例），双極 1 型障害（2 例），潰瘍性大腸炎（1 例），感情障害（1 例），不眠症（1 例），大うつ病（1 例）であった。

IM デポ群の重症度別副作用の発現割合は，高度 0.8%（1/132 例），中等度 22.7%（30/132 例），軽度 38.6%（51/132 例）であり，プラセボ群では，高度 3.0%（4/133 例），中等度 19.5%（26/133

例），軽度 27.8%（37/133 例）であった（表 2.7.4.7-219 参照）。

IM デポ群で高度と判定された副作用の 1 例は，アカシジアであった。

高度と判定された有害事象及び副作用の発現割合は IM デポ群でプラセボ群と比較して約 2%～約 5%低く，2 例以上に発現した有害事象及び副作用はなかった。

(d) 初回発現時期別

二重盲検試験でアリピプラゾール IM デポ注射剤を投与された後に初めて発現した有害事象の発現時期を検討するため，二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）のデータを統合することとした。

二重盲検試験でアリピプラゾール IM デポ注射剤投与後に発現した初回発現時期別有害事象を表 2.7.4.2.1-7 及び表 2.7.4.7-33 に示した。

最も有害事象の発現割合が高かった初回発現時期は，投与 3 ヵ月以下で 59.5%（253/425 例）であった。3～6 ヵ月では 24.0%（84/350 例），6～9 ヵ月では 19.8%（46/232 例），9～12 ヵ月では 20.0%（33/165 例），12 ヵ月超では 18.3%（23/126 例）であった。

二重盲検試験でアリピプラゾール IM デポ注射剤投与後に発現した有害事象では，投与期間の後期に発現割合が高くなることはなかった。

二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）を通じて発現割合が最も高かった有害事象は，体重増加 9.9%（42/425 例）で，次いでアカシジア 9.2%（39/425 例）であった。これらの有害事象はいずれも 3 ヵ月以下での発現割合が最も高く，投与期間に伴い発現割合が高くなることはなかった。

表 2.7.4.2.1-7　アリピプラゾール IM デポ注射剤投与後のいずれかの時期で 5%以上に発現した初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

	IMデポ剤安定期（Phase C）（425例）［IMデポ剤安定期（Phase C）から二重盲検期（PhaseD）の期間］					
器官別大分類	3ヵ月以下 (425例)	3～6ヵ月 (350例)	6～9ヵ月 (232例)	9～12ヵ月 (165例)	12ヵ月超 (126例)	計 (425例)
基本語	例数 (%)	例数 (%)	例数 (%)	例数 (%)	例数 (%)	例数 (%)
有害事象	253 (59.5)	84 (24.0)	46 (19.8)	33 (20.0)	23 (18.3)	278 (65.4)
臨床検査						
体重増加	29 (6.8)	6 (1.7)	4 (1.7)	2 (1.2)	1 (0.8)	42 (9.9)
神経系障害						
アカシジア	30 (7.1)	6 (1.7)	1 (0.4)	3 (1.8)	2 (1.6)	39 (9.2)
精神障害						
不眠症	24 (5.6)	8 (2.3)	3 (1.3)	2 (1.2)	1 (0.8)	37 (8.7)

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＜資料番号 5.3.5.3-01：SCS-CT-3.3 より作成＞

(e) 持続期間別

二重盲検試験の二重盲検期（Phase D）で発現した持続期間別有害事象及び副作用を

表 2.7.4.7-34 及び表 2.7.4.7-35 に示した。

持続期間別有害事象のうち発現割合が高かったのは，IM デポ群では 15～28 日間で 8.3%（11/132 例）であった。次いで 29～56 日間及び 113～336 日間でいずれも 6.8%（9/132 例）であった。プラセボ群では 1～14 日間が 10.5%（14/133 例），次いで 113～336 日間が 9.8%（13/133 例）であった。

持続期間の長かった有害事象（持続期間が 57 日以上の事象）に着目すると，持続期間が 57～112 日間の事象で，発現割合が 2%以上であった事象は IM デポ群及びプラセボ群共になかったが，持続期間が 113～336 日間の事象で発現割合が 2%以上であった事象は，IM デポ群ではアカシジア 2.3%（3/132 例）で，プラセボ群では，体重増加 4.5%（6/133 例），アカシジア 3.0%（4/133 例），落ち着きのなさ 2.3%（3/133 例）であった。

IM デポ群での持続期間別有害事象で最も発現割合が高かったのは 15～28 日間であったが，長い持続期間（113～336 日間）での発現割合はプラセボ群より IM デポ群で低かった。また，持続期間の長かった事象はプラセボ群で多かった。

(f)　転帰別

二重盲検試験の二重盲検期（Phase D）で発現した転帰別有害事象及び副作用を表 2.7.4.7-36 及び表 2.7.4.7-37 に示した。

IM デポ群で発現した転帰別有害事象の発現割合は，回復 31.8%（42/132 例），軽快（回復途上）9.8%（13/132 例），未回復 33.3%（44/132 例），死亡 0.8%（1/132 例），不明 0.8%（1/132 例）であった。プラセボ群では，回復 39.1%（52/133 例），軽快（回復途上）6.8%（9/133 例），未回復 33.8%（45/133 例），回復したが後遺症あり 0.8%（1/133 例）であった。

IM デポ群及びプラセボ群共に，発現した有害事象の多くが回復又は軽快（回復途上）であった。

事象ごとにみると，基本語別有害事象で 5%以上に発現している事象のうち，転帰が回復又は軽快（回復途上）の発現割合より，転帰が未回復の発現割合が高かった事象は，IM デポ群では体重増加（未回復の発現割合 17.4%，23/132 例），プラセボ群でも体重増加（未回復の発現割合 9.8%，13/133 例）であった。

(g)　人口統計学的及び他の基準値の特性別

i)　年齢別

二重盲検試験の二重盲検期（Phase D）で発現した年齢別有害事象を表 2.7.4.7-38 に示した。

年齢別有害事象の発現割合は，IM デポ群では 45 歳未満で 73.9%（65/88 例），45 歳以上で 81.8%（36/44 例）であり，プラセボ群では 45 歳未満で 80.0%（68/85 例），45 歳以上で 81.3%（39/48 例）であった。IM デポ群及びプラセボ群共に，有害事象の発現割合は年齢で大きく異ならなかった。

IM デポ群で発現した年齢別有害事象のうち，45 歳未満と 45 歳以上で 10%以上発現割合の違いのある事象はなかった。

ii)　性別

二重盲検試験の二重盲検期（Phase D）で発現した性別有害事象を表 2.7.4.7-39 に示した。

IM デポ群での性別有害事象の発現割合は，男性 76.0%（38/50 例），女性 76.8%（63/82 例）であり，プラセボ群では男性 81.0%（51/63 例），女性 80.0%（56/70 例）であった。IM デポ群及びプラセボ群共に，有害事象の発現割合は性別で大きく異ならなかった。

IM デポ群で発現した性別有害事象のうち，性別特異的な事象を除き，男性と女性で 10%以上発現割合の違いのある事象は，体重増加で，女性 28.0%（23/82 例），男性 16.0%（8/50 例であった。体重増加はプラセボ群の女性の発現割合と比べても IM デポ群で 10%以上高かった（プラセボ群の女性 17.1%，12/70 例）。

iii)　BMI 別

二重盲検試験の二重盲検期（Phase D）で発現した BMI 別有害事象を表 2.7.4.7-40 に示した。

BMI 別有害事象の発現割合は，IM デポ群では 28 kg/m^2 以下で 73.3%（33/45 例），28 kg/m^2 超で 78.2%（68/87 例）であり，プラセボ群では 28 kg/m^2 以下で 81.0%（47/58 例），28 kg/m^2 超で 80.0%（60/75 例）であった。IM デポ群及びプラセボ群共に，有害事象の発現割合は BMI 別で大きく異ならなかった。

IM デポ群で発現した BMI 別有害事象のうち，28 kg/m^2 以下と 28 kg/m^2 超で 10%以上発現割合の違いのある事象はなかった。

iv)　人種，民族，地域別

二重盲検試験の二重盲検期（Phase D）で発現した人種別有害事象を表 2.7.4.7-41，表 2.7.4.7-42 に，民族別有害事象を表 2.7.4.7-43 に，地域別有害事象を表 2.7.4.7-44，表 2.7.4.7-45 にそれぞれ示した。

人種別にみると，IM デポ群，プラセボ群共に，アジア人での有害事象の発現割合は他の人種と大きく異ならなかった。地域別にみると，IM デポ群，プラセボ群共に，日本で有害事象の発現割合は他のいずれの地域と比べても，10%以上高いものではなかった。

(2)　二重盲検試験の IM デポ剤安定期（Phase C）

(a)　器官別大分類別

二重盲検試験の IM デポ剤安定期（Phase C）で発現した器官別大分類別有害事象及び副作用を表 2.7.4.7-46 及び表 2.7.4.7-47 に示した。

器官別大分類別有害事象で発現割合が最も高かったのは，神経系障害 32.0%（136/425 例）であった。器官別大分類別副作用で発現割合が最も高かったのも神経系障害 28.9%（123/425 例）であった。

(b)　基本語別

二重盲検試験の IM デポ剤安定期（Phase C）で発現した有害事象のうち，発現割合が 5%以上の有害事象を表 2.7.4.2.1-8 に，すべての有害事象及び副作用を表 2.7.4.7-48 及び表 2.7.4.7-49 に

示した。

IM デポ剤安定期（Phase C）で発現割合が 5%以上の有害事象は，アカシジア 17.4%（74/425 例），体重増加 11.1%（47/425 例），不眠症 9.6%（41/425 例），落ち着きのなさ 5.6%（24/425 例），疲労 5.2%（22/425 例），鼻咽頭炎 5.2%（22/425 例）であった。

IM デポ剤安定期（Phase C）で発現割合が 5%以上の副作用は，アカシジア 17.4%（74/425 例），体重増加 11.1%（47/425 例），不眠症 6.1%（26/425 例），落ち着きのなさ 5.6%（24/425 例）であった。

表 2.7.4.2.1-8　二重盲検試験の IM デポ剤安定期（Phase C）で 5%以上に発現した有害事象

器官別大分類 基本語	安全性解析対象集団 (425例) 例数 (%)
有害事象	291 (68.5)
一般・全身障害および投与部位の状態	
疲労	22 (5.2)
感染症および寄生虫症	
鼻咽頭炎	22 (5.2)
臨床検査	
体重増加	47 (11.1)
神経系障害	
アカシジア	74 (17.4)
精神障害	
不安	30 (7.1)
不眠症	41 (9.6)
落ち着きのなさ	24 (5.6)

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＜資料番号 5.3.5.1-01：CT-21.1，CT-21.2.4.1 より作成＞

(c)　重症度別

二重盲検試験の IM デポ剤安定期（Phase C）で発現した重症度別有害事象及び副作用を表 2.7.4.7-50 及び表 2.7.4.7-51 に示した。

IM デポ剤安定期（Phase C）で発現した有害事象のうち，高度と判定された有害事象の発現割合は 6.6%（28/425 例）であった（表 2.7.4.2.1-1 参照）。2 例以上に発現した高度と判定された有害事象は，不安 4 例，躁病 4 例，双極 1 型障害 3 例，うつ病 3 例，背部痛 2 例，アカシジア 2 例，傾眠 2 例であった。

2 例以上に発現した高度と判定された有害事象は，ほとんどが副作用であった。

(d)　持続期間別

二重盲検試験の IM デポ剤安定期（Phase C）で発現した持続期間別有害事象及び副作用を表 2.7.4.7-52 及び表 2.7.4.7-53 に示した。

持続期間のうち発現割合が高かったのは 1～14 日間で，11.1%（47/425 例），次いで 29～56

日間で，5.4%（23/425 例）であった。

持続期間が長かった事象（持続期間が 57 日以上の事象）のうち，発現割合が 2%以上であった事象はなかった。

(e)　転帰別

二重盲検試験の IM デポ剤安定期（Phase C）で発現した転帰別有害事象及び副作用を表 2.7.4.7-54 及び表 2.7.4.7-55 に示した。

IM デポ剤安定期（Phase C）で発現した転帰別有害事象の発現割合は，回復 39.3%（167/425 例），軽快（回復途上）6.1%（26/425 例），未回復 21.4%（91/425 例），回復したが後遺症あり 0.5%（2/425 例），不明 1.2%（5/425 例）であった。

IM デポ剤安定期（Phase C）で発現した有害事象の多くが回復又は軽快（回復途上）であった。

事象ごとにみると，基本語別有害事象で 5%以上に発現していた事象のうち，転帰が未回復の発現割合が 5%以上であった事象は，体重増加（6.1%，26/425 例）であった。

(3)　長期投与試験

(a)　器官別大分類別

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した器官別大分類別有害事象及び副作用を表 2.7.4.7-56 及び表 2.7.4.7-57 に示した。

器官別大分類別有害事象で発現割合が最も高かったのは，神経系障害 37.9%（176/464 例）であった。器官別大分類別副作用で発現割合が最も高かったのは，神経系障害 32.1%（149/464 例）であった。

(b)　基本語別

長期投与試験の IM デポ剤維持治療期（Phase C）で発現したすべての有害事象及び副作用を表 2.7.4.7-58 及び表 2.7.4.7-59 に示した。

IM デポ剤維持治療期（Phase C）で発現割合が 5%以上の有害事象は，アカシジア 14.7%（68/464 例），体重増加 13.4%（62/464 例），鼻咽頭炎 12.1%（56/464 例），不眠症 11.0%（51/464 例），不安 9.9%（46/464 例），注射部位疼痛 7.3%（34/464 例），頭痛 6.3%（29/464 例），振戦 6.0%（28/464 例），うつ病 5.6%（26/464 例），上気道感染 5.2%（24/464 例）であった。

IM デポ剤維持治療期（Phase C）で発現割合が 5%以上の副作用は，アカシジア 14.7%（68/464 例），体重増加 11.9%（55/464 例），注射部位疼痛 6.9%（32/464 例），不眠症 6.7%（31/464 例），振戦 5.4%（25/464 例），不安 5.2%（24/464 例）であった。

(c)　重症度別

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した重症度別有害事象及び副作用を表 2.7.4.7-60 及び表 2.7.4.7-61 に示した。

IM デポ剤維持治療期（Phase C）で発現した有害事象のうち，高度と判定された有害事象の発現割合は 8.8%（41/464 例）であった。2 例以上に発現した高度と判定された有害事象は，体

重増加 4 例，躁病 3 例，胸痛 2 例，筋肉痛 2 例，鎮静 2 例，双極 1 型障害 2 例，自殺念慮 2 例であった。

高度と判定された有害事象のうち，副作用と判断され，2 例以上に発現したのは体重増加 4 例，鎮静 2 例であった。

(d) 初回発現時期別

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した初回発現時期別有害事象を表 2.7.4.7-62 に示した。

最も有害事象の発現割合が高かった発現時期は投与 3 ヵ月以下で 58.2%（270/464 例）であった。3～6 ヵ月では 41.1%（173/421 例），6～9 ヵ月では 34.9%（129/370 例），9～12 ヵ月では 31.7%（89/281 例），12 ヵ月超では 13.9%（34/245 例）であった。

IM デポ剤維持治療期（Phase C）で発現した初回発現時期別有害事象では，投与期間の後期に発現割合が高くなることはなかった。

IM デポ剤維持治療期（Phase C）で発現割合が 5%以上であったアカシジア，体重増加，鼻咽頭炎，不眠症，不安，注射部位疼痛，頭痛，振戦，うつ病，上気道感染は，投与期間に伴い発現割合が高くなることはなかった。

(e) 持続期間別

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した持続期間別有害事象及び副作用を表 2.7.4.7-63 及び表 2.7.4.7-64 に示した。

持続期間のうち発現割合が高かったのは，1～14 日間で，8.8%（41/464 例），次いで 29～56 日間で，8.0%（37/464 例）であった。

持続期間が長かった事象（持続期間が 57 日以上の事象）のうち，発現割合が 2%以上であった事象は 113～336 日間の体重増加 2.4%（11/464 例）であった。

(f) 転帰別

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した転帰別有害事象及び副作用を表 2.7.4.7-65 及び表 2.7.4.7-66 に示した。

IM デポ剤維持治療期（Phase C）で発現した転帰別有害事象の発現割合は，回復 37.5%（174/464 例），軽快（回復途上）7.1%（33/464 例），未回復 33.8%（157/464 例），回復したが後遺症あり 0.4%（2/464 例），不明 1.5%（7/464 例），死亡 0.2%（1/464 例）であった。

IM デポ剤維持治療期（Phase C）で発現した有害事象の多くが回復又は軽快（回復途上）であった。

事象ごとにみると，基本語別有害事象で 5%以上に発現している事象のうち，転帰が回復又は軽快（回復途上）の発現割合より，転帰が未回復の発現割合が高かった事象は，体重増加（7.1%，33/464 例）であった。

2.7.4.2.1.2　死亡

(1)　二重盲検試験

二重盲検試験での死亡例一覧表を表 2.7.4.7-27 に示した。

二重盲検試験で死亡は 2 例であった。1 例は錠剤安定期（Phase B）で認められ，1 例は二重盲検期（Phase D）で IM デポ群に割付けられた被験者に認められた。いずれの事象もアリピプラゾール IM デポ注射剤との関連性はなかった。

二重盲検期（Phase D）の IM デポ群で認められた死亡例の叙述を「2.7.6.1.1.5(1)」に，錠剤安定期（Phase B）で認められた死亡例の叙述は総括報告書（資料番号 5.3.5.1-01，Section 14.3.1）に示した。

(2)　長期投与試験

長期投与試験での死亡例一覧表を表 2.7.4.7-28 に示した。

長期投与試験で死亡は 3 例であった。1 例は錠剤切り替え期（Phase A）で，1 例は錠剤安定期（Phase B）で，1 例は IM デポ剤維持治療期（Phase C）で認められた。いずれの事象もアリピプラゾール IM デポ注射剤との関連性なしであった。

IM デポ剤維持治療期（Phase C）で認められた死亡例の叙述を「2.7.6.1.2.5(1)」に，錠剤切り替え期（Phase A）及び錠剤安定期（Phase B）で認められた死亡例の叙述は総括報告書（資料番号 5.3.5.2-01，Section 14.3.1）に示した。

2.7.4.2.1.3　その他の重篤な有害事象

(1)　二重盲検試験

(a)　二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）で発現した重篤な有害事象（死亡例を含む）を表 2.7.4.2.1-9 に，器官別大分類別重篤な有害事象（死亡例を含む）を表 2.7.4.7-67 に，重症度別重篤な有害事象（死亡例を含む）を表 2.7.4.7-68 に示した。死亡以外のその他の重篤な有害事象を発現した被験者の一覧表を表 2.7.4.7-69 に示した。

二重盲検期（Phase D）で発現した重篤な有害事象の発現割合は，IM デポ群で 7.6%（10/132 例），プラセボ群で 18.8%（25/133 例）であった。IM デポ群で 2 例以上に発現した重篤な有害事象は，双極 1 型障害 2 例（1.5%，プラセボ群 3 例，2.3%），躁病 2 例（1.5%，プラセボ群 10 例，7.5%）であった。

IM デポ群で発現した重篤な副作用を表 2.7.4.7-70 に示した。IM デポ群で発現した重篤な副作用は双極性障害 1 例（0.8%，プラセボ群 1 例，0.8%），アカシジア 1 例（0.8%，プラセボ群 0 例，0.0%）であった。

IM デポ群で発現した重篤な有害事象の発現割合はプラセボ群と比較して約 11%低かった。IM デポ群では重篤な有害事象の発現は各事象 2 例以下であり，発現時期に一定の傾向は認められなかった。また，IM デポ群では転帰が「死亡」であった脳損傷，呼吸不全（IM デポ群各 1 例，同一被験者），転帰が「回復したが後遺症あり」であった心肺停止（IM デポ群 1 例，死亡例と

同一被験者）を除いて，いずれの重篤な有害事象も転帰は「回復」であった。

重篤な有害事象の詳細な叙述は治験総括報告書中（資料番号 5.3.5.1-01，Section 12.3）に示すと共に「2.7.6.1.1.5（2）」にも記載した。

表 2.7.4.2.1-9　　重篤な有害事象［二重盲検試験の二重盲検期（Phase D）］

器官別大分類 基本語	IMデポ群 (132例) 例数 (%)	プラセボ群 (133例) 例数 (%)
重篤な有害事象	10 (7.6)	25 (18.8)
心臓障害		
心房細動	1 (0.8)	0 (0.0)
心肺停止	1 (0.8)	0 (0.0)
胃腸障害		
潰瘍性大腸炎	0 (0.0)	1 (0.8)
痔出血	1 (0.8)	0 (0.0)
感染症および寄生虫症		
肺炎	0 (0.0)	1 (0.8)
傷害、中毒および処置合併症		
橈骨骨折	0 (0.0)	1 (0.8)
神経系障害		
アカシジア	1 (0.8)	0 (0.0)
脳損傷	1 (0.8)	0 (0.0)
一過性脳虚血発作	1 (0.8)	0 (0.0)
精神障害		
感情不安定	1 (0.8)	0 (0.0)
感情障害	0 (0.0)	1 (0.8)
攻撃性	0 (0.0)	1 (0.8)
双極性障害	1 (0.8)	3 (2.3)
双極 1 型障害	2 (1.5)	3 (2.3)
軽躁	1 (0.8)	0 (0.0)
大うつ病	0 (0.0)	2 (1.5)
躁病	2 (1.5)	10 (7.5)
自殺企図	1 (0.8)	1 (0.8)
生殖系および乳房障害		
骨盤癒着症	0 (0.0)	1 (0.8)
呼吸器、胸郭および縦隔障害		
喘息	1 (0.8)	0 (0.0)
呼吸不全	1 (0.8)	0 (0.0)

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＜資料番号 5.3.5.1-01：CT-8.5.2，CT-21.1 より作成＞

(b)　IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）で発現した重篤な有害事象（死亡例を含む）を表 2.7.4.7-71 に，器官別大分類別重篤な有害事象（死亡例を含む）を表 2.7.4.7-72 に，重症度別重篤な有害事象（死亡例を含む）を表 2.7.4.7-73 に示した。死亡以外のその他の重篤な有害事象を発現した被験者の一覧表を表 2.7.4.7-69 に示した。

IM デポ剤安定期（Phase C）では，8.5%（36/425 例）に重篤な有害事象が発現した。2 例以上に発現した重篤な有害事象は，うつ病 8 例（1.9%），躁病 7 例（1.6%），双極 1 型障害 4 例（0.9%），自殺念慮 3 例（0.7%）であった。

IM デポ剤安定期（Phase C）で発現した重篤な副作用を表 2.7.4.7-74 に示した。IM デポ剤安定期（Phase C）で発現した重篤な副作用は，うつ病（2 例，0.5%），振戦，不安，抑うつ症状（各 1 例，0.2%）であった。

IM デポ剤安定期（Phase C）で 3 例以上に発現した重篤な有害事象では，投与期間に伴い発現割合が高くなることはなかった。また，転帰が「未回復」であった乳癌（1 例），転帰が「回復したが後遺症あり」であった外陰部膿瘍（1 例），転帰が「不明」であった腎結石症（1 例）を除いて，いずれの重篤な有害事象も転帰は「回復」であった。

(2) 長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した重篤な有害事象（死亡例を含む）を表 2.7.4.2.1-10 に，器官別大分類別重篤な有害事象（死亡例を含む）を表 2.7.4.7-75 に，重症度別重篤な有害事象（死亡例を含む）を表 2.7.4.7-76 に示した。死亡例を含む重篤な有害事象を発現した被験者の一覧表を表 2.7.4.7-77 に示した。

IM デポ剤維持治療期（Phase C）では，6.5%（30/464 例）に重篤な有害事象が発現した。2 例以上に発現した重篤な有害事象は，双極 1 型障害 4 例（0.9%），自殺念慮 4 例（0.9%），双極性障害 2 例（0.4%），胸痛 2 例（0.4%），躁病 3 例（0.6%）であった。

IM デポ剤維持治療期（Phase C）で 3 例以上に発現した重篤な有害事象では，投与期間に伴い発現例数が多くなることはなかった。また，転帰が「死亡」であった心停止（1 例），転帰が「未回復」の呼吸困難 1 例，肥満 1 例，遅発性ジスキネジア 1 例，転帰が「回復したが後遺症あり」であった糖尿病 1 例を除いて，いずれの重篤な有害事象も転帰は「回復」又は「軽快（回復途上）」であった。

表 2.7.4.2.1-10　　重篤な有害事象（長期投与試験）

器官別大分類 基本語	新規例 (379例) 例数 (%)	継続例 (85例) 例数 (%)	計 (464例) 例数 (%)
重篤な有害事象	27 (7.1)	3 (3.5)	30 (6.5)
心臓障害			
急性心筋梗塞	1 (0.3)	0 (0.0)	1 (0.2)
心停止	1 (0.3)	0 (0.0)	1 (0.2)
心筋梗塞	1 (0.3)	0 (0.0)	1 (0.2)
プリンツメタル狭心症	1 (0.3)	0 (0.0)	1 (0.2)
内分泌障害			
高プロラクチン血症	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			
胸痛	2 (0.5)	0 (0.0)	2 (0.4)
肝胆道系障害			
急性胆嚢炎	1 (0.3)	0 (0.0)	1 (0.2)
感染症および寄生虫症			
腎感染	1 (0.3)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症			
節足動物咬傷	1 (0.3)	0 (0.0)	1 (0.2)
代謝および栄養障害			
糖尿病	0 (0.0)	1 (1.2)	1 (0.2)
コントロール不良の糖尿病	1 (0.3)	0 (0.0)	1 (0.2)
肥満	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）			
乳癌	1 (0.3)	0 (0.0)	1 (0.2)
神経系障害			
傾眠	1 (0.3)	0 (0.0)	1 (0.2)
遅発性ジスキネジア	1 (0.3)	0 (0.0)	1 (0.2)
精神障害			
攻撃性	1 (0.3)	0 (0.0)	1 (0.2)
双極性障害	2 (0.5)	0 (0.0)	2 (0.4)
双極１型障害	4 (1.1)	0 (0.0)	4 (0.9)
大うつ病	1 (0.3)	0 (0.0)	1 (0.2)
躁病	2 (0.5)	1 (1.2)	3 (0.6)
社会逃避行動	1 (0.3)	0 (0.0)	1 (0.2)
自殺念慮	3 (0.8)	1 (1.2)	4 (0.9)
自殺企図	1 (0.3)	0 (0.0)	1 (0.2)
呼吸器、胸郭および縦隔障害			
呼吸困難	1 (0.3)	0 (0.0)	1 (0.2)

高プロラクチン血症，コントロール不良の糖尿病は投与開始日の投与前の臨床検査の値で判断された。

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＜資料番号 5.3.5.2-01：Table 12.3.1.2-1 より作成＞

2.7.4.2.1.4　その他の重要な有害事象

(1)　二重盲検試験

(a)　二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）で発現した投与中止に至った有害事象を表 2.7.4.2.1-11 に，器官別大分類別投与中止に至った有害事象を表 2.7.4.7-78 に，重症度別投与中止に至った有害事象を表 2.7.4.7-79 に示した。投与中止に至った有害事象一覧表を表 2.7.4.7-80 に示した。

二重盲検期（Phase D）で発現した投与中止に至った有害事象の発現割合は，IM デポ群では 17.4%（23/132 例），プラセボ群では 25.6%（34/133 例）であった。IM デポ群で 2 例以上に発現した投与中止に至った有害事象は，双極性障害 5 例（3.8%，プラセボ群 4 例，3.0%），うつ病 4 例（3.0%，プラセボ群 3 例，2.3%），躁病 3 例（2.3%，プラセボ群 11 例，8.3%），アカシジア 2 例（1.5%，プラセボ群 0 例，0.0%），双極 1 型障害 2 例（1.5%，プラセボ群 8 例，6.0%）であった。

IM デポ群で発現した投与中止に至った有害事象の発現割合はプラセボ群と比較して約 8%低かった。

表 2.7.4.2.1-11　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）］

器官別大分類 基本語	IMデポ群 (132例) 例数 (%)	プラセボ群 (133例) 例数 (%)
投与中止に至った有害事象	23 (17.4)	34 (25.6)
臨床検査		
体重増加	1 (0.8)	0 (0.0)
神経系障害		
アカシジア	2 (1.5)	0 (0.0)
傾眠	1 (0.8)	0 (0.0)
精神障害		
感情不安定	1 (0.8)	0 (0.0)
感情障害	0 (0.0)	2 (1.5)
攻撃性	0 (0.0)	1 (0.8)
不安	1 (0.8)	0 (0.0)
双極性障害	5 (3.8)	4 (3.0)
双極 1 型障害	2 (1.5)	8 (6.0)
抑うつ気分	1 (0.8)	1 (0.8)
うつ病	4 (3.0)	3 (2.3)
大うつ病	0 (0.0)	2 (1.5)
躁病	3 (2.3)	11 (8.3)
自殺企図	1 (0.8)	1 (0.8)
呼吸器、胸郭および縦隔障害		
呼吸不全	1 (0.8)	0 (0.0)
血管障害		
高血圧	0 (0.0)	1 (0.8)

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＜資料番号 5.3.5.1-01：CT-8.1，CT-8.6.2 より作成＞

(b) IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）で発現した投与中止に至った有害事象を表 2.7.4.7-81 に示した。器官別大分類別投与中止に至った有害事象を表 2.7.4.7-82 に，重症度別投与中止に至った有害事象を表 2.7.4.7-83 に示した。投与中止に至った有害事象一覧表を表 2.7.4.7-80 に示した。

IM デポ剤安定期（Phase C）では，8.7%（37/425 例）に投与中止に至った有害事象が発現した。2 例以上に発現した投与中止に至った有害事象は，うつ病 8 例（1.9%），躁病 6 例（1.4%），双極 1 型障害 4 例（0.9%），疲労 3 例（0.7%），双極性障害 3 例（0.7%），アカシジア 2 例（0.5%），落ち着きのなさ 2 例（0.5%）であった。

(2) 長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）に発現した投与中止に至った有害事象を表 2.7.4.2.1-12 に，器官別大分類別投与中止に至った有害事象を表 2.7.4.7-84 に，重症度別投与中止に至った有害事象を表 2.7.4.7-85 に示した。投与中止に至った有害事象一覧表を表 2.7.4.7-86 に示した。

IM デポ剤維持治療期（Phase C）では，10.1%（47/464 例）に投与中止に至った有害事象が発現した。2 例以上に発現した投与中止に至った有害事象は，体重増加 7 例（1.5%），双極 1 型障害 4 例（0.9%），アカシジア 3 例（0.6%），うつ病 3 例（0.6%），躁病 3 例（0.6%），自殺念慮 3 例（0.6%），コントロール不良の糖尿病 2 例（0.4%），錐体外路障害 2 例（0.4%），傾眠 2 例（0.4%），遅発性ジスキネジア 2 例（0.4%），振戦 2 例（0.4%），双極性障害 2 例（0.4%），不眠症 2 例（0.4%），落ち着きのなさ 2 例（0.4%）であった。

IM デポ剤維持治療期（Phase C）に発現した投与中止に至った有害事象で最も発現例数の多かった体重増加のうちアリピプラゾール IM デポ注射剤投与後に発現したのは 4 例であった（表 2.7.4.7-86 参照）。このうち 3 例は IM デポ注射剤投与開始から 3 ヵ月未満で発現していた。

表 2.7.4.2.1-12　　投与中止に至った有害事象（長期投与試験）

器官別大分類 基本語	新規例 (379例) 例数 (%)	継続例 (85例) 例数 (%)	計 (464例) 例数 (%)
投与中止に至った有害事象	44 (11.6)	3 (3.5)	47 (10.1)
心臓障害			
プリンツメタル狭心症	1 (0.3)	0 (0.0)	1 (0.2)
内分泌障害			
高プロラクチン血症	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			
無力症	1 (0.3)	0 (0.0)	1 (0.2)
疲労	1 (0.3)	0 (0.0)	1 (0.2)
感染症および寄生虫症			
ウイルス性胃腸炎	1 (0.3)	0 (0.0)	1 (0.2)
臨床検査			
肝機能検査値上昇	1 (0.3)	0 (0.0)	1 (0.2)
体重増加	7 (1.8)	0 (0.0)	7 (1.5)
代謝および栄養障害			
糖尿病	1 (0.3)	0 (0.0)	1 (0.2)
コントロール不良の糖尿病	1 (0.3)	1 (1.2)	2 (0.4)
食欲亢進	1 (0.3)	0 (0.0)	1 (0.2)
筋骨格系および結合組織障害			
筋萎縮	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）			
乳癌	1 (0.3)	0 (0.0)	1 (0.2)
神経系障害			
アカシジア	3 (0.8)	0 (0.0)	3 (0.6)
錐体外路障害	2 (0.5)	0 (0.0)	2 (0.4)
嗜眠	1 (0.3)	0 (0.0)	1 (0.2)
パーキンソニズム	1 (0.3)	0 (0.0)	1 (0.2)
鎮静	1 (0.3)	0 (0.0)	1 (0.2)
傾眠	2 (0.5)	0 (0.0)	2 (0.4)
遅発性ジスキネジア	2 (0.5)	0 (0.0)	2 (0.4)
振戦	2 (0.5)	0 (0.0)	2 (0.4)
精神障害			
不安	1 (0.3)	0 (0.0)	1 (0.2)
双極性障害	2 (0.5)	0 (0.0)	2 (0.4)
双極１型障害	4 (1.1)	0 (0.0)	4 (0.9)
歯ぎしり	1 (0.3)	0 (0.0)	1 (0.2)
うつ病	3 (0.8)	0 (0.0)	3 (0.6)
不眠症	2 (0.5)	0 (0.0)	2 (0.4)
大うつ病	1 (0.3)	0 (0.0)	1 (0.2)
躁病	2 (0.5)	1 (1.2)	3 (0.6)
落ち着きのなさ	2 (0.5)	0 (0.0)	2 (0.4)
社会逃避行動	1 (0.3)	0 (0.0)	1 (0.2)
自殺念慮	2 (0.5)	1 (1.2)	3 (0.6)
呼吸器、胸郭および縦隔障害			
咽頭反射亢進	1 (0.3)	0 (0.0)	1 (0.2)

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＜資料番号 5.3.5.2-01：Table 12.3.1.3-1 より作成＞

2.7.4.2.1.5　器官別又は症候群別有害事象の解析

本項では，抗精神病薬の投与時に留意が必要な項目として錐体外路系有害事象および錐体外路系症状，体重，糖・脂質代謝，白血球異常，起立性障害，QT 間隔延長，プロラクチン，及び自殺，並びに IM デポ注射剤の特徴から注射部位反応に着目した。

各項目ではそれぞれの特徴を反映するような有害事象を定義し集計した。定義は表 2.7.4.7-1 に示した。また，体重，糖・脂質代謝，プロラクチンでは臨床的に重要な検査値の変動を示した被験者の割合を分析した。臨床的に重要な検査値の変動の基準は表 2.7.4.7-2 及び表 2.7.4.7-3 に示した。

(1)　錐体外路系有害事象及び錐体外路症状

錐体外路系有害事象はアカシジア症状，ジスキネジア症状，ジストニア症状，パーキンソン症状及び残遺症状でカテゴリ分類し，表 2.7.4.7-1 に示した定義で集計した。

(a)　二重盲検試験の二重盲検期（Phase D）

i)　錐体外路系有害事象

二重盲検試験の二重盲検期（Phase D）で発現した錐体外路系有害事象を表 2.7.4.2.1-13 に示した。

二重盲検期（Phase D）では，IM デポ群で 27.3%（36/132 例），プラセボ群で 16.5%（22/133 例）に錐体外路系有害事象が発現した。発現割合が 2%以上の錐体外路系有害事象カテゴリは，IM デポ群ではアカシジア症状 22.0%（29/132 例），パーキンソン症状 5.3%（7/132 例），ジストニア症状 2.3%（3 例）及びジスキネジア症状 2.3%（3 例）で，プラセボ群では，アカシジア症状 12.8%（17/133 例）及びパーキンソン症状 3.8%（5/133 例）であった。

二重盲検期（Phase D）では，IM デポ群で 19.7%（26/132 例）及びプラセボ群で 15.0%（20/133 例）の被験者が抗コリン薬を使用していた。このうち，アカシジア症状は，IM デポ群で 26 例中 17 例，プラセボ群で 20 例中 8 例，パーキンソン症状は IM デポ群で 26 例中 2 例，プラセボ群で 20 例中 0 例に発現した（資料番号 5.3.5.1-01：CT-8.2.5.1.2 参照）。

二重盲検期（Phase D）で発現した重篤と判断された錐体外路系有害事象は，IM デポ群でアカシジア 1 例（0.8%），プラセボ群では認められなかった。IM デポ群で発現したアカシジアは，二重盲検期（Phase D）開始 57 日目に発現し，高度と判定され，投与中止に至った。治験薬との因果関係は「関連性は明らかにあり」であった。転帰は「回復」であった。二重盲検期（Phase D）で発現した投与中止に至った錐体外路系有害事象は，IM デポ群でアカシジア 2 例（1.5%），プラセボ群では認められなかった。IM デポ群で発現したアカシジア 2 例のうち 1 例は，重篤と判断された事象である。もう 1 例のアカシジアも転帰は「回復」であった。

事象ごとでは，最も発現割合が高かった事象は，IM デポ群ではアカシジア 21.2%（28/132 例），プラセボ群ではアカシジア 12.8%（17/133 例）であった。IM デポ群で発現した錐体外路系有害事象のうち，プラセボ群と比較して発現割合が 5%以上高かった事象は，アカシジアであった。

また，IM デポ群の 1 例で遅発性ジスキネジアが発現した（被験者番号 [redacted]）。事象は二重盲検期（Phase D）開始 45 日目に発現し，軽度と判定された。治験薬との因果関係は「関連性は多分あり」であった。最終観察時点では転帰は「未回復」であった。当該被験者は，IM デポ剤安定期（Phase C）でも遅発性ジスキネジアを発現していた。

表 2.7.4.2.1-13　錐体外路系有害事象［二重盲検試験の二重盲検期（Phase D）］

器官別大分類 基本語	IMデポ群 (132例) 例数 (%)	プラセボ群 (133例) 例数 (%)
錐体外路系有害事象	36 (27.3)	22 (16.5)
アカシジア除く	12 (9.1)	8 (6.0)
アカシジア症状		
計	29 (22.0)	17 (12.8)
アカシジア	28 (21.2)	17 (12.8)
精神運動亢進	1 (0.8)	0 (0.0)
ジスキネジア症状		
計	3 (2.3)	2 (1.5)
ジスキネジア	2 (1.5)	2 (1.5)
遅発性ジスキネジア	1 (0.8)	0 (0.0)
ジストニア症状		
計	3 (2.3)	0 (0.0)
筋痙縮	2 (1.5)	0 (0.0)
開口障害	1 (0.8)	0 (0.0)
パーキンソン症状		
計	7 (5.3)	5 (3.8)
運動緩慢	2 (1.5)	0 (0.0)
錐体外路障害	2 (1.5)	2 (1.5)
パーキンソニズム	1 (0.8)	1 (0.8)
振戦	3 (2.3)	2 (1.5)
残遺症状		
計	0 (0.0)	2 (1.5)
筋攣縮	0 (0.0)	2 (1.5)

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＜資料番号 5.3.5.1-01：CT-8.2.5.1.1 より作成＞

ii)　錐体外路症状評価尺度：DIEPSS

二重盲検期（Phase D）での DIEPSS のベースラインからの変化量を表 2.7.4.7-87 及び表 2.7.4.7-88 に示した。

二重盲検期（Phase D）を通して，IM デポ群及びプラセボ群で DIEPSS に特記すべき変化は認められなかった。

iii)　錐体外路症状評価尺度：AIMS

二重盲検期（Phase D）での AIMS 合計スコア（項目 1～7 の合計スコア）のベースラインからの変化量を表 2.7.4.7-89 及び表 2.7.4.7-90 に示した。

二重盲検期（Phase D）を通して，IM デポ群及びプラセボ群で AIMS 合計スコアに特記すべき変化は認められなかった。

iv)　錐体外路症状評価尺度：BAS

二重盲検期（Phase D）での BAS スコア（アカシジアの包括的臨床評価）のベースラインからの変化量を表 2.7.4.7-91 及び表 2.7.4.7-92 に示した。

二重盲検期（Phase D）を通して，IM デポ群及びプラセボ群で BAS スコアに特記すべき変化は認められなかった。

v)　錐体外路症状評価尺度：SAS

二重盲検期（Phase D）での SAS 合計スコアのベースラインからの変化量を表 2.7.4.7-93 及び表 2.7.4.7-94 に示した。二重盲検期（Phase D）を通して，IM デポ群及びプラセボ群で SAS 合計スコアに特記すべき変化は認められなかった。

(b)　二重盲検試験の IM デポ剤安定期（Phase C）

i)　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）で発現した錐体外路系有害事象を表 2.7.4.7-95 に示した。

IM デポ剤安定期（Phase C）では 21.6%（92/425 例）に錐体外路系有害事象が発現した。発現割合が 2%以上の錐体外路系有害事象カテゴリは，アカシジア症状 18.4%（78/425 例），パーキンソン症状 3.5%（15/425 例）であった。

IM デポ剤安定期（Phase C）では 17.9%（76/425 例）の被験者が抗コリン薬を使用していた。この 76 例のうち，アカシジア症状は 40 例，パーキンソン症状は 10 例に発現した（表 2.7.4.7-96 参照）。

IM デポ剤安定期（Phase C）で発現した重篤と判断された錐体外路系有害事象は，振戦 1 例であった。振戦は IM デポ剤安定期（Phase C）開始 104 日目に発現し，中等度と判定された。用量の変更は行われず，治験薬との因果関係は「関連性は多分あり」であった。転帰は「回復」であった。IM デポ剤安定期（Phase C）で発現した投与中止に至った錐体外路系有害事象は，アカシジア 2 例（0.5%），振戦 1 例（0.2%）であった。

事象ごとでは，最も発現割合が高かった事象は，アカシジア 17.4%（74 例）であった。

また，3 例で遅発性ジスキネジアが発現した。重症度は軽度又は中等度で，投与中止には至らなかった。

ii)　錐体外路症状：DIEPSS

IM デポ剤安定期（Phase C）での DIEPSS のベースラインからの変化量を表 2.7.4.7-97 及び表 2.7.4.7-98 に示した。

IM デポ剤安定期（Phase C）を通して，IM デポ群及びプラセボ群で DIEPSS に特記すべき変化は認められなかった。

iii) 錐体外路症状評価尺度：AIMS

IM デポ剤安定期（Phase C）での AIMS 合計スコア（項目 1～7 の合計スコア）のベースラインからの変化量を表 2.7.4.7-99 及び表 2.7.4.7-100 に示した。

IM デポ剤安定期（Phase C）を通して，IM デポ群及びプラセボ群で AIMS 合計スコアに特記すべき変化は認められなかった。

iv) 錐体外路症状評価尺度：BAS

IM デポ剤安定期（Phase C）での BAS スコア（アカシジアの包括的臨床評価）のベースラインからの変化量を表 2.7.4.7-101 及び表 2.7.4.7-102 に示した。

IM デポ剤安定期（Phase C）を通して，IM デポ群及びプラセボ群で BAS スコアに特記すべき変化は認められなかった。

v) 錐体外路症状評価尺度：SAS

IM デポ剤安定期(Phase C)での SAS 合計スコアのベースラインからの変化量を表 2.7.4.7-103 及び表 2.7.4.7-104 に示した。IM デポ剤安定期（Phase C）を通して，SAS 合計スコアに特記すべき変化は認められなかった。

(c) 長期投与試験

i) 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）で発現した錐体外路系有害事象を表 2.7.4.2.1-14 に示した。

IM デポ剤維持治療期(Phase C)では 25.6%(119/464 例)に錐体外路系有害事象が発現した。発現割合が 5%以上の錐体外路系有害事象カテゴリは，アカシジア症状 14.9%（69/464 例），パーキンソン症状 10.6%（49/464 例）であった。

IM デポ剤維持治療期（Phase C）では 16.4%（76/464 例）の被験者が抗コリン薬を使用していた。この 76 例のうち，アカシジア症状は 28 例，パーキンソン症状は 23 例に発現した（表 2.7.4.7-105 参照）。

IM デポ剤維持治療期（Phase C）で発現した重篤と判断された錐体外路系有害事象は，遅発性ジスキネジア 1 例（被験者番号 [redacted]）であった（表 2.7.4.7-77 参照）。遅発性ジスキネジアは IM デポ剤維持治療期（Phase C）開始 169 日目に発現し，高度と判定され，投与中止に至った。治験薬との因果関係は「関連性は明らかにあり」で，最終観察時点で転帰は「未回復」であった。IM デポ剤維持治療期（Phase C）で発現した投与中止に至った錐体外路系有害事象は，アカシジア 3 例（0.6%），錐体外路障害 2 例（0.4%），パーキンソニズム 1 例（0.2%），振戦 2 例（0.4%），遅発性ジスキネジア 2 例（0.4%）であった。遅発性ジスキネジアの 1 例は重篤と判断された事象で，他の 1 例は IM デポ剤維持治療期（Phase C）開始 246 日目に発現した事象で，軽度と判定された。投与中止に至った錐体外路系有害事象では遅発性ジスキネジア 2 例及び遅発性ジスキネジアを発現した被験者が発現していたアカシジア 1 例を除き，転帰は「回復」であった。

事象ごとでは，最も発現割合が高かったのは，アカシジア 14.7%（68 例）であった。

表 2.7.4.2.1-14　　錐体外路系有害事象（長期投与試験）

器官別大分類 基本語	新規例 (379例) 例数 (%)	継続例 (85例) 例数 (%)	計 (464例) 例数 (%)
錐体外路系有害事象	107 (28.2)	12 (14.1)	119 (25.6)
アカシジア症状			
計	61 (16.1)	8 (9.4)	69 (14.9)
アカシジア	60 (15.8)	8 (9.4)	68 (14.7)
運動過多	1 (0.3)	0 (0.0)	1 (0.2)
ジスキネジア症状			
計	9 (2.4)	2 (2.4)	11 (2.4)
ジスキネジア	6 (1.6)	2 (2.4)	8 (1.7)
遅発性ジスキネジア	3 (0.8)	0 (0.0)	3 (0.6)
ジストニア症状			
計	11 (2.9)	0 (0.0)	11 (2.4)
ジストニア	4 (1.1)	0 (0.0)	4 (0.9)
筋固縮	1 (0.3)	0 (0.0)	1 (0.2)
筋痙縮	4 (1.1)	0 (0.0)	4 (0.9)
項部硬直	1 (0.3)	0 (0.0)	1 (0.2)
開口障害	1 (0.3)	0 (0.0)	1 (0.2)
パーキンソン症状			
計	47 (12.4)	2 (2.4)	49 (10.6)
運動緩慢	3 (0.8)	0 (0.0)	3 (0.6)
錐体外路障害	12 (3.2)	0 (0.0)	12 (2.6)
企図振戦	2 (0.5)	0 (0.0)	2 (0.4)
パーキンソニズム	4 (1.1)	1 (1.2)	5 (1.1)
振戦	27 (7.1)	1 (1.2)	28 (6.0)
残遺症状			
計	2 (0.5)	0 (0.0)	2 (0.4)
筋攣縮	2 (0.5)	0 (0.0)	2 (0.4)

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ii)　錐体外路症状評価尺度：DIEPSS

IM デポ剤維持治療期（Phase C）での DIEPSS のベースラインからの変化量を表 2.7.4.7-106 及び表 2.7.4.7-107 に示した。

IM デポ剤維持治療期（Phase C）を通して，DIEPSS に特記すべき変化は認められなかった。

iii)　錐体外路症状評価尺度：AIMS

IM デポ剤維持治療期（Phase C）での AIMS 合計スコア（項目 1～7 の合計スコア）のベースラインからの変化量を表 2.7.4.7-108 及び表 2.7.4.7-109 に示した。

IM デポ剤維持治療期（Phase C）を通して，AIMS 合計スコアに特記すべき変化は認められなかった。

iv)　錐体外路症状評価尺度：BAS

IM デポ剤維持治療期（Phase C）での BAS スコア（アカシジアの包括的臨床評価）のベースラインからの変化量を表 2.7.4.7-110 及び表 2.7.4.7-111 に示した。

IM デポ剤維持治療期（Phase C）を通して，BAS スコアに特記すべき変化は認められなかった。

v)　錐体外路症状評価尺度：SAS

IM デポ剤維持治療期（Phase C）での SAS 合計スコアのベースラインからの変化量を表 2.7.4.7-112 及び表 2.7.4.7-113 に示した。IM デポ剤維持治療期（Phase C）を通して，SAS 合計スコアに特記すべき変化は認められなかった。

(2)　体重への影響

(a)　二重盲検試験の二重盲検期（Phase D）

i)　体重の経時的変化

二重盲検試験の二重盲検期（Phase D）での体重の記述統計量を表 2.7.4.7-114 に示した。

二重盲検期（Phase D）でのベースラインの体重の実測値（平均値 ± SD，以下同様）は，IM デポ群で 89.5 ± 24.1 kg（132 例），プラセボ群で 89.2 ± 22.6 kg（133 例）であり，52 週後の実測値及びベースラインからの体重の平均変化量は，IM デポ群で 90.3 ± 25.6 kg，1.3 ± 5.9 kg（64 例），プラセボ群で 89.3 ± 22.8 kg，1.5 ± 6.1 kg（41 例），最終時点の実測値及びベースラインからの体重の平均変化量は，IM デポ群で 89.6 ± 24.0 kg，0.9 ± 5.3 kg（128 例），プラセボ群で 89.4 ± 23.1 kg，0.0 ± 5.9 kg（132 例）であった。

二重盲検期(Phase D)でのベースライン BMI 別体重の記述統計量を表 2.7.4.7-116 に示した。最終時点のベースラインからの体重の平均変化量は，IM デポ群では 23 kg/m^2 未満で 2.1 kg（12 例），23 kg/m^2 以上 27 kg/m^2 以下で 0.5 kg（25 例），27 kg/m^2 超で 0.9 kg（91 例）であった。プラセボ群では，23 kg/m^2 未満で−0.8 kg（16 例），23 kg/m^2 以上 27 kg/m^2 以下で 1.7 kg（33 例），27 kg/m^2 超で−0.4 kg（83 例）であった。

ii)　臨床的に重要な体重の変動

二重盲検期（Phase D）で 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を表 2.7.4.2.1-15 に，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を表 2.7.4.7-117 に示した。

治験薬投与後，二重盲検期（Phase D）のいずれかの時点で，臨床的に重要な体重増加（7%以上）を示した被験者の割合は，IM デポ群で 18.0%（23/128 例），プラセボ群で 12.9%（17/132 例）であった。また，臨床的に重要な体重減少（7%以上）を示した被験者の割合は，IM デポ群で 9.4%（12/128 例），プラセボ群で 12.1%（16/133 例）であった。最終時点では，臨床的に重要な体重増加（7%以上）を示した被験者の割合は，IM デポ群で 13.3%（17/128 例），プラセボ群で 12.1%（16/132 例）であった。また，最終時点で臨床的に重要な体重減少（7%以上）を示した被験者の割合は，IM デポ群で 5.5%（7/128 例），プラセボ群で 10.6%（14/132

例）であった。

BMI カテゴリ別の 7%以上の体重の増加を示した被験者の割合は，IM デポ群の最終時点では 23 kg/m^2 未満で 25.0%（3/12 例），23 kg/m^2 以上 27 kg/m^2 以下で 16.0%（4/25 例），27 kg/m^2 超で 11.0%（10/91 例）であった。プラセボ群では，23 kg/m^2 未満で 6.3%（1/16 例），23 kg/m^2 以上 27 kg/m^2 以下で 18.2%（6/33 例），27 kg/m^2 超で 10.8%（9/83 例）であった。また，BMI カテゴリ別の 7%以上の体重の減少を示した被験者の割合は，IM デポ群の最終時点では 23 kg/m^2 未満で 8.3%（1/12 例），23 kg/m^2 以上 27 kg/m^2 以下で 8.0%（2/25 例），27 kg/m^2 超で 4.4%（4/91 例）であった。プラセボ群では，23 kg/m^2 未満で 12.5%（2/16 例），23 kg/m^2 以上 27 kg/m^2 以下で 6.1%（2/33 例），27 kg/m^2 超で 12.0%（10/83 例）であった。

表 2.7.4.2.1-15　時期ごとの臨床的に重要な体重の変動［二重盲検試験の二重盲検期（Phase D）］

	IMデポ群 (132例)		プラセボ群 (133例)	
時期	対象例数[a]	例数[b](%)	対象例数[a]	例数[b](%)
7%以上の体重増加				
いずれかの時点	128	23 (18.0)	132	17 (12.9)
8週後	105	3 (2.9)	101	1 (1.0)
16週後	88	5 (5.7)	79	4 (5.1)
24週後	79	13 (16.5)	65	7 (10.8)
32週後	75	18 (24.0)	56	8 (14.3)
40週後	69	14 (20.3)	51	6 (11.8)
48週後	67	13 (19.4)	47	8 (17.0)
52週後	64	11 (17.2)	41	8 (19.5)
最終来院時	128	17 (13.3)	132	16 (12.1)
7%以上の体重減少				
いずれかの時点	128	12 (9.4)	132	16 (12.1)
8週後	105	1 (1.0)	101	2 (2.0)
16週後	88	4 (4.5)	79	3 (3.8)
24週後	79	4 (5.1)	65	5 (7.7)
32週後	75	5 (6.7)	56	3 (5.4)
40週後	69	3 (4.3)	51	6 (11.8)
48週後	67	6 (9.0)	47	4 (8.5)
52週後	64	3 (4.7)	41	2 (4.9)
最終来院時	128	7 (5.5)	132	14 (10.6)

臨床的に重要な体重の増加又は減少はベースラインより 7%以上の増加又は減少とした。

[a]：治験薬投与開始後に 1 回以上体重について測定結果のある被験者数

[b]：体重の臨床的に重要な変動が認められた被験者数。%の分母は対象例数

＜資料番号 5.3.5.1-01：CT-14.1，CT-14.3.1 より作成＞

iii) 体重関連有害事象

二重盲検期（Phase D）で発現した体重関連有害事象を表 2.7.4.7-118 に示した。

二重盲検期（Phase D）では，体重関連有害事象は，IM デポ群で 23.5%（31/132 例），プラセボ群で 22.6%（30/133 例）に発現した。IM デポ群とプラセボ群の発現割合の違いは 1%未満であった。二重盲検期（Phase D）で発現した体重関連有害事象はほとんどが体重増加であり，体重増加は IM デポ群で 23.5%（31/132 例），プラセボ群で 18.0%（24/133 例）に発現した。体重減少は IM デポ群で 0.0%（0/132 例），プラセボ群で 4.5%（6/133 例）に発現した。

二重盲検期（Phase D）で発現した重篤と判断された体重関連有害事象は認められなかった（表 2.7.4.2.1-9 参照）。投与中止に至った体重増加が IM デポ群で 1 例（0.8%）に発現した（表 2.7.4.2.1-11 参照）。

二重盲検期（Phase D）で発現した体重増加は，IM デポ群及びプラセボ群ともに軽度又は中等度であった（表 2.7.4.7-31 参照）。

アリピプラゾール IM デポ注射剤投与後に発現した体重増加は，3 ヵ月以下での発現割合が最も高く，投与期間に伴い発現割合が高くなることはなかった（表 2.7.4.2.1-7 参照）。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

i) 体重の経時的変化

二重盲検試験の IM デポ剤安定期（Phase C）での体重の記述統計量を表 2.7.4.7-119 に示した。

IM デポ剤安定期（Phase C）でのベースラインの体重の実測値（平均値 ± SD，以下同様）は，87.7 ± 22.4 kg（425 例），最終時点の実測値及びベースラインからの体重の平均変化量は 88.6 ± 22.9 kg，1.0 ± 4.0 kg（403 例）であった。

BMI 及びウエスト周囲径でも同様であった（表 2.7.4.7-119）。

ii) 臨床的に重要な体重の変動

IM デポ剤安定期（Phase C）で 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を表 2.7.4.2.1-16 に示した。

治験薬投与後，IM デポ剤安定期（Phase C）のいずれかの時点で，臨床的に重要な体重増加（7%以上）を示した被験者の割合は 10.9%（44/403 例），臨床的に重要な体重減少（7%以上）を示した被験者の割合は 4.7%（19/403 例）であった。

表 2.7.4.2.1-16　時期ごとの臨床的に重要な体重の変動［二重盲検試験の IM デポ剤安定期（Phase C）］

	安全性解析対象集団 (425例)	
時期	対象例数[a]	例数[b](%)
7%以上の体重増加		
いずれかの時点	403	44 (10.9)
8週後	356	18 (5.1)
16週後	93	11 (11.8)
24週後	28	4 (14.3)
28週後	8	1 (12.5)
最終来院時	403	40 (9.9)
7%以上の体重減少		
いずれかの時点	403	19 (4.7)
8週後	356	4 (1.1)
16週後	93	6 (6.5)
24週後	28	2 (7.1)
28週後	8	1 (12.5)
最終来院時	403	15 (3.7)

臨床的に重要な体重の増加又は減少はベースラインより 7%以上の増加又は減少とした。
[a]：治験薬投与開始後に 1 回以上体重について測定結果のある被験者数
[b]：体重の臨床的に重要な異常が認められた被験者数。%の分母は対象例数
＜資料番号 5.3.5.1-01：CT-23.2.1，CT-23.2.2 より作成＞

iii)　体重関連有害事象

IM デポ剤安定期（Phase C）で発現した体重関連有害事象を表 2.7.4.7-120 に示した。IM デポ剤安定期（Phase C）では，体重関連有害事象は 12.7%（54/425 例）に発現した。IM デポ剤安定期（Phase C）で発現した体重関連有害事象はほとんどが体重増加であり，体重増加は 11.1%（47/425 例）に発現した。

IM デポ剤安定期（Phase C）で発現した重篤と判断された体重関連有害事象は認められなかった（表 2.7.4.7-71 参照）。投与中止に至った体重増加が 1 例（0.2%）に発現した（表 2.7.4.7-81 参照）。治験薬との因果関係は「関連性は多分あり」で，最終観察時点で転帰は「未回復」であった。

IM デポ剤安定期（Phase C）で発現した体重増加は軽度又は中等度であった（表 2.7.4.7-50 参照）。

(c)　長期投与試験

i)　体重の経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）での体重の記述統計量を表 2.7.4.7-122 に示した。

IM デポ剤維持治療期（Phase C）でのベースラインの体重の実測値（平均値 ± SD，以下同様）は，86.6 ± 24.8 kg（464 例），52 週後の実測値及びベースラインからの体重の平均変化量は 86.3 ± 25.5 kg，1.0 ± 7.5 kg（238 例），最終時点の実測値及びベースラインからの体重の平均

変化量は 87.0 ± 25.3 kg，0.5 ± 6.7 kg（454 例）であった。IM デポ剤維持治療期（Phase C）を通して臨床的に意味のある体重の変化は認められなかった。

IM デポ剤維持治療期（Phase C）のすべての被験者を対象として算出した BMI 及びウエスト周囲径の変化量でも同様に変化は小さかった（表 2.7.4.7-122）。

IM デポ剤維持治療期（Phase C）での，ベースライン BMI 別体重の記述統計量を表 2.7.4.7-121 に示した。最終時点のベースラインからの体重の平均変化量は 23 kg/m^2 未満で 0.9 kg（68 例），23 kg/m^2 以上 27 kg/m^2 以下で 0.6kg（106 例），27 kg/m^2 超で 0.4 kg（280 例）であった。

ii) 臨床的に重要な体重の変動

IM デポ剤維持治療期（Phase C）で 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を表 2.7.4.2.1-17 に示した。

治験薬投与後，IM デポ剤維持治療期（Phase C）のいずれかの時点で，臨床的に重要な体重増加（7%以上）を示した被験者の割合は 20.5%（93/454 例），臨床的に重要な体重減少（7%以上）を示した被験者の割合は 14.5%（66/454 例）であった。最終時点では，臨床的に重要な体重増加（7%以上）を示した被験者の割合は 15.6%（71/454 例），臨床的に重要な体重減少（7%以上）を示した被験者の割合は 10.6%（48/454 例）であった。

表 2.7.4.2.1-17　時期ごとの臨床的に重要な体重の変動［長期投与試験］

	新規例(379例)		継続例(85例)		計(464例)	
時期	対象例数[a]	例数[b](%)	対象例数[a]	例数[b](%)	対象例数[a]	例数[b](%)
7%以上の体重増加						
IMデポ剤維持治療期（Phase C）のいずれかの週	370	79 (21.4)	84	14 (16.7)	454	93 (20.5)
8週後	337	12 (3.6)	77	2 (2.6)	414	14 (3.4)
16週後	319	28 (8.8)	74	8 (10.8)	393	36 (9.2)
24週後	285	36 (12.6)	71	5 (7.0)	356	41 (11.5)
32週後	257	35 (13.6)	30	5 (16.7)	287	40 (13.9)
40週後	229	36 (15.7)	18	4 (22.2)	247	40 (16.2)
48週後	221	44 (19.9)	15	2 (13.3)	236	46 (19.5)
52週後	224	43 (19.2)	14	2 (14.3)	238	45 (18.9)
最終来院時	370	61 (16.5)	84	10 (11.9)	454	71 (15.6)
7%以上の体重減少						
IMデポ剤維持治療期（Phase C）のいずれかの週	370	57 (15.4)	84	9 (10.7)	454	66 (14.5)
8週後	337	4 (1.2)	77	4 (5.2)	414	8 (1.9)
16週後	319	12 (3.8)	74	6 (8.1)	393	18 (4.6)
24週後	285	20 (7.0)	71	8 (11.3)	356	28 (7.9)
32週後	257	25 (9.7)	30	4 (13.3)	287	29 (10.1)
40週後	229	24 (10.5)	18	2 (11.1)	247	26 (10.5)
48週後	221	27 (12.2)	15	3 (20.0)	236	30 (12.7)
52週後	224	25 (11.2)	14	2 (14.3)	238	27 (11.3)
最終来院時	370	42 (11.4)	84	6 (7.1)	454	48 (10.6)

臨床的に重要な体重の増加又は減少はベースラインより 7%以上の増加又は減少とした。

[a]：治験薬投与開始後に 1 回以上体重について測定結果のある被験者数

[b]：体重の臨床的に重要な異常が認められた被験者数

＜資料番号 5.3.5.2-01：Table 12.5.5.3-1 より作成＞

iii) 体重関連有害事象

IM デポ剤維持治療期（Phase C）で発現した体重関連有害事象を表 2.7.4.7-123 に示した。

IM デポ剤維持治療期（Phase C）では，体重関連有害事象は 16.2%（75/464 例）に発現した。IM デポ剤維持治療期（Phase C）で発現した体重関連有害事象は多くが体重増加であり，体重増加は 13.4%（62/464 例）に発現した。

IM デポ剤維持治療期（Phase C）では重篤と判断された体重関連有害事象は認められず（表 2.7.4.2.1-10 参照），7 例（1.5%）が体重増加により投与中止に至った（表 2.7.4.2.1-12 参照）。アリピプラゾール IM デポ注射剤投与後に発現し投与中止に至った 4 例の体重増加は，いずれも中等度で，治験薬との因果関係は「関連性は多分あり」が 2 例，「関連性はあるかもしれない」が 1 例，「関連性はない」が 1 例であった。最終観察時点で転帰は「未回復」が 2 例，「回復」が 2 例であった（表 2.7.4.7-86 参照）。

IM デポ剤維持治療期（Phase C）で発現した体重増加は，4 例（0.9%）が高度であったことを除き，ほとんどが軽度又は中等度であった（表 2.7.4.7-60 参照）。

IM デポ剤維持治療期（Phase C）でアリピプラゾール IM デポ注射剤投与後に初めて発現した体重増加は 50 例（10.8%）であった。そのうち 21 例（4.5%）が 3 ヵ月以下で発現し，24 例（5.7%）が 3 ヵ月超 6 ヵ月未満で発現していた。投与期間に伴い発現割合が増加することはなかった（表 2.7.4.7-62 参照）。

(3) 血糖への影響

(a) 二重盲検試験の二重盲検期（Phase D）

i) 血糖値の経時的変化

二重盲検試験の二重盲検期（Phase D）での血糖の記述統計量を表 2.7.4.7-124 に示した。二重盲検期（Phase D）でのベースラインの空腹時血糖の実測値（平均値 ± SD，以下同様）は，IM デポ群で 95.21 ± 20.02 mg/dL（112 例），プラセボ群で 97.49 ± 26.18 mg/dL（118 例）であり，52 週後ベースラインからの血糖の平均変化量は，IM デポ群で 3.27 mg/dL（51 例），プラセボ群で−1.69 mg/dL（35 例），最終時点のベースラインからの血糖の平均変化量は，IM デポ群で 0.60 mg/dL（96 例），プラセボ群で 0.45 mg/dL（97 例）であった。

空腹時血糖のベースラインから最終時点までの変化量は，IM デポ群とプラセボ群とで同程度であり，臨床的に意味のある違いではなかった。

ii) 臨床的に重要な糖代謝に関連する検査値の変動

二重盲検期（Phase D）で臨床的に重要な血糖値の変動を示した被験者の割合を表 2.7.4.7-125 に示した。また，投与前後の血糖値の変化を表 2.7.4.7-126 に示した。

治験薬投与後，二重盲検期（Phase D）のいずれかの時点で，臨床的に重要な空腹時血糖値の変動を示した被験者の割合は，IM デポ群で 12.5%（14/112 例），プラセボ群で 15.3%（17/111 例）であり，IM デポ群で低い割合であった。

投与前に基準値内又は軽度高値（126 mg/dL 未満）であった空腹時血糖が，投与後に高値

（126 mg/dL 以上）に変化した被験者の割合は，IM デポ群で 4.3%（4/94 例），プラセボ群で 5.5%（5/91 例）であった。IM デポ群及びプラセボ群のいずれも，投与前後の空腹時血糖の変化に臨床的に意味のある傾向は認められなかった。

iii) 糖代謝関連有害事象

二重盲検期（Phase D）で発現した糖代謝関連有害事象を表 2.7.4.7-127 に示した。

二重盲検期（Phase D）では，糖代謝関連有害事象は，IM デポ群で 0.0%（0/132 例），プラセボ群で 1.5%（2/133 例）に発現した。プラセボ群で発現した事象は，いずれも血中ブドウ糖増加であった。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

i) 血糖値の経時的変化

二重盲検試験の IM デポ剤安定期（Phase C）での空腹時血糖の記述統計量を表 2.7.4.7-128 に示した。

IM デポ剤安定期（Phase C）でのベースラインの空腹時血糖の実測値（平均値 ± SD，以下同様）は，95.13 ± 19.53 mg/dL（369 例），最終時点のベースラインからの血糖の平均変化量は 1.24 mg/dL（285 例）であった。IM デポ剤安定期（Phase C）を通して臨床的に意味のある空腹時血糖の変化は認められなかった。

ii) 臨床的に重要な糖代謝に関連する検査値の変動

IM デポ剤安定期（Phase C）で臨床的に重要な血糖値の変動を示した被験者の割合を表 2.7.4.7-129 に示した。また，投与前後の変化を表 2.7.4.7-130 に示した。

治験薬投与後，IM デポ剤安定期（Phase C）のいずれかの時点で，臨床的に重要な空腹時血糖値の変動を示した被験者の割合は 9.2%（29/316 例）であった。

投与前に基準値内又は軽度高値（126 mg/dL 未満）であった空腹時血糖が，投与後に高値（126 mg/dL 以上）に変化した被験者の割合は，2.6%（7/273 例）であった。

iii) 糖代謝関連有害事象

IM デポ剤安定期（Phase C）で発現した糖代謝関連有害事象を表 2.7.4.7-131 に示した。

IM デポ剤安定期（Phase C）で発現した糖代謝関連有害事象は 0.5%（2/425 例）であった。

(c) 長期投与試験

i) 血糖値の経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）での空腹時血糖の記述統計量を表 2.7.4.7-132 に示した。

IM デポ剤維持治療期（Phase C）でのベースラインの空腹時血糖の実測値（平均値 ± SD，以下同様）は，97.30 ± 27.02 mg/dL（400 例），最終時点のベースラインからの血糖の平均変化量は 1.72 mg/dL（312 例）であった。IM デポ剤維持治療期（Phase C）を通して臨床的に意味

のある空腹時血糖の変化は認められなかった。

ii)　臨床的に重要な糖代謝に関連する検査値の変動

IM デポ剤維持治療期（Phase C）で臨床的に重要な血糖値の変動を示した被験者の割合を表 2.7.4.7-133 に示した。また，投与前後の変化を表 2.7.4.7-134 に示した。

治験薬投与後，IM デポ剤維持治療期（Phase C）のいずれかの時点で，臨床的に重要な空腹時血糖値の変動を示した被験者の割合は 11.4%（39/342 例）であった。

投与前に基準値内又は軽度高値（126 mg/dL 未満）であった空腹時血糖が，投与後に高値（126 mg/dL 以上）に変化した被験者の割合は，3.3%（10/299 例）であった。

iii)　糖代謝関連有害事象

IM デポ剤維持治療期（Phase C）で発現した糖代謝関連有害事象を表 2.7.4.7-135 に示した。

IM デポ剤維持治療期（Phase C）で発現した糖代謝関連有害事象は 1.1%（5/464 例）であり，発現した事象は血中ブドウ糖増加 4 例（0.9%），尿中ブドウ糖陽性 1 例（0.2%），耐糖能障害 1 例（0.2%）であった。

(4)　脂質への影響

(a)　二重盲検試験の二重盲検期（Phase D）

i)　脂質パラメータの経時的変化

二重盲検試験の二重盲検期（Phase D）の脂質パラメータの記述統計量を表 2.7.4.7-124 に示した。二重盲検期（Phase D）でのベースラインの空腹時コレステロールの実測値（平均値 ± SD，以下同様）は，IM デポ群で 191.11 ± 40.00 mg/dL（112 例），プラセボ群で 190.88 ± 38.10 mg/dL（119 例）であり，最終時点のベースラインからの平均変化量は，IM デポ群で 1.48 mg/dL（93 例），プラセボ群で 3.03 mg/dL（98 例）であった。空腹時 HDL コレステロールでは，ベースラインの実測値は，IM デポ群で 53.05 ± 15.45 mg/dL（112 例），プラセボ群で 53.08 ± 16.30 mg/dL（119 例）であり，最終時点のベースラインからの平均変化量は，IM デポ群で−1.89 mg/dL（93 例），プラセボ群で 0.55 mg/dL（98 例）であった。空腹時 LDL コレステロールでは，ベースラインの実測値は，IM デポ群で 109.58 ± 35.11 mg/dL（110 例），プラセボ群で 109.92 ± 32.64 mg/dL（117 例）であり，最終時点のベースラインからの平均変化量は，IM デポ群で 3.35 mg/dL（92 例），プラセボ群で 2.58 mg/dL（95 例）であった。空腹時トリグリセライドでは，ベースラインの実測値は，IM デポ群で 144.57 ± 108.49 mg/dL（112 例），プラセボ群で 148.08 ± 104.97 mg/dL（119 例）であり，最終時点のベースラインからの平均変化量は，IM デポ群で 0.95 mg/dL（93 例），プラセボ群で−7.33 mg/dL（98 例）であった。

脂質パラメータのベースラインから最終時点までの変化量は，いずれのパラメータも IM デポ群とプラセボ群との間に臨床的に意味のある違いは認められなかった。

ii)　臨床的に重要な脂質パラメータの変動

二重盲検期（Phase D）で臨床的に重要な脂質パラメータの変動を示した被験者の割合を

表 2.7.4.7-125 に示した。また，投与前後の変化を表 2.7.4.7-136 に示した。

治験薬投与後，二重盲検期（Phase D）のいずれかの時点で，臨床的に重要な脂質パラメータの変動を示した被験者の割合は，空腹時コレステロールで IM デポ群 11.9%（13/109 例），プラセボ群 13.5%（15/111 例），空腹時 HDL コレステロールで IM デポ群 2.8%（3/109 例），プラセボ群 5.4%（6/111 例），空腹時 LDL コレステロールで IM デポ群 11.1%（12/108 例），プラセボ群 13.0%（14/108 例），空腹時トリグリセライドで IM デポ群 41.3%（45/109 例），プラセボ群 37.8%（42/111 例）であった。

臨床的に重要な脂質パラメータの変動を示した被験者の割合は，IM デポ群とプラセボ群の間で臨床的に意味のある違いは認められなかった。

投与前に基準値又は軽度高値であった脂質パラメータの値が投与後に高値に変化した被験者の割合は，空腹時コレステロールで IM デポ群 8.1%（7/86 例），プラセボ群 9.2%（8/87 例），空腹時 LDL コレステロールで IM デポ群 8.2%（7/85 例），プラセボ群 8.3%（7/84 例），空腹時トリグリセライドで IM デポ群 15.2%（12/79 例），プラセボ群 7.5%（6/80 例）であった。空腹時トリグリセライドでは，変化した被験者の割合が IM デポ群でプラセボ群の 2 倍であったが，500 mg/dL を超える被験者は認められなかった。

iii) 脂質代謝関連有害事象

二重盲検期（Phase D）で発現した脂質代謝関連有害事象を表 2.7.4.7-137 に示した。

二重盲検期（Phase D）では，IM デポ群及びプラセボ群共に，脂質代謝関連有害事象は発現しなかった。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

i) 脂質パラメータの経時的変化

二重盲検試験の，IM デポ剤安定期（Phase C）の脂質パラメータの記述統計量を表 2.7.4.7-128 に示した。

IM デポ剤安定期（Phase C）でのベースラインの空腹時コレステロールの実測値（平均値 ± SD，以下同様）は 189.73 ± 40.50 mg/dL（369 例），最終時点のベースラインからの平均変化量は −1.01 mg/dL（282 例）であった。空腹時 HDL コレステロールでは，ベースラインの実測値は 54.79 ± 15.79 mg/dL（369 例），最終時点のベースラインからの平均変化量は−1.69 mg/dL（282 例）であった。空腹時 LDL コレステロールでは，ベースラインの実測値は 109.58 ± 34.60 mg/dL（364 例），最終時点のベースラインからの平均変化量は−1.09 mg/dL（274 例）であった。空腹時トリグリセライドでは，ベースラインの実測値は 129.13 ± 81.98 mg/dL（369 例），最終時点のベースラインからの平均変化量は 9.00 mg/dL（282 例）であった。

IM デポ剤安定期（Phase C）を通して臨床的に意味のある脂質パラメータの変化は認められなかった。

ii) 臨床的に重要な脂質パラメータの変動

IM デポ剤安定期（Phase C）で臨床的に重要な脂質パラメータの変動を示した被験者の割合

を表 2.7.4.7-129 に示した。また，投与前後の変化を表 2.7.4.7-138 に示した。

治験薬投与後，IM デポ剤安定期（Phase C）のいずれかの時点で，臨床的に重要な脂質パラメータの変動を示した被験者の割合は，空腹時コレステロールで 10.6%（33/311 例），空腹時 HDL コレステロールで 3.2%（10/311 例），空腹時 LDL コレステロールで 8.8%（27/306 例），空腹時トリグリセライドで 44.1%（137/311 例）であった。

投与前に基準値又は軽度高値であった脂質パラメータの値が投与後に高値に変化した被験者の割合は，空腹時コレステロールで 4.8%（12/248 例），空腹時 LDL コレステロールで 4.1%（10/245 例），空腹時トリグリセライドで 9.5%（22/231 例）であった。

iii) 脂質代謝関連有害事象

IM デポ剤安定期（Phase C）で発現した脂質代謝関連有害事象を表 2.7.4.7-139 に示した。

IM デポ剤安定期（Phase C）で発現した脂質代謝関連有害事象は 0.2%（1/425 例）であり，発現した事象は血中トリグリセリド増加，高比重リポ蛋白減少で，同一被験者に発現した。

(c) 長期投与試験

i) 脂質パラメータの経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）での脂質パラメータの記述統計量を表 2.7.4.7-132 に示した。

IM デポ剤維持治療期（Phase C）でのベースラインの空腹時コレステロールの実測値（平均値 ± SD，以下同様）は 192.16 ± 39.88 mg/dL（402 例），最終時点のベースラインからの平均変化量は 0.49 mg/dL（309 例）であった。空腹時 HDL コレステロールでは，ベースラインの実測値は 55.26 ± 15.81 mg/dL（402 例），最終時点のベースラインからの平均変化量は −1.00 mg/dL（309 例）であった。空腹時 LDL コレステロールでは，ベースラインの実測値は 108.74 ± 30.44 mg/dL（395 例），最終時点のベースラインからの平均変化量は 1.88 mg/dL（298 例）であった。空腹時トリグリセライドでは，ベースラインの実測値は 135.72 ± 82.11 mg/dL（402 例），最終時点のベースラインからの平均変化量は 3.42 mg/dL（309 例）であった。

IM デポ剤維持治療期（Phase C）を通して臨床的に意味のある脂質パラメータの変化は認められなかった。

ii) 臨床的に重要な脂質パラメータの変動

IM デポ剤維持治療期（Phase C）で臨床的に重要な脂質パラメータの変動を示した被験者の割合を表 2.7.4.7-133 に示した。また，投与前後の変化を表 2.7.4.7-140 に示した。

治験薬投与後，IM デポ剤維持治療期（Phase C）のいずれかの時点で，臨床的に重要な脂質パラメータの変動を示した被験者の割合は，空腹時コレステロールで 15.7%（53/338 例），空腹時 HDL コレステロールで 2.7%（9/338 例），空腹時 LDL コレステロールで 9.7%（32/331 例），空腹時トリグリセライドで 36.7%（124/338 例）であった。

投与前に基準値又は軽度高値であった脂質パラメータの値が投与後に高値に変化した被験者の割合は，空腹時コレステロールで 9.3%（25/269 例），空腹時 LDL コレステロールで 6.5%

（18/279 例），空腹時トリグリセライドで 8.7%（22/252 例）であった。

iii)　脂質代謝関連有害事象

IM デポ剤維持治療期（Phase C）で発現した脂質代謝関連有害事象を表 2.7.4.7-141 に示した。

IM デポ剤維持治療期（Phase C）で発現した脂質代謝関連有害事象は 0.4%（2/464 例）であり，発現した事象は血中コレステロール増加 2 例（0.4%），血中トリグリセリド増加 1 例（0.2%）であった。

(5)　白血球異常

(a)　二重盲検試験の二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）での好中球，好塩基球，好酸球及び白血球数の記述統計量を表 2.7.4.7-142 に示した。IM デポ群及びプラセボ群共に，ベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

二重盲検期（Phase D）で臨床的に重要な好中球，好酸球及び白血球数の変動を示した被験者の割合を表 2.7.4.7-143 に示した。IM デポ群とプラセボ群で変動を示した被験者の割合は小さく，IM デポ群とプラセボ群の間で臨床的に意味のある違いは認められなかった。

二重盲検期（Phase D）で発現した白血球異常に関連する有害事象を表 2.7.4.7-144 に示した。二重盲検期（Phase D）で発現した白血球異常に関連する有害事象は，IM デポ群，プラセボ群ともに 1 例（0.8%）であり，発現した事象は IM デポ群では白血球減少症，好中球減少症（同一被験者），プラセボ群では好中球減少症であった。

(b)　二重盲検試験の IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）での好中球，好塩基球，好酸球及び白血球数の記述統計量を表 2.7.4.7-145 に示した。IM デポ剤安定期（Phase C）での好中球，好塩基球，好酸球及び白血球数のベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

IM デポ剤安定期（Phase C）で臨床的に重要な好中球，好塩基球，好酸球及び白血球数の変動を示した被験者の割合を表 2.7.4.7-146 に示した。IM デポ剤安定期（Phase C）では変動を示した被験者の割合は小さく，臨床的に意味のある変化は認められなかった。

IM デポ剤安定期（Phase C）で発現した白血球異常に関連する有害事象を表 2.7.4.7-147 に示した。IM デポ剤安定期（Phase C）で発現した白血球異常に関連する有害事象は 1 例（0.2%）で，好中球減少症であった。

(c)　長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）での好中球，好塩基球，好酸球及び白血球数の記述統計量を表 2.7.4.7-148 に示した。IM デポ剤維持治療期（Phase C）での好中球，好塩基球，好酸球及び白血球数のベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

IM デポ剤維持治療期（Phase C）で臨床的に重要な好中球，好酸球及び白血球数の変動を示

した被験者の割合を表 2.7.4.7-149 に示した。IM デポ剤維持治療期（Phase C）では変動を示した被験者の割合は小さく，臨床的に意味のある変化は認められなかった。

IM デポ剤維持治療期（Phase C）では白血球異常に関連する有害事象は発現しなかった（表 2.7.4.7-58 参照）。

(6) 起立性障害

(a) 二重盲検試験の二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）での起立性低血圧に該当する検査値の変動の基準（以下，起立性低血圧の基準）に該当する被験者の割合を表 2.7.4.7-150 に示した。二重盲検期（Phase D）で起立性低血圧の基準に該当した被験者の割合は IM デポ群及びプラセボ群ともに認められなかった。

二重盲検期（Phase D）で発現した起立性障害に関連する有害事象を表 2.7.4.7-151 に示した。二重盲検期（Phase D）で発現した起立性障害に関連する有害事象は，プラセボ群に 1 例（0.8%）であり，事象は失神であった。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）での起立性低血圧の基準に該当する被験者の割合を表 2.7.4.7-152 に示した。IM デポ剤安定期（Phase C）では 1 例（0.2%）に起立性低血圧の基準に該当する被験者が認められた。

IM デポ剤安定期（Phase C）で発現した起立性障害に関連する有害事象を表 2.7.4.7-153 に示した。IM デポ剤安定期（Phase C）で発現した起立性障害に関連する有害事象は 1 例（0.2%）であった。発現した事象は中等度の失神で，治験薬との関連性はなく，転帰は「回復」であった（表 2.7.4.7-49，表 2.7.4.7-50，表 2.7.4.7-54 参照）。

(c) 長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）での起立性低血圧の基準に該当する被験者の割合を表 2.7.4.7-154 に示した。IM デポ剤維持治療期（Phase C）では起立性低血圧の基準に該当する被験者は認められなかった。

IM デポ剤維持治療期（Phase C）で発現した起立性障害に関連する有害事象を表 2.7.4.7-155 に示した。IM デポ剤維持治療期（Phase C）では，2.6%（12/464 例）に起立性障害に関連する有害事象が発現した。最も発現割合が高かった事象は体位性めまい，起立性低血圧で，いずれも 1.1%（5/464 例）の被験者に発現した。IM デポ剤維持治療期（Phase C）で発現した体位性めまい，起立性低血圧はすべて軽度であった。

(7) QT 間隔への影響

QTc 間隔は QTcB，QTcF，QTcN の 3 種類の補正方法を用い，それぞれについてカテゴリカル解析を行ったが，心拍数の影響が少ないとされている QTcF の結果を中心に記載した。他の心電図パラメータの評価結果は「2.7.4.4.3 心電図の評価」に記載した。

(a) 二重盲検試験の二重盲検期（Phase D）

二重盲検試験の二重盲検期（Phase D）での QTc 間隔カテゴリカル解析の結果を表 2.7.4.7-156 に示した。

二重盲検期（Phase D）では，最悪時の QTcF が 500 msec 超であった被験者は，IM デポ群及びプラセボ群のいずれでも認められず，480 msec 超であった被験者も認められなかった。QTcF が 450 msec 超であった被験者は，IM デポ群で 4.1%（5/123 例），プラセボ群で 6.4%（8/125 例）であった。最悪時のベースラインからの変化量では，QTcF の変化量が 60 msec 以上の増加であった被験者は，IM デポ群及びプラセボ群のいずれでも認められず，30 msec 以上 60 msec 未満の増加であった被験者は，IM デポ群で 1.7%（2/121 例），プラセボ群で 4.1%（5/122 例）であった。

QTcB では，最悪時の QTcB が 500 msec 超であった被験者がプラセボ群で 0.8%（1/125 例）に認められた。480 msec 超であった被験者は，IM デポ群で 1.6%（2/123 例），プラセボ群で 1.6%（2/125 例，うち 1 例は 500 msec 超）であった。450 msec 超であった被験者は，IM デポ群で 16.3%（20/123 例，うち 2 例は 480 msec 超），プラセボ群で 9.6%（12/125 例，うち 1 例は 480 msec 超，1 例は 500 msec 超）であった。最悪時のベースラインからの変化量では，QTcB の変化量が 60 msec 以上の増加であった被験者は，IM デポ群及びプラセボ群のいずれでも認められず，30 msec 以上 60 msec 未満の増加であった被験者は，IM デポ群で 10.7%（13/121 例），プラセボ群で 12.3%（15/122 例）であった。

QTcN については，QTcF による結果と同様であった。

二重盲検期（Phase D）では，IM デポ群及びプラセボ群のいずれでも QT 延長関連有害事象は発現しなかった（表 2.7.4.7-29 参照）。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

二重盲検試験の IM デポ剤安定期（Phase C）での QTc 間隔カテゴリカル解析の結果を表 2.7.4.7-157 に示した。

IM デポ剤安定期（Phase C）では，最悪時の QTcF が 500 msec 超であった被験者，480 msec 超であった被験者のいずれも認められなかった。QTcF が 450 msec 超であった被験者は，1.9%（7/377 例）であった。最悪時のベースラインからの変化量では，QTcF の変化量が 60 msec 以上の増加であった被験者は認められず，30 msec 以上 60 msec 未満の増加であった被験者は 0.5%（2/374 例）であった。

QTcB では，最悪時の QTcB が 500 msec 超であった被験者は認められず，480 msec 超であった被験者は 0.5%（2/377 例），450 msec 超であった被験者は 8.5%（32/377 例，うち 2 例は 480 msec 超）であった。最悪時のベースラインからの変化量では，QTcB の変化量が 60 msec 以上の増加であった被験者は認められず，30 msec 以上 60 msec 未満の増加であった被験者は 4.3%（16/374 例）であった。

QTcN については，QTcF による結果と同様であった。

IM デポ剤安定期（Phase C）では QT 延長関連有害事象は発現しなかった（表 2.7.4.7-48 参照）。

(c)　長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）での QTc 間隔カテゴリカル解析の結果を表 2.7.4.7-158 に示した。

IM デポ剤維持治療期（Phase C）では，最悪時の QTcF が 500 msec 超であった被験者，480 msec 超であった被験者のいずれも認められなかった。QTcF が 450 msec 超であった被験者は 2.4%（10/412 例）であった。最悪時のベースラインからの変化量では，QTcF の変化量が 60 msec 以上の増加であった被験者は認められず，30 msec 以上 60 msec 未満の増加であった被験者は 1.7%（7/409 例）であった。

QTcB では，最悪時の QTcB が 500 msec 超であった被験者は認められず，480 msec 超であった被験者は 1.0%（4/412 例），450 msec 超であった被験者は 7.3%（30/412 例，うち 4 例は 480 msec 超）であった。最悪時のベースラインからの変化量では，QTcB の変化量が 60 msec 以上の増加であった被験者は 0.2%（1/409 例）で，30 msec 以上 60 msec 未満の増加であった被験者は 3.7%（15/409 例）であった。

QTcN については，QTcF による結果と大きく異ならなかった。

IM デポ剤維持治療期（Phase C）では QT 延長関連有害事象は発現しなかった（表 2.7.4.7-58 参照）。

(8)　プロラクチン値への影響

(a)　二重盲検試験の二重盲検期（Phase D）

i)　プロラクチン値の経時的変化

二重盲検試験の二重盲検期（Phase D）でのプロラクチンの記述統計量を表 2.7.4.7-159 に示した。

二重盲検期（Phase D）でのベースラインでのプロラクチンの実測値の平均値（以下，実測値）は，女性では，IM デポ群が 8.58 ng/mL（76 例），プラセボ群が 8.22 ng/mL（69 例），男性では，IM デポ群が 2.41 ng/mL（46 例），プラセボ群が 3.04 ng/mL（59 例）であった。最終評価時の実測値及びベースラインからのプロラクチンの平均変化量は女性では，IM デポ群が 8.88 ng/mL（76 例），0.30 ng/mL（70 例），プラセボ群が 10.48 ng/mL（65 例），2.58 ng/mL（64 例），男性では，IM デポ群が 2.29 ng/mL（41 例），−0.11 ng/mL（39 例），プラセボ群が 7.47 ng/mL（52 例），3.55 ng/mL（49 例）であった。

ii)　臨床的に重要なプロラクチン値の変動

二重盲検期（Phase D）で臨床的に重要なプロラクチン値の変動が認められた被験者の割合を表 2.7.4.7-160 に示した。

二重盲検期（Phase D）のいずれかの時点で臨床的に重要なプロラクチンの上昇（基準値上限の 1 倍超）が認められた被験者の割合は IM デポ群が 3.4%（4/117 例），プラセボ群が 6.8%（8/117 例）であった。基準値上限の 2 倍超であった被験者の割合は IM デポ群及びプラセボ群ともに 0.9%（1/117 例）であった。3 倍超であった被験者はいずれの群でも認められなかっ

た。

iii) プロラクチン関連有害事象

二重盲検期（Phase D）で発現したプロラクチン関連有害事象を表 2.7.4.7-161 に示した。二重盲検期（Phase D）では，プロラクチン関連有害事象はプラセボ群で 0.8%（1/133 例）に発現し，事象は高プロラクチン血症であった。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

i) プロラクチン値の経時的変化

二重盲検試験の IM デポ剤安定期（Phase C）でのプロラクチンの記述統計量を表 2.7.4.7-162 に示した。

IM デポ剤安定期（Phase C）では，プロラクチンのベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

ii) 臨床的に重要なプロラクチン値の変動

IM デポ剤安定期（Phase C）で臨床的に重要なプロラクチン値の変動が認められた被験者の割合を表 2.7.4.7-163 に示した。

IM デポ剤安定期（Phase C）のいずれかの時点で臨床的に重要なプロラクチンの上昇（基準値上限の 1 倍超）が認められた被験者の割合は 2.2%（8/357 例）であった。基準値上限の 2 倍超であった被験者の割合は 0.3%（1/357 例），3 倍超であった被験者は認められなかった。

iii) プロラクチン関連有害事象

IM デポ剤安定期(Phase C)で発現したプロラクチン関連有害事象を表 2.7.4.7-164 に示した。

IM デポ剤安定期（Phase C）では，プロラクチン関連有害事象は 1 例（0.2%）に発現し，事象は血中プロラクチン増加であった。

(c) 長期投与試験

i) プロラクチン値の経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）でのプロラクチンの記述統計量を表 2.7.4.7-165 に示した。

IM デポ剤維持治療期（Phase C）では，プロラクチンのベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

ii) 臨床的に重要なプロラクチン値の変動

IM デポ剤維持治療期（Phase C）で臨床的に重要なプロラクチン値の変動が認められた被験者の割合を表 2.7.4.7-166 に示した。

IM デポ剤維持治療期（Phase C）の 52 週後に臨床的に重要なプロラクチンの上昇（基準値上限の 1 倍超）が認められた被験者の割合は女性が 0.7%（1/141 例），男性が 3.2%（3/95 例）

であった。うち男性 1 例（1.1%）は基準値上限の 3 倍超であった。

iii) プロラクチン関連有害事象

IM デポ剤維持治療期（Phase C）で発現したプロラクチン関連有害事象を表 2.7.4.7-167 に示した。

IM デポ剤維持治療期（Phase C）では，プロラクチン関連有害事象は 1.1%（5/464 例）に発現し，高プロラクチン血症が 0.6%（3/464 例），血中プロラクチン増加が 0.2%（1/464 例），血中プロラクチン減少が 0.2%（1/464 例）であった。

(9) 自殺への影響

C-SSRS から C-CASA への変換方法及び解析方法は，各治験総括報告書で示した。

(a) 二重盲検試験の二重盲検期（Phase D）

i) 自殺関連有害事象

二重盲検試験の二重盲検期（Phase D）で発現した自殺関連有害事象を表 2.7.4.7-168 に示した。二重盲検期（Phase D）では，IM デポ群で 0.8%（1/132 例），プラセボ群 0.8%（1/133 例）に自殺関連有害事象が発現した。発現した事象はいずれも自殺企図であった。IM デポ群及びプラセボ群で発現した事象はいずれも重篤と判断され，投与中止に至った。IM デポ群の自殺企図は高度，プラセボ群の自殺企図は中等度と判定された。治験薬との因果関係は IM デポ群が「関連性は多分ない」，プラセボ群が「関連性はない」であった。転帰はいずれも「回復」であった（資料番号 5.3.5.1-01：CT-9.4 参照）。

ii) C-SSRS

二重盲検期（Phase D）での C-SSRS のベースラインからの変化量を表 2.7.4.7-170 に示した。IM デポ群及びプラセボ群共に，ベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

C-CASA/C-SSRS では，IM デポ群で 6.9%（9/131 例），プラセボ群で 12.0%（16/133 例）に「自殺の可能性」が認められた（表 2.7.4.7-171 参照）。

C-SSRS では，IM デポ群及びプラセボ群のいずれも 0.8%に「自殺行動の出現」が認められた。「自殺念慮の出現」は IM デポ群で 6.1%（8/131 例），プラセボ群で 11.3%（15/133 例）に認められた（表 2.7.4.7-172 参照）。

(b) 二重盲検試験の IM デポ剤安定期（Phase C）

i) 自殺関連有害事象

二重盲検試験の IM デポ剤安定期（Phase C）で発現した自殺関連有害事象を表 2.7.4.7-173 に示した。IM デポ剤安定期（Phase C）では，1.9%（8/425 例）に自殺関連有害事象が発現した。発現した事象は，自殺念慮が 1.6%（7/425 例），自殺企図が 0.2%（1/425 例）であった。このうち，自殺念慮 3 例，自殺企図 1 例が重篤と判断され，自殺念慮の 1 例，自殺企図は投与

中止に至った。治験薬との因果関係は「関連性は多分ない」又は「関連性はない」であった。転帰はいずれも「回復」であった（表 2.7.4.7-169 参照）。

ii) C-SSRS

IM デポ剤安定期（Phase C）での C-SSRS のベースラインからの変化量を表 2.7.4.7-174 に示した。IM デポ剤安定期（Phase C）ではベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

C-CASA/C-SSRS では，11.2%（47/425 例）に「自殺の可能性」が認められた。C-CASA 項目のうち，最も割合が高かったのは「自殺念慮」で 11.2%（47/425 例）であった（表 2.7.4.7-175 参照）。

C-SSRS では「自殺行動の出現」が 0.7%（3/421 例）に認められ，「自殺念慮の出現」が 10.9%（46 例）に認められた（表 2.7.4.7-176 参照）。

(c) 長期投与試験

i) 自殺関連有害事象

長期投与試験の IM デポ剤維持治療期（Phase C）で発現した自殺関連有害事象を表 2.7.4.7-177 に示した。IM デポ剤維持治療期（Phase C）では，2.4%（11/464 例）に自殺関連有害事象が発現した。発現した事象は，故意の自傷行為 0.2%（1/464 例），自殺念慮 1.9%（9/464 例），自殺企図 0.6%（3/464 例）であった。このうち，自殺念慮 4 例，自殺企図 1 例が重篤と判断された。また，重篤と判断された 2 例を含む，自殺念慮 3 例は投与中止に至った。治験薬との因果関係は故意の自傷行為 1 例，非重篤の自殺念慮 1 例が「関連性はあるかもしれない」で，そのほかは「関連性は多分ない」又は「関連性はない」であった。転帰はいずれも「回復」であった（表 2.7.4.7-178 参照）。

ii) C-SSRS

IM デポ剤維持治療期（Phase C）での C-SSRS のベースラインからの変化量を表 2.7.4.7-179 に示した。IM デポ剤維持治療期（Phase C）ではベースラインから最終時点までの変化量は小さく，臨床的に意味のある変化は認められなかった。

C-CASA/C-SSRS では，9.9%（46/463 例）に「自殺の可能性」が認められた。C-CASA 項目のうち，最も割合が高かったのは「自殺念慮」で 9.9%（46/463 例）であった（表 2.7.4.7-180 参照）。

C-SSRS では「自殺行動の出現」が 1.7%（8/464 例）に認められ，「自殺念慮の出現」が 9.1%（42/464 例）に認められた（表 2.7.4.7-181 参照）。

(10) 注射部位反応関連

(a) 二重盲検試験の二重盲検期（Phase D）

二重盲検期（Phase D）での被験者による VAS を使った注射部位疼痛の自己評価を表 2.7.4.7-182 に示した。

二重盲検期（Phase D）では VAS による注射部位疼痛の程度（0 mm = no pain～100 mm = unbearably painful）は，IM デポ群で初回投与後 5.2 であり，最終投与後に 4.0 に減少した。プラセボ群では初回投与後 5.7 であり，最終投与後には 5.8 であった。IM デポ群では VAS による注射部位疼痛の程度は減少し，13 回目の投与まで低い値で推移した。

治験責任医師等による注射部位の疼痛，発赤，腫脹及び硬結について評価した。二重盲検期（Phase D）では，IM デポ群で初回投与後にそれぞれの項目で「なし」と判定された被験者の割合は，81.8%～100.0%であり，最終投与後では 87.1%～100.0%であった。プラセボ群では，初回投与後に「なし」と判定された被験者の割合は，81.2%～100.0%であり，最終投与後では 85.0%～100.0%であった（表 2.7.4.7-183～表 2.7.4.7-186 参照）。IM デポ群及びプラセボ群のいずれも，初回投与後から「なし」と判定された被験者の割合は 80%以上であり，最終投与後まで「なし」と判定された被験者の割合は 80%前後と，高い割合で推移した。

二重盲検試験の二重盲検期（Phase D）で発現した注射部位反応関連有害事象を表 2.7.4.7-187 に示した。

注射部位反応関連有害事象は，IM デポ群で 0.8%（1/132 例），プラセボ群で 1.5%（2/133 例）に発現した。IM デポ群で発現した事象は注射部位疼痛であり，プラセボ群では注射部位疼痛，注射部位そう痒感がそれぞれ 1 例に発現した。

(b)　二重盲検試験の IM デポ剤安定期（Phase C）

IM デポ剤安定期（Phase C）での被験者による VAS を使った注射部位疼痛の自己評価を表 2.7.4.7-188 に示した。

IM デポ剤安定期（Phase C）では，VAS による注射部位疼痛の程度は，初回投与後は 6.1 で最終投与後に 5.6 であった。

治験責任医師等による注射部位の疼痛，発赤，腫脹及び硬結について評価した。IM デポ剤安定期（Phase C）で初回投与後にそれぞれの項目で「なし」と判定された被験者の割合は，81.0%～100.0%であり，最終投与後では 84.2%～99.5%であった（表 2.7.4.7-189～表 2.7.4.7-192 参照）。

IM デポ剤安定期（Phase C）で発現した注射部位反応関連有害事象を表 2.7.4.7-193 に示した。注射部位反応関連有害事象は，IM デポ剤安定期（Phase C）で 5.4%（23/425 例）に発現した。

(c)　二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）

IM デポ剤安定期（Phase C）から二重盲検期（Phase D）での VAS による注射部位疼痛の程度は，二重盲検期（Phase D）で IM デポ剤の投与を受けた IM デポ群の 132 例で，初回投与後 6.4（131 例）であり，最終投与後に 4.0（132 例）に減少した。プラセボ群の 133 例では初回投与後 5.7（133 例）であり，最終投与後には 5.8（133 例）であった（表 2.7.4.7-194 参照）。

治験責任医師等による注射部位の疼痛，発赤，腫脹及び硬結についての評価では，IM デポ群で初回投与後にそれぞれの項目で「なし」と判定された被験者の割合は，78.6%～100.0%であり，最終投与後では 87.1%～100.0%であった。プラセボ群では，初回投与後に「なし」と判定された被験者の割合は，75.9%～100.0%であり，最終投与後では 85.0%～100.0%であった（表 2.7.4.7-195～表 2.7.4.7-198 参照）。

(d)　長期投与試験

長期投与試験の IM デポ剤維持治療期（Phase C）での被験者による VAS を使った注射部位疼痛の自己評価を表 2.7.4.7-199 に示した。

IM デポ剤維持治療期（Phase C）では，VAS による注射部位疼痛の程度は，初回投与後は 4.9 で最終投与後に 2.4 であった。

治験責任医師等による注射部位の疼痛，発赤，腫脹及び硬結について評価した。IM デポ剤維持治療期（Phase C）で初回投与後にそれぞれの項目で「なし」と判定された被験者の割合は，87.9%～99.6%であり，最終投与後では 91.6%～100.0%であった（表 2.7.4.7-200～表 2.7.4.7-203 参照）。

IM デポ剤維持治療期（Phase C）で発現した注射部位反応関連有害事象を表 2.7.4.7-204 に示した。注射部位反応関連有害事象は，IM デポ剤維持治療期（Phase C）で 9.1%（42/464 例）に発現した。

2.7.4.2.2　個別有害事象の文章による説明

死亡例及びその他の重篤な有害事象の叙述は各試験の治験総括報告書に示すと共に「2.7.6 個々の試験のまとめ」にも記載した。表 2.7.4.2.2-1 に各治験総括報告書での叙述記載箇所を示した。

表 2.7.4.2.2-1　本申請のための試験での死亡，その他の重篤な有害事象に関する叙述記載箇所一覧表

資料名 添付資料番号	項目	死亡及びその他の重篤な有害事象の叙述記載箇所
二重盲検試験（31-08-250）の 治験総括報告書 5.3.5.1-01	12.3	12.3.2 死亡，その他の重篤な有害事象及び他のいくつかの重要な有害事象の叙述
長期投与試験（31-08-252）の 治験総括報告書 5.3.5.2-01	12.3	12.3.2 死亡，その他の重篤な有害事象及び他のいくつかの重要な有害事象の叙述

2.7.4.3　臨床検査値の評価

本項では「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目以外の検査値での検討結果を示した。臨床的に重要な臨床検査値の変動が認められた被験者の割合を求める際の基準は表 2.7.4.7-2 に示した。

なお，二重盲検試験の IM デポ剤安定期（Phase C）は，期間を 12 週間から 28 週間と設定していたため，パラメータの経時的変化を最終投与時で検討した。

2.7.4.3.1　二重盲検試験の二重盲検期（Phase D）

2.7.4.3.1.1　生化学的検査

(1)　パラメータの経時的変化

二重盲検試験の二重盲検期（Phase D）での生化学的検査値の記述統計量を表 2.7.4.7-124 に示した。IM デポ群で，ベースライン値から Week 52 までの変化量が 10%以上変動した項目［臨床的に重要な臨床検査値（表 2.7.4.7-2）に規定した項目は同じ方向に変動した場合とした］はなかった。

(2)　臨床的に重要なパラメータの変動

二重盲検期（Phase D）での臨床的に重要な生化学的検査値の変動が認められた被験者の割合を表 2.7.4.7-143 に示した。「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，臨床的に重要な生化学的検査値の変動が認められた被験者の割合が 5%以上に認められた項目は，IM デポ群及びプラセボ群でのいずれも CK のみであり，その割合は同程度であった（IM デポ群 7.2%，9/125 例，プラセボ群 5.6%，7/126 例）。

また，Hy’s Law の基準（「2.7.4.1.1.4(2)(b) 臨床検査」参照）に該当する被験者は認められなかった（表 2.7.4.7-205）。

(3)　生化学的検査結果に関連する有害事象

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，生化学的検査に関連する有害事象の発現割合は，IM デポ群及びプラセボ群のいずれも 3%未満であった。最も発現割合が高かった有害事象は，IM デポ群で血中クレアチンホスホキナーゼ増加（2.3%，3/132 例），プラセボ群ではアラニンアミノトランスフェラーゼ増加，アスパラギン酸アミノトランスフェラーゼ増加で，いずれも 1.5%（2/133 例）であった。生化学的検査結果に関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象は発現しなかった。悪性症候群は発現しなかった（表 2.7.4.7-29）。

2.7.4.3.1.2　血液学的検査

(1)　パラメータの経時的変化

二重盲検期（Phase D）での血液学的検査値の記述統計量を表 2.7.4.7-142 に示した。IM デポ群で，ベースライン値から Week 52 までの変化量が 10%以上変動した項目［臨床的に重要な臨床検査値（表 2.7.4.7-2）に規定した項目は同じ方向に変動した場合とした］はなかった。

(2)　臨床的に重要なパラメータの変動

二重盲検期（Phase D）での臨床的に重要な生化学的検査値の変動が認められた被験者の割合を表 2.7.4.7-143 に示した。「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，臨床的に重要な血液学的検査値の変動が認められた被験者の割合が 5%以上に認められた項目は，IM デポ群及びプラセボ群のいずれもなかった。

(3) 血液学的検査結果に関連する有害事象

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，血液学的検査に関連する有害事象は，IM デポ群では発現せず，プラセボ群ではグリコシル化ヘモグロビン増加が 1.5%（2/133 例）に発現した（表 2.7.4.7-29）。血液学的検査に関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。

2.7.4.3.1.3 尿検査

二重盲検期（Phase D）での尿検査値の記述統計量を表 2.7.4.7-206 に示した。ベースラインからの変化量は IM デポ群及びプラセボ群のいずれも小さく，臨床的に意味のある変化はなかった。また，臨床的に重要な尿検査値の変動が認められた被験者の割合も IM デポ群及びプラセボ群でのいずれも 2%未満であった（表 2.7.4.7-143）。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，尿検査結果に関連する有害事象も IM デポ群及びプラセボ群共に発現しなかった（表 2.7.4.7-29）。

2.7.4.3.2 二重盲検試験の IM デポ剤安定期（Phase C）

2.7.4.3.2.1 生化学的検査

(1) パラメータの経時的変化

二重盲検試験の IM デポ剤安定期（Phase C）での生化学的検査値の記述統計量を表 2.7.4.7-128 に示した。ベースライン値から最終投与時までの変化量が 10%以上変動した項目［臨床的に重要な臨床検査値（表 2.7.4.7-2）に規定した項目は同じ方向に変動した場合とした］はなかった。

(2) 臨床的に重要なパラメータの変動

IM デポ剤安定期（Phase C）での臨床的に重要な生化学的検査値の変動が認められた被験者の割合を表 2.7.4.7-146 に示した。「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，臨床的に重要な生化学的検査値の変動が認められた被験者の割合が 5%以上に認められた項目はなかった。

また，Hy’s Law の基準に該当する被験者は認められなかった（表 2.7.4.7-205）。

(3) 生化学的検査結果に関連する有害事象

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，生化学的検査に関連する有害事象の発現割合は 1%未満であった（表 2.7.4.7-48）。生化学的検査結果に関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。悪性症候群は発現しなかった（表 2.7.4.7-48）。

2.7.4.3.2.2　血液学的検査

(1)　パラメータの経時的変化

IM デポ剤安定期（Phase C）での血液学的検査値の記述統計量を表 2.7.4.7-145 に示した。ベースライン値から最終投与時までの変化量が 10%以上変動した項目［臨床的に重要な臨床検査値（表 2.7.4.7-2）に規定した項目は同じ方向に変動した場合とした］はなかった。

(2)　臨床的に重要なパラメータの変動

IM デポ剤安定期（Phase C）での臨床的に重要な生化学的検査値の変動が認められた被験者の割合を表 2.7.4.7-146 に示した。「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，臨床的に重要な血液学的検査値の変動が認められた被験者の割合が 5%以上に認められた項目はなかった。

(3)　血液学的検査結果に関連する有害事象

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，血液学的検査に関連する有害事象の発現割合は 1%未満であった（表 2.7.4.7-48）。血液学的検査に関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。

2.7.4.3.2.3　尿検査

IM デポ剤安定期（Phase C）での尿検査値の記述統計量を表 2.7.4.7-207 に示した。ベースラインからの変化量はいずれも小さく，臨床的に意味のある変化はなかった。また，臨床的に重要な尿検査値の変動が認められた被験者の割合も 5%未満であった（表 2.7.4.7-146）。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，尿検査結果に関連する有害事象も発現しなかった（表 2.7.4.7-48）。

2.7.4.3.3　長期投与試験

2.7.4.3.3.1　生化学的検査

(1)　パラメータの経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）での生化学的検査値の記述統計量を表 2.7.4.7-132 に示した。ベースライン値から Week 52 までの変化量が 10%以上変動した項目［臨床的に重要な臨床検査値（表 2.7.4.7-2）に規定した項目は同じ方向に変動した場合とした］は，CK（上昇），空腹時インスリン（上昇）であったが，ともにばらつきが大きく，CK はベースライン値から最終投与時で 10%以上減少，空腹時インスリンは Week 28 で 10%以上減少しており，臨床的に意味のある変化はなかった。

(2)　臨床的に重要なパラメータの変動

IM デポ剤維持治療期（Phase C）での臨床的に重要な生化学的検査値の変動が認められた被験

者の割合を表 2.7.4.7-149 に示した。「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，臨床的に重要な生化学的検査値の変動が認められた被験者の割合が 5%以上に認められた項目はなかった。

また，Hy's Law の基準に該当する被験者は認められなかった（表 2.7.4.7-216）。

(3) 生化学的検査結果に関連する有害事象

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，生化学的検査に関連する有害事象の発現割合は 2%未満であった（表 2.7.4.7-58）。生化学的検査結果に関連する有害事象のうち，重篤と判断された事象はなかった。肝機能検査値上昇により 1 例が治験薬の投与中止に至った。悪性症候群は発現しなかった（表 2.7.4.7-58）。

2.7.4.3.3.2 血液学的検査

(1) パラメータの経時的変化

IM デポ剤維持治療期（Phase C）での血液学的検査値の記述統計量を表 2.7.4.7-148 に示した。ベースライン値から Week 52 までの変化量が 10%以上変動した項目［臨床的に重要な臨床検査値（表 2.7.4.7-2）に規定した項目は同じ方向に変動した場合とした］はなかった。

(2) 臨床的に重要なパラメータの変動

IM デポ剤維持治療期（Phase C）での臨床的に重要な血液学的検査値の変動が認められた被験者の割合を表 2.7.4.7-149 に示した。臨床的に重要な血液学的検査値の変動が認められた被験者の割合が 5%以上に認められた項目はなかった。

(3) 血液学的検査結果に関連する有害事象

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，血液学的検査に関連する有害事象はなかった（表 2.7.4.7-58）。

2.7.4.3.3.3 尿検査

IM デポ剤維持治療期（Phase C）での尿検査値の記述統計量を表 2.7.4.7-208 に示した。ベースラインからの変化量はいずれも小さく，臨床的に意味のある変化はなかった。また，臨床的に重要な尿検査値の変動が認められた被験者の割合は 1%未満であった（表 2.7.4.7-149）。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，尿検査結果に関連する有害事象の発現割合は 1%未満であった（表 2.7.4.7-58）。

2.7.4.4　バイタルサイン，身体的所見及び安全性に関連する他の観察項目

2.7.4.4.1　バイタルサインの評価

本項では「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討したバイタルサイン項目以外の検討結果を示した。臨床的に重要なバイタルサインの変動が認められた被験者の割合を求める際の基準は表 2.7.4.7-3 に示した。

2.7.4.4.1.1　二重盲検試験の二重盲検期（Phase D）

(1)　パラメータの経時的変化

二重盲検試験の二重盲検期（Phase D）でのバイタルサインの記述統計量を表 2.7.4.7-115 に示した。バイタルサイン各項目の変化量は IM デポ群及びプラセボ群のいずれも小さく，群間に特記すべき違いはなく，臨床的に意味のある変化はなかった。

(2)　臨床的に重要なパラメータの変動及びバイタルサインパラメータに関連する有害事象

二重盲検期（Phase D）での臨床的に重要なバイタルサインの変動が認められた被験者の割合を表 2.7.4.7-150 に示した。臨床的に重要なバイタルサインの変動が認められた被験者の割合が 5%以上に認められた項目は IM デポ群及びプラセボ群でいずれもなかった。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，バイタルサインパラメータに関連する有害事象の発現割合は，IM デポ群及びプラセボ群のいずれも 2%未満であった（表 2.7.4.7-29）。バイタルサインパラメータに関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。

2.7.4.4.1.2　二重盲検試験の IM デポ剤安定期（Phase C）

(1)　パラメータの経時的変化

二重盲検試験の IM デポ剤安定期（Phase C）でのバイタルサインの記述統計量を表 2.7.4.7-119 に示した。バイタルサイン各項目の変化量はいずれも小さく，臨床的に意味のある変化はなかった。

(2)　臨床的に重要なパラメータの変動及びバイタルサインパラメータに関連する有害事象

IM デポ剤安定期（Phase C）での臨床的に重要なバイタルサインの変動が認められた被験者の割合を表 2.7.4.7-152 に示した。臨床的に重要なバイタルサインの変動が認められた被験者の割合が 5%以上に認められた項目はなかった。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，バイタルサインパラメータに関連する有害事象の発現割合は 1%未満であった（表 2.7.4.7-48）。バイタルサインパラメータに関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。

2.7.4.4.1.3　長期投与試験

(1)　パラメータの経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）でのバイタルサインの記述統計量を表 2.7.4.7-122 に示した。バイタルサイン各項目の変化量はいずれも小さく，臨床的に意味のある変化はなかった。

(2)　臨床的に重要なパラメータの変動及びバイタルサインパラメータに関連する有害事象

IM デポ剤維持治療期（Phase C）での臨床的に重要なバイタルサインの変動が認められた被験者の割合を表 2.7.4.7-154 に示した。臨床的に重要なバイタルサインの変動が認められた被験者の割合が 5%以上に認められた項目はなかった。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，「2.7.4.2.1.5 器官別又は症候群別有害事象の解析」で検討した臨床検査項目を除き，バイタルサインパラメータに関連する有害事象の発現割合は 1%未満であった（表 2.7.4.7-58）。バイタルサインパラメータに関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。

2.7.4.4.2　体重及び BMI の評価

体重及び BMI に関する結果は「2.7.4.2.1.5(2) 体重への影響」に示した。

2.7.4.4.3　心電図の評価

QT 間隔への影響に関する検討結果は「2.7.4.2.1.5(7) QT 間隔への影響」に示した。

臨床的に重要な心電図所見の変化は，臨床的に重要な心電図所見の変化の基準（表 2.7.4.7-4）及び心電図所見判定基準（表 2.7.4.7-5）に従い，変化が認められた被験者の割合を求めた。

なお，二重盲検試験の IM デポ剤安定期（Phase C）は，期間を 12 週間から 28 週間と設定していたため，パラメータの経時的変化を最終投与時で検討した。

2.7.4.4.3.1　二重盲検試験の二重盲検期（Phase D）

(1)　パラメータの経時的変化

二重盲検試験の二重盲検期（Phase D）での心電図パラメータの記述統計量を表 2.7.4.7-209 に示した。IM デポ群でベースライン値から Week 52 までの変化量が 10%以上変動した項目はなかった。

(2)　臨床的に重要なパラメータの変動及び心電図パラメータに関連する有害事象

二重盲検期（Phase D）での臨床的に重要な心電図所見の変化が認められた被験者の割合を表 2.7.4.7-212 に示した。臨床的に重要な心電図所見の変化が認められた被験者の割合が 5%以上に認められた項目は，IM デポ群及びプラセボ群のいずれもなかった。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，心電図パラメータに関連する有害事象の発現割合は，IM デポ群及びプラセボ群のいずれも 1%未満であった（表 2.7.4.7-29）。心電図パラメータに関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象は

なかった。

2.7.4.4.3.2　二重盲検試験の IM デポ剤安定期（Phase C）

(1)　パラメータの経時的変化

二重盲検試験の IM デポ剤安定期（Phase C）での心電図パラメータの記述統計量を表 2.7.4.7-210 に示した。ベースライン値から最終投与時までの変化量が 10%以上変動した項目はなかった。

(2)　臨床的に重要なパラメータの変動及び心電図パラメータに関連する有害事象

IM デポ剤安定期（Phase C）での臨床的に重要な心電図所見の変化が認められた被験者の割合を表 2.7.4.7-213 に示した。臨床的に重要な心電図所見の変化が認められた被験者の割合が 5%以上に認められた項目はなかった。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，心電図パラメータに関連する有害事象の発現割合は 1%未満であった（表 2.7.4.7-48）。心電図パラメータに関連する有害事象のうち，重篤と判断された事象，投与中止に至った事象はなかった。

2.7.4.4.3.3　長期投与試験

(1)　パラメータの経時的変化

長期投与試験の IM デポ剤維持治療期（Phase C）での心電図パラメータの記述統計量を表 2.7.4.7-211 に示した。ベースライン値から Week 52 までの変化量が 10%以上変動した項目はなかった。

(2)　臨床的に重要なパラメータの変動及び心電図パラメータに関連する有害事象

IM デポ剤維持治療期（Phase C）での臨床的に重要な心電図所見の変化が認められた被験者の割合を表 2.7.4.7-214 に示した。臨床的に重要な心電図所見の変化が認められた被験者の割合が 5%以上に認められた項目はなかった。

MedDRA の器官別大分類で臨床検査に分類される有害事象のうち，心電図パラメータに関連する有害事象の発現はなかった（表 2.7.4.7-58）。

2.7.4.5　特別な患者集団及び状況下における安全性

2.7.4.5.1　日本人集団での安全性

二重盲検試験では日本人の例数が限られているため，本項で詳細な解析は行わず，長期投与試験の日本人被験者（以下，日本人）の安全性に関して主に記載する。

なお，二重盲検試験には，40 例の日本人が組み入れられ，うち 19 例が無作為割付された（資料番号 5.3.5.1-01 CT-3.1.1 参照）。IM デポ群に割り付けられた日本人 9 例のうち，開始用量が 400 mg は 6 例，300 mg は 3 例であり，無作為化後に 400 mg から 300 mg に減量した被験者はなかった（表 2.7.4.7-217）。また，日本人で二重盲検期（Phase D）の IM デポ群及び IM デポ剤安定期（Phase C）に発現した有害事象の発現状況は，二重盲検期（Phase D）の IM デポ群全体及び IM デポ剤安定期（Phase C）の全体集団と比較して特記すべき懸念はなかった（表 2.7.4.7-218，表 2.7.4.7-219，表 2.7.4.7-220，表 2.7.4.7-221）。

長期投与試験では，除外基準としてスクリーニング登録時に大うつ病エピソードにある被験者を除外したため，スクリーニング登録時に躁病エピソード，軽躁病エピソード，混合性エピソード及び寛解期又は維持期にある患者が参加可能であった。なお，寛解期又は維持期にある患者の中には寛解期又は維持期に至る前に気分エピソードがうつ病の患者も含まれていた。長期投与試験での維持療法開始前の気分エピソードを「最も新しい気分エピソード」とし，日本人で最も新しいエピソードが躁病とうつ病の被験者での安全性の比較を行った。安全性を検討する際には，躁病エピソード，軽躁病エピソード，混合性エピソードを「躁病エピソード」とし，大うつ病エピソードを「うつ病エピソード」のカテゴリとした。なお，31-08-250 試験からの継続例は，31-08-250 試験スクリーニング開始時が躁病エピソードであるため，最も新しいエピソードは躁病として扱った。

長期投与試験の IM デポ剤維持治療期（Phase C）では日本人 75 例に IM デポ注射剤が投与された。75 例の最も新しいエピソードの分布は，最も新しいエピソードが躁病であった被験者が 39 例（うち 31-08-250 試験からの継続例 10 例），最も新しいエピソードが軽躁病エピソードであった被験者が 7 例，最も新しいエピソードが混合性エピソードであった被験者が 4 例，最も新しいエピソードがうつ病であった被験者が 25 例であった（表 2.7.4.7-222）。

2.7.4.5.1.1　長期投与試験の日本人集団での曝露状況

長期投与試験の日本人での IM デポ剤維持治療期（Phase C）の治験薬の曝露状況を表 2.7.4.5.1-1 に示した。用量を変更した被験者の割合を（表 2.7.4.7-223）にそれぞれ示した。

長期投与試験の IM デポ剤維持治療期（Phase C）では，75 例の日本人がアリピプラゾール IM デポ注射剤の投与を受けた。開始用量が 400 mg であった 74 例のうち 50 例の被験者が用量を変更しなかった。400 mg で開始し，300 mg に減量した後に増量しなかった被験者は 23 例であった。400 mg で開始し，300 mg に減量した後に 400 mg に増量した被験者は 1 例であった。開始用量が 300 mg であった 1 例は用量を変更しなかった。

IM デポ剤維持治療期（Phase C）では，84.0%（63/75 例）の被験者が 7 回以上投与され，64.0%（48/75 例）の被験者が 13 回以上投与された。

また，長期投与試験の新規被験者については全員，及び継続例については医師の判断により，IM デポ剤維持治療期（Phase C）開始後 2 週間はアリピプラゾール錠剤の投与も継続した（図 2.7.4.1.1-2 参照）。日本人に対しても，図 2.7.4.1.1-2 に示す用量でアリピプラゾール錠剤を投与した。IM デポ剤維持治療期（Phase C）でアリピプラゾール錠剤を併用した日本人は 65 例で，新規例全例であった（1 日平均用量 ± SD = 8.7 ± 3.0 mg）（表 2.7.4.7-224）。

表 2.7.4.5.1-1　　長期投与試験の日本人での IM デポ剤維持治療期（Phase C）の治験薬の曝露状況

	IMデポ剤維持治療期(Phase C)
	日本人集団 全体(75例)
	対象例数[a]
1回目	75 (100.0)
2回目	72 (96.0)
3回目	68 (90.7)
4回目	66 (88.0)
5回目	66 (88.0)
6回目	64 (85.3)
7回目	63 (84.0)
8回目	53 (70.7)
9回目	52 (69.3)
10回目	50 (66.7)
11回目	49 (65.3)
12回目	48 (64.0)
13回目	48 (64.0)

[a] 分母は，IM デポ剤維持治療期（Phase C）に割付けられた被験者数

＜資料番号 5.3.5.3-01：CT-7.2.1.1 より作成＞

2.7.4.5.1.2　日本人集団の被験者背景

長期投与試験の日本人の人口統計学的特性及び他の基準値の特性を表 2.7.4.7-226 及び表 2.7.4.7-227 に示した。

(1)　IM デポ剤維持治療期（Phase C）

IM デポ剤維持治療期（Phase C）75 例の年齢は 43.9 ± 10.2 歳（平均値 ± SD，以下同様），男性は 48.0%（36 例），女性は 52.0%（39 例），体重は 67.7± 13.7 kg であり，体重は全体集団と比べてやや軽い傾向であったが，その他の項目については長期投与試験の全体集団と類似していた。

IM デポ維持治療期（Phase C）のベースラインの YMRS 合計スコア，MADRS 合計スコア及び CGI-BP-S（躁病）の平均値はそれぞれ 0.8 ± 1.6，3.6 ± 3.9 及び 1.2 ± 0.5 であり，全体集団と類似していた。

(2) 錠剤安定期（Phase B）

錠剤安定期（Phase B）72 例の年齢は 44.5 ± 10.7 歳（平均値 ± SD，以下同様），男性は 48.6%（35 例），女性は 51.4%（37 例），体重は 67.4 ± 12.9 kg であり，体重は全体集団と比べてやや軽い傾向であったが，その他の項目については長期投与試験の全体集団と類似していた。

また，錠剤安定期（Phase B）72 例のベースラインの YMRS 合計スコア，MADRS 合計スコア及び CGI-BP-S（躁病）の平均値はそれぞれ 2.2 ± 4.8，4.6 ± 4.7 及び 1.4 ± 0.9 であり，全体集団と類似していた。

2.7.4.5.1.3 日本人集団で発現した有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

(1) 日本人全体

IM デポ剤維持治療期（Phase C）で発現した，日本人，日本人以外，全体での有害事象を，表 2.7.4.7-228，重症度別有害事象を表 2.7.4.7-229，重篤な有害事象を表 2.7.4.7-230，投与中止に至った有害事象を表 2.7.4.7-231 にそれぞれ示した。

IM デポ剤維持治療期（Phase C）の日本人での有害事象発現割合は，94.7%（71/75 例）であった。10%以上の被験者で発現した有害事象は，鼻咽頭炎 38.7%（29/75 例），双極 1 型障害 18.7%（14/75 例），アカシジア 18.7%（14/75 例），不眠症 14.7%（11/75 例），不安 13.3%（10/75 例），注射部位疼痛 13.3%（10/75 例），体重増加 16.0%（12/75 例）であり，全体集団での発現状況と顕著な違いは認められなかった。さらに，既承認エビリファイ錠 3 mg 他（双極性障害躁症状効能追加申請時）及び既承認エビリファイ持続性水懸筋注用 300 mg 他（新投与経路申請時）の CTD で報告した有害事象発現状況と比較して特記すべき事項はなかった。

重篤な有害事象は 2 例に発現した。事象はいずれも双極 1 型障害で，1 例は治験薬の投与を中止した。いずれも転帰は「回復」であった（表 2.7.4.7-247）。

投与中止に至った有害事象は 6 例に発現した。事象の内訳は双極 1 型障害 3 例，体重増加，筋萎縮，糖尿病がそれぞれ 1 例であった。

以上より，長期投与試験で得られた日本人での有害事象発現状況は全体集団と大きく異ならず，既承認エビリファイ錠 3 mg 他（双極性障害躁症状効能追加申請時）及び既承認エビリファイ持続性水懸筋注用 300 mg 他（新投与経路申請時）の CTD で報告した有害事象発現状況と比較して特記すべき事項はなかった。

(2) 最も新しい気分エピソード別

IM デポ剤維持治療期（Phase C）で発現した，日本人の最も新しいエピソード別での有害事象，重症度別有害事象，重篤な有害事象，投与中止に至った有害事象を，表 2.7.4.7-232，表 2.7.4.7-233，表 2.7.4.7-234，表 2.7.4.7-235 に示した。

なお，躁病エピソード，軽躁病エピソード，混合性エピソードを「躁病エピソード」とし，大うつ病エピソードを「うつ病エピソード」として，有害事象を検討した。

(a)　最も新しいエピソードが躁病の被験者

最も新しいエピソードが躁病の日本人が IM デポ剤維持治療期（Phase C）で発現した有害事象の発現割合は，92.0%（46/50 例）であった。10%以上の割合で発現した有害事象は，鼻咽頭炎 38.0%（19/50 例），アカシジア 18.0%（9/50 例），体重増加 20.0%（10/50 例），不安 14.0%（7/50 例），双極 1 型障害 14.0%（7/50 例），頭痛 14.0%（7/50 例），不眠症 12.0%（6/50 例）であった。

重篤な有害事象は 2 例に発現した。事象はいずれも双極 1 型障害で，転帰はいずれも「回復」であった（表 2.7.4.7-77，表 2.7.4.7-247）。

投与中止に至った有害事象は 4 例に発現した。事象の内訳は双極 1 型障害，体重増加，筋萎縮，糖尿病がそれぞれ 1 例であった。糖尿病は軽度であったが，それ以外の事象は中等度であった（表 2.7.4.7-236）。

(b)　最も新しいエピソードがうつ病の被験者

最も新しいエピソードがうつ病の日本人が IM デポ剤維持治療期（Phase C）で発現した有害事象の発現割合は，100.0%（25/25 例）であった。10%以上の被験者で発現した有害事象は，鼻咽頭炎 40.0%（10/25 例），双極 1 型障害 28.0%（7/25 例），注射部位疼痛 24.0%（6/25 例），不眠症 20.0%（5/25 例），アカシジア 20.0%（5/25 例），不安 12.0%（3/25 例），齲歯 12.0%（3/25 例），下痢 12.0%（3/25 例），倦怠感 12.0%（3/25 例）であった。

直近エピソードがうつ病の被験者では重篤な有害事象は発現しなかった。

投与中止に至った有害事象は 2 例に発現した。事象はいずれも双極 1 型障害で，中等度であった（表 2.7.4.7-236）。

(c)　結論

以上の結果から，最も新しいエピソードが躁病又はうつ病の被験者での有害事象の発現状況に大きな違いはなかった。また，最も新しいエピソードが躁病又はうつ病の被験者での有害事象の発現状況は，既承認エビリファイ錠 3 mg 他（双極性障害躁症状効能追加申請時）及び既承認エビリファイ持続性水懸筋注用 300 mg 他（新投与経路申請時）の申請時資料で報告した有害事象発現状況と比較して，特記すべき事項はなかった。

(3)　錠剤安定期の最終錠剤用量別

IM デポ剤維持治療期（Phase C）での有害事象を錠剤安定期（Phase B）の最終用量別に示した（表 2.7.4.7-237 参照）。

最終用量別の有害事象の発現割合は，12 mg/日で 97.2%（35/36 例），18 mg/日で 100.0%（13/13 例），24 mg/日で 100.0%（11/11 例），30 mg/日で 100.0%（5/5 例）であった。

重篤な有害事象は 12 mg/日で 2 例（双極 1 型障害 2 例）に発現した（表 2.7.4.7-238 参照）。

投与中止に至った有害事象は，12 mg/日で 11.1%（4/36 例）（双極 1 型障害 3 例，体重増加 1 例），18 mg/日で 0.0%（0/13 例），24 mg/日で 18.2%（2/11 例）（糖尿病，筋萎縮），30 mg/日で 0.0%（0/5 例）であった（表 2.7.4.7-239 参照）。

以上の結果から，錠剤投与の最終用量とアリピプラゾール IM デポ注射剤投与後の安全性に明

確な関連性はなく，特記すべき懸念は認められなかった。

2.7.4.5.2　内因性要因

年齢別・性別・BMI カテゴリ別の有害事象の結果は「2.7.4.2.1.1(1)(g) 人口統計学的及び他の基準値の特性別」に示した。IM デポ群及びプラセボ群共に，有害事象の発現割合は年齢，性別，BMI カテゴリ別，人種別で大きく異ならなかった。

2.7.4.5.3　外因性要因

2.7.4.5.3.1　地域ごとの有害事象

二重盲検試験の二重盲検期（Phase D）での地域ごとの有害事象を表 2.7.4.7-44 及び表 2.7.4.7-45 に示した。IM デポ群で発現した有害事象の発現割合は北米で他の地域と比べて高く［北米 82.4%（84/102 例），欧州 50.0%（6/12 例），日本 66.7%（6/9 例），日本以外のアジア 55.6%（5/9 例）］，プラセボ群での発現割合より高かった（プラセボ群の北米 77.5%，79/102 例）。北米以外の，欧州，日本，日本以外のアジアでは，IM デポ群の発現割合はプラセボ群より低かった［各地域のプラセボ群：欧州 100.0%（13/13 例），日本 80.0%（8/10 例），日本以外のアジア 87.5%（7/9 例）］。なお，日本人での安全性の詳細は「2.7.4.5.1 日本人集団での安全性」に示した。

2.7.4.5.4　薬物相互作用

アリピプラゾール IM デポ注射剤での薬物相互作用試験は実施していない。

統合失調症患者では，日本人と米国人との間でアリピプラゾール IM デポ注射剤投与時の薬物動態に顕著な差はなく［既承認エビリファイ持続性水懸筋注用 300 mg 他（新投与経路申請時）の CTD 2.7.2.3.1.2(3) 参照］，双極 I 型障害患者でも，日本人と日本人以外との間でアリピプラゾール IM デポ注射剤投与時の薬物動態に顕著な差はなかった（2.7.2.3.1.2）。また，統合失調症患者と双極 I 型障害患者間でアリピプラゾール IM デポ注射剤投与時の薬物動態に顕著な差はなかった（2.7.2.3.1.1）。したがって，日本人双極 I 型障害患者での薬物間相互作用が及ぼすアリピプラゾール IM デポ注射剤投与時の薬物動態への影響については，日本人統合失調症患者での影響［既承認エビリファイ持続性水懸筋注用 300 mg 他（新投与経路申請時）の CTD 2.7.2.3.1.9 参照］と同様と考えられる。

このため，現行の添付文書「用法・用量に関連する使用上の注意」及び「相互作用」と同様の注意が必要と考えられる。

2.7.4.5.5　妊娠及び授乳時の使用

二重盲検試験及び長期投与試験では妊婦，授乳中の女性，妊娠している可能性のある女性への投与は除外基準に設定していた。二重盲検試験では二重盲検期に IM デポ群で妊娠例は報告されなかった。二重盲検試験で，妊娠検査で陽性であった被験者が錠剤切り替え期（Phase A）で 1 例，錠剤安定期（Phase B）で 1 例，IM デポ剤安定期（Phase C）で 1 例の計 3 例認められた。これら 3 例の被験者はいずれも治験を中止した。2 例の被験者は治験中止後，妊娠に関する情報は得られなかった。錠剤安定期（Phase B）での 1 例は治験中止後，妊娠約 37 週に異常なく健康児を出産した。

長期投与試験では，錠剤安定期（Phase B）で 1 例，IM デポ剤維持治療期（Phase C）で 2 例，計 3 例の妊娠が報告された。2 例の被験者は治験中止後，妊娠に関する情報は得られなかった。IM デポ剤維持治療期（Phase C）の 1 例の被験者は中絶を選択し，治験薬の投与を完了した。

アリピプラゾール IM デポ注射剤はアリピプラゾール錠剤同様，妊娠中及び授乳中の投与に関する安全性は確立していないことから，妊婦又は妊娠している可能性のある患者，及び授乳中の患者には，治療上の有益性が危険性を上回ると判断される場合にのみ，投与されるべきである。

2.7.4.5.6　過量投与

二重盲検試験及び長期投与試験共にアリピプラゾール IM デポ注射剤 400 mg 又は 300 mg を一度に 2 倍量投与するなどの過量投与はなかった。長期投与試験の 2 例が，いずれも 1 回だけ 25 日間隔で投与されていたのを除き，ほとんどの IM デポ注射剤が 26 日以上の間隔で投与されていた（表 2.7.4.7-243，表 2.7.4.7-244，表 2.7.4.7-246，資料番号 5.3.5.1-01 PDATA-7.2）。

アリピプラゾール IM デポ注射剤は，医療従事者により投与されるため，複数・同科の病院に通院しているなど特別な場合を除き，過量投与の可能性は低いと考えられる。

なお，既に市販されているアリピプラゾール錠剤では，海外の臨床試験及び市販後自発報告では，最高 1260 mg まで偶発的又は企図的に急性過量投与された成人で嗜眠，傾眠，血圧上昇，頻脈，嘔吐等の症状が報告されているが，死亡例はない。また，最高 195 mg まで偶発的に服用した小児では，一過性の意識消失，傾眠等の症状が発現したが，死亡例はない。

2.7.4.5.7　薬物乱用

本申請のための試験では，薬物乱用に関して観察することを目的とした試験は実施していない。二重盲検試験及び長期投与試験では，薬物依存・多幸気分などの薬物乱用を示唆する有害事象の発現は認められなかった。

アリピプラゾール IM デポ注射剤は，医療従事者により投与されるため，乱用の可能性は低いと考えられる。

2.7.4.5.8　離脱症状及び反跳現象

本申請のための試験では，離脱症状及び反跳現象を観察することを目的とした試験は実施していない。

二重盲検試験及び長期投与試験では，二重盲検期終了，又は中止後 4 週後まで被験者の安全性を調査したが，二重盲検期（Phase D）終了，IM デポ剤維持治療期（Phase C）又は中止後は，アリピプラゾール錠剤を含む他の薬剤の使用を制限しなかったため，反跳現象についての評価は困難であった。

二重盲検試験の IM デポ剤安定期（Phase C）の有害事象発現割合は 68.5%，二重盲検期（Phase D）の IM デポ群では，76.5%であった（表 2.7.4.2.1-1）。二重盲検期（Phase D）の IM デポ群の発現割合はプラセボ群 80.5%より低かった。また，二重盲検試験の二重盲検期（Phase D）及び長期投与試験の IM デポ剤維持治療期（Phase C）の発現時期別の有害事象発現割合からも離脱症状及び反跳現象を示唆する結果は認められなかった。また，IM デポ剤安定期（Phase C）で 8 週間以上アリピプラゾール IM デポ注射剤の治療を受け，その後二重盲検期にプラセボ群に割付けられた

被験者でも，離脱症状や反跳現象を示唆する結果は認められなかった（表 2.7.4.7-215）。

2.7.4.5.9　自動車運転及び機械操作に対する影響又は精神機能の障害

本申請のための試験では，自動車運転及び機械操作に対する影響又は精神機能の障害を観察することを目的とした試験は実施していない。

二重盲検試験の IM デポ剤安定期（Phase C）では，傾眠 3.8%（16/425 例），鎮静 2.8%（12/425 例），浮動性めまい 1.2%（5/425 例）が発現した（表 2.7.4.7-48）。また，二重盲検期（Phase D）では，傾眠（IM デポ群 4.5%，6/132 例，プラセボ群 0.8%，1/133 例，以下同様），鎮静（1.5%, 2/132 例, 0.0%, 0/133 例），浮動性めまい（0.8%, 1/132 例, 1.5%, 2/133 例）が発現した（表 2.7.4.7-29）。これらの有害事象のうち，IM デポ群で発現した傾眠 1 例は投与中止に至った有害事象であった。重篤と判断された事象はなかった。

現行のアリピプラゾール IM デポ注射剤の添付文書には，これらの注意喚起を既に記載していることから，添付文書に記載されている内容と同様の注意が必要と考える。

2.7.4.6　市販後データ

本項では，20[redacted] 年 [redacted]月 [redacted] 日～20[redacted] 年 [redacted] 月 [redacted]日までに収集された安全性情報より作成されたアリピプラゾールの定期的ベネフィット・リスク評価報告（Periodic Benefit-Risk Evaluation Report, 以下 PBRER）第 [redacted] 版のうちアリピプラゾール IM デポ注射剤の安全性について記載した。

アリピプラゾールの最初の承認は，統合失調症治療用として 20[redacted] 年 [redacted] 月 [redacted] 日（[redacted]）にメキシコで取得された。

2.7.4.6.1　推定曝露患者数

20[redacted] 年 [redacted] 月 [redacted] 日までに販売されたアリピプラゾール IM デポ注射剤 300 mg は 168,070,255 mg，アリピプラゾール IM デポ注射剤 400 mg は 1,461,180,146 mg（主要な国のデータを元にした近似値）であり，患者 1 人あたり 0.5 年間でアリピプラゾール IM デポ注射剤 300 mg が計 1800 mg，アリピプラゾール IM デポ注射剤 400 mg が計 2400 mg 投与されたとすると，351,099 人・年の患者に投与されたと推定される。

2.7.4.6.2　国内及び海外で報告された重篤な副作用

20[redacted] 年 [redacted] 月 [redacted] 日～20[redacted] 年 [redacted] 月 [redacted] 日までに情報収集して作成された PBRER 第 [redacted] 版の重篤な副作用を表 2.7.4.7-249 に示した。

PBRER 第 [redacted] 版で収集されたアリピプラゾール IM デポ注射剤の自発報告の重篤な副作用は 892 件，市販後の非介入試験からの報告は 308 件である。このうち，多く報告された事象は，自発報告の重篤な副作用では入院 73 件，体重増加 20 件，自殺念慮 19 件，市販後の非介入試験からの報告では入院 58 件，精神症状 30 件，社会的入院 15 件であった。

2.7.4.6.3　本剤及び経口剤における突然死リスクについて

アリピプラゾール IM デポ注射剤（IM Depot）と経口剤について承認から 20[redacted] 年 [redacted] 月 [redacted] 日まで

に自発報告及び非介入の製造販売後調査の情報源より収集した副作用のうち，「突然死関連事象[a]」について，発現数及び PBRER に基づく推定曝露人年（person-years）を母数として 1,000 人年あたりの副作用報告率を表 2.7.4.6.3-1 に示した。

IM Depot と経口剤の突然死関連事象の副作用の発現数（1000 人年当たりの報告率，以下同様）は，Interval で IM Depot で 15 件（0.13），経口剤が 26 件（0.05）で，Cumulative で IM Depot が 152 件（0.43），経口剤が 831 件（0.07）であった。

事象別にみると，器官別大分類の一般・全身障害および投与部位の状態で「死亡」が Interval で IM Depot が 7 件（0.06）で，経口剤が 14 件（0.03）で，Cumulative で IM Depot が 66 件（0.19），経口剤が 339 件（0.03）で，器官別大分類の精神障害で「自殺既遂」が Interval で IM Depot が 8 件（0.07）で，経口剤が 12 件（0.02）で，Cumulative で IM Depot が 81 件（0.23），経口剤が 395 件（0.03）であった。

なお，主な各突然死関連事象について，各製剤の全副作用報告数に占める割合は，「死亡」は IM Depot が 0.3%（66/19,951），経口剤で 0.2%（339/166,260），「突然死」は IM Depot が 0.02%（4/19,951），経口剤で 0.03%（53/166,260），「自殺既遂」は IM Depot が 0.4%（81/19,951），経口剤で 0.2%（395/166,260）と両製剤の各事象報告率は類似していた。

以上より，本剤の突然死関連事象の報告率は経口剤に比べて高い傾向であった。

[a] 製造販売後における突然死のリスクを評価するため，MedDRA HLT「死亡および突然死」を「突然死関連事象」と定義した。

表 2.7.4.6.3-1　　国内外の市販後における突然死関連事象の副作用（推定曝露人年：IM Depot 351,099*，経口剤 11,442,081**）

		IM Depot				Oral			
		Interval*		Cumulative**		Interval*		Cumulative**	
Estimated exposure		119,029 person-years		351,099 person-years		553,537 person-years		11,442,081 person-years	
Number of reported ADRs Total		5,380		19,951		33,225		166,260	
Event System Organ Class	Event Preferred Term	Number of ADR (per 1,000 person-years)		Number of ADR (per 1,000 person-years)		Number of ADR (per 1,000 person-years)		Number of ADR (per 1,000 person-years)	
General disorders and administration site conditions	Accidental death	0	-	0	-	0	-	2	(0.0002)
	Brain death	0	-	0	-	0	-	5	(0.0004)
	Cardiac death	0	-	0	-	0	-	3	(0.0003)
	Death	7	(0.06)	66	(0.19)	14	(0.03)	339	(0.03)
	Drowning	0	-	0	-	0	-	5	(0.0004)
	Sudden cardiac death	0	-	1	(0.003)	0	-	13	(0.001)
	Sudden death	0	-	4	(0.01)	0	-	53	(0.005)
Pregnancy, puerperium and perinatal conditions	Foetal death	0	-	0	-	0	-	8	(0.0007)
	Stillbirth	0	-	0	-	0	-	8	(0.0007)
Psychiatric disorders	Completed suicide	8	(0.07)	81	(0.23)	12	(0.02)	395	(0.03)
Total (MedDRA HLT : Death and sudden death)		15	(0.13)	152	(0.43)	26	(0.05)	831	(0.07)

* ：　PBRER の推定曝露量（経口剤：[redacted]，IM Depot：[redacted] の 1 年間の販売量を根拠とする）

** ：　PBRER の推定曝露量（経口剤：[redacted]，IM Depot：[redacted] の集積期間の販売量を根拠とする）

＜資料番号 5.3.5.3-01：表 2.7.4.6.3-1＞

2.7.4.6.4　適応疾患別の突然死リスクについて

最新 PBRER（経口剤承認後 20[redacted] 年 [redacted] 月 [redacted] 日から 20[redacted] 年 [redacted] 月 [redacted] 日までの全ての期間〔Cumulative〕）の適応疾患が判断できる死亡症例 3,124 例における突然死の適応疾患ごとの例数を表 2.7.4.6.4-1，表 2.7.4.6.4-2 に示した。

本剤の突然死関連事象は発現例数順に，統合失調症では Death，Sudden death 及び Sudden cardiac death であり，双極性障害においては，Death のみであったことから，本剤の双極性障害投与において新たに見られた死因はなかった。

本薬経口剤の突然死関連事象は発現例数順に，統合失調症では Death，Sudden death，Sudden cardiac death, Cardiac Daeth, Accidental death 及び Drowning が見られ，双極性障害では，Death, Sudden

death 及び Sudden cardiac death であり，双極性障害への投与において新たに見られた死因はなかった。

また，突然死関連事象について，疾患ごとに本剤と本薬経口剤を比較すると，双極性障害への投与時に本薬経口剤と比較し本剤のみに見られた事象はなかった。統合失調症についても同様に，本薬経口剤と比較し本剤のみに見られた事象はなかった。

以上より，限られたデータのため結果の解釈には限界があるものの，対象疾患の違いによる本剤と本薬経口剤の突然死リスクに明確な差異は認められないと考えられた。

表 2.7.4.6.4-1　　適応疾患別の突然死の種類（本剤）

		統合失調症	双極性障害
Estimated exposure（person-years）		-	-
突然死　例数計		35 例	5 例
SOC	PT	例数	例数
General disorders and administration site conditions	Death	31	5
	Sudden cardiac death	1	0
	Sudden death	3	0

＜資料番号 5.3.5.3-01：表 2.7.4.6.4-1＞

表 2.7.4.6.4-2　　適応疾患別の突然死の種類（本薬経口剤）

		統合失調症	双極性障害
Estimated exposure（person-years）		-	-
突然死　例数計		66 例	32 例
SOC	PT	例数	例数
General disorders and administration site conditions	Accidental death	1	0
	Cardiac death	2	0
	Death	44	23
	Drowning	1	0
	Sudden cardiac death	4	3
	Sudden death	16	5

＜資料番号 5.3.5.3-01：表 2.7.4.6.4-2＞

2.7.4.7　付録

表 2.7.4.7-1 有害事象の定義

症候群別有害事象	基本語
錐体外路系関連	ジストニア症状: ジストニア, 前弯痙攣, 不随意性筋収縮, 筋固縮, 筋痙縮, 筋痙直, ミオトニー, 項部硬直, 眼球回転発作, 弓なり緊張, 側反弓, 痙笑, 斜頚, 開口障害 パーキンソン症状:無動, 固定姿勢保持困難, アテトーゼ, 運動緩慢, 歯車様固縮, 本態性振戦, 錐体外路障害, すくみ現象, 筋緊張亢進, 運動低下, 新生児運動減退, 企図振戦, 仮面状顔貌, パーキンソン病, パーキンソン発症, パーキンソン歩行, パーキンソン病安静時振戦, パーキンソニズム, 振戦 アカシジア症状:アカシジア, 運動過多, 新生児運動過多, 精神運動亢進 ジスキネジア症状: バリズム, 頬舌症候群, 舞踏病アテトーゼ, 不器用, ジスキネジア, 新生児ジスキネジア, 食道ジスキネジア, ファンブル, 頭部動揺, オンオフ現象, 遅発性ジスキネジア 残遺症状: 舞踏病, 間代, ハンチントン病, 筋攣縮, ミオクローヌス
自殺・自殺企図関連	自殺既遂, 希死念慮を有するうつ病, 家族性危険因子, 故意の自傷行為, 自殺行為, 自殺念慮, 自殺企図, 仲間の自殺, 近親者の自殺
注射部位反応関連	投与に伴う反応, 投与部位膿瘍, 投与部位感染, 投与部位疼痛, 投与部位発疹, 投与部位反応, 適用部位膿瘍, 適用部位ざ瘡, 適用部位脱毛, 適用部位知覚消失, 適用部位萎縮, 適用部位内出血, 適用部位熱傷, 適用部位蜂巣炎, 適用部位冷感*, 適用部位皮膚炎, 適用部位分泌物, 適用部位変色, 適用部位不快感, 適用部位乾燥, 適用部位湿疹, 適用部位びらん, 適用部位紅斑, 適用部位皮膚剥脱, 適用部位亀裂, 適用部位毛包炎, 適用部位血腫, 適用部位出血, 適用部位知覚過敏, 適用部位過敏反応, 適用部位硬結, 適用部位感染, 適用部位炎症, 適用部位刺激感, 適用部位腫瘤, 適用部位壊死, 適用部位結節, 適用部位臭, 適用部位浮腫, 適用部位疼痛, 適用部位蒼白, 適用部位丘疹, 適用部位異常感覚, 適用部位発汗, 適用部位光線過敏反応, 適用部位そう痒感, 適用部位膿疱, 適用部位発疹, 適用部位反応, 適用部位痂皮, 適用部位瘢痕, 適用部位腫脹, 適用部位毛細血管拡張症, 適用部位潰瘍, 適用部位蕁麻疹, 適用部位小水疱, 適用部位熱感, 薬剤性塞栓性皮膚症, 注射による四肢の運動低下, 注射部位膿瘍, 注射部位無菌性膿瘍, 注射部位知覚消失, 注射部位萎縮, 注射部位内出血, 注射部位石灰化, 注射部位蜂巣炎, 注射部位冷感, 注射部位嚢胞, 注射部位皮膚炎, 注射部位分泌物, 注射部位変色, 注射部位不快感, 注射部位乾燥, 注射部位知覚不全, 注射部位湿疹, 注射部位びらん, 注射部位紅斑, 注射部位皮膚剥脱, 注射部位漏出, 注射部位線維症, 注射部位関節発赤*, 注射部位肉芽腫, 注射部位血腫, 注射部位出血, 注射部位知覚過敏, 注射部位過敏反応, 注射部位肥厚, 注射部位硬結, 注射部位感染, 注射部位炎症, 注射部位損傷, 注射部位刺激感, 注射部位虚血, 注射部位関節不快感, 注射部位関節滲出液, 注射部位関節の炎症, 注射部位関節運動障害, 注射部位関節痛, 注射部位関節腫脹, 注射部位関節熱感, 注射部位裂傷, 注射部位リンパ節腫脹, 注射部位斑, 注射部位腫瘤, 注射部位運動障害, 注射部位壊死, 注射部位神経損傷, 注射部位結節, 注射部位浮腫, 注射部位疼痛, 注射部位蒼白, 注射部位丘疹, 注射部位知覚異常, 注射部位静脈炎, 注射部位光線過敏反応, 注射部位局面, 注射部位そう痒感, 注射部位膿疱, 注射部位発疹, 注射部位反応, 注射部位リコール反応, 注射部位痂皮, 注射部位瘢痕, 注射部位線条, 注射部位腫脹, 注射部位血栓, 注射部位潰瘍, 注射部位蕁麻疹, 注射部位血管炎, 注射部位小水疱, 注射部位熱感, 滴下投与部位合併症, 滴下投与部位不快感, 滴下投与部位乾燥, 滴下投与部位紅斑, 滴下投与部位異物感, 滴下投与部位刺激感, 滴下投与部位流涙, 滴下投与部位痛, 滴下投与部位異常感覚, 滴下投与部位そう痒感, 滴下投与部位反応, 注射部位からの吸収不良, 穿刺部位膿瘍, 穿刺部位分泌物, 穿刺部位出血, 穿刺部位硬結, 穿刺部位感染, 穿刺部位疼痛, 穿刺部位反応, 穿刺部位腫脹, 全身系への漏出, 血管穿刺部位知覚消失, 血管穿刺部位内出血, 血管穿刺部位分泌物, 血管穿刺部位血腫, 血管穿刺部位出血, 血管穿刺部位硬結, 血管穿刺部位感染, 血管穿刺部位炎症, 血管穿刺部位疼痛, 血管穿刺部位知覚異常, 血管穿刺部位そう痒感, 血管穿刺部位反応, 血管穿刺部位腫脹, 血管穿刺部位血栓
糖代謝関連	血中ブドウ糖, 血中ブドウ糖異常, 血中ブドウ糖減少, 血中ブドウ糖増加, 血中ブドウ糖正常, CSFブドウ糖, CSFブドウ糖減少, CSFブドウ糖増加, CSFブドウ糖正常, 耐糖能障害, ブドウ糖負荷試験, 尿中ブドウ糖, 尿中ブドウ糖陰性, 尿中ブドウ糖陽性, 滑液中ブドウ糖

表 2.7.4.7-1 有害事象の定義

症候群別有害事象	基本語
QT間隔延長関連	心電図QT間隔, 心電図QT間隔異常, 心電図QT間隔正常, 心電図QT延長, 心電図QT短縮, QT延長症候群, 先天性QT延長症候群
プロラクチン関連	血中プロラクチン, 血中プロラクチン異常, 血中プロラクチン減少, 血中プロラクチン増加, 血中プロラクチン正常, 異所性プロラクチン分泌, 高プロラクチン血症, 低プロラクチン血症, プロラクチン産生腫瘍, プロラクチン産生性下垂体腫瘍, 抗プロラクチン療法
白血球減少関連	無顆粒球症, 白血球減少症, 好中球減少症
起立性障害関連	起立血圧, 起立血圧異常, 起立血圧低下, 起立血圧上昇, 起立血圧正常, 体位性めまい, 重力性浮腫, 装具使用者, 起立時心拍数増加, 起立性高血圧, 起立性低血圧, 起立不耐性, 起立性蛋白尿症, 起立時振戦, 起立性頻脈症候群, 失神寸前の状態, 失神
脂質代謝関連	アポリポ蛋白B／アポリポ蛋白A－I比増加, 血中コレステロール異常, 血中コレステロール減少, 血中コレステロール増加, 血中トリグリセリド異常, 血中トリグリセリド減少, 血中トリグリセリド増加, 糖尿病性脂質異常症, 脂質異常症, 家族性高トリグリセリド血症, 高比重リポ蛋白異常, 高比重リポ蛋白減少, 高比重リポ蛋白増加, 高コレステロール血症, 低HDLコレステロール血症, 低トリグリセリド血症, 中間比重リポ蛋白減少, 中間比重リポ蛋白増加, LDL／HDL比減少, LDL／HDL比増加, 脂質代謝障害, 脂質異常, 脂質減少, 脂質増加, リポ蛋白(a)異常, リポ蛋白(a)減少, リポ蛋白(a)増加, 低比重リポ蛋白異常, 低比重リポ蛋白減少, 低比重リポ蛋白増加, レムナント高脂血症, 総コレステロール／HDL比異常, 総コレステロール／HDL比減少, 総コレステロール／HDL比増加, 1型高脂血症, 2型高脂血症, 5型高脂血症, 非高比重リポ蛋白コレステロール減少, 非高比重リポ蛋白コレステロール増加
体重関連	異常体重減少, 異常体重増加, 骨密度減少, ドライウェイト評価, 体重増加恐怖, 浮腫, 過体重, 過少体重, 体重異常, 体重管理, 体重減少, 体重変動, 体重増加不良, 体重増加, 減量食, 体重正常

*:LLT用語

MedDRA version 19.0

＜資料番号5.3.5.1-01:CT-8.2.5.1.1, CT-21.2.5.1.1, CT-8.2.5.2, CT-21.2.5.2, CT-8.2.5.3, CT-21.2.5.3, CT-8.2.5.4, CT-21.2.5.4, CT-8.2.5.5, CT-21.2.5.5, CT-8.2.5.6, CT-21.2.5.6, CT-8.2.5.7, CT-21.2.5.7, CT-8.2.5.8, CT-21.2.5.8, CT-8.2.5.9, CT-21.2.5.9, CT-8.2.5.10, CT-21.2.5.10より作成＞

表 2.7.4.7-2　臨床的に重要な臨床検査値の異常の基準

CT-10.3
Criteria for Laboratory Values of Potential Clinical Relevance

	LABORATORY TEST	POTENTIAL CLINICAL RELEVANCE CRITERION[1]
CHEMISTRY	ALANINE AMINOTRANSFERASE (U/L)	>= 3 x ULN
	ALKALINE PHOSPHATASE (U/L)	>= 3 x ULN
	ASPARTATE AMINOTRANSFERASE (U/L)	>= 3 x ULN
	BILIRUBIN (mg/dL)	>= 2.0 mg/dL
	BLOOD UREA NITROGEN (mg/dL)	>= 30 mg/dL
	CALCIUM (mg/dL)	>= 12 mg/dL OR <= 8.2 mg/dL
	CHLORIDE (mEq/L)	>= 118 mEq/L OR <= 90 mEq/L
	CHOLESTEROL, FASTING (mg/dL)	>= 240 mg/dL
	CREATINE KINASE (U/L)	>= 3 x ULN
	CREATININE (mg/dL)	>= 2.0 mg/dL
	GLUCOSE (mg/dL)	>= 200 mg/dL
	GLUCOSE, FASTING (mg/dL)	>= 115 mg/dL
	HDL CHOLESTEROL, FASTING (mg/dL)	<= 30 mg/dL
	LACTATE DEHYDROGENASE (U/L)	>= 3 x ULN
	LDL CHOLESTEROL, FASTING (mg/dL)	>= 160 mg/dL

[1]ULN = UPPER LIMIT OF THE NORMAL RANGE.

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表 2.7.4.7-2　臨床的に重要な臨床検査値の異常の基準

CT-10.3
Criteria for Laboratory Values of Potential Clinical Relevance

	LABORATORY TEST	POTENTIAL CLINICAL RELEVANCE CRITERION[1]
CHEMISTRY	POTASSIUM (mEq/L)	>= 5.5 mEq/L OR <= 3.0 mEq/L
	PROLACTIN (ng/mL)	> 1 x ULN
	SODIUM (mEq/L)	>= 156 mEq/L OR <= 126 mEq/L
	TRIGLYCERIDES, FASTING (mg/dL)	FEMALE >= 120 mg/dL MALE >= 160 mg/dL
	URATE (mg/dL)	FEMALE >= 8.5 mg/dL MALE >= 10.5 mg/dL
HEMATOLOGY	EOSINOPHILS/LEUKOCYTES (%)	>= 10%
	HEMATOCRIT (%)	<= 32% AND 3 POINT DECREASE FROM BASELINE <= 37% AND 3 POINT DECREASE FROM BASELINE
	HEMOGLOBIN (g/dL)	<= 11.5 g/dL <= 9.5 g/dL
	LEUKOCYTES (10^9/L)	>= 16.0 x10^3/uL OR <= 2.8 x10^3/uL
	NEUTROPHILS (10^9/L)	<= 1.5 x10^3/uL
	PLATELETS (10^9/L)	>= 700 x10^3/uL OR <= 75 x10^3/uL
URINALYSIS	GLUCOSE	INCREASE OF >= 2 UNITS
	PROTEIN	INCREASE OF >= 2 UNITS

[1]ULN = UPPER LIMIT OF THE NORMAL RANGE.

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表 2.7.4.7-3　臨床的に重要なバイタルサインの異常の基準

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CT-11.2
Criteria for Potentially Clinically Relevant Vital Sign Abnormalities

PARAMETER	POTENTIALLY CLINICALLY RELEVANT VITAL SIGN ABNORMALITY CRITERION
HEART RATE (BEATS/MIN)	> 120 BPM AND INCREASE >= 15 BPM < 50 BPM AND DECREASE >= 15 BPM
SYSTOLIC BLOOD PRESSURE (mmHg)	> 180 BPM AND INCREASE >= 20 BPM < 90 BPM AND DECREASE >= 20 BPM
DIASTOLIC BLOOD PRESSURE (mmHg)	> 105 BPM AND INCREASE >= 15 BPM < 50 BPM AND DECREASE >= 15 BPM
ORTHOSTATIC HYPOTENSION	>= 20 MMHG DECREASE IN SYSTOLIC BLOOD PRESSURE AND >= 25 BPM INCREASE IN HEART RATE FROM SUPINE TO SITTING
WEIGHT (kg)	INCREASE >= 7% DECREASE >= 7%
TEMPERATURE (°C)	>= 37.8°C AND INCREASE >= 1.1°C

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＜資料番号 5.3.5.1-01：CT-11.2＞

表 2.7.4.7-4　臨床的に重要な心電図所見の変化の基準

CT-12.2
Criteria for ECG Measurements of Potential Clinical Relevance

TYPE	PARAMETER	CRITERION VALUE	CHANGE RELATIVE TO BASELINE
RATE	TACHYCARDIA	>= 120 BPM	INCREASE >= 15 BPM
	BRADYCARDIA	<= 50 BPM	DECREASE >= 15 BPM
RHYTHM	SINUS TACHYCARDIA[1]	>= 120 BPM	INCREASE >= 15 BPM
	SINUS BRADYCARDIA[2]	<= 50 BPM	DECREASE >= 15 BPM
	SUPRAVENTRICULAR PREMATURE BEAT	PRESENT	NOT PRESENT TO PRESENT
	VENTRICULAR PREMATURE BEAT	PRESENT	NOT PRESENT TO PRESENT
	SUPRAVENTRICULAR TACHYCARDIA	PRESENT	NOT PRESENT TO PRESENT
	VENTRICULAR TACHYCARDIA	PRESENT	NOT PRESENT TO PRESENT
	ATRIAL FIBRILLATION	PRESENT	NOT PRESENT TO PRESENT
	ATRIAL FLUTTER	PRESENT	NOT PRESENT TO PRESENT
CONDUCTION	1° ATRIOVENTRICULAR BLOCK	PR >= 0.20 SECONDS	INCREASE >= 0.05 SECONDS
	2° ATRIOVENTRICULAR BLOCK	PRESENT	NOT PRESENT TO PRESENT
	3° ATRIOVENTRICULAR BLOCK	PRESENT	NOT PRESENT TO PRESENT
	LEFT BUNDLE BRANCH BLOCK	PRESENT	NOT PRESENT TO PRESENT
	RIGHT BUNDLE BRANCH BLOCK	PRESENT	NOT PRESENT TO PRESENT
	PRE-EXCITATION SYNDROME	PRESENT	NOT PRESENT TO PRESENT
	OTHER INTRAVENTRICULAR CONDUCTION BLOCK[3]	QRS >= 0.12 SECONDS	INCREASE >= 0.02 SECONDS
INFARCTION	ACUTE OR SUBACUTE	PRESENT	NOT PRESENT TO PRESENT
	OLD	PRESENT	NOT PRESENT TO PRESENT AT >= 12 WEEKS POST ENTRY INTO THE TRIAL
ST/T MORPHOLOGY	MYOCARDIAL ISCHEMIA	PRESENT	NOT PRESENT TO PRESENT
	SYMMETRICAL T-WAVE INVERSION	PRESENT	NOT PRESENT TO PRESENT

NOTE: A POST-BASELINE VALUE WILL BE JUDGED TO BE CLINICALLY RELEVANTLY ABNORMAL IF (1) IT MEETS THE CRITERION VALUE AND (2) ALSO REPRESENTS
A CHANGE FROM THE SUBJECT'S PRE-TREATMENT VALUE OF AT LEAST THE MAGNITUDE SHOWN IN THE 'CHANGE RELATIVE TO BASELINE' COLUMN.
[1]NO CURRENT DIAGNOSIS OF SUPRAVENTRICULAR TACHYCARDIA, VENTRICULAR TACHYCARDIA, ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR OTHER RHYTHM ABNORMALITY.
[2]NO CURRENT DIAGNOSIS OF ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR OTHER RHYTHM ABNORMALITY.
[3]NO CURRENT DIAGNOSIS OF LEFT BUNDLE BRANCH BLOCK OR RIGHT BUNDLE BRANCH BLOCK.

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表 2.7.4.7-4　臨床的に重要な心電図所見の変化の基準

CT-12.2
Criteria for ECG Measurements of Potential Clinical Relevance

TYPE	PARAMETER	CRITERION VALUE	CHANGE RELATIVE TO BASELINE
ST/T MORPHOLOGY	QTcB	QTcB >= 450 MSEC	>= 10% INCREASE
	QTcF	QTcF >= 450 MSEC	>= 10% INCREASE
	QTcN	QTcN >= 450 MSEC	>= 10% INCREASE

NOTE: A POST-BASELINE VALUE WILL BE JUDGED TO BE CLINICALLY RELEVANTLY ABNORMAL IF (1) IT MEETS THE CRITERION VALUE AND (2) ALSO REPRESENTS
A CHANGE FROM THE SUBJECT'S PRE-TREATMENT VALUE OF AT LEAST THE MAGNITUDE SHOWN IN THE 'CHANGE RELATIVE TO BASELINE' COLUMN.
[1]NO CURRENT DIAGNOSIS OF SUPRAVENTRICULAR TACHYCARDIA, VENTRICULAR TACHYCARDIA, ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR OTHER RHYTHM ABNORMALITY.
[2]NO CURRENT DIAGNOSIS OF ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR OTHER RHYTHM ABNORMALITY.
[3]NO CURRENT DIAGNOSIS OF LEFT BUNDLE BRANCH BLOCK OR RIGHT BUNDLE BRANCH BLOCK.

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表 2.7.4.7-5　臨床的に重要な心電図所見判定基準

CT-12.3
ECG Diagnosis Mapping for ECG Measurements of Potential Clinical Relevance

REPORTED		POTENTIALLY CLINICALLY SIGNIFICANT ECG ABNORMALITY	
ECG DIAGNOSIS GROUP	ECG DIAGNOSIS	DIAGNOSIS GROUP	DIAGNOSIS
ATRIOVENTRICULAR CONDUCTION	1ST DEGREE AV BLOCK	NOT APPLICABLE	NOT APPLICABLE
	AV MOBITZ I	CONDUCTION	2° ATRIOVENTRICULAR BLOCK
AXIS AND VOLTAGE	LOW QRS VOLTAGE	NOT APPLICABLE	NOT APPLICABLE
CHAMBER HYPERTROPHY OR ENLARGEMENT	LEFT ATRIAL ABNORMALITY	NOT APPLICABLE	NOT APPLICABLE
	LEFT VENTRICULAR HYPERTROPHY	NOT APPLICABLE	NOT APPLICABLE
INTRAVENTRICULAR-INTRAATRIAL CONDUCTION	INCOMPLETE RIGHT BUNDLE BRANCH BLOCK	CONDUCTION	RIGHT BUNDLE BRANCH BLOCK
	INTRAVENTRICULAR CONDUCTION DELAY, NONSPECIFIC	NOT APPLICABLE	NOT APPLICABLE
	LEFT ANTERIOR FASCICULAR BLOCK	CONDUCTION	LEFT BUNDLE BRANCH BLOCK
	RIGHT BUNDLE BRANCH BLOCK	CONDUCTION	RIGHT BUNDLE BRANCH BLOCK
MYOCARDIAL INFARCTION	OTHER	INFARCTION	ACUTE OR SUBACUTE
	SEPTAL MYOCARDIAL INFARCTION	INFARCTION	ACUTE OR SUBACUTE
RHYTHM	OTHER	NOT APPLICABLE	NOT APPLICABLE
SINUS NODE RHYTHMS AND ARRHYTHMIAS	SINUS BRADYCARDIA	NOT APPLICABLE	NOT APPLICABLE
	SINUS TACHYCARDIA	NOT APPLICABLE	NOT APPLICABLE
ST SEGMENT, T WAVE, AND U WAVE	QTC PROLONGATION	NOT APPLICABLE	NOT APPLICABLE
	ST DEPRESSION	ST/T MORPHOLOGY	MYOCARDIAL ISCHEMIA
	ST ELEVATION	ST/T MORPHOLOGY	MYOCARDIAL ISCHEMIA

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表 2.7.4.7-5　臨床的に重要な心電図所見判定基準

CT-12.3
ECG Diagnosis Mapping for ECG Measurements of Potential Clinical Relevance

REPORTED		POTENTIALLY CLINICALLY SIGNIFICANT ECG ABNORMALITY	
ECG DIAGNOSIS GROUP	ECG DIAGNOSIS	DIAGNOSIS GROUP	DIAGNOSIS
ST SEGMENT, T WAVE, AND U WAVE	T WAVE INVERSION	ST/T MORPHOLOGY	SYMMETRICAL T-WAVE INVERSION
	T WAVES BIPHASIC	ST/T MORPHOLOGY	SYMMETRICAL T-WAVE INVERSION
	T WAVES FLAT	NOT APPLICABLE	NOT APPLICABLE
SUPRAVENTRICULAR ARRHYTHMIAS	ATRIAL BIGEMINY	RHYTHM	SUPRAVENTRICULAR PREMATURE BEAT
	ECTOPIC ATRIAL RHYTHM	NOT APPLICABLE	NOT APPLICABLE
	JUNCTIONAL PREMATURE COMPLEX	NOT APPLICABLE	NOT APPLICABLE
	JUNCTIONAL RHYTHM	NOT APPLICABLE	NOT APPLICABLE
	PREMATURE ATRIAL COMPLEXES	RHYTHM	SUPRAVENTRICULAR PREMATURE BEAT
	WANDERING ATRIAL PACEMAKER	NOT APPLICABLE	NOT APPLICABLE
SUPRAVENTRICULAR TACHYARRHYTHMIAS	ATRIAL FIBRILLATION	RHYTHM	ATRIAL FIBRILLATION
	SUPRAVENTRICULAR TACHYCARDIA	RHYTHM	SUPRAVENTRICULAR TACHYCARDIA
VENTRICULAR ARRHYTHMIAS	PREMATURE VENTRICULAR COMPLEX	RHYTHM	VENTRICULAR PREMATURE BEAT
	VENTRICULAR BIGEMINY	NOT APPLICABLE	NOT APPLICABLE

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表 2.7.4.7-6　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤安定期（Phase C）］

CT-20.1.1
Extent of Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A, B and C
(Enrolled Sample)

		ARIP 5-15MG (N=466)						
				AVERAGE DAILY DOSE (MG)				
PHASE	TRIAL WEEK	n	(%)	MEAN	SD	MEDIAN	MIN	MAX
PHASE A	WEEK 1 (DAY 1-7)	459	(98.5)	9.0	6.4	5.0	2.1	30.0
	WEEK 2 (DAY 8-14)	448	(96.1)	13.1	6.1	10.0	0.0	30.0
	WEEK 3 (DAY 15-21)	437	(93.8)	16.1	5.8	15.0	3.6	34.3
	WEEK 4 (DAY 22-28)	415	(89.1)	17.9	5.6	15.0	5.0	30.0
	WEEK 5 (DAY 29-35)	293	(62.9)	19.5	6.5	20.0	0.0	40.0
	WEEK 6 (DAY 36-42)	174	(37.3)	20.7	6.9	20.0	5.0	33.3
	WEEK 7 (DAY 43-49)	41	(8.8)	20.5	6.7	20.0	8.6	30.0
	WEEK 8 (DAY 50-56)	2	(0.4)	20.0	14.1	20.0	10.0	30.0
	OVERALL DURING PHASE A	459	(98.5)	14.8	5.3	13.5	5.0	30.0

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED IN CORRESPONDING PHASE.

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表 2.7.4.7-6　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤安定期（Phase C）］

CT-20.1.1
Extent of Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A, B and C
(Enrolled Sample)

		ARIP 10-30MG (N=632)						
				AVERAGE DAILY DOSE (MG)				
PHASE	TRIAL WEEK	n	(%)	MEAN	SD	MEDIAN	MIN	MAX
PHASE B	WEEK 1 (DAY 1-7)	614	(97.2)	18.7	5.8	15.0	2.9	30.0
	WEEK 2 (DAY 8-14)	586	(92.7)	18.9	5.8	15.0	0.0	30.0
	WEEK 3 (DAY 15-21)	455	(72.0)	19.9	6.1	20.0	0.0	30.0
	WEEK 4 (DAY 22-28)	402	(63.6)	20.4	6.3	20.0	0.0	30.0
	WEEK 5 (DAY 29-35)	287	(45.4)	21.5	6.4	20.0	2.1	30.0
	WEEK 6 (DAY 36-42)	250	(39.6)	22.0	6.3	20.0	2.1	34.3
	WEEK 7 (DAY 43-49)	169	(26.7)	22.8	6.7	25.0	0.0	34.3
	WEEK 8 (DAY 50-56)	137	(21.7)	23.5	6.5	25.0	6.4	30.0
	WEEK 9 (DAY 57-63)	52	(8.2)	23.8	8.3	25.0	15.0	60.0
	OVERALL DURING PHASE B	614	(97.2)	19.8	5.6	19.2	3.8	30.5

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED IN CORRESPONDING PHASE.

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表 2.7.4.7-6　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A），錠剤安定期（Phase B），IM デポ剤安定期（Phase C）］

CT-20.1.1
Extent of Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A, B and C
(Enrolled Sample)

PHASE	TRIAL WEEK	ARIP 10-30MG (N=425) n	(%)	AVERAGE DAILY DOSE (MG) MEAN	SD	MEDIAN	MIN	MAX
PHASE C	WEEK 1 (DAY 1-7)	423	(99.5)	12.2	3.7	10.0	0.0	30.0
	WEEK 2 (DAY 8-14)	414	(97.4)	12.0	2.9	10.0	5.0	20.0
	WEEK 3 (DAY 15-21)	87	(20.5)	12.0	2.8	10.0	5.0	20.0
	>WEEK 3 (DAY 22-23)	1	(0.2)	10.0		10.0	10.0	10.0
	OVERALL DURING PHASE C	423	(99.5)	12.1	3.0	10.0	4.4	25.0

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED IN CORRESPONDING PHASE.

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＜資料番号 5.3.5.1-01：CT-20.1.1＞

表 2.7.4.7-7　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A）－錠剤安定期（Phase B）］

CT-20.1.2
Cumulative Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A and B
(Enrolled Sample)

		ARIP 5-30MG (N=731)		AVERAGE DAILY DOSE (MG)				
PHASE	TRIAL WEEK	n	(%)	MEAN	SD	MEDIAN	MIN	MAX
PHASE A-B	WEEK 1 (DAY 1-7)	720	(98.5)	11.5	6.4	10.0	2.1	30.0
	WEEK 2 (DAY 8-14)	696	(95.2)	14.2	5.7	15.0	0.0	30.0
	WEEK 3 (DAY 15-21)	652	(89.2)	17.0	5.7	15.0	3.6	34.3
	WEEK 4 (DAY 22-28)	604	(82.6)	18.5	5.4	17.9	5.0	30.0
	WEEK 5 (DAY 29-35)	535	(73.2)	20.1	6.1	20.0	0.0	34.3
	WEEK 6 (DAY 36-42)	499	(68.3)	20.7	6.3	20.0	0.0	33.3
	WEEK 7 (DAY 43-49)	395	(54.0)	21.3	6.6	20.0	0.0	30.0
	WEEK 8 (DAY 50-56)	337	(46.1)	21.7	6.8	20.0	0.0	30.0
	WEEK 9 (DAY 57-63)	223	(30.5)	21.5	7.4	20.0	0.0	60.0
	WEEK 10 (DAY 64-70)	151	(20.7)	21.6	7.0	20.0	6.4	34.3
	WEEK 11 (DAY 71-77)	121	(16.6)	22.0	7.2	20.0	0.0	30.0
	WEEK 12 (DAY 78-84)	91	(12.4)	22.8	6.9	25.0	10.7	34.3

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED.

表 2.7.4.7-7　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A）－錠剤安定期（Phase B）］

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CT-20.1.2
Cumulative Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A and B
(Enrolled Sample)

		ARIP 5-30MG (N=731)						
				AVERAGE DAILY DOSE (MG)				
PHASE	TRIAL WEEK	n	(%)	MEAN	SD	MEDIAN	MIN	MAX
PHASE A-B	WEEK 13 (DAY 85-91)	64	(8.8)	23.4	6.6	25.0	15.0	30.0
	WEEK 14 (DAY 92-98)	44	(6.0)	24.1	6.6	27.5	15.0	30.0
	>WEEK 14 (DAY 99-106)	12	(1.6)	21.4	7.0	18.1	15.0	30.0
	OVERALL	720	(98.5)	17.3	5.2	15.8	5.0	30.0

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED.

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表 2.7.4.7-8　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A）－IM デポ剤安定期（Phase C）］

CT-20.1.3
Cumulative Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A, B and C
(Enrolled Sample)

PHASE	TRIAL WEEK	ARIP 5-30MG (N=731) n	(%)	AVERAGE DAILY DOSE (MG) MEAN	SD	MEDIAN	MIN	MAX
PHASE A-C	WEEK 1 (DAY 1-7)	720	(98.5)	11.5	6.4	10.0	2.1	30.0
	WEEK 2 (DAY 8-14)	696	(95.2)	14.2	5.6	15.0	0.0	30.0
	WEEK 3 (DAY 15-21)	673	(92.1)	16.7	5.7	15.0	3.6	34.3
	WEEK 4 (DAY 22-28)	635	(86.9)	18.1	5.5	16.4	5.0	30.0
	WEEK 5 (DAY 29-35)	581	(79.5)	19.3	6.4	20.0	0.0	34.3
	WEEK 6 (DAY 36-42)	541	(74.0)	19.9	6.5	20.0	0.0	33.3
	WEEK 7 (DAY 43-49)	473	(64.7)	19.4	7.2	18.6	0.0	30.0
	WEEK 8 (DAY 50-56)	434	(59.4)	19.2	7.4	17.1	0.0	30.0
	WEEK 9 (DAY 57-63)	342	(46.8)	17.4	7.2	15.0	0.0	30.0
	WEEK 10 (DAY 64-70)	294	(40.2)	17.1	7.1	15.0	5.7	34.3
	WEEK 11 (DAY 71-77)	202	(27.6)	17.9	7.6	15.0	0.0	30.0
	WEEK 12 (DAY 78-84)	134	(18.3)	19.1	7.9	15.0	5.7	34.3

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED.

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表 2.7.4.7-8　アリピプラゾール錠剤の曝露量［二重盲検試験，錠剤切り替え期（Phase A）－IM デポ剤安定期（Phase C）］

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CT-20.1.3
Cumulative Exposure to Investigational Medicinal Product - Oral Aripiprazole Tablet in Phase A, B and C
(Enrolled Sample)

PHASE	TRIAL WEEK	ARIP 5-30MG (N=731) n	(%)	AVERAGE DAILY DOSE (MG) MEAN	SD	MEDIAN	MIN	MAX
PHASE A-C	WEEK 13 (DAY 85-91)	103	(14.1)	18.2	8.0	15.0	5.0	30.0
	WEEK 14 (DAY 92-98)	77	(10.5)	18.1	8.0	15.0	8.0	30.0
	WEEK 15 (DAY 99-105)	50	(6.8)	13.3	2.7	15.0	10.0	19.3
	WEEK 16 (DAY 106-112)	34	(4.7)	13.8	3.0	15.0	10.0	20.0
	>WEEK 16 (DAY 113-115)	8	(1.1)	12.5	2.7	12.5	10.0	15.0
	OVERALL	720	(98.5)	16.4	4.8	15.0	5.0	30.0

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED.

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表 2.7.4.7-9　アリピプラゾール IM デポ注射剤の各投与までの平均期間［二重盲検試験の二重盲検期（Phase D）］

CT-7.2.2
Descriptive Statistics for Trial Days of Aripiprazole IM Depot/Placebo Injections by Phase
(Phase D Safety Sample)

		PHASE D TREATMENT															
		ARIP IMD (N=132)						PLACEBO (N=133)						TOTAL (N=265)					
PHASE	INJECTION	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX
PHASE C	1ST INJECTION	132	1.0	0.1	1.0	1	2	133	1.0	0.1	1.0	1	2	265	1.0	0.1	1.0	1	2
	2ND INJECTION	132	29.3	1.8	29.0	27	39	133	29.5	1.8	29.0	27	44	265	29.4	1.8	29.0	27	44
	3RD INJECTION	132	57.5	2.0	57.0	54	67	133	57.5	2.2	57.0	55	73	265	57.5	2.1	57.0	54	73
	4TH INJECTION	40	87.6	4.9	86.0	83	111	27	87.2	4.4	85.0	84	105	67	87.5	4.7	86.0	83	111
	5TH INJECTION	30	116.4	5.3	116.5	112	140	12	114.9	2.6	114.5	111	119	42	116.0	4.7	115.5	111	140
	6TH INJECTION	14	144.9	7.2	144.5	139	168	4	143.5	2.9	143.5	141	146	18	144.6	6.5	144.5	139	168
	7TH INJECTION	3	170.7	2.1	170.0	169	173	2	171.0	2.8	171.0	169	173	5	170.8	2.0	170.0	169	173
	LAST INJECTION	132	76.6	32.9	57.0	55	173	133	67.2	22.8	57.0	55	173	265	71.9	28.6	57.0	55	173

表 2.7.4.7-9　アリピプラゾール IM デポ注射剤の各投与までの平均期間［二重盲検試験の二重盲検期（Phase D）］

CT-7.2.2
Descriptive Statistics for Trial Days of Aripiprazole IM Depot/Placebo Injections by Phase
(Phase D Safety Sample)

		PHASE D TREATMENT															
		ARIP IMD (N=132)						PLACEBO (N=133)						TOTAL (N=265)					
PHASE	INJECTION	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX
PHASE D	1ST INJECTION	132	1.0	0.0	1.0	1	1	133	1.0	0.0	1.0	1	1	265	1.0	0.0	1.0	1	1
	2ND INJECTION	120	29.7	1.8	29.0	27	38	111	29.4	1.3	29.0	27	34	231	29.5	1.6	29.0	27	38
	3RD INJECTION	105	57.9	2.2	57.0	55	66	97	57.7	1.8	57.0	55	64	202	57.8	2.0	57.0	55	66
	4TH INJECTION	99	86.0	2.2	85.0	83	94	87	86.2	2.6	85.0	83	99	186	86.1	2.4	85.0	83	99
	5TH INJECTION	87	114.0	2.8	113.0	111	129	81	114.2	2.3	113.0	111	124	168	114.1	2.5	113.0	111	129
	6TH INJECTION	85	142.2	3.2	141.0	138	156	72	142.2	2.4	141.0	139	152	157	142.2	2.9	141.0	138	156
	7TH INJECTION	82	170.5	3.5	169.0	166	186	65	170.5	2.7	169.0	167	180	147	170.5	3.2	169.0	166	186
	8TH INJECTION	78	198.4	3.4	197.0	194	217	57	198.3	2.8	197.0	195	208	135	198.4	3.1	197.0	194	217
	9TH INJECTION	73	226.3	2.8	225.0	223	239	53	227.2	4.1	225.0	223	248	126	226.7	3.4	225.0	223	248
	10TH INJECTION	70	254.8	3.0	253.0	251	267	51	255.6	4.9	253.0	251	281	121	255.1	3.9	253.0	251	281
	11TH INJECTION	69	282.7	3.0	281.0	279	295	49	284.1	5.0	282.0	279	309	118	283.3	4.0	281.0	279	309
	12TH INJECTION	68	310.7	3.0	309.0	306	323	46	312.0	5.2	310.0	307	337	114	311.2	4.1	309.5	306	337
	13TH INJECTION	65	338.8	3.2	337.0	334	351	41	339.8	3.7	338.0	335	349	106	339.2	3.4	338.0	334	351

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表 2.7.4.7-9　アリピプラゾール IM デポ注射剤の各投与までの平均期間［二重盲検試験の二重盲検期（Phase D）］

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CT-7.2.2
Descriptive Statistics for Trial Days of Aripiprazole IM Depot/Placebo Injections by Phase
(Phase D Safety Sample)

		PHASE D TREATMENT														
		ARIP IMD (N=132)						PLACEBO (N=133)						TOTAL (N=265)					
PHASE	INJECTION	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX
PHASE D	LAST INJECTION	132	215.3	137.6	311.5	1	351	133	173.3	136.2	143.0	1	349	265	194.2	138.3	197.0	1	351

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表 2.7.4.7-10　アリピプラゾール IM デポ注射剤の投与量を変更した被験者の割合［二重盲検試験の二重盲検期（Phase D）］

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CT-7.2.3
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=132)		PLACEBO (N=133)		TOTAL (N=265)	
PHASE	STARTING DOSE LEVEL	CHANGE	n	(%)	n	(%)	n	(%)
PHASE C	400 MG	NO CHANGE	111	(84.1)	115	(86.5)	226	(85.3)
		DECREASED	19	(14.4)	16	(12.0)	35	(13.2)
		DECREASED-INCREASED	2	(1.5)	2	(1.5)	4	(1.5)
PHASE D	400 MG	NO CHANGE	103	(78.0)	113	(85.0)	216	(81.5)
		DECREASED	8	(6.1)	5	(3.8)	13	(4.9)
		DECREASED-INCREASED	2	(1.5)	0	(0.0)	2	(0.8)
	300 MG	NO CHANGE	18	(13.6)	12	(9.0)	30	(11.3)
		INCREASED	1	(0.8)	3	(2.3)	4	(1.5)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS TREATED IN PHASE D.

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表 2.7.4.7-11　アリピプラゾール IM デポ注射剤の各投与までの平均期間［二重盲検試験の IM デポ剤安定期（Phase C）］

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CT-20.2.2
Descriptive Statistics for Trial Days of Aripiprazole IM Depot Injections in Phase C
(Phase C Safety Sample)

PHASE	INJECTION	ARIP IMD 400/300MG (N=425) n	MEAN	SD	MEDIAN	MIN	MAX
PHASE C	1ST INJECTION	425	1.0	0.1	1.0	1	2
	2ND INJECTION	377	29.5	2.5	29.0	27	65
	3RD INJECTION	352	57.6	2.1	57.0	54	73
	4TH INJECTION	105	87.3	4.2	85.0	83	111
	5TH INJECTION	67	116.0	4.5	115.0	111	140
	6TH INJECTION	36	144.3	5.4	143.0	139	168
	7TH INJECTION	8	171.4	2.3	171.5	169	174
	LAST INJECTION	425	64.2	38	57.0	1	174

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表 2.7.4.7-12　アリピプラゾール IM デポ注射剤の投与量を変更した被験者の割合［二重盲検試験の IM デポ剤安定期（Phase C）］

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CT-20.2.3
Descriptive Statistics for Starting and Ending Dose Level of Aripiprazole IM Depot in Phase C by Titration Pattern
(Phase C Safety Sample)

STARTING DOSE LEVEL	CHANGE	PHASE C (N=425) n	(%)
400 MG	NO CHANGE	366	(86.1)
	DECREASED	51	(12.0)
	DECREASED-INCREASED	8	(1.8)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS TREATED WITH ARIPIPRAZOLE IM DEPOT IN PHASE C.

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表 2.7.4.7-13　アリピプラゾール IM デポ注射剤の投与までの平均期間［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-7.2.2
Descriptive Statistics for Trial Days of Aripiprazole IM Depot Injections
(Phase C Enrolled Sample)

	ENROLLMENT SOURCE															
	DE NOVO (N=379)						ROLLOVER (N=85)						TOTAL (N=464)			
INJECTION	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX	n	MEAN	SD	MEDIAN	MIN	MAX
1ST IM DEPOT INJECTION	379	1.0	0.0	1	1	1	85	1.0	0.0	1	1	1	464	1.0	0.0	1	1	1
2ND IM DEPOT INJECTION	355	29.3	1.7	29	26	47	80	29.4	2.2	29	27	43	435	29.3	1.8	29	26	47
3RD IM DEPOT INJECTION	346	57.6	2.3	57	54	75	76	57.3	1.6	57	54	64	422	57.5	2.2	57	54	75
4TH IM DEPOT INJECTION	327	86.0	3.1	85	81	110	75	85.4	1.8	85	81	92	402	85.9	2.9	85	81	110
5TH IM DEPOT INJECTION	313	114.3	3.6	113	109	138	74	113.6	1.9	113	110	122	387	114.2	3.3	113	109	138
6TH IM DEPOT INJECTION	294	142.7	4.0	141	138	172	72	141.7	2.4	141	138	151	366	142.5	3.8	141	138	172
7TH IM DEPOT INJECTION	282	171.0	4.4	169	166	202	71	169.7	2.5	169	165	179	353	170.8	4.1	169	165	202
8TH IM DEPOT INJECTION	268	199.4	4.8	197	194	230	27	197.3	1.8	197	195	205	295	199.2	4.6	197	194	230
9TH IM DEPOT INJECTION	259	227.9	5.7	225	222	268	25	225.4	2.1	225	222	233	284	227.7	5.5	225	222	268
10TH IM DEPOT INJECTION	245	256.2	5.9	254	250	294	19	254.0	2.1	253	252	261	264	256.1	5.7	254	250	294
11TH IM DEPOT INJECTION	236	284.4	5.9	282	278	316	19	282.3	3.8	281	279	295	255	284.2	5.8	282	278	316
12TH IM DEPOT INJECTION	232	312.5	6.4	310	304	347	15	311.1	5.7	309	307	330	247	312.5	6.4	310	304	347
13TH IM DEPOT INJECTION	210	339.1	3.9	337	332	353	13	338.0	2.9	337	335	346	223	339.1	3.8	337	332	353

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表 2.7.4.7-14　アリピプラゾール IM デポ注射剤の投与量を変更した被験者の割合［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-7.2.3
Descriptive Statistics for Starting and Ending Dose Level of Aripiprazole IM Depot in Phase C
(Phase C Enrolled Sample)

		ENROLLMENT SOURCE					
		DE NOVO (N=379)		ROLLOVER (N=85)		TOTAL (N=464)	
STARTING DOSE LEVEL	CHANGE	n	(%)	n	(%)	n	(%)
400 MG	NO CHANGE	262	(69.1)	72	(84.7)	334	(72.0)
	DECREASED	105	(27.7)	12	(14.1)	117	(25.2)
	DECREASED-INCREASED	11	(2.9)	0	(0.0)	11	(2.4)
300 MG	NO CHANGE	1	(0.3)	1	(1.2)	2	(0.4)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED PHASE C.

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＜資料番号 5.3.5.2-01：CT-7.2.3＞

表 2.7.4.7-15　アリピプラゾール錠剤の曝露量［長期投与試験，IM デポ剤維持治療期（Phase C）］

CT-7.1
Extent of Exposure to Trial Medication - Aripiprazole Tablets
(Phase C Enrolled Sample)

		ENROLLMENT SOURCE					
		DE NOVO (N=379)					
				AVERAGE DAILY DOSE (MG)			
PHASE	TRIAL WEEK	n	(%)	MEAN	SD	MEDIAN	MIN	MAX
PHASE B	<= WEEK 1 (DAY 1-7)	379	(100.0)	18.0	5.2	15.0	10.0	30
	WEEK 2 (DAY 8-21)	379	(100.0)	18.0	5.3	15.0	4.3	30
	WEEK 4 (DAY 22-35)	379	(100.0)	18.6	5.4	17.1	9.3	30
	WEEK 6 (DAY 36-49)	149	(39.3)	19.8	5.8	20.0	10.0	30
	WEEK 8 (DAY 50-63)	96	(25.3)	20.4	6.2	20.0	9.6	30
	WEEK 10 (DAY 64-77)	56	(14.8)	21.5	6.5	20.0	12.9	30
	WEEK 12 (DAY 78-91)	27	(7.1)	23.3	6.7	25.0	15.0	30
	OVERALL DURING PHASE B	379	(100.0)	18.5	5.3	16.7	10.0	30

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED CORRESPONDING PHASE.

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表 2.7.4.7-15　アリピプラゾール錠剤の曝露量［長期投与試験，IM デポ剤維持治療期（Phase C）］

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CT-7.1
Extent of Exposure to Trial Medication - Aripiprazole Tablets
(Phase C Enrolled Sample)

		ENROLLMENT SOURCE																	
		DE NOVO (N=379)						ROLLOVER (N=85)						TOTAL (N=464)					
				AVERAGE DAILY DOSE (MG)						AVERAGE DAILY DOSE (MG)						AVERAGE DAILY DOSE (MG)					
PHASE	TRIAL WEEK	n	(%)	MEAN	SD	MEDIAN	MIN	MAX	n	(%)	MEAN	MEDIAN	MIN	MAX	n	(%)	MEAN	SD	MEDIAN	MIN	MAX
PHASE C	<= WEEK 1 (DAY 1-7)	378	(99.7)	10.9	3.2	10.0	3.4	30	1	(1.2)	15.0	15.0	15.0	15	379	(81.7)	10.9	3.2	10.0	3.4	30
	WEEK 2 (DAY 8-14)	369	(97.4)	10.6	2.7	10.0	4.3	25	1	(1.2)	15.0	15.0	15.0	15	370	(79.7)	10.6	2.7	10.0	4.3	25
	WEEK 3 (DAY 15-21)	76	(20.1)	10.4	2.1	10.0	5.0	15	0	(0.0)					76	(16.4)	10.4	2.1	10.0	5.0	15
	> WEEK 3 (DAY 22-24)	3	(0.8)	10.0	0.0	10.0	10.0	10	0	(0.0)					3	(0.6)	10.0	0.0	10.0	10.0	10
	OVERALL DURING PHASE C	378	(99.7)	10.7	2.8	10.0	4.5	25	1	(1.2)	15.0	15.0	15.0	15	379	(81.7)	10.7	2.8	10.0	4.5	25

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENTERED CORRESPONDING PHASE.

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表 2.7.4.7-16　被験者の内訳（二重盲検試験の全 Phase）

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CT-1.1.1
Subject Disposition (Enrolled Sample)

NUMBER OF SUBJECTS	PHASE A N (%)	PHASE B N (%)	PHASE C N (%)	PHASE D N (%)	TOTAL N (%)
SCREENED					1175
SCREEN FAILURE					444
ENTERED	466 (100.0)	632 (100.0)	425 (100.0)	266 (100.0)	731 (100.0)
DISCONTINUED	99 (21.2)	207 (32.8)	159 (37.4)	164 (61.7)	629 (86.0)
COMPLETED[1]	N/A	N/A	N/A	102 (38.3)	102 (14.0)
ENTERED NEXT PHASE	367 (78.8)	425 (67.2)	266 (62.6)	N/A	N/A
ANALYZED FOR SAFETY[2]	459 (98.5)	614 (97.2)	425 (100.0)	265 (99.6)	N/A
ANALYZED FOR EFFICACY[3]	N/A	588 (93.0)	425 (100.0)	265 (99.6)	N/A

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF ENROLLED SUBJECTS IN THE CORRESPONDING PHASE.
[1]SUBJECTS COMPLETED THE PHASE D WEEK 52 VISIT.
[2]SUBJECTS RECEIVING AT LEAST ONE DOSE OF TRIAL MEDICATION IN THE CORRESPONDING PHASE ARE INCLUDED IN THE SAFETY ANALYSIS.
[3]TREATED SUBJECTS EVALUATED FOR AT LEAST ONE EFFICACY ENDPOINT IN THE CORRESPONDING PHASE ARE INCLUDED IN THE EFFICACY ANALYSIS.

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PROGRAM: K:\OPC14597\P3108250\PROGRAM.DEV\ADSL2.SAS
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表 2.7.4.7-16　被験者の内訳（二重盲検試験の全 Phase）

CT-1.1.1
Subject Disposition (Enrolled Sample)

PHASE A (ARIP 5-15MG): CONVERSION FROM OTHER ANTIPSYCHOTICS TO ORAL ARIPIPRAZOLE MONOTHERAPY

PHASE B (ARIP 10-30MG): STABILIZATION ON ORAL ARIPIPRAZOLE

PHASE C (ARIP IMD 400/300MG): STABILIZATION ON IM DEPOT ARIPIPRAZOLE

PHASE D: IM DEPOT ARIPIPRAZOLE 400/300MG (ARIP IMD) OR PLACEBO DOUBLE BLIND RANDOMIZATION

＜資料番号 5.3.5.1-01：CT-1.1.1＞

表 2.7.4.7-17　被験者の内訳［二重盲検試験の二重盲検期（Phase D）］

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CT-1.1.2
Subject Disposition in Phase D (Phase D Randomized Sample)

	PHASE D TREATMENT		
	ARIP IMD	PLACEBO	TOTAL
NUMBER OF SUBJECTS	N (%)	N (%)	N (%)
RANDOMIZED	133 (100.0)	133 (100.0)	266 (100.0)
DISCONTINUED	69 (51.9)	95 (71.4)	164 (61.7)
COMPLETED	64 (48.1)	38 (28.6)	102 (38.3)
ANALYZED FOR SAFETY[1]	132 (99.2)	133 (100.0)	265 (99.6)
ANALYZED FOR EFFICACY[2]	132 (99.2)	133 (100.0)	265 (99.6)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
[1]SUBJECTS RECEIVING AT LEAST INJECTION IN PHASE D ARE INCLUDED IN THE SAFETY ANALYSIS.
[2]SUBJECTS RECEIVING AT LEAST ONE INJECTION IN PHASE D AND EVALUATED FOR AT LEAST ONE EFFICACY ENDPOINT IN PHASE D ARE INCLUDED IN THE EFFICACY ANALYSIS.

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＜資料番号 5.3.5.1-01：CT-1.1.2＞

表 2.7.4.7-18　被験者の内訳（長期投与試験の全 Phase）

CT-1.1.1
Subject Disposition
(Enrolled Sample)

ENROLLMENT SOURCE	NUMBER OF SUBJECTS	PHASE A N (%)	PHASE B N (%)	PHASE C N (%)	TOTAL N (%)
DE NOVO	SCREENED				958
	SCREEN FAILURE				295
	ENROLLED	501 (100.0)	555 (100.0)	379 (100.0)	663 (100.0)
	TREATED	498 (99.4)	540 (97.3)	379 (100.0)	655 (98.8)
	COMPLETED[1]	N/A	N/A	223 (58.8)	223 (33.6)
	DISCONTINUED	108 (21.6)	176 (31.7)	156 (41.2)	440 (66.4)
	ENTERED NEXT PHASE	393 (78.4)	379 (68.3)	N/A	N/A
	ANALYZED FOR SAFETY[2]	498 (99.4)	540 (97.3)	379 (100.0)	N/A
	ANALYZED FOR EFFICACY[3]	N/A	531 (95.7)	379 (100.0)	N/A
ROLLOVER	SCREENED				N/A
	SCREEN FAILURE				N/A
	ENROLLED			85 (100.0)	85 (100.0)
	TREATED			85 (100.0)	85 (100.0)
	COMPLETED[1]			68 (80.0)	68 (80.0)
	DISCONTINUED			17 (20.0)	17 (20.0)
	ENTERED NEXT PHASE			N/A	N/A
	ANALYZED FOR SAFETY[2]			85 (100.0)	N/A
	ANALYZED FOR EFFICACY[3]			85 (100.0)	N/A
TOTAL	SCREENED				958
	SCREEN FAILURE				295
	ENROLLED	501 (100.0)	555 (100.0)	464 (100.0)	748 (100.0)
	TREATED	498 (99.4)	540 (97.3)	464 (100.0)	740 (98.9)

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF ENROLLED SUBJECTS IN THE CORRESPONDING PHASE.
[1]SUBJECTS COMPLETED THE LAST SCHEDULED VISIT (I.E., WEEK 28, 32, 36, 40, 44, 48 AND 52) IN PHASE C.
[2]SUBJECTS RECEIVING AT LEAST ONE DOSE OF TRIAL MEDICATION IN THE CORRESPONDING PHASE ARE INCLUDED IN THE SAFETY ANALYSIS.
[3]SUBJECTS EVALUATED FOR AT LEAST ONE EFFICACY ENDPOINT IN THE CORRESPONDING PHASE ARE INCLUDED IN THE EFFICACY ANALYSIS.

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表 2.7.4.7-18　被験者の内訳（長期投与試験の全 Phase）

CT-1.1.1
Subject Disposition
(Enrolled Sample)

ENROLLMENT SOURCE	NUMBER OF SUBJECTS	PHASE A N	PHASE A (%)	PHASE B N	PHASE B (%)	PHASE C N	PHASE C (%)	TOTAL N	TOTAL (%)
TOTAL	COMPLETED[1]	N/A		N/A		291	(62.7)	291	(38.9)
	DISCONTINUED	108	(21.6)	176	(31.7)	173	(37.3)	457	(61.1)
	ENTERED NEXT PHASE	393	(78.4)	379	(68.3)	N/A		N/A	
	ANALYZED FOR SAFETY[2]	498	(99.4)	540	(97.3)	464	(100.0)	N/A	
	ANALYZED FOR EFFICACY[3]	N/A		531	(95.7)	464	(100.0)	N/A	

NOTE: PERCENTAGES ARE BASED ON THE NUMBER OF ENROLLED SUBJECTS IN THE CORRESPONDING PHASE.
[1]SUBJECTS COMPLETED THE LAST SCHEDULED VISIT (I.E., WEEK 28, 32, 36, 40, 44, 48 AND 52) IN PHASE C.
[2]SUBJECTS RECEIVING AT LEAST ONE DOSE OF TRIAL MEDICATION IN THE CORRESPONDING PHASE ARE INCLUDED IN THE SAFETY ANALYSIS.
[3]SUBJECTS EVALUATED FOR AT LEAST ONE EFFICACY ENDPOINT IN THE CORRESPONDING PHASE ARE INCLUDED IN THE EFFICACY ANALYSIS.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-1.1.1　FINAL

表 2.7.4.7-18　被験者の内訳（長期投与試験の全 Phase）

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CT-1.1.1
Subject Disposition
(Enrolled Sample)

PHASE A (ARIP 5-15MG, JAPAN SITES ARIP 6-12MG): CONVERSION FROM OTHER ANTIPSYCHOTICS TO ORAL ARIPIPRAZOLE MONOTHERAPY

PHASE B (ARIP 10-30MG, JAPAN SITES ARIP 12-30MG): STABILIZATION ON ORAL ARIPIPRAZOLE

PHASE C (ARIP IMD 400/300MG): OPEN LABEL IM DEPOT ARIPIPRAZOLE MAINTENANCE

ROLLOVER: SUBJECTS COMPLETED 31-08-250 TRIAL, ENROLLED INTO PHASE C (ARIP IMD 400/300MG - OPEN LABEL IM DEPOT ARIPIPRAZOLE MAINTENANCE)

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＜資料番号 5.3.5.2-01：CT-1.1.1＞

表 2.7.4.7-19　他の基準値の特性［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-3.2.1
Baseline Disease Severity (Enrolled Sample)

BASELINE CHARACTERISTICS		PHASE B (N=632)	PHASE C (N=425)	PHASE D (N=266)
YMRS TOTAL SCORE	N	632	425	266
	MEAN	16.9	5.8	2.8
	SD	10.5	4.1	3.3
	MEDIAN	17.0	6.0	2.0
	MIN	0	0	0
	MAX	44	28	12
MADRS TOTAL SCORE	N	632	425	266
	MEAN	5.7	3.7	2.7
	SD	6.0	4.1	3.4
	MEDIAN	4.0	2.0	1.0
	MIN	0	0	0
	MAX	40	28	12
MADRS SUICIDAL THOUGHTS SCORE	N	632	425	266
	MEAN	0.1	0.0	0.0
	SD	0.3	0.2	0.2
	MEDIAN	0.0	0.0	0.0
	MIN	0	0	0
	MAX	3	3	2
CGI-BP SEVERITY - MANIA	N	632	423	266
	MEAN	3.3	2.0	1.5
	SD	1.3	0.8	0.7
	MEDIAN	4.0	2.0	1.0
	MIN	1	1	1
	MAX	6	5	4

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B, C, AND D ARE INCLUDED RESPECTIVELY.

表 2.7.4.7-19　他の基準値の特性［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-3.2.1
Baseline Disease Severity (Enrolled Sample)

BASELINE CHARACTERISTICS		PHASE B (N=632)	PHASE C (N=425)	PHASE D (N=266)
CGI-BP SEVERITY - DEPRESSION	N	632	423	266
	MEAN	1.6	1.5	1.4
	SD	0.9	0.7	0.7
	MEDIAN	1.0	1.0	1.0
	MIN	1	1	1
	MAX	5	7	5
CGI-BP SEVERITY - OVERALL	N	632	423	266
	MEAN	3.4	2.1	1.7
	SD	1.2	0.8	0.7
	MEDIAN	4.0	2.0	2.0
	MIN	1	1	1
	MAX	6	5	4
CGI-BP CHANGE FROM PRECEEDING PHASE - MANIA	N		421	266
	MEAN		2.1	3.0
	SD		1.0	1.2
	MEDIAN		2.0	3.0
	MIN		1	1
	MAX		6	5
CGI-BP CHANGE FROM PRECEEDING PHASE - DEPRESSION	N		419	266
	MEAN		3.5	3.7
	SD		1.0	1.0
	MEDIAN		4.0	4.0
	MIN		1	1
	MAX		7	6

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B, C, AND D ARE INCLUDED RESPECTIVELY.

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表 2.7.4.7-19　他の基準値の特性［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-3.2.1
Baseline Disease Severity (Enrolled Sample)

BASELINE CHARACTERISTICS		PHASE C (N=425)	PHASE D (N=266)
CGI-BP CHANGE FROM PRECEEDING PHASE - OVERALL	N	421	266
	MEAN	2.2	3.0
	SD	1.0	1.2
	MEDIAN	2.0	3.0
	MIN	1	1
	MAX	5	5

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B, C, AND D ARE INCLUDED RESPECTIVELY.

表 2.7.4.7-19　他の基準値の特性［二重盲検試験の IM デポ剤安定期（Phase C）］

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CT-3.2.1
Baseline Disease Severity (Enrolled Sample)

BASELINE CHARACTERISTICS		PHASE B (N=632) n (%)	PHASE C (N=425) n (%)	PHASE D (N=266) n (%)
C-SSRS ACTIVE SUICIDAL IDEATION WITH SOME INTENT TO ACT WITHOUT SPECIFIC PLAN	NO	632 (100.0)	425 (100.0)	266 (100.0)
	YES	0 (0.0)	0 (0.0)	0 (0.0)
C-SSRS ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	NO	632 (100.0)	425 (100.0)	266 (100.0)
	YES	0 (0.0)	0 (0.0)	0 (0.0)
OUTPATIENT STATUS	YES		425 (100.0)	266 (100.0)
	NO		0 (0.0)	0 (0.0)

NOTE: THE CORRESPONDING ENROLLED SAMPLES IN THE PHASE B, C, AND D ARE INCLUDED RESPECTIVELY.

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＜資料番号 5.3.5.1-01：CT-3.2.1＞

表 2.7.4.7-20　人口統計学的特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.1.2
Demographic Characteristics by Sex
(Phase C Enrolled Sample)

PHASE	DEMOGRAPHIC CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO MALE (N=159)	DE NOVO FEMALE (N=220)	DE NOVO TOTAL (N=379)
PHASE B	AGE (YEARS)	N	159	220	379
		MEAN	42.5	39.8	40.9
		SD	12.0	11.9	12.0
		MEDIAN	44.0	39.0	41.0
		MIN	18.0	18.0	18.0
		MAX	65.0	66.0	66.0
	WEIGHT (KG)	N	159	219	378
		MEAN	91.3	81.5	85.6
		SD	23.8	24.4	24.6
		MEDIAN	86.8	77.5	82.0
		MIN	48.8	43.8	43.8
		MAX	189.1	181.0	189.1
	HEIGHT (CM)	N	159	220	379
		MEAN	176.4	163.2	168.7
		SD	8.0	7.7	10.2
		MEDIAN	176.0	163.0	168.0
		MIN	151.0	141.0	141.0
		MAX	196.0	187.0	196.0
	BODY MASS INDEX (kg/m²)	N	159	219	378

NOTE: AGE, WEIGHT AND BMI REPRESENT VALUES AT BASELINE OF PHASE B AND C RESPECTIVELY.

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表 2.7.4.7-20　人口統計学的特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.1.2
Demographic Characteristics by Sex
(Phase C Enrolled Sample)

PHASE	DEMOGRAPHIC CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO MALE (N=159)	DE NOVO FEMALE (N=220)	DE NOVO TOTAL (N=379)
PHASE B	BODY MASS INDEX (kg/m²)	MEAN	29.2	30.5	29.9
		SD	6.5	8.4	7.7
		MEDIAN	27.9	28.8	28.2
		MIN	18.0	17.2	17.2
		MAX	54.3	62.6	62.6

NOTE: AGE, WEIGHT AND BMI REPRESENT VALUES AT BASELINE OF PHASE B AND C RESPECTIVELY.

表 2.7.4.7-20　人口統計学的特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.1.2
Demographic Characteristics by Sex
(Phase C Enrolled Sample)

PHASE	DEMOGRAPHIC CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO MALE (N=159)	DE NOVO FEMALE (N=220)	DE NOVO TOTAL (N=379)	ROLLOVER MALE (N=37)	ROLLOVER FEMALE (N=48)	ROLLOVER TOTAL (N=85)	TOTAL MALE (N=196)	TOTAL FEMALE (N=268)	TOTAL TOTAL (N=464)
PHASE C	AGE (YEARS)	N	159	220	379	37	48	85	196	268	464
		MEAN	42.5	39.9	41.0	43.8	39.9	41.6	42.8	39.9	41.1
		SD	12.0	12.0	12.0	9.7	11.3	10.7	11.6	11.8	11.8
		MEDIAN	44.0	39.0	41.0	43.0	36.0	42.0	43.0	39.0	41.0
		MIN	18.0	18.0	18.0	21.0	25.0	21.0	18.0	18.0	18.0
		MAX	65.0	66.0	66.0	64.0	66.0	66.0	65.0	66.0	66.0
	WEIGHT (KG)	N	159	220	379	37	48	85	196	268	464
		MEAN	91.7	81.7	85.9	98.0	82.9	89.5	92.9	81.9	86.6
		SD	24.0	24.3	24.7	23.2	25.4	25.5	23.9	24.5	24.8
		MEDIAN	87.7	79.3	83.5	92.0	81.6	85.1	88.6	79.4	83.9
		MIN	46.2	43.4	43.4	60.1	46.2	46.2	46.2	43.4	43.4
		MAX	187.3	181.0	187.3	164.2	183.6	183.6	187.3	183.6	187.3
	BODY MASS INDEX (kg/m²)	N	159	220	379	37	48	85	196	268	464
		MEAN	29.3	30.6	30.0	30.6	31.2	30.9	29.5	30.7	30.2
		SD	6.5	8.4	7.7	6.2	9.4	8.1	6.5	8.5	7.7
		MEDIAN	28.1	28.8	28.5	28.8	29.4	29.4	28.4	28.9	28.6
		MIN	17.4	16.9	16.9	19.2	19.9	19.2	17.4	16.9	16.9
		MAX	55.1	62.6	62.6	46.0	67.4	67.4	55.1	67.4	67.4

NOTE: AGE, WEIGHT AND BMI REPRESENT VALUES AT BASELINE OF PHASE B AND C RESPECTIVELY.

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表 2.7.4.7-20　人口統計学的特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.1.2
Demographic Characteristics by Sex
(Phase C Enrolled Sample)

			ENROLLMENT SOURCE: DE NOVO					
PHASE	DEMOGRAPHIC CHARACTERISTICS		MALE (N=159) n	MALE (N=159) (%)	FEMALE (N=220) n	FEMALE (N=220) (%)	TOTAL (N=379) n	TOTAL (N=379) (%)
PHASE B	AGE (YEARS)[1]	< 45	84	(52.8)	133	(60.5)	217	(57.3)
		>= 45	75	(47.2)	87	(39.5)	162	(42.7)
	BMI (kg/m²)[1]	<18.5	1	(0.6)	5	(2.3)	6	(1.6)
		18.5 - <25	37	(23.3)	53	(24.1)	90	(23.7)
		25 - <30	70	(44.0)	66	(30.0)	136	(35.9)
		>=30	51	(32.1)	95	(43.2)	146	(38.5)
	BMI (kg/m²)[1]	<= 28	82	(51.6)	100	(45.5)	182	(48.0)
		> 28	77	(48.4)	119	(54.1)	196	(51.7)
	AGE (YEARS)[1]	18 - 64	157	(98.7)	218	(99.1)	375	(98.9)
		65 - 84	2	(1.3)	2	(0.9)	4	(1.1)

[1]PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL SUBJECTS ENROLLED IN PHASE C.

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表 2.7.4.7-20　人口統計学的特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.1.2
Demographic Characteristics by Sex
(Phase C Enrolled Sample)

PHASE	DEMOGRAPHIC CHARACTE-RISTICS		ENROLLMENT SOURCE: DE NOVO MALE (N=159) n (%)	DE NOVO FEMALE (N=220) n (%)	DE NOVO TOTAL (N=379) n (%)	TOTAL MALE (N=196) n (%)	TOTAL FEMALE (N=268) n (%)	TOTAL TOTAL (N=464) n (%)	ROLLOVER MALE (N=37) n (%)	ROLLOVER FEMALE (N=48) n (%)	ROLLOVER TOTAL (N=85) n (%)
PHASE C	AGE (YEARS)[1]	< 45	84 (52.8)	133 (60.5)	217 (57.3)	106 (54.1)	165 (61.6)	271 (58.4)	22 (59.5)	32 (66.7)	54 (63.5)
		>= 45	75 (47.2)	87 (39.5)	162 (42.7)	90 (45.9)	103 (38.4)	193 (41.6)	15 (40.5)	16 (33.3)	31 (36.5)
	BMI (kg/m²)[1]	<18.5	1 (0.6)	8 (3.6)	9 (2.4)	1 (0.5)	8 (3.0)	9 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)
		18.5 - <25	40 (25.2)	48 (21.8)	88 (23.2)	46 (23.5)	65 (24.3)	111 (23.9)	6 (16.2)	17 (35.4)	23 (27.1)
		25 - <30	60 (37.7)	68 (30.9)	128 (33.8)	76 (38.8)	76 (28.4)	152 (32.8)	16 (43.2)	8 (16.7)	24 (28.2)
		>=30	58 (36.5)	96 (43.6)	154 (40.6)	73 (37.2)	119 (44.4)	192 (41.4)	15 (40.5)	23 (47.9)	38 (44.7)
	BMI (kg/m²)[1]	<= 28	77 (48.4)	98 (44.5)	175 (46.2)	91 (46.4)	117 (43.7)	208 (44.8)	14 (37.8)	19 (39.6)	33 (38.8)
		> 28	82 (51.6)	122 (55.5)	204 (53.8)	105 (53.6)	151 (56.3)	256 (55.2)	23 (62.2)	29 (60.4)	52 (61.2)
	AGE (YEARS)[1]	18 - 64	156 (98.1)	218 (99.1)	374 (98.7)	193 (98.5)	265 (98.9)	458 (98.7)	37(100.0)	47 (97.9)	84 (98.8)
		65 - 84	3 (1.9)	2 (0.9)	5 (1.3)	3 (1.5)	3 (1.1)	6 (1.3)	0 (0.0)	1 (2.1)	1 (1.2)

[1]PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL SUBJECTS ENROLLED IN PHASE C.

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表 2.7.4.7-20　人口統計学的特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-3.1.2
Demographic Characteristics by Sex
(Phase C Enrolled Sample)

DEMOGRAPHIC CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO MALE (N=159) n	(%)	DE NOVO FEMALE (N=220) n	(%)	DE NOVO TOTAL (N=379) n	(%)	ROLLOVER MALE (N=37) n	(%)	ROLLOVER FEMALE (N=48) n	(%)	ROLLOVER TOTAL (N=85) n	(%)	TOTAL MALE (N=196) n	(%)	TOTAL FEMALE (N=268) n	(%)	TOTAL TOTAL (N=464) n	(%)
RACE[1]	WHITE	90	(56.6)	126	(57.3)	216	(57.0)	17	(45.9)	22	(45.8)	39	(45.9)	107	(54.6)	148	(55.2)	255	(55.0)
	BLACK OR AFRICAN AMERICAN	28	(17.6)	49	(22.3)	77	(20.3)	12	(32.4)	15	(31.3)	27	(31.8)	40	(20.4)	64	(23.9)	104	(22.4)
	AMERICAN INDIAN OR ALASKA NATIVE	0	(0.0)	1	(0.5)	1	(0.3)	0	(0.0)	1	(2.1)	1	(1.2)	0	(0.0)	2	(0.7)	2	(0.4)
	ASIAN	37	(23.3)	41	(18.6)	78	(20.6)	8	(21.6)	8	(16.7)	16	(18.8)	45	(23.0)	49	(18.3)	94	(20.3)
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1	(0.6)	1	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)	1	(0.4)	2	(0.4)
	OTHER	3	(1.9)	2	(0.9)	5	(1.3)	0	(0.0)	2	(4.2)	2	(2.4)	3	(1.5)	4	(1.5)	7	(1.5)
ETHNICITY[1]	HISPANIC OR LATINO	9	(5.7)	15	(6.8)	24	(6.3)	4	(10.8)	1	(2.1)	5	(5.9)	13	(6.6)	16	(6.0)	29	(6.3)
	NOT HISPANIC OR LATINO	150	(94.3)	205	(93.2)	355	(93.7)	33	(89.2)	47	(97.9)	80	(94.1)	183	(93.4)	252	(94.0)	435	(93.8)
REGION[1]	NORTH AMERICA	110	(69.2)	155	(70.5)	265	(69.9)	26	(70.3)	34	(70.8)	60	(70.6)	136	(69.4)	189	(70.5)	325	(70.0)
	EUROPE	13	(8.2)	26	(11.8)	39	(10.3)	3	(8.1)	5	(10.4)	8	(9.4)	16	(8.2)	31	(11.6)	47	(10.1)
	JAPAN	30	(18.9)	35	(15.9)	65	(17.2)	6	(16.2)	4	(8.3)	10	(11.8)	36	(18.4)	39	(14.6)	75	(16.2)
	OTHER ASIAN COUNTRIES	6	(3.8)	4	(1.8)	10	(2.6)	2	(5.4)	5	(10.4)	7	(8.2)	8	(4.1)	9	(3.4)	17	(3.7)
SEX[1]	MALE	159	(100.0)	0	(0.0)	159	(42.0)	37	(100.0)	0	(0.0)	37	(43.5)	196	(100.0)	0	(0.0)	196	(42.2)
	FEMALE	0	(0.0)	220	(100.0)	220	(58.0)	0	(0.0)	48	(100.0)	48	(56.5)	0	(0.0)	268	(100.0)	268	(57.8)

[1]PERCENTAGES ARE BASED ON THE NUMBER OF MALE, FEMALE OR TOTAL SUBJECTS ENROLLED IN PHASE C.

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＜資料番号 5.3.5.2-01：CT-3.1.2＞

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379)	ROLLOVER (N = 85)	TOTAL (N = 464)
AGE AT FIRST MANIC EPISODE	N	376	85	461
	MEAN	24.9	25.3	25.0
	SD	10.5	9.9	10.4
	MEDIAN	22.5	23.0	23.0
	MIN	2	10	2
	MAX	64	55	64
AGE AT FIRST MIXED EPISODE	N	239	40	279
	MEAN	27.2	26.6	27.1
	SD	11.2	10.5	11.1
	MEDIAN	25.0	25.0	25.0
	MIN	4	13	4
	MAX	57	53	57
AGE AT FIRST DEPRESSIVE EPISODE	N	355	75	430
	MEAN	23.9	24.8	24.1
	SD	10.5	9.9	10.4
	MEDIAN	22.0	23.0	22.0
	MIN	3	7	3
	MAX	60	57	60
NUMBER OF MOOD EPISODES PAST 12 MONTHS	N	378	85	463
	MEAN	2.1	2.2	2.1
	SD	1.8	1.3	1.7
	MEDIAN	2.0	2.0	2.0
	MIN	0	1	0
	MAX	8	8	8

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379)	ROLLOVER (N = 85)	TOTAL (N = 464)
NUMBER OF MOOD EPISODES LAST 10 YEARS	N	363	85	448
	MEAN	13.6	10.3	13.0
	SD	15.8	13.9	15.5
	MEDIAN	8.0	5.0	7.0
	MIN	0	2	0
	MAX	100	80	100
NUMBER OF MANIC EPISODES LIFETIME	N	371	85	456
	MEAN	11.2	10.7	11.1
	SD	17.8	26.9	19.8
	MEDIAN	5.0	4.0	5.0
	MIN	0	1	0
	MAX	120	240	240
NUMBER OF MIXED EPISODES LIFETIME	N	351	83	434
	MEAN	5.5	2.8	5.0
	SD	12.5	6.2	11.6
	MEDIAN	2.0	0.0	1.0
	MIN	0	0	0
	MAX	120	30	120
NUMBER OF DEPRESSIVE EPISODES LIFETIME	N	368	84	452
	MEAN	10.3	5.4	9.4
	SD	17.7	7.6	16.4
	MEDIAN	4.0	3.0	4.0
	MIN	0	0	0
	MAX	123	38	123

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379)	ROLLOVER (N = 85)	TOTAL (N = 464)
NUMBER OF PRIOR HOSPITALIZATIONS FOR A MOOD EPISODE	N	375	85	460
	MEAN	2.5	2.7	2.5
	SD	3.2	3.1	3.2
	MEDIAN	1.0	2.0	2.0
	MIN	0	0	0
	MAX	23	12	23
AGE AT FIRST BIPOLAR I DIAGNOSIS	N	379	85	464
	MEAN	29.3	28.1	29.1
	SD	11.8	11.5	11.7
	MEDIAN	28.0	25.0	27.0
	MIN	6	4	4
	MAX	64	54	64
DURATION OF DISEASE PRIOR TO ENROLLMENT (YEARS)	N	379	85	464
	MEAN	11.5	13.6	11.9
	SD	9.5	9.4	9.5
	MEDIAN	9.4	11.9	10.1
	MIN	0	2	0
	MAX	45	40	45
DURATION OF DISEASE PRIOR TO ENROLLMENT (DAYS)	N	379	85	464
	MEAN	4204.9	4957.7	4342.8
	SD	3459.2	3421.6	3460.9
	MEDIAN	3416.0	4340.0	3674.0
	MIN	14	720	14
	MAX	16237	14704	16237

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		ENROLLMENT SOURCE DE NOVO (N = 379)
PHASE B	YMRS TOTAL SCORE	N	379
		MEAN	5.0
		SD	6.1
		MEDIAN	3.0
		MIN	0
		MAX	36
	MADRS TOTAL SCORE	N	379
		MEAN	6.1
		SD	6.4
		MEDIAN	4.0
		MIN	0
		MAX	48
	MADRS SUICIDAL THOUGHTS SCORE	N	379
		MEAN	0.1
		SD	0.4
		MEDIAN	0.0
		MIN	0
		MAX	3
	CGI-BP SEVERITY - MANIA	N	379
		MEAN	2.0
		SD	1.1
		MEDIAN	2.0
		MIN	1

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		ENROLLMENT SOURCE DE NOVO (N = 379)
PHASE B	CGI-BP SEVERITY - MANIA	MAX	6
	CGI-BP SEVERITY - DEPRESSION	N	379
		MEAN	2.0
		SD	1.0
		MEDIAN	2.0
		MIN	1
		MAX	6
	CGI-BP SEVERITY - OVERALL BIPOLAR ILLNESS	N	379
		MEAN	2.3
		SD	1.1
		MEDIAN	2.0
		MIN	1
		MAX	6

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379)	ROLLOVER (N = 85)	TOTAL (N = 464)
PHASE C	YMRS TOTAL SCORE	N	379	85	464
		MEAN	2.3	2.4	2.3
		SD	2.7	3.3	2.9
		MEDIAN	1.0	0.0	1.0
		MIN	0	0	0
		MAX	11	12	12
	MADRS TOTAL SCORE	N	379	85	464
		MEAN	3.6	1.7	3.2
		SD	3.2	2.8	3.2
		MEDIAN	3.0	0.0	2.0
		MIN	0	0	0
		MAX	12	13	13
	MADRS SUICIDAL THOUGHTS SCORE	N	379	85	464
		MEAN	0.0	0.0	0.0
		SD	0.2	0.2	0.2
		MEDIAN	0.0	0.0	0.0
		MIN	0	0	0
		MAX	2	1	2
	CGI-BP SEVERITY - MANIA	N	379	85	464
		MEAN	1.5	1.4	1.5
		SD	0.8	0.6	0.8
		MEDIAN	1.0	1.0	1.0
		MIN	1	1	1
		MAX	4	3	4

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379)	ROLLOVER (N = 85)	TOTAL (N = 464)
PHASE C	CGI-BP SEVERITY - DEPRESSION	N	379	85	464
		MEAN	1.7	1.3	1.6
		SD	0.9	0.6	0.8
		MEDIAN	1.0	1.0	1.0
		MIN	1	1	1
		MAX	4	3	4
	CGI-BP SEVERITY - OVERALL BIPOLAR ILLNESS	N	379	85	464
		MEAN	1.8	1.5	1.7
		SD	0.9	0.6	0.8
		MEDIAN	2.0	1.0	2.0
		MIN	1	1	1
		MAX	4	3	4
	CGI-BP CHANGE FROM PRECEDING PHASE - MANIA	N	377	85	462
		MEAN	2.8	3.7	2.9
		SD	1.2	0.8	1.2
		MEDIAN	3.0	4.0	3.0
		MIN	1	1	1
		MAX	5	5	5
	CGI-BP CHANGE FROM PRECEDING PHASE - DEPRESSION	N	379	85	464
		MEAN	2.9	3.8	3.0
		SD	1.2	0.8	1.2
		MEDIAN	3.0	4.0	3.0
		MIN	1	1	1
		MAX	5	5	5

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379)	ROLLOVER (N = 85)	TOTAL (N = 464)
PHASE C	CGI-BP CHANGE FROM PRECEDING PHASE - OVERALL	N	379	85	464
		MEAN	2.8	3.6	2.9
		SD	1.1	0.9	1.2
		MEDIAN	3.0	4.0	3.0
		MIN	1	1	1
		MAX	5	5	5

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		_ENROLLMENT SOURCE_ DE NOVO (N = 379) n	(%)
PHASE B	C-SSRS ACTIVE SUICIDAL IDEATION WITH SOME INTENT TO ACT WITHOUT SPECIFIC PLAN	NO	379	(0.0)
		YES	0	(0.0)
	C-SSRS ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	NO	379	(100.0)
		YES	0	(0.0)

表 2.7.4.7-21　他の基準値の特性［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-3.2.2
Baseline Disease Severity (Phase C Enrolled Sample)

PHASE	BASELINE CHARACTERISTICS		ENROLLMENT SOURCE: DE NOVO (N = 379) n	DE NOVO (%)	ROLLOVER (N = 85) n	ROLLOVER (%)	TOTAL (N = 464) n	TOTAL (%)
PHASE C	C-SSRS ACTIVE SUICIDAL IDEATION WITH SOME INTENT TO ACT WITHOUT SPECIFIC PLAN	NO	379	(0.0)	85	(0.0)	464	(0.0)
		YES	0	(0.0)	0	(0.0)	0	(0.0)
	C-SSRS ACTIVE SUICIDAL IDEATION WITH SPECIFIC PLAN AND INTENT	NO	379	(100.0)	85	(100.0)	464	(100.0)
		YES	0	(0.0)	0	(0.0)	0	(0.0)
	OUTPATIENT STATUS	YES	379	(100.0)	85	(100.0)	464	(100.0)
		NO	0	(0.0)	0	(0.0)	0	(0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-3.2.2　FINAL
＜資料番号 5.3.5.2-01：CT-3.2.2＞

表 2.7.4.7-22　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［二重盲検試験の二重盲検期（Phase D）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase D Randomized Sample)

PHASE		MEDICATION PREFERRED NAME	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE B	ANTICHOLINERGICS	ANTICHOLINERGIC AGENTS[1]	266	30	(11.3)	30	1.69	0.81	1.93	0.50	4.00
		BENZATROPINE MESILATE	266	26	(9.8)	26	1.66	0.71	2.00	0.50	4.00
		BIPERIDEN	266	3	(1.1)	3	3.33	2.31	2.00	2.00	6.00
		TRIHEXYPHENIDYL HYDROCHLORIDE	266	1	(0.4)	1	2.56		2.56	2.56	2.56
	BENZODIAZEPINES	BENZODIAZEPINE DERIVATIVES[1]	266	83	(31.2)	61	1.29	0.62	1.00	0.50	2.78
		BROTIZOLAM	266	2	(0.8)	2	0.25	0.00	0.25	0.25	0.25
		CLONAZEPAM	266	7	(2.6)	3	0.67	0.29	0.50	0.50	1.00
		DIAZEPAM	266	4	(1.5)	1	10.00		10.00	10.00	10.00
		FLUNITRAZEPAM	266	2	(0.8)	2	1.11	0.16	1.11	1.00	1.23
		LORAZEPAM	266	69	(25.9)	57	1.28	0.62	1.00	0.50	2.78
PHASE C	ANTICHOLINERGICS	ANTICHOLINERGIC AGENTS[1]	266	45	(16.9)	40	1.60	0.85	1.43	0.42	4.00
		BENZATROPINE	266	1	(0.4)	1	1.00		1.00	1.00	1.00
		BENZATROPINE MESILATE	266	35	(13.2)	34	1.62	0.75	1.62	0.50	3.55
		BIPERIDEN	266	5	(1.9)	4	2.91	2.28	2.50	0.63	6.00
		BIPERIDEN HYDROCHLORIDE	266	2	(0.8)	2	2.10	0.14	2.10	2.00	2.20
		TRIHEXYPHENIDYL HYDROCHLORIDE	266	2	(0.8)	2	1.82	0.26	1.82	1.63	2.00
	BENZODIAZEPINES	BENZODIAZEPINE DERIVATIVES[1]	266	70	(26.3)	46	0.99	0.43	1.00	0.50	2.00
		ALPRAZOLAM	266	1	(0.4)	1	1.00		1.00	1.00	1.00
		BROTIZOLAM	266	2	(0.8)	2	0.25	0.00	0.25	0.25	0.25
		CLONAZEPAM	266	7	(2.6)	3	0.58	0.38	0.50	0.25	1.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
[3]NUMBER OF SUBJECTS RANDOMIZED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
§NUMBER OF RANDOMIZED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

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表 2.7.4.7-22　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［二重盲検試験の二重盲検期（Phase D）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase D Randomized Sample)

PHASE	MEDICATION PREFERRED NAME	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE C BENZODIAZEPINES	DIAZEPAM	266	6	(2.3)	2	6.88	4.41	6.88	3.76	10.00
	FLUNITRAZEPAM	266	1	(0.4)	1	0.95		0.95	0.95	0.95
	LORAZEPAM	266	52	(19.5)	41	0.93	0.35	1.00	0.50	2.00
	MIDAZOLAM	266	2	(0.8)	2	1.50	0.71	1.50	1.00	2.00
	TEMAZEPAM	266	1	(0.4)	1	15.00		15.00	15.00	15.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
[3]NUMBER OF SUBJECTS RANDOMIZED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
§NUMBER OF RANDOMIZED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

表 2.7.4.7-22　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［二重盲検試験の二重盲検期（Phase D）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase D Randomized Sample)

PHASE	MEDICATION PREFERRED NAME	PHASE D TREATMENT	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE D ANTICHOLINERGICS	ANTICHOLINERGIC AGENTS[1]	ARIP IMD	133	24	(18.0)	23	1.72	1.06	1.71	0.50	4.00
		PLACEBO	133	19	(14.3)	17	1.68	0.91	1.00	0.89	4.00
		TOTAL	266	43	(16.2)	40	1.70	0.99	1.62	0.50	4.00
	BENZATROPINE MESILATE	ARIP IMD	133	20	(15.0)	19	1.75	0.96	1.91	0.50	4.00
		PLACEBO	133	16	(12.0)	16	1.63	0.92	1.00	0.89	4.00
		TOTAL	266	36	(13.5)	35	1.69	0.93	1.71	0.50	4.00
	BIPERIDEN	ARIP IMD	133	1	(0.8)	1	6.00		6.00	6.00	6.00
		PLACEBO	133	2	(1.5)	1	3.68		3.68	3.68	3.68
		TOTAL	266	3	(1.1)	2	4.84	1.64	4.84	3.68	6.00
	BIPERIDEN HYDROCHLORIDE	PLACEBO	133	1	(0.8)	1	1.47		1.47	1.47	1.47
		TOTAL	266	1	(0.4)	1	1.47		1.47	1.47	1.47
	ORPHENADRINE	ARIP IMD	133	1	(0.8)	1	60.00		60.00	60.00	60.00
		TOTAL	266	1	(0.4)	1	60.00		60.00	60.00	60.00
	TRIHEXYPHENIDYL HYDROCHLORIDE	ARIP IMD	133	2	(1.5)	2	2.00	0.00	2.00	2.00	2.00
		TOTAL	266	2	(0.8)	2	2.00	0.00	2.00	2.00	2.00
BENZODIAZEPINES	BENZODIAZEPINE DERIVATIVES[1]	ARIP IMD	133	37	(27.8)	28	1.16	0.75	1.00	0.50	4.00
		PLACEBO	133	32	(24.1)	24	1.44	1.23	1.00	0.36	6.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
[3]NUMBER OF SUBJECTS RANDOMIZED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
§NUMBER OF RANDOMIZED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

FILE: ADCM3AB.LIS, RUN: [redacted]20[redacted] 12:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:33
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

表 2.7.4.7-22　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［二重盲検試験の二重盲検期（Phase D）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase D Randomized Sample)

PHASE	MEDICATION PREFERRED NAME	PHASE D TREATMENT	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE D BENZODIAZEPINES	BENZODIAZEPINE DERIVATIVES[1]	TOTAL	266	69	(25.9)	52	1.29	1.00	1.00	0.36	6.00
	ALPRAZOLAM	PLACEBO	133	1	(0.8)	1	0.13		0.13	0.13	0.13
		TOTAL	266	1	(0.4)	1	0.13		0.13	0.13	0.13
	CLONAZEPAM	ARIP IMD	133	4	(3.0)	2	0.75	0.35	0.75	0.50	1.00
		PLACEBO	133	4	(3.0)	3	0.60	0.38	0.56	0.25	1.00
		TOTAL	266	8	(3.0)	5	0.66	0.33	0.56	0.25	1.00
	DIAZEPAM	ARIP IMD	133	3	(2.3)	3	12.08	7.11	10.00	6.25	20.00
		PLACEBO	133	4	(3.0)	3	12.26	15.45	5.00	1.78	30.00
		TOTAL	266	7	(2.6)	6	12.17	10.75	8.13	1.78	30.00
	FLUNITRAZEPAM	ARIP IMD	133	1	(0.8)	1	0.50		0.50	0.50	0.50
		PLACEBO	133	1	(0.8)	1	1.00		1.00	1.00	1.00
		TOTAL	266	2	(0.8)	2	0.75	0.35	0.75	0.50	1.00
	LORAZEPAM	ARIP IMD	133	29	(21.8)	23	0.96	0.47	1.00	0.50	2.00
		PLACEBO	133	25	(18.8)	21	1.31	0.83	1.00	0.50	3.00
		TOTAL	266	54	(20.3)	44	1.13	0.68	1.00	0.50	3.00
	TEMAZEPAM	ARIP IMD	133	1	(0.8)	1	18.64		18.64	18.64	18.64
		PLACEBO	133	2	(1.5)	1	15.00		15.00	15.00	15.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
[3]NUMBER OF SUBJECTS RANDOMIZED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
§NUMBER OF RANDOMIZED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

FILE: ADCM3AB.LIS, RUN: [redacted]20[redacted] 12:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:33
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

表 2.7.4.7-22　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［二重盲検試験の二重盲検期（Phase D）］

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CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase D Randomized Sample)

PHASE	MEDICATION PREFERRED NAME	PHASE D TREATMENT	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE D	BENZODIAZEPINES TEMAZEPAM	TOTAL	266	3	(1.1)	2	16.82	2.58	16.82	15.00	18.64

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
[3]NUMBER OF SUBJECTS RANDOMIZED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS RANDOMIZED IN PHASE D.
§NUMBER OF RANDOMIZED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

FILE: ADCM3AB.LIS, RUN: [redacted]20[redacted] 12:05; ANALYSIS DATASET CREATED: [redacted]20[redacted] 21:33
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL
＜資料番号 5.3.5.1-01：CT-4.4.1.2＞

表 2.7.4.7-23　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.1
Concomitant Benzodiazepines and Anticholinergics Use by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION[1]	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE B	ANTICHOLINERGIC AGENTS	DE NOVO	379	46	(12.1)	375	0.165	0.571	0.000	0.000	4.000
	BENZODIAZEPINE DERIVATIVES	DE NOVO	379	76	(20.1)	350	0.147	0.577	0.000	0.000	8.000

[1]SEE CONVERSION FACTORS AT THE END OF THE TABLE.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS NOT TAKING ANY BENZODIAZEPINES (ANTICHOLINERGICS) OR TAKING MEDICATION WITH AVAILABLE DAILY DOSAGE DURING THE PHASE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS FROM ENTRY TO THE END OF THE PHASE);
AVERAGE DAILY DOSE (MG) SET TO 0 FOR SUBJECTS WHO DID NOT TAKE ANY BENZODIAZEPINES (ANTICHOLINERGICS) DURING THE PHASE.
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表 2.7.4.7-23　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.1
Concomitant Benzodiazepines and Anticholinergics Use by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION[1]	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE C	ANTICHOLINERGIC AGENTS	DE NOVO	379	67	(17.7)	374	0.227	0.704	0.000	0.000	7.077
		ROLLOVER	85	9	(10.6)	84	0.172	0.640	0.000	0.000	3.549
		TOTAL	464	76	(16.4)	458	0.217	0.692	0.000	0.000	7.077
	BENZODIAZEPINE DERIVATIVES	DE NOVO	379	115	(30.3)	334	0.148	0.558	0.000	0.000	8.000
		ROLLOVER	85	9	(10.6)	83	0.012	0.063	0.000	0.000	0.500
		TOTAL	464	124	(26.7)	417	0.121	0.503	0.000	0.000	8.000

[1]SEE CONVERSION FACTORS AT THE END OF THE TABLE.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS NOT TAKING ANY BENZODIAZEPINES (ANTICHOLINERGICS) OR TAKING MEDICATION WITH AVAILABLE DAILY DOSAGE DURING THE PHASE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS FROM ENTRY TO THE END OF THE PHASE);
AVERAGE DAILY DOSE (MG) SET TO 0 FOR SUBJECTS WHO DID NOT TAKE ANY BENZODIAZEPINES (ANTICHOLINERGICS) DURING THE PHASE.
FILE: ADCM3AA.LIS, RUN: [redacted]20[redacted] 16:07; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:41
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.1 FINAL

表 2.7.4.7-23　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.1
Concomitant Benzodiazepines and Anticholinergics Use by Phase
(Phase C Enrolled Sample)

CONVERSION FACTORS

ANTICHOLINERGIC AGENT - 1 MG BENZTROPINE EQUIVALENT:

AMANTADINE	75 MG
BIPERIDEN	1.5 MG
DEXETIMIDE	0.25 MG
METIXENE	7.5 MG
ORPHENADRINE	50 MG
PROCYCLIDINE	6.25 MG
TROPATEPINE	5 MG
TRIHEXYPHENIDYL	3.25 MG

BENZODIAZEPINE DERIVATIVE - 1 MG LORAZEPAM EQUIVALENT:

ALPRAZOLAM	0.5 MG
BENTAZEPAM	25 MG
BROMAZEPAM	6 MG
CHLORDIAZEPOXIDE	25 MG
CINOLAZEPAM	40 MG
CLOBAZAM	5 MG
CLONAZEPAM	0.5 MG
CLORAZEPATE	15 MG
CLOTIAZEPAM	5 MG
CLOXAZOLAM	1 MG
DELORAZEPAM	1 MG
DIAZEPAM	5 MG
ESTAZOLAM	1 MG
ETHYL LOFLAZEPATE	0.5 MG
ETIFOXINE	150 MG
ETIZOLAM	0.5 MG
FLUDIAZEPAM	0.5 MG
HALAZEPAM	20 MG

表 2.7.4.7-23　ベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.1
Concomitant Benzodiazepines and Anticholinergics Use by Phase
(Phase C Enrolled Sample)

KETAZOLAM	15 MG
MEDAZEPAM	10 MG
NITRAZEPAM	5 MG
NORDAZEPAM	2.5 MG
OXAZEPAM	15 MG
PINAZEPAM	2.5 MG
TEMAZEPAM	15 MG

＜資料番号 5.3.5.2-01：CT-4.4.1.1＞

表 2.7.4.7-24 薬剤名ごとのベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION PREFERRED NAME	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE B ANTICHOLINERGICS	ANTICHOLINERGIC AGENTS[1]	DE NOVO	379	46	(12.1)	42	1.88	0.99	2.00	0.62	4.00
	BENZATROPINE MESILATE	DE NOVO	379	20	(5.3)	20	2.23	0.98	2.00	1.00	4.00
	BIPERIDEN	DE NOVO	379	7	(1.8)	7	3.21	1.41	3.00	2.00	6.00
	BIPERIDEN HYDROCHLORIDE	DE NOVO	379	6	(1.6)	6	1.88	0.70	2.00	1.00	3.00
	PROMETHAZINE	DE NOVO	379	2	(0.5)	1	25.00		25.00	25.00	25.00
	PROMETHAZINE HYDROCHLORIDE	DE NOVO	379	1	(0.3)	0					
	TRIHEXYPHENIDYL	DE NOVO	379	1	(0.3)	1	4.93		4.93	4.93	4.93
	TRIHEXYPHENIDYL HYDROCHLORIDE	DE NOVO	379	9	(2.4)	8	4.16	3.40	2.88	2.00	12.00
BENZODIAZEPINES	BENZODIAZEPINE DERIVATIVES[1]	DE NOVO	379	76	(20.1)	47	1.41	1.12	1.00	0.50	8.00
	BROMAZEPAM	DE NOVO	379	1	(0.3)	1	7.00		7.00	7.00	7.00
	BROTIZOLAM	DE NOVO	379	8	(2.1)	8	0.29	0.09	0.25	0.25	0.50
	CLONAZEPAM	DE NOVO	379	13	(3.4)	10	0.99	1.09	0.50	0.38	4.00
	CLOXAZOLAM	DE NOVO	379	1	(0.3)	1	1.00		1.00	1.00	1.00
	DIAZEPAM	DE NOVO	379	3	(0.8)	2	7.50	3.54	7.50	5.00	10.00
	FLUNITRAZEPAM	DE NOVO	379	7	(1.8)	7	1.30	0.38	1.11	1.00	2.00
	LORAZEPAM	DE NOVO	379	38	(10.0)	30	1.28	0.57	1.00	0.50	3.00
	LORMETAZEPAM	DE NOVO	379	1	(0.3)	1	1.00		1.00	1.00	1.00
	NITRAZEPAM	DE NOVO	379	2	(0.5)	2	5.60	0.85	5.60	5.00	6.20
	OXAZEPAM	DE NOVO	379	2	(0.5)	1	10.00		10.00	10.00	10.00
	QUAZEPAM	DE NOVO	379	2	(0.5)	2	19.51	0.69	19.51	19.02	20.00
	TEMAZEPAM	DE NOVO	379	2	(0.5)	1	30.00		30.00	30.00	30.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

表 2.7.4.7-24 薬剤名ごとのベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION PREFERRED NAME	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE C ANTICHOLINERGICS	ANTICHOLINERGIC AGENTS[1]	DE NOVO	379	67	(17.7)	62	1.99	1.05	2.00	0.62	7.08
		ROLLOVER	85	9	(10.6)	8	2.05	1.21	2.00	0.50	3.84
		TOTAL	464	76	(16.4)	70	2.00	1.06	2.00	0.50	7.08
	BENZATROPINE	DE NOVO	379	1	(0.3)	1	3.23		3.23	3.23	3.23
		TOTAL	464	1	(0.2)	1	3.23		3.23	3.23	3.23
	BENZATROPINE MESILATE	DE NOVO	379	38	(10.0)	36	2.18	1.11	2.00	1.00	7.08
		ROLLOVER	85	9	(10.6)	8	2.05	1.21	2.00	0.50	3.84
		TOTAL	464	47	(10.1)	44	2.16	1.12	2.00	0.50	7.08
	BIPERIDEN	DE NOVO	379	8	(2.1)	8	3.79	1.38	3.01	2.67	6.00
		TOTAL	464	8	(1.7)	8	3.79	1.38	3.01	2.67	6.00
	BIPERIDEN HYDROCHLORIDE	DE NOVO	379	9	(2.4)	9	2.27	0.91	2.00	1.00	4.00
		TOTAL	464	9	(1.9)	9	2.27	0.91	2.00	1.00	4.00
	PROMETHAZINE	DE NOVO	379	1	(0.3)	0					
		TOTAL	464	1	(0.2)	0					
	PROMETHAZINE HYDROCHLORIDE	DE NOVO	379	1	(0.3)	0					
		TOTAL	464	1	(0.2)	0					

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

FILE: ADCM3AB.LIS, RUN: [redacted]20[redacted] 16:07; ANALYSIS DATASET CREATED: [redacted]20[redacted] 10:41
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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

表 2.7.4.7-24 薬剤名ごとのベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION PREFERRED NAME	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE C ANTICHOLINERGICS	TRIHEXYPHENIDYL	DE NOVO	379	1	(0.3)	1	4.00		4.00	4.00	4.00
		TOTAL	464	1	(0.2)	1	4.00		4.00	4.00	4.00
	TRIHEXYPHENIDYL HYDROCHLORIDE	DE NOVO	379	9	(2.4)	8	3.99	2.60	2.68	2.00	8.46
		TOTAL	464	9	(1.9)	8	3.99	2.60	2.68	2.00	8.46
BENZODIAZEPINES	BENZODIAZEPINE DERIVATIVES[1]	DE NOVO	379	115	(30.3)	70	1.44	1.36	1.00	0.50	8.54
		ROLLOVER	85	9	(10.6)	7	0.97	0.60	0.62	0.50	2.00
		TOTAL	464	124	(26.7)	77	1.40	1.32	1.00	0.50	8.54
	ALPRAZOLAM	DE NOVO	379	3	(0.8)	3	8.95	13.90	1.36	0.50	25.00
		TOTAL	464	3	(0.6)	3	8.95	13.90	1.36	0.50	25.00
	BROMAZEPAM	DE NOVO	379	2	(0.5)	2	5.15	0.93	5.15	4.50	5.81
		TOTAL	464	2	(0.4)	2	5.15	0.93	5.15	4.50	5.81
	BROTIZOLAM	DE NOVO	379	11	(2.9)	11	0.27	0.08	0.25	0.25	0.50
		TOTAL	464	11	(2.4)	11	0.27	0.08	0.25	0.25	0.50
	CLONAZEPAM	DE NOVO	379	23	(6.1)	19	1.04	0.91	0.62	0.25	4.00
		TOTAL	464	23	(5.0)	19	1.04	0.91	0.62	0.25	4.00
	CLOXAZOLAM	DE NOVO	379	1	(0.3)	1	1.00		1.00	1.00	1.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

表 2.7.4.7-24 薬剤名ごとのベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION PREFERRED NAME	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE C BENZODIAZEPINES	CLOXAZOLAM	TOTAL	464	1	(0.2)	1	1.00		1.00	1.00	1.00
	DIAZEPAM	DE NOVO	379	9	(2.4)	7	9.16	9.40	5.00	4.00	30.00
		ROLLOVER	85	1	(1.2)	1	8.08		8.08	8.08	8.08
		TOTAL	464	10	(2.2)	8	9.03	8.71	5.08	4.00	30.00
	ETIZOLAM	DE NOVO	379	1	(0.3)	1	0.50		0.50	0.50	0.50
		TOTAL	464	1	(0.2)	1	0.50		0.50	0.50	0.50
	FLUNITRAZEPAM	DE NOVO	379	9	(2.4)	9	1.01	0.02	1.00	1.00	1.06
		TOTAL	464	9	(1.9)	9	1.01	0.02	1.00	1.00	1.06
	LORAZEPAM	DE NOVO	379	58	(15.3)	44	1.18	0.51	1.00	0.50	2.09
		ROLLOVER	85	7	(8.2)	5	0.84	0.65	0.58	0.50	2.00
		TOTAL	464	65	(14.0)	49	1.14	0.52	1.00	0.50	2.09
	LORMETAZEPAM	DE NOVO	379	1	(0.3)	1	1.00		1.00	1.00	1.00
		TOTAL	464	1	(0.2)	1	1.00		1.00	1.00	1.00
	MIDAZOLAM HYDROCHLORIDE	DE NOVO	379	1	(0.3)	1	2.00		2.00	2.00	2.00
		TOTAL	464	1	(0.2)	1	2.00		2.00	2.00	2.00
	NITRAZEPAM	DE NOVO	379	6	(1.6)	6	4.86	0.34	5.00	4.17	5.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

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表 2.7.4.7-24 薬剤名ごとのベンゾジアゼピン系薬剤又は抗コリン薬の使用状況［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-4.4.1.2
Concomitant Benzodiazepines and Anticholinergics Use by Preferred Medication Name by Phase
(Phase C Enrolled Sample)

PHASE	MEDICATION PREFERRED NAME	ENROLLMENT SOURCE	N[2]	n[3]	(%)	AVERAGE DAILY DOSE (MG) DURING THE PHASE¥ Ne§	MEAN	SD	MEDIAN	MIN	MAX
PHASE C BENZODIAZEPINES	NITRAZEPAM	TOTAL	464	6	(1.3)	6	4.86	0.34	5.00	4.17	5.00
	OXAZEPAM	DE NOVO	379	1	(0.3)	0					
		TOTAL	464	1	(0.2)	0					
	PRAZEPAM	DE NOVO	379	1	(0.3)	1	10.00		10.00	10.00	10.00
		TOTAL	464	1	(0.2)	1	10.00		10.00	10.00	10.00
	QUAZEPAM	DE NOVO	379	2	(0.5)	2	20.00	0.00	20.00	20.00	20.00
		TOTAL	464	2	(0.4)	2	20.00	0.00	20.00	20.00	20.00
	TEMAZEPAM	DE NOVO	379	4	(1.1)	3	10.83	3.82	10.00	7.50	15.00
		ROLLOVER	85	1	(1.2)	1	15.00		15.00	15.00	15.00
		TOTAL	464	5	(1.1)	4	11.88	3.75	12.50	7.50	15.00

[1]SEE CONVERSION FACTORS AT THE END OF TABLE CT-4.4.1.1.
[2]NUMBER OF SUBJECTS ENROLLED IN PHASE C.
[3]NUMBER OF SUBJECTS ENROLLED TAKING THE MEDICATION DURING THE PHASE; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS ENROLLED IN PHASE C.
§NUMBER OF ENROLLED SUBJECTS TAKING THE MEDICATION DURING THE PHASE WITH AVAILABLE DAILY DOSAGE.
¥AVERAGE DAILY DOSE (MG) DURING THE PHASE = (TOTAL MG TAKEN DURING THE PHASE)/(NUMBER OF THE DAYS SUBJECT WAS TAKING MEDICATION DURING THE PHASE).

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OPDC, NEW DRUG APPLICATION, IND # 114,284 OPC14597 CT-4.4.1.2 FINAL

＜資料番号 5.3.5.2-01：CT-4.4.1.2＞

表 2.7.4.7-25　救済治療薬の使用状況［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-4.5
Rescue Therapy Use in Phase C
(Phase C Efficacy Sample)

RESCUE MEDICATION	ENROLLMENT SOURCE	N[1]	n[2]	(%)	DURATION (DAYS)[3] MEAN	SD	MEDIAN	MIN	MAX
LITHIUM	DE NOVO	379	28	(7.4)	147.86	101.78	131.50	13.00	361.00
	ROLLOVER	85	0	(0.0)					
	TOTAL	464	28	(6.0)	147.86	101.78	131.50	13.00	361.00
VALPROATE	DE NOVO	379	35	(9.2)	114.54	96.61	100.00	1.00	356.00
	ROLLOVER	85	1	(1.2)	84.00		84.00	84.00	84.00
	TOTAL	464	36	(7.8)	113.69	95.36	92.00	1.00	356.00
LITIUM OR VALPROATE	DE NOVO	379	61	(16.1)	133.56	100.31	117.00	1.00	361.00
	ROLLOVER	85	1	(1.2)	84.00		84.00	84.00	84.00
	TOTAL	464	62	(13.4)	132.76	99.68	115.00	1.00	361.00

[1]NUMBER OF SUBJECTS TREATED WITH ARIP IM DEPOT IN PHASE C.
[2]NUMBER OF SUBJECTS TREATED WITH ARIP IM DEPOT IN PHASE C TAKING THE RESCUE MEDICATION DURING PHASE C; PERCENTAGES ARE BASED ON THE NUMBER OF SUBJECTS TREATED WITH ARIP IM DEPOT IN PHASE C.
[3]STATISTICS FOR DURATION CALCULATED FOR SUBJECTS TREATED WITH ARIP IM DEPOT IN PHASE C TAKING THE RESCUE MEDICATION DURING PHASE C.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-4.5　FINAL

＜資料番号 5.3.5.2-01：CT-4.5＞

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
感染症および寄生虫症	膿瘍	1	(0.1)
	細菌性膣症	1	(0.1)
	乳房蜂巣炎	1	(0.1)
	気管支炎	16	(2.0)
	蜂巣炎	5	(0.6)
	膀胱炎	3	(0.4)
	耳感染	4	(0.5)
	毛包炎	1	(0.1)
	真菌感染	1	(0.1)
	せつ	1	(0.1)
	胃腸炎	5	(0.6)
	ウイルス性胃腸炎	14	(1.7)
	歯肉炎	1	(0.1)
	単純ヘルペス	1	(0.1)
	ヘルペスウイルス感染	1	(0.1)
	帯状疱疹	1	(0.1)
	麦粒腫	5	(0.6)
	感染	1	(0.1)
	インフルエンザ	14	(1.7)
	腎感染	1	(0.1)
	喉頭炎	1	(0.1)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
感染症および寄生虫症	限局性感染	1	(0.1)
	下気道感染	2	(0.2)
	鼻咽頭炎	85	(10.6)
	外耳炎	4	(0.5)
	中耳炎	3	(0.4)
	急性中耳炎	1	(0.1)
	爪囲炎	1	(0.1)
	歯周炎	1	(0.1)
	咽頭炎	9	(1.1)
	レンサ球菌性咽頭炎	6	(0.7)
	毛巣嚢胞	1	(0.1)
	肺炎	1	(0.1)
	マイコプラズマ性肺炎	1	(0.1)
	腎盂腎炎	2	(0.2)
	鼻炎	2	(0.2)
	敗血症	1	(0.1)
	性行為感染症	1	(0.1)
	副鼻腔炎	15	(1.9)
	皮下組織膿瘍	1	(0.1)
	須毛瘡	1	(0.1)
	足部白癬	1	(0.1)
	歯膿瘍	9	(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 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　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
感染症および寄生虫症	トリコモナス症	2	(0.2)
	上気道感染	42	(5.2)
	尿路感染	17	(2.1)
	ウイルス性上気道感染	2	(0.2)
	外陰部膿瘍	1	(0.1)
	外陰部腟炎	1	(0.1)
	歯感染	7	(0.9)
	無症候性細菌尿	1	(0.1)
	ブドウ球菌感染	1	(0.1)
	白癬感染	1	(0.1)
	クラミジア感染	1	(0.1)
	真菌性口腔咽頭炎	1	(0.1)
	ウイルス性気道感染	1	(0.1)
	気道感染	1	(0.1)
	ダニ皮膚炎	4	(0.5)
	外陰腟真菌感染	1	(0.1)
	口腔ヘルペス	1	(0.1)
	ノロウイルス性胃腸炎	1	(0.1)
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	1	(0.1)
	乳癌	2	(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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) 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）	脂肪腫	1	(0.1)
	皮膚の新生物	1	(0.1)
	扁平上皮癌	1	(0.1)
	子宮平滑筋腫	2	(0.2)
	肛門性器疣贅	1	(0.1)
血液およびリンパ系障害	貧血	4	(0.5)
	白血球減少症	1	(0.1)
	好中球減少症	2	(0.2)
免疫系障害	動物アレルギー	1	(0.1)
	食物アレルギー	1	(0.1)
	季節性アレルギー	5	(0.6)
内分泌障害	高プロラクチン血症	3	(0.4)
	甲状腺機能低下症	2	(0.2)
代謝および栄養障害	糖尿病	5	(0.6)
	コントロール不良の糖尿病	3	(0.4)
	体液貯留	1	(0.1)
	耐糖能障害	1	(0.1)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
代謝および栄養障害	痛風	1	(0.1)
	高血糖	3	(0.4)
	低カリウム血症	1	(0.1)
	食欲亢進	36	(4.5)
	鉄欠乏	1	(0.1)
	肥満	2	(0.2)
	食欲減退	15	(1.9)
	高脂血症	3	(0.4)
	過小食	1	(0.1)
	２型糖尿病	3	(0.4)
精神障害	異常な夢	8	(1.0)
	急性ストレス反応	1	(0.1)
	攻撃性	1	(0.1)
	激越	19	(2.4)
	広場恐怖症	1	(0.1)
	不安	78	(9.7)
	無感情	3	(0.4)
	注意喚起行動	1	(0.1)
	双極１型障害	25	(3.1)
	情動鈍麻	1	(0.1)
	歯ぎしり	5	(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: ADAE26B.LIS, RUN: [redacted]20[redacted] 15:47
PROGRAM: C:¥OPC14597¥P3108250252¥PROGRAM.DEV¥ADAE26.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
精神障害	錯乱状態	1	(0.1)
	抑うつ気分	6	(0.7)
	うつ病	48	(6.0)
	不快気分	1	(0.1)
	感情の貧困	2	(0.2)
	幻聴	1	(0.1)
	軽躁	4	(0.5)
	衝動行為	1	(0.1)
	初期不眠症	2	(0.2)
	不眠症	100	(12.4)
	故意の自傷行為	1	(0.1)
	易刺激性	6	(0.7)
	リビドー減退	12	(1.5)
	躁病	14	(1.7)
	中期不眠症	1	(0.1)
	気分変化	2	(0.2)
	気分動揺	1	(0.1)
	神経過敏	2	(0.2)
	悪夢	3	(0.4)
	パニック発作	3	(0.4)
	妄想症	1	(0.1)
	精神運動制止遅滞	1	(0.1)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
精神障害	落ち着きのなさ	51	(6.3)
	睡眠障害	2	(0.2)
	社会逃避行動	2	(0.2)
	夢遊症	2	(0.2)
	自殺念慮	16	(2.0)
	自殺企図	5	(0.6)
	せっかち	1	(0.1)
	抑うつ症状	9	(1.1)
	感情不安定	1	(0.1)
	ディスフェミア	1	(0.1)
	双極性障害	12	(1.5)
	大うつ病	2	(0.2)
	異常行動	1	(0.1)
	自傷行動	4	(0.5)
	精神活動過多	1	(0.1)
	早朝覚醒型不眠症	1	(0.1)
神経系障害	アカシジア	149	(18.5)
	失語症	1	(0.1)
	自律神経失調	1	(0.1)
	運動緩慢	5	(0.6)
	意識レベルの低下	1	(0.1)

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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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
神経系障害	糖尿病性ニューロパチー	1	(0.1)
	注意力障害	4	(0.5)
	浮動性めまい	16	(2.0)
	体位性めまい	5	(0.6)
	よだれ	3	(0.4)
	構語障害	1	(0.1)
	味覚異常	1	(0.1)
	ジスキネジア	11	(1.4)
	ジストニア	6	(0.7)
	錐体外路障害	19	(2.4)
	顔面麻痺	1	(0.1)
	頭痛	45	(5.6)
	運動過多	1	(0.1)
	過眠症	4	(0.5)
	感覚鈍麻	5	(0.6)
	企図振戦	2	(0.2)
	嗜眠	12	(1.5)
	記憶障害	1	(0.1)
	精神的機能障害	1	(0.1)
	片頭痛	6	(0.7)
	ミオクローヌス	1	(0.1)
	錯感覚	2	(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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
神経系障害	パーキンソニズム	8	(1.0)
	精神運動亢進	4	(0.5)
	神経根障害	1	(0.1)
	坐骨神経痛	3	(0.4)
	鎮静	30	(3.7)
	痙攣発作	1	(0.1)
	感覚障害	1	(0.1)
	副鼻腔炎に伴う頭痛	2	(0.2)
	傾眠	38	(4.7)
	失神	2	(0.2)
	遅発性ジスキネジア	6	(0.7)
	一過性脳虚血発作	1	(0.1)
	振戦	38	(4.7)
	眉間反射異常	1	(0.1)
	下肢静止不能症候群	7	(0.9)
	大脳動脈狭窄	1	(0.1)
	慢性多発ニューロパチー	1	(0.1)
	脳損傷	1	(0.1)
	微細運動機能障害	1	(0.1)
眼障害	眼瞼痙攣	4	(0.5)
	糖尿病性白内障	1	(0.1)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

		ARIP IMD (N=804)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)
眼障害	羞明	2	(0.2)
	霧視	9	(1.1)
	注視麻痺	1	(0.1)
	瞬目過多	2	(0.2)
耳および迷路障害	耳痛	1	(0.1)
	耳鳴	1	(0.1)
	回転性めまい	2	(0.2)
心臓障害	急性心筋梗塞	2	(0.2)
	心房細動	1	(0.1)
	第一度房室ブロック	2	(0.2)
	徐脈	2	(0.2)
	心停止	1	(0.1)
	心肺停止	1	(0.1)
	心筋梗塞	1	(0.1)
	動悸	1	(0.1)
	プリンツメタル狭心症	1	(0.1)
	洞性頻脈	1	(0.1)
	頻脈	4	(0.5)
血管障害	本態性高血圧症	1	(0.1)

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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 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

		ARIP IMD (N=804)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)
血管障害	潮紅	2	(0.2)
	血腫	2	(0.2)
	高血圧	8	(1.0)
	低血圧	1	(0.1)
	起立性低血圧	5	(0.6)
	血栓症	1	(0.1)
呼吸器、胸郭および縦隔障害	喘息	5	(0.6)
	慢性閉塞性肺疾患	1	(0.1)
	咳嗽	9	(1.1)
	咽喉乾燥	1	(0.1)
	呼吸困難	2	(0.2)
	鼻出血	2	(0.2)
	しゃっくり	2	(0.2)
	低酸素症	1	(0.1)
	肺障害	1	(0.1)
	鼻閉	6	(0.7)
	鼻乾燥	1	(0.1)
	鼻中隔弯曲	1	(0.1)
	胸膜炎	1	(0.1)
	呼吸不全	1	(0.1)
	鼻漏	3	(0.4)

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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.
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5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
呼吸器、胸郭および縦隔障害	副鼻腔うっ血	1	(0.1)
	睡眠時無呼吸症候群	2	(0.2)
	くしゃみ	1	(0.1)
	咽喉絞扼感	1	(0.1)
	アレルギー性副鼻腔炎	3	(0.4)
	上気道の炎症	1	(0.1)
	気道うっ血	2	(0.2)
	口腔咽頭痛	10	(1.2)
	咽頭反射亢進	1	(0.1)
胃腸障害	腹部不快感	4	(0.5)
	腹部膨満	2	(0.2)
	腹痛	9	(1.1)
	上腹部痛	8	(1.0)
	アフタ性潰瘍	1	(0.1)
	慢性胃炎	1	(0.1)
	便秘	19	(2.4)
	齲歯	6	(0.7)
	下痢	36	(4.5)
	口内乾燥	20	(2.5)
	消化不良	4	(0.5)
	嚥下障害	2	(0.2)

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5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

		ARIP IMD (N=804)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)
胃腸障害	腸炎	1	(0.1)
	鼓腸	1	(0.1)
	食中毒	1	(0.1)
	胃炎	2	(0.2)
	胃食道逆流性疾患	5	(0.6)
	消化器痛	1	(0.1)
	血便排泄	1	(0.1)
	痔核	1	(0.1)
	過敏性腸症候群	1	(0.1)
	悪心	26	(3.2)
	口腔内不快感	1	(0.1)
	歯周病	1	(0.1)
	流涎過多	22	(2.7)
	歯の知覚過敏	1	(0.1)
	口内炎	1	(0.1)
	舌腫脹	1	(0.1)
	舌障害	2	(0.2)
	歯の脱落	1	(0.1)
	歯痛	21	(2.6)
	嘔吐	22	(2.7)
	心窩部不快感	1	(0.1)
	痔出血	1	(0.1)

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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.
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Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
胃腸障害	口の感覚鈍麻	1	(0.1)
	口の錯感覚	1	(0.1)
	腹部ヘルニア	1	(0.1)
肝胆道系障害	胆嚢炎	2	(0.2)
	急性胆嚢炎	1	(0.1)
	脂肪肝	1	(0.1)
	肝炎	1	(0.1)
	高ビリルビン血症	1	(0.1)
皮膚および皮下組織障害	ざ瘡	1	(0.1)
	嚢胞性ざ瘡	1	(0.1)
	水疱	1	(0.1)
	皮膚炎	4	(0.5)
	ざ瘡様皮膚炎	1	(0.1)
	接触性皮膚炎	2	(0.2)
	皮膚乾燥	2	(0.2)
	斑状出血	1	(0.1)
	湿疹	3	(0.4)
	紅斑	1	(0.1)
	多汗症	6	(0.7)
	嵌入爪	1	(0.1)

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: ADAE26B.LIS, RUN: [redacted]20[redacted] 15:47
PROGRAM: C:¥OPC14597¥P3108250252¥PROGRAM.DEV¥ADAE26.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
皮膚および皮下組織障害	寝汗	2	(0.2)
	光線過敏性反応	1	(0.1)
	粃糠疹	1	(0.1)
	そう痒症	6	(0.7)
	乾癬	1	(0.1)
	発疹	11	(1.4)
	斑状皮疹	1	(0.1)
	斑状丘疹状皮疹	1	(0.1)
	そう痒性皮疹	1	(0.1)
	脂漏性皮膚炎	1	(0.1)
	皮膚病変	1	(0.1)
	顔面腫脹	2	(0.2)
	蕁麻疹	3	(0.4)
筋骨格系および結合組織障害	関節痛	20	(2.5)
	関節炎	3	(0.4)
	背部痛	28	(3.5)
	外骨腫	1	(0.1)
	鼡径部痛	1	(0.1)
	関節硬直	1	(0.1)
	筋萎縮	1	(0.1)
	筋肉内出血	1	(0.1)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
筋骨格系および結合組織障害	筋固縮	1	(0.1)
	筋痙縮	6	(0.7)
	筋攣縮	2	(0.2)
	筋骨格痛	5	(0.6)
	筋肉痛	5	(0.6)
	頚部痛	4	(0.5)
	骨端症	1	(0.1)
	骨壊死	1	(0.1)
	四肢痛	13	(1.6)
	顎痛	1	(0.1)
	横紋筋融解症	1	(0.1)
	肩回旋筋腱板症候群	1	(0.1)
	滑液嚢腫	1	(0.1)
	顎関節症候群	1	(0.1)
	腱炎	1	(0.1)
	開口障害	2	(0.2)
	線維筋痛	1	(0.1)
	関節可動域低下	1	(0.1)
	頚部腫瘤	1	(0.1)
	筋緊張	1	(0.1)
	椎間板突出	2	(0.2)
	筋骨格系胸痛	2	(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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
筋骨格系および結合組織障害	筋骨格硬直	11	(1.4)
	項部硬直	1	(0.1)
	椎間板障害	1	(0.1)
	関節過伸展	1	(0.1)
	関節不安定	1	(0.1)
	筋浮腫	1	(0.1)
腎および尿路障害	排尿困難	1	(0.1)
	血尿	1	(0.1)
	緊張性膀胱	1	(0.1)
	尿意切迫	1	(0.1)
	腎結石症	4	(0.5)
	夜間頻尿	2	(0.2)
	頻尿	3	(0.4)
	蛋白尿	1	(0.1)
	腎尿細管壊死	1	(0.1)
	尿失禁	1	(0.1)
	急性腎障害	1	(0.1)
	尿管結石症	2	(0.2)
生殖系および乳房障害	無月経	2	(0.2)
	良性前立腺肥大症	1	(0.1)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
生殖系および乳房障害	月経困難症	1	(0.1)
	射精遅延	1	(0.1)
	乳汁漏出症	1	(0.1)
	性器発疹	1	(0.1)
	月経過多	2	(0.2)
	月経障害	1	(0.1)
	月経遅延	1	(0.1)
	不規則月経	2	(0.2)
	不正子宮出血	1	(0.1)
	卵巣嚢胞	3	(0.4)
	頻発月経	1	(0.1)
	性機能不全	3	(0.4)
	子宮ポリープ	1	(0.1)
	外陰腟乾燥	1	(0.1)
	勃起不全	9	(1.1)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1	(0.1)
一般・全身障害および投与部位の状態	無菌膿瘍	1	(0.1)
	無力症	8	(1.0)
	胸部不快感	1	(0.1)
	胸痛	4	(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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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
一般・全身障害および投与部位の状態	悪寒	1	(0.1)
	嚢胞	1	(0.1)
	疲労	41	(5.1)
	異常感	1	(0.1)
	歩行障害	1	(0.1)
	インフルエンザ様疾患	4	(0.5)
	注射部位内出血	2	(0.2)
	注射部位紅斑	1	(0.1)
	注射部位硬結	2	(0.2)
	注射部位腫瘤	2	(0.2)
	注射部位疼痛	55	(6.8)
	倦怠感	4	(0.5)
	末梢性浮腫	5	(0.6)
	疼痛	3	(0.4)
	発熱	10	(1.2)
	不活発	2	(0.2)
	口渇	1	(0.1)
	活力増進	1	(0.1)
	カテーテル留置部位疼痛	1	(0.1)
	注射部位腫脹	5	(0.6)
	小結節	1	(0.1)
	非心臓性胸痛	3	(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.
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5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
臨床検査	アラニンアミノトランスフェラーゼ増加	5	(0.6)
	アスパラギン酸アミノトランスフェラーゼ増加	4	(0.5)
	血中コレステロール増加	2	(0.2)
	血中クレアチンホスホキナーゼ増加	9	(1.1)
	血中ブドウ糖増加	6	(0.7)
	血中インスリン増加	2	(0.2)
	血圧低下	2	(0.2)
	拡張期血圧上昇	2	(0.2)
	血圧上昇	6	(0.7)
	血中プロラクチン減少	1	(0.1)
	血中プロラクチン増加	2	(0.2)
	血中トリグリセリド増加	2	(0.2)
	血中尿酸増加	1	(0.1)
	心雑音	1	(0.1)
	心電図ＳＴ部分下降	1	(0.1)
	心電図Ｔ波振幅減少	1	(0.1)
	γ－グルタミルトランスフェラーゼ増加	3	(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.
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5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
臨床検査	尿中ブドウ糖陽性	1	(0.1)
	グリコヘモグロビン増加	1	(0.1)
	尿中血陽性	1	(0.1)
	ヘモグロビン減少	1	(0.1)
	心拍数増加	3	(0.4)
	高比重リポ蛋白減少	1	(0.1)
	血小板数減少	1	(0.1)
	体重減少	21	(2.6)
	体重増加	118	(14.7)
	尿中白血球陽性	2	(0.2)
	血小板数増加	1	(0.1)
	起立血圧上昇	1	(0.1)
	肝酵素上昇	1	(0.1)
	ビタミンD減少	1	(0.1)
	ヘリコバクター検査陽性	1	(0.1)
	肝機能検査値上昇	2	(0.2)
傷害、中毒および処置合併症	偶発的過量投与	1	(0.1)
	足関節部骨折	1	(0.1)
	節足動物咬傷	4	(0.5)
	凍瘡	1	(0.1)
	転倒	6	(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.
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5.3.5.3-250252-2

Incidence of Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C
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(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
傷害、中毒および処置合併症	足骨折	2	(0.2)
	頭部損傷	1	(0.1)
	裂傷	5	(0.6)
	靭帯捻挫	10	(1.2)
	ストレス骨折	1	(0.1)
	脛骨骨折	1	(0.1)
	擦過傷	2	(0.2)
	肉離れ	4	(0.5)
	挫傷	5	(0.6)
	肛門損傷	1	(0.1)
	関節損傷	1	(0.1)
	四肢損傷	1	(0.1)
	胸部損傷	3	(0.4)
	歯牙破折	5	(0.6)
	処置による疼痛	13	(1.6)
	皮膚擦過傷	1	(0.1)
	脊柱損傷	1	(0.1)
	注射に伴う反応	1	(0.1)
	外傷後頚部症候群	1	(0.1)
	処置後挫傷	1	(0.1)
社会環境	個人衛生不良	1	(0.1)

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.
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by System Organ Class and MedDRA Preferred Term
(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
TOTAL1)		645	(80.2)

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　ARIPIPRAZOLE　5.3.5.3-250252-2　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
感染症および寄生虫症	気管支炎	2	(0.2)
	ウイルス性胃腸炎	1	(0.1)
	鼻咽頭炎	1	(0.1)
	上気道感染	2	(0.2)
	尿路感染	2	(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）	脂肪腫	1	(0.1)
血液およびリンパ系障害	貧血	1	(0.1)
	白血球減少症	1	(0.1)
	好中球減少症	2	(0.2)
免疫系障害	季節性アレルギー	1	(0.1)
内分泌障害	高プロラクチン血症	1	(0.1)
代謝および栄養障害	糖尿病	3	(0.4)
	コントロール不良の糖尿病	1	(0.1)
	耐糖能障害	1	(0.1)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

		ARIP IMD (N=804)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)
代謝および栄養障害	高血糖	2	(0.2)
	食欲亢進	35	(4.4)
	肥満	2	(0.2)
	食欲減退	7	(0.9)
	高脂血症	1	(0.1)
	過小食	1	(0.1)
	２型糖尿病	1	(0.1)
精神障害	異常な夢	6	(0.7)
	激越	13	(1.6)
	広場恐怖症	1	(0.1)
	不安	40	(5.0)
	無感情	3	(0.4)
	双極１型障害	5	(0.6)
	歯ぎしり	5	(0.6)
	錯乱状態	1	(0.1)
	抑うつ気分	3	(0.4)
	うつ病	26	(3.2)
	感情の貧困	2	(0.2)
	幻聴	1	(0.1)
	軽躁	2	(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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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
精神障害	衝動行為	1	(0.1)
	初期不眠症	2	(0.2)
	不眠症	59	(7.3)
	故意の自傷行為	1	(0.1)
	易刺激性	2	(0.2)
	リビドー減退	10	(1.2)
	躁病	2	(0.2)
	中期不眠症	1	(0.1)
	気分動揺	1	(0.1)
	神経過敏	2	(0.2)
	悪夢	1	(0.1)
	妄想症	1	(0.1)
	落ち着きのなさ	47	(5.8)
	睡眠障害	2	(0.2)
	夢遊症	1	(0.1)
	自殺念慮	1	(0.1)
	せっかち	1	(0.1)
	抑うつ症状	4	(0.5)
	ディスフェミア	1	(0.1)
	双極性障害	3	(0.4)
	大うつ病	1	(0.1)

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.
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5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
精神障害	異常行動	1	(0.1)
	精神活動過多	1	(0.1)
神経系障害	アカシジア	148	(18.4)
	運動緩慢	5	(0.6)
	注意力障害	3	(0.4)
	浮動性めまい	11	(1.4)
	体位性めまい	5	(0.6)
	よだれ	3	(0.4)
	構語障害	1	(0.1)
	ジスキネジア	11	(1.4)
	ジストニア	5	(0.6)
	錐体外路障害	18	(2.2)
	頭痛	12	(1.5)
	運動過多	1	(0.1)
	過眠症	4	(0.5)
	感覚鈍麻	2	(0.2)
	企図振戦	1	(0.1)
	嗜眠	12	(1.5)
	記憶障害	1	(0.1)
	精神的機能障害	1	(0.1)

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.
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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
神経系障害	片頭痛	2	(0.2)
	ミオクローヌス	1	(0.1)
	錯感覚	1	(0.1)
	パーキンソニズム	8	(1.0)
	精神運動亢進	2	(0.2)
	坐骨神経痛	1	(0.1)
	鎮静	29	(3.6)
	感覚障害	1	(0.1)
	傾眠	33	(4.1)
	遅発性ジスキネジア	6	(0.7)
	振戦	35	(4.4)
	眉間反射異常	1	(0.1)
	下肢静止不能症候群	7	(0.9)
	大脳動脈狭窄	1	(0.1)
眼障害	眼瞼痙攣	3	(0.4)
	糖尿病性白内障	1	(0.1)
	羞明	2	(0.2)
	霧視	8	(1.0)
	注視麻痺	1	(0.1)
	瞬目過多	2	(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.
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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
耳および迷路障害	耳鳴	1	(0.1)
	回転性めまい	1	(0.1)
心臓障害	第一度房室ブロック	2	(0.2)
	動悸	1	(0.1)
	洞性頻脈	1	(0.1)
	頻脈	4	(0.5)
血管障害	潮紅	1	(0.1)
	高血圧	4	(0.5)
	起立性低血圧	3	(0.4)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1	(0.1)
	呼吸困難	1	(0.1)
	鼻出血	1	(0.1)
	しゃっくり	1	(0.1)
	鼻乾燥	1	(0.1)
胃腸障害	腹部膨満	1	(0.1)
	腹痛	3	(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.
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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
胃腸障害	便秘	9	(1.1)
	下痢	6	(0.7)
	口内乾燥	15	(1.9)
	消化不良	1	(0.1)
	嚥下障害	1	(0.1)
	胃食道逆流性疾患	3	(0.4)
	悪心	10	(1.2)
	流涎過多	21	(2.6)
	歯の知覚過敏	1	(0.1)
	舌障害	2	(0.2)
	嘔吐	6	(0.7)
	口の錯感覚	1	(0.1)
肝胆道系障害	肝炎	1	(0.1)
	高ビリルビン血症	1	(0.1)
皮膚および皮下組織障害	嚢胞性ざ瘡	1	(0.1)
	皮膚炎	2	(0.2)
	ざ瘡様皮膚炎	1	(0.1)
	皮膚乾燥	1	(0.1)
	多汗症	6	(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.
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5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
皮膚および皮下組織障害	寝汗	1	(0.1)
	発疹	4	(0.5)
	顔面腫脹	1	(0.1)
筋骨格系および結合組織障害	関節痛	4	(0.5)
	関節炎	1	(0.1)
	背部痛	1	(0.1)
	関節硬直	1	(0.1)
	筋萎縮	1	(0.1)
	筋固縮	1	(0.1)
	筋痙縮	2	(0.2)
	筋攣縮	2	(0.2)
	筋骨格痛	2	(0.2)
	筋肉痛	3	(0.4)
	四肢痛	4	(0.5)
	顎関節症候群	1	(0.1)
	開口障害	2	(0.2)
	線維筋痛	1	(0.1)
	筋緊張	1	(0.1)
	筋骨格硬直	6	(0.7)
	項部硬直	1	(0.1)

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.
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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
腎および尿路障害	排尿困難	1	(0.1)
	血尿	1	(0.1)
	夜間頻尿	1	(0.1)
	頻尿	1	(0.1)
	尿失禁	1	(0.1)
生殖系および乳房障害	無月経	1	(0.1)
	射精遅延	1	(0.1)
	月経過多	1	(0.1)
	月経障害	1	(0.1)
	月経遅延	1	(0.1)
	不規則月経	2	(0.2)
	不正子宮出血	1	(0.1)
	卵巣嚢胞	1	(0.1)
	頻発月経	1	(0.1)
	性機能不全	3	(0.4)
	外陰腟乾燥	1	(0.1)
	勃起不全	9	(1.1)

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表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

		ARIP IMD (N=804)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	n	(%)
一般・全身障害および投与部位の状態	無菌膿瘍	1	(0.1)
	無力症	5	(0.6)
	疲労	39	(4.9)
	異常感	1	(0.1)
	歩行障害	1	(0.1)
	注射部位内出血	1	(0.1)
	注射部位紅斑	1	(0.1)
	注射部位硬結	2	(0.2)
	注射部位腫瘤	2	(0.2)
	注射部位疼痛	53	(6.6)
	倦怠感	2	(0.2)
	末梢性浮腫	1	(0.1)
	疼痛	1	(0.1)
	発熱	2	(0.2)
	不活発	2	(0.2)
	口渇	1	(0.1)
	注射部位腫脹	5	(0.6)
	非心臓性胸痛	1	(0.1)
臨床検査	アラニンアミノトランスフェラーゼ増加	2	(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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

		ARIP IMD (N=804)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	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	2	(0.2)
	血中コレステロール増加	1	(0.1)
	血中クレアチンホスホキナーゼ増加	4	(0.5)
	血中ブドウ糖増加	2	(0.2)
	血中インスリン増加	1	(0.1)
	血圧低下	2	(0.2)
	拡張期血圧上昇	1	(0.1)
	血圧上昇	1	(0.1)
	血中プロラクチン減少	1	(0.1)
	血中プロラクチン増加	1	(0.1)
	血中トリグリセリド増加	2	(0.2)
	γ－グルタミルトランスフェラーゼ増加	2	(0.2)
	尿中血陽性	1	(0.1)
	心拍数増加	3	(0.4)
	高比重リポ蛋白減少	1	(0.1)
	体重減少	8	(1.0)
	体重増加	110	(13.7)
	血小板数増加	1	(0.1)
	起立血圧上昇	1	(0.1)
	肝酵素上昇	1	(0.1)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE26D.LIS, RUN: [redacted]20[redacted] 15:47
PROGRAM: C:¥OPC14597¥P3108250252¥PROGRAM.DEV¥ADAE26.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　5.3.5.3-250252-4　FINAL

表 2.7.4.7-26　本申請の評価資料とした試験の統合データでの全有害事象及び全副作用

5.3.5.3-250252-4

Incidence of Potentially Drug-related Treatment-emergent Adverse Events in Trial 31-08-250 Phase C, Phase D Aripiprazole Treated Period or Trial 31-08-252 Phase C by System Organ Class and MedDRA Preferred Term

(Trial 31-08-250 Phase C Safety Sample, Phase D Safety Sample Aripiprazole Treated Subjects or Trial 31-08-252 Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	ARIP IMD (N=804) n	(%)
臨床検査	肝機能検査値上昇	1	(0.1)
傷害、中毒および処置合併症	挫傷	1	(0.1)
	歯牙破折	1	(0.1)
	注射に伴う反応	1	(0.1)
TOTAL1)		500	(62.2)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE26D.LIS, RUN: [redacted]20[redacted] 15:47
PROGRAM: C:¥OPC14597¥P3108250252¥PROGRAM.DEV¥ADAE26.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　ARIPIPRAZOLE　5.3.5.3-250252-4　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-250252-2, 5.3.5.3-250252-4＞

表 2.7.4.7-27　　死亡例一覧表（二重盲検試験）

投与期	被験者番号	二重盲検期(Phase D)の投与群	年齢/性別/人種	MedDRA基本語[a]/症例報告書記載用語	器官別大分類	発現日/時刻	回復日/時刻	発現までの期間（日数）[b]	重症度	重篤度	治験薬との関連性	治験薬投与に対する処置	転帰
錠剤安定期（Phase B）	[redacted]		4[redacted]/[redacted]/[redacted]	心筋梗塞* / 心筋梗塞	心臓障害	20[redacted]/03/04	同年*/3/4 5:45	15	高度	重篤	否定できる	なし	死亡
二重盲検期（Phase D）	[redacted]	IMデポ群	4[redacted]/[redacted]/[redacted]	脳損傷* / ANOXIC BRAIN INJURY	神経系障害	20[redacted]/05/19	同年*/7/15 1:31	258	高度	重篤	否定できる	なし	死亡
				呼吸不全* / 呼吸不全	呼吸器、胸郭および縦隔障害	20[redacted]/05/19	同年*/7/15 1:31	258	高度	重篤	否定できる	中止	死亡

[a]：MedDRA 基本語の後ろに記載したアスタリスクは，有害事象として集計されたことを示す。

[b]：発現までの期間(日数) = 有害事象の発現日 − 当該投与期の初回投与日 + 1

MedDRA version 19.0

＜資料番号 5.3.5.1-01：CT-9.1 より作成＞

＊新薬承認情報提供時に置き換え

表 2.7.4.7-28　　死亡例一覧表（長期投与試験）

投与期	治験薬	被験者番号	年齢/性別/人種	MedDRA基本語[a]/症例報告書記載用語	器官別大分類	発現日/時刻	回復日/時刻	発現までの期間（日数）[b]	重症度	重篤度	治験薬との関連性	治験薬投与に対する処置	転帰
錠剤切り替え期（Phase A）	アリピプラゾール 錠剤5～15 mg	[redacted]	5[redacted]/[redacted]/[redacted]	死亡*/DEATH,CAUSE UNKNOWN	一般・全身障害および投与部位の状態	20[redacted]/10/13	同年*/10/13	20	高度	重篤	否定できる	該当なし	死亡
錠剤安定期（Phase B）	アリピプラゾール 錠剤15～30 mg	[redacted]	2[redacted]/[redacted]/[redacted]	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	高度	重篤	否定できる	なし	死亡
IM デポ剤維持治療期（Phase C）	アリピプラゾール IMデポ注射剤 400/300 mg	[redacted]	5[redacted]/[redacted]/[redacted]	心停止*/心停止	心臓障害	20[redacted]/09/25	同年*/09/25	277	高度	重篤	ない	なし	死亡

[a]：MedDRA 基本語の後ろに記載したアスタリスクは，有害事象として集計されたことを示す。

[b]：発現までの期間(日数) = 有害事象の発現日 − 当該投与期の初回投与日 + 1

MedDRA version 19.0

＜資料番号 5.3.5.2-01：CT-9.1 より作成＞

＊新薬承認情報提供時に置き換え

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
感染症および寄生虫症	乳房蜂巣炎	1	(0.8)	0	(0.0)	1	(0.4)
	気管支炎	3	(2.3)	2	(1.5)	5	(1.9)
	蜂巣炎	1	(0.8)	0	(0.0)	1	(0.4)
	結膜炎	0	(0.0)	1	(0.8)	1	(0.4)
	真菌感染	0	(0.0)	1	(0.8)	1	(0.4)
	胃腸炎	1	(0.8)	0	(0.0)	1	(0.4)
	ウイルス性胃腸炎	2	(1.5)	1	(0.8)	3	(1.1)
	麦粒腫	2	(1.5)	0	(0.0)	2	(0.8)
	インフルエンザ	3	(2.3)	2	(1.5)	5	(1.9)
	喉頭炎	1	(0.8)	0	(0.0)	1	(0.4)
	シラミ寄生	0	(0.0)	1	(0.8)	1	(0.4)
	限局性感染	0	(0.0)	1	(0.8)	1	(0.4)
	鼻咽頭炎	10	(7.6)	13	(9.8)	23	(8.7)
	精巣炎	0	(0.0)	1	(0.8)	1	(0.4)
	外耳炎	2	(1.5)	0	(0.0)	2	(0.8)
	中耳炎	2	(1.5)	0	(0.0)	2	(0.8)
	咽頭炎	1	(0.8)	2	(1.5)	3	(1.1)
	レンサ球菌性咽頭炎	2	(1.5)	1	(0.8)	3	(1.1)
	肺炎	0	(0.0)	2	(1.5)	2	(0.8)
	鼻炎	0	(0.0)	1	(0.8)	1	(0.4)
	副鼻腔炎	5	(3.8)	1	(0.8)	6	(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.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
感染症および寄生虫症	須毛瘡	1	(0.8)	0	(0.0)	1	(0.4)
	足部白癬	1	(0.8)	1	(0.8)	2	(0.8)
	歯膿瘍	1	(0.8)	1	(0.8)	2	(0.8)
	トリコモナス症	1	(0.8)	1	(0.8)	2	(0.8)
	上気道感染	4	(3.0)	6	(4.5)	10	(3.8)
	尿路感染	4	(3.0)	2	(1.5)	6	(2.3)
	ウイルス性上気道感染	0	(0.0)	1	(0.8)	1	(0.4)
	歯感染	1	(0.8)	2	(1.5)	3	(1.1)
	無症候性細菌尿	1	(0.8)	0	(0.0)	1	(0.4)
	クラミジア感染	1	(0.8)	0	(0.0)	1	(0.4)
	ウイルス性耳感染	0	(0.0)	1	(0.8)	1	(0.4)
	真菌性口腔咽頭炎	1	(0.8)	0	(0.0)	1	(0.4)
	ウイルス性気道感染	0	(0.0)	1	(0.8)	1	(0.4)
	気道感染	1	(0.8)	0	(0.0)	1	(0.4)
	口腔ヘルペス	0	(0.0)	1	(0.8)	1	(0.4)
	カンジダ感染	0	(0.0)	1	(0.8)	1	(0.4)
血液およびリンパ系障害	貧血	3	(2.3)	0	(0.0)	3	(1.1)
	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)
内分泌障害	高プロラクチン血症	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 ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
代謝および栄養障害	脱水	0	(0.0)	1	(0.8)	1	(0.4)
	高血糖	1	(0.8)	0	(0.0)	1	(0.4)
	食欲亢進	4	(3.0)	1	(0.8)	5	(1.9)
	高インスリン血症	0	(0.0)	1	(0.8)	1	(0.4)
	食欲減退	2	(1.5)	0	(0.0)	2	(0.8)
	高脂血症	0	(0.0)	1	(0.8)	1	(0.4)
	２型糖尿病	0	(0.0)	1	(0.8)	1	(0.4)
精神障害	感情障害	0	(0.0)	2	(1.5)	2	(0.8)
	攻撃性	0	(0.0)	1	(0.8)	1	(0.4)
	激越	1	(0.8)	4	(3.0)	5	(1.9)
	不安	9	(6.8)	6	(4.5)	15	(5.7)
	無感情	1	(0.8)	0	(0.0)	1	(0.4)
	双極１型障害	2	(1.5)	8	(6.0)	10	(3.8)
	歯ぎしり	0	(0.0)	1	(0.8)	1	(0.4)
	抑うつ気分	1	(0.8)	2	(1.5)	3	(1.1)
	うつ病	4	(3.0)	3	(2.3)	7	(2.6)
	軽躁	1	(0.8)	0	(0.0)	1	(0.4)
	初期不眠症	1	(0.8)	0	(0.0)	1	(0.4)
	不眠症	10	(7.6)	10	(7.5)	20	(7.5)
	易刺激性	1	(0.8)	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.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	リビドー減退	3	(2.3)	2	(1.5)	5	(1.9)
	躁病	3	(2.3)	14	(10.5)	17	(6.4)
	中期不眠症	1	(0.8)	0	(0.0)	1	(0.4)
	神経過敏	0	(0.0)	1	(0.8)	1	(0.4)
	悪夢	1	(0.8)	0	(0.0)	1	(0.4)
	パニック発作	1	(0.8)	0	(0.0)	1	(0.4)
	精神運動制止遅滞	1	(0.8)	0	(0.0)	1	(0.4)
	落ち着きのなさ	6	(4.5)	5	(3.8)	11	(4.2)
	睡眠障害	0	(0.0)	2	(1.5)	2	(0.8)
	社会逃避行動	1	(0.8)	0	(0.0)	1	(0.4)
	夢遊症	1	(0.8)	0	(0.0)	1	(0.4)
	自殺企図	1	(0.8)	1	(0.8)	2	(0.8)
	緊張	0	(0.0)	1	(0.8)	1	(0.4)
	感情不安定	1	(0.8)	0	(0.0)	1	(0.4)
	ディスフェミア	1	(0.8)	0	(0.0)	1	(0.4)
	双極性障害	5	(3.8)	5	(3.8)	10	(3.8)
	大うつ病	0	(0.0)	2	(1.5)	2	(0.8)
	精神活動過多	0	(0.0)	1	(0.8)	1	(0.4)
神経系障害	アカシジア	28	(21.2)	17	(12.8)	45	(17.0)
	運動緩慢	2	(1.5)	0	(0.0)	2	(0.8)
	注意力障害	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 ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
神経系障害	浮動性めまい	1	(0.8)	2	(1.5)	3	(1.1)
	構語障害	0	(0.0)	1	(0.8)	1	(0.4)
	ジスキネジア	2	(1.5)	2	(1.5)	4	(1.5)
	錐体外路障害	2	(1.5)	2	(1.5)	4	(1.5)
	頭痛	4	(3.0)	9	(6.8)	13	(4.9)
	過眠症	1	(0.8)	0	(0.0)	1	(0.4)
	感覚鈍麻	1	(0.8)	1	(0.8)	2	(0.8)
	嗜眠	1	(0.8)	1	(0.8)	2	(0.8)
	片頭痛	0	(0.0)	2	(1.5)	2	(0.8)
	錯感覚	1	(0.8)	0	(0.0)	1	(0.4)
	パーキンソニズム	1	(0.8)	1	(0.8)	2	(0.8)
	精神運動亢進	1	(0.8)	0	(0.0)	1	(0.4)
	坐骨神経痛	1	(0.8)	0	(0.0)	1	(0.4)
	鎮静	2	(1.5)	0	(0.0)	2	(0.8)
	傾眠	6	(4.5)	1	(0.8)	7	(2.6)
	失神	0	(0.0)	1	(0.8)	1	(0.4)
	遅発性ジスキネジア	1	(0.8)	0	(0.0)	1	(0.4)
	一過性脳虚血発作	1	(0.8)	0	(0.0)	1	(0.4)
	振戦	3	(2.3)	2	(1.5)	5	(1.9)
	下肢静止不能症候群	0	(0.0)	2	(1.5)	2	(0.8)
	脳損傷	1	(0.8)	0	(0.0)	1	(0.4)

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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　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
眼障害	眼痛	0	(0.0)	1	(0.8)	1	(0.4)
	羞明	1	(0.8)	1	(0.8)	2	(0.8)
	霧視	3	(2.3)	0	(0.0)	3	(1.1)
耳および迷路障害	耳鳴	1	(0.8)	0	(0.0)	1	(0.4)
心臓障害	心房細動	1	(0.8)	0	(0.0)	1	(0.4)
	第一度房室ブロック	1	(0.8)	0	(0.0)	1	(0.4)
	徐脈	1	(0.8)	0	(0.0)	1	(0.4)
	心肺停止	1	(0.8)	0	(0.0)	1	(0.4)
血管障害	本態性高血圧症	0	(0.0)	1	(0.8)	1	(0.4)
	高血圧	1	(0.8)	3	(2.3)	4	(1.5)
呼吸器、胸郭および縦隔障害	喘息	2	(1.5)	0	(0.0)	2	(0.8)
	咳嗽	0	(0.0)	2	(1.5)	2	(0.8)
	呼吸不全	1	(0.8)	0	(0.0)	1	(0.4)
	アレルギー性副鼻腔炎	1	(0.8)	0	(0.0)	1	(0.4)
	気道うっ血	1	(0.8)	1	(0.8)	2	(0.8)
	口腔咽頭痛	1	(0.8)	0	(0.0)	1	(0.4)
胃腸障害	腹部膨満	1	(0.8)	0	(0.0)	1	(0.4)

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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-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
胃腸障害	腹痛	0	(0.0)	1	(0.8)	1	(0.4)
	上腹部痛	2	(1.5)	1	(0.8)	3	(1.1)
	潰瘍性大腸炎	0	(0.0)	1	(0.8)	1	(0.4)
	便秘	4	(3.0)	4	(3.0)	8	(3.0)
	齲歯	1	(0.8)	1	(0.8)	2	(0.8)
	下痢	1	(0.8)	4	(3.0)	5	(1.9)
	口内乾燥	4	(3.0)	3	(2.3)	7	(2.6)
	消化不良	1	(0.8)	4	(3.0)	5	(1.9)
	食中毒	1	(0.8)	0	(0.0)	1	(0.4)
	胃食道逆流性疾患	0	(0.0)	1	(0.8)	1	(0.4)
	歯肉痛	0	(0.0)	2	(1.5)	2	(0.8)
	血便排泄	0	(0.0)	1	(0.8)	1	(0.4)
	悪心	3	(2.3)	6	(4.5)	9	(3.4)
	口腔内不快感	1	(0.8)	0	(0.0)	1	(0.4)
	流涎過多	3	(2.3)	3	(2.3)	6	(2.3)
	歯の知覚過敏	0	(0.0)	1	(0.8)	1	(0.4)
	舌腫脹	1	(0.8)	0	(0.0)	1	(0.4)
	歯痛	1	(0.8)	3	(2.3)	4	(1.5)
	嘔吐	2	(1.5)	2	(1.5)	4	(1.5)
	腹壁嚢胞	0	(0.0)	1	(0.8)	1	(0.4)
	痔出血	1	(0.8)	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.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
肝胆道系障害	脂肪肝	0	(0.0)	1	(0.8)	1	(0.4)
皮膚および皮下組織障害	ざ瘡	1	(0.8)	1	(0.8)	2	(0.8)
	皮膚炎	2	(1.5)	0	(0.0)	2	(0.8)
	接触性皮膚炎	1	(0.8)	1	(0.8)	2	(0.8)
	皮膚乾燥	0	(0.0)	1	(0.8)	1	(0.4)
	湿疹	0	(0.0)	1	(0.8)	1	(0.4)
	紅斑	0	(0.0)	1	(0.8)	1	(0.4)
	多汗症	0	(0.0)	1	(0.8)	1	(0.4)
	寝汗	1	(0.8)	0	(0.0)	1	(0.4)
	粃糠疹	1	(0.8)	0	(0.0)	1	(0.4)
	そう痒症	0	(0.0)	1	(0.8)	1	(0.4)
	発疹	1	(0.8)	1	(0.8)	2	(0.8)
筋骨格系および結合組織障害	関節痛	1	(0.8)	3	(2.3)	4	(1.5)
	関節炎	2	(1.5)	0	(0.0)	2	(0.8)
	背部痛	3	(2.3)	4	(3.0)	7	(2.6)
	筋肉内出血	1	(0.8)	0	(0.0)	1	(0.4)
	筋痙縮	2	(1.5)	0	(0.0)	2	(0.8)
	筋攣縮	0	(0.0)	2	(1.5)	2	(0.8)
	筋力低下	0	(0.0)	1	(0.8)	1	(0.4)
	筋骨格痛	1	(0.8)	0	(0.0)	1	(0.4)

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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 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
筋骨格系および結合組織障害	筋肉痛	0	(0.0)	2	(1.5)	2	(0.8)
	頚部痛	1	(0.8)	1	(0.8)	2	(0.8)
	四肢痛	0	(0.0)	4	(3.0)	4	(1.5)
	顎痛	0	(0.0)	1	(0.8)	1	(0.4)
	足底筋膜炎	0	(0.0)	1	(0.8)	1	(0.4)
	肩回旋筋腱板症候群	1	(0.8)	0	(0.0)	1	(0.4)
	顎関節症候群	0	(0.0)	1	(0.8)	1	(0.4)
	開口障害	1	(0.8)	0	(0.0)	1	(0.4)
	筋骨格硬直	1	(0.8)	2	(1.5)	3	(1.1)
	筋浮腫	1	(0.8)	0	(0.0)	1	(0.4)
腎および尿路障害	排尿困難	0	(0.0)	1	(0.8)	1	(0.4)
	緊張性膀胱	1	(0.8)	0	(0.0)	1	(0.4)
	腎結石症	1	(0.8)	0	(0.0)	1	(0.4)
	夜間頻尿	0	(0.0)	1	(0.8)	1	(0.4)
生殖系および乳房障害	子宮頚部嚢胞	0	(0.0)	1	(0.8)	1	(0.4)
	月経困難症	0	(0.0)	1	(0.8)	1	(0.4)
	射精遅延	1	(0.8)	0	(0.0)	1	(0.4)
	射精障害	0	(0.0)	1	(0.8)	1	(0.4)
	月経過多	1	(0.8)	0	(0.0)	1	(0.4)
	不規則月経	0	(0.0)	2	(1.5)	2	(0.8)

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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.
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表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
生殖系および乳房障害	卵巣嚢胞	1	(0.8)	0	(0.0)	1	(0.4)
	骨盤癒着症	0	(0.0)	1	(0.8)	1	(0.4)
	性機能不全	1	(0.8)	1	(0.8)	2	(0.8)
	陰茎分泌物	0	(0.0)	1	(0.8)	1	(0.4)
	勃起不全	2	(1.5)	1	(0.8)	3	(1.1)
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)	1	(0.4)
	疲労	4	(3.0)	5	(3.8)	9	(3.4)
	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)
	倦怠感	0	(0.0)	1	(0.8)	1	(0.4)
	末梢性浮腫	2	(1.5)	0	(0.0)	2	(0.8)
	不活発	1	(0.8)	1	(0.8)	2	(0.8)
	非心臓性胸痛	1	(0.8)	0	(0.0)	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	1	(0.8)	2	(1.5)	3	(1.1)
	アスパラギン酸アミノトランスフェラーゼ増加	0	(0.0)	2	(1.5)	2	(0.8)
	血中クレアチンホスホキナーゼ増加	3	(2.3)	1	(0.8)	4	(1.5)
	血中ブドウ糖増加	0	(0.0)	2	(1.5)	2	(0.8)

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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 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
臨床検査	血中インスリン増加	1	(0.8)	2	(1.5)	3	(1.1)
	血中カリウム減少	0	(0.0)	1	(0.8)	1	(0.4)
	血圧上昇	1	(0.8)	2	(1.5)	3	(1.1)
	心電図ＳＴ部分下降	1	(0.8)	0	(0.0)	1	(0.4)
	グリコヘモグロビン増加	0	(0.0)	2	(1.5)	2	(0.8)
	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)
	肝機能検査値上昇	1	(0.8)	1	(0.8)	2	(0.8)
傷害、中毒および処置合併症	節足動物咬傷	1	(0.8)	0	(0.0)	1	(0.4)
	転倒	0	(0.0)	1	(0.8)	1	(0.4)
	足骨折	1	(0.8)	0	(0.0)	1	(0.4)
	裂傷	1	(0.8)	1	(0.8)	2	(0.8)
	靱帯捻挫	0	(0.0)	2	(1.5)	2	(0.8)
	橈骨骨折	0	(0.0)	1	(0.8)	1	(0.4)
	挫傷	2	(1.5)	0	(0.0)	2	(0.8)
	胸部損傷	1	(0.8)	0	(0.0)	1	(0.4)
	歯牙破折	1	(0.8)	0	(0.0)	1	(0.4)
	処置による疼痛	4	(3.0)	1	(0.8)	5	(1.9)
	脊柱損傷	1	(0.8)	0	(0.0)	1	(0.4)
	注射に伴う反応	1	(0.8)	0	(0.0)	1	(0.4)
	外傷後頚部症候群	1	(0.8)	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.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2　FINAL

表 2.7.4.7-29　すべての有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.2
Incidence of 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	(%)
社会環境	個人衛生不良	1	(0.8)	0	(0.0)	1	(0.4)
TOTAL1)		101	(76.5)	107	(80.5)	208	(78.5)

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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.2 より作成＞

表 2.7.4.7-30　すべての副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.2

Incidence of Potentially Drug-related 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	(%)
感染症および寄生虫症	鼻咽頭炎	0	(0.0)	2	(1.5)	2	(0.8)
	鼻炎	0	(0.0)	1	(0.8)	1	(0.4)
	尿路感染	1	(0.8)	0	(0.0)	1	(0.4)
血液およびリンパ系障害	貧血	1	(0.8)	0	(0.0)	1	(0.4)
	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)
代謝および栄養障害	高血糖	1	(0.8)	0	(0.0)	1	(0.4)
	食欲亢進	4	(3.0)	1	(0.8)	5	(1.9)
	高インスリン血症	0	(0.0)	1	(0.8)	1	(0.4)
精神障害	激越	1	(0.8)	2	(1.5)	3	(1.1)
	不安	6	(4.5)	2	(1.5)	8	(3.0)
	無感情	1	(0.8)	0	(0.0)	1	(0.4)
	双極１型障害	0	(0.0)	2	(1.5)	2	(0.8)
	歯ぎしり	0	(0.0)	1	(0.8)	1	(0.4)
	抑うつ気分	0	(0.0)	1	(0.8)	1	(0.4)
	うつ病	4	(3.0)	1	(0.8)	5	(1.9)
	初期不眠症	1	(0.8)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-8.3.2　FINAL

表 2.7.4.7-30　すべての副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.2
Incidence of Potentially Drug-related 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	不眠症	4	(3.0)	6	(4.5)	10	(3.8)
	リビドー減退	2	(1.5)	2	(1.5)	4	(1.5)
	躁病	1	(0.8)	4	(3.0)	5	(1.9)
	中期不眠症	1	(0.8)	0	(0.0)	1	(0.4)
	神経過敏	0	(0.0)	1	(0.8)	1	(0.4)
	落ち着きのなさ	4	(3.0)	5	(3.8)	9	(3.4)
	睡眠障害	0	(0.0)	1	(0.8)	1	(0.4)
	夢遊症	1	(0.8)	0	(0.0)	1	(0.4)
	緊張	0	(0.0)	1	(0.8)	1	(0.4)
	ディスフェミア	1	(0.8)	0	(0.0)	1	(0.4)
	双極性障害	1	(0.8)	2	(1.5)	3	(1.1)
	精神活動過多	0	(0.0)	1	(0.8)	1	(0.4)
神経系障害	アカシジア	27	(20.5)	17	(12.8)	44	(16.6)
	運動緩慢	2	(1.5)	0	(0.0)	2	(0.8)
	浮動性めまい	1	(0.8)	1	(0.8)	2	(0.8)
	ジスキネジア	2	(1.5)	2	(1.5)	4	(1.5)
	錐体外路障害	1	(0.8)	2	(1.5)	3	(1.1)
	頭痛	0	(0.0)	2	(1.5)	2	(0.8)
	過眠症	1	(0.8)	0	(0.0)	1	(0.4)
	感覚鈍麻	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-8.3.2　FINAL

表 2.7.4.7-30　すべての副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.2
Incidence of Potentially Drug-related 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	(%)
神経系障害	嗜眠	1	(0.8)	1	(0.8)	2	(0.8)
	片頭痛	0	(0.0)	1	(0.8)	1	(0.4)
	錯感覚	1	(0.8)	0	(0.0)	1	(0.4)
	パーキンソニズム	1	(0.8)	1	(0.8)	2	(0.8)
	鎮静	2	(1.5)	0	(0.0)	2	(0.8)
	傾眠	5	(3.8)	1	(0.8)	6	(2.3)
	遅発性ジスキネジア	1	(0.8)	0	(0.0)	1	(0.4)
	振戦	3	(2.3)	2	(1.5)	5	(1.9)
	下肢静止不能症候群	0	(0.0)	1	(0.8)	1	(0.4)
眼障害	羞明	1	(0.8)	1	(0.8)	2	(0.8)
	霧視	3	(2.3)	0	(0.0)	3	(1.1)
耳および迷路障害	耳鳴	1	(0.8)	0	(0.0)	1	(0.4)
心臓障害	第一度房室ブロック	1	(0.8)	0	(0.0)	1	(0.4)
血管障害	高血圧	1	(0.8)	2	(1.5)	3	(1.1)
胃腸障害	便秘	2	(1.5)	1	(0.8)	3	(1.1)
	口内乾燥	2	(1.5)	3	(2.3)	5	(1.9)

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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-8.3.2　FINAL

表 2.7.4.7-30　すべての副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.2
Incidence of Potentially Drug-related 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	(%)
胃腸障害	消化不良	0	(0.0)	1	(0.8)	1	(0.4)
	悪心	1	(0.8)	2	(1.5)	3	(1.1)
	流涎過多	3	(2.3)	3	(2.3)	6	(2.3)
	嘔吐	1	(0.8)	1	(0.8)	2	(0.8)
皮膚および皮下組織障害	ざ瘡	0	(0.0)	1	(0.8)	1	(0.4)
	皮膚炎	1	(0.8)	0	(0.0)	1	(0.4)
	多汗症	0	(0.0)	1	(0.8)	1	(0.4)
	そう痒症	0	(0.0)	1	(0.8)	1	(0.4)
筋骨格系および結合組織障害	筋攣縮	0	(0.0)	2	(1.5)	2	(0.8)
	筋骨格痛	1	(0.8)	0	(0.0)	1	(0.4)
	顎痛	0	(0.0)	1	(0.8)	1	(0.4)
	顎関節症候群	0	(0.0)	1	(0.8)	1	(0.4)
	開口障害	1	(0.8)	0	(0.0)	1	(0.4)
腎および尿路障害	夜間頻尿	0	(0.0)	1	(0.8)	1	(0.4)
生殖系および乳房障害	射精遅延	1	(0.8)	0	(0.0)	1	(0.4)
	月経過多	1	(0.8)	0	(0.0)	1	(0.4)
	不規則月経	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.2　FINAL

表 2.7.4.7-30　すべての副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.2
Incidence of Potentially Drug-related 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	(%)
生殖系および乳房障害	卵巣嚢胞	1	(0.8)	0	(0.0)	1	(0.4)
	性機能不全	1	(0.8)	1	(0.8)	2	(0.8)
	勃起不全	2	(1.5)	0	(0.0)	2	(0.8)
一般・全身障害および投与部位の状態	疲労	4	(3.0)	4	(3.0)	8	(3.0)
	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)
	倦怠感	0	(0.0)	1	(0.8)	1	(0.4)
	不活発	1	(0.8)	1	(0.8)	2	(0.8)
臨床検査	血中クレアチンホスホキナーゼ増加	2	(1.5)	0	(0.0)	2	(0.8)
	血中ブドウ糖増加	0	(0.0)	1	(0.8)	1	(0.4)
	血中インスリン増加	0	(0.0)	1	(0.8)	1	(0.4)
	グリコヘモグロビン増加	0	(0.0)	2	(1.5)	2	(0.8)
	体重減少	0	(0.0)	4	(3.0)	4	(1.5)
	体重増加	30	(22.7)	21	(15.8)	51	(19.2)
傷害、中毒および処置合併症	挫傷	1	(0.8)	0	(0.0)	1	(0.4)
	注射に伴う反応	1	(0.8)	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.
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表 2.7.4.7-30　すべての副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.2

Incidence of Potentially Drug-related 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	(%)
TOTAL1)		82	(62.1)	67	(50.4)	149	(56.2)

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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＜資料番号 5.3.5.1-01：CT-8.3.2 より作成＞

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気管支炎	1 (0.8)	2 (1.5)	0 (0.0)	3 (2.3)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	蜂巣炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	胃腸炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	麦粒腫	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)	0 (0.0)	2 (1.5)	0 (0.0)	2 (1.5)
	喉頭炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	鼻咽頭炎	9 (6.8)	1 (0.8)	0 (0.0)	10 (7.6)	12 (9.0)	1 (0.8)	0 (0.0)	13 (9.8)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	外耳炎	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	レンサ球菌性咽頭炎	0 (0.0)	2 (1.5)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	副鼻腔炎	2 (1.5)	3 (2.3)	0 (0.0)	5 (3.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	須毛瘡	1 (0.8)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	気管支炎	2 (0.8)	3 (1.1)	0 (0.0)	5 (1.9)
	蜂巣炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	結膜炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	真菌感染	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	胃腸炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	ウイルス性胃腸炎	1 (0.4)	2 (0.8)	0 (0.0)	3 (1.1)
	麦粒腫	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	インフルエンザ	2 (0.8)	3 (1.1)	0 (0.0)	5 (1.9)
	喉頭炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	シラミ寄生	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	限局性感染	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	鼻咽頭炎	21 (7.9)	2 (0.8)	0 (0.0)	23 (8.7)
	精巣炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	外耳炎	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	中耳炎	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	咽頭炎	2 (0.8)	1 (0.4)	0 (0.0)	3 (1.1)
	レンサ球菌性咽頭炎	1 (0.4)	2 (0.8)	0 (0.0)	3 (1.1)
	肺炎	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	鼻炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	副鼻腔炎	3 (1.1)	3 (1.1)	0 (0.0)	6 (2.3)
	須毛瘡	1 (0.4)	0 (0.0)	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.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
感染症および寄生虫症	足部白癬	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	歯膿瘍	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	トリコモナス症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	上気道感染	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	3 (2.3)	3 (2.3)	0 (0.0)	6 (4.5)
	尿路感染	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	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)	0 (0.0)	0 (0.0)	1 (0.8)
	歯感染	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	無症候性細菌尿	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	クラミジア感染	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	真菌性口腔咽頭炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	気道感染	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
血液およびリンパ系障害	貧血	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白血球減少症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	好中球減少症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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)	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 (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
感染症および寄生虫症	足部白癬	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	歯膿瘍	0 (0.0)	2 (0.8)	0 (0.0)	2 (0.8)
	トリコモナス症	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	上気道感染	6 (2.3)	4 (1.5)	0 (0.0)	10 (3.8)
	尿路感染	5 (1.9)	1 (0.4)	0 (0.0)	6 (2.3)
	ウイルス性上気道感染	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	歯感染	2 (0.8)	1 (0.4)	0 (0.0)	3 (1.1)
	無症候性細菌尿	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	クラミジア感染	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	ウイルス性耳感染	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	真菌性口腔咽頭炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	ウイルス性気道感染	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	気道感染	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	口腔ヘルペス	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	カンジダ感染	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
血液およびリンパ系障害	貧血	3 (1.1)	0 (0.0)	0 (0.0)	3 (1.1)
	白血球減少症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	好中球減少症	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
内分泌障害	高プロラクチン血症	1 (0.4)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
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)	1 (0.8)	0 (0.0)	1 (0.8)
	高血糖	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	食欲減退	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
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)
	激越	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.5)	2 (1.5)	0 (0.0)	4 (3.0)
	不安	5 (3.8)	4 (3.0)	0 (0.0)	9 (6.8)	5 (3.8)	1 (0.8)	0 (0.0)	6 (4.5)
	無感情	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)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	抑うつ気分	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	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)
	軽躁	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	5 (3.8)	4 (3.0)	1 (0.8)	10 (7.6)	7 (5.3)	2 (1.5)	1 (0.8)	10 (7.5)
	易刺激性	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	2 (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 (VERSION 19.0) PREFERRED TERM.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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	(%)
代謝および栄養障害	脱水	0	(0.0)	1	(0.4)	0	(0.0)	1	(0.4)
	高血糖	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	食欲亢進	5	(1.9)	0	(0.0)	0	(0.0)	5	(1.9)
	高インスリン血症	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	食欲減退	2	(0.8)	0	(0.0)	0	(0.0)	2	(0.8)
	高脂血症	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	２型糖尿病	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
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)
	激越	3	(1.1)	2	(0.8)	0	(0.0)	5	(1.9)
	不安	10	(3.8)	5	(1.9)	0	(0.0)	15	(5.7)
	無感情	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)
	歯ぎしり	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	抑うつ気分	2	(0.8)	1	(0.4)	0	(0.0)	3	(1.1)
	うつ病	4	(1.5)	3	(1.1)	0	(0.0)	7	(2.6)
	軽躁	0	(0.0)	1	(0.4)	0	(0.0)	1	(0.4)
	初期不眠症	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	不眠症	12	(4.5)	6	(2.3)	2	(0.8)	20	(7.5)
	易刺激性	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	リビドー減退	5	(1.9)	0	(0.0)	0	(0.0)	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 (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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	躁病	1 (0.8)	1 (0.8)	1 (0.8)	3 (2.3)	0 (0.0)	8 (6.0)	6 (4.5)	14 (10.5)
	中期不眠症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	悪夢	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パニック発作	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神運動制止遅滞	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	2 (1.5)	4 (3.0)	0 (0.0)	6 (4.5)	4 (3.0)	1 (0.8)	0 (0.0)	5 (3.8)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	社会逃避行動	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夢遊症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	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)
	ディスフェミア	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)	4 (3.0)	5 (3.8)
	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)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
神経系障害	アカシジア	16 (12.1)	11 (8.3)	1 (0.8)	28 (21.2)	11 (8.3)	6 (4.5)	0 (0.0)	17 (12.8)
	運動緩慢	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	浮動性めまい	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	2 (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 (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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	躁病	1 (0.4)	9 (3.4)	7 (2.6)	17 (6.4)
	中期不眠症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	神経過敏	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	悪夢	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	パニック発作	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	精神運動制止遅滞	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	落ち着きのなさ	6 (2.3)	5 (1.9)	0 (0.0)	11 (4.2)
	睡眠障害	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	社会逃避行動	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	夢遊症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	自殺企図	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
	緊張	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	感情不安定	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	ディスフェミア	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	双極性障害	0 (0.0)	5 (1.9)	5 (1.9)	10 (3.8)
	大うつ病	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
	精神活動過多	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	27 (10.2)	17 (6.4)	1 (0.4)	45 (17.0)
	運動緩慢	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	注意力障害	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	浮動性めまい	3 (1.1)	0 (0.0)	0 (0.0)	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.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
神経系障害	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	ジスキネジア	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	錐体外路障害	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	頭痛	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	6 (4.5)	3 (2.3)	0 (0.0)	9 (6.8)
	過眠症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	嗜眠	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	錯感覚	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	精神運動亢進	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	4 (3.0)	2 (1.5)	0 (0.0)	6 (4.5)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	遅発性ジスキネジア	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	脳損傷	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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)	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 (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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	(%)
神経系障害	構語障害	0	(0.0)	1	(0.4)	0	(0.0)	1	(0.4)
	ジスキネジア	4	(1.5)	0	(0.0)	0	(0.0)	4	(1.5)
	錐体外路障害	2	(0.8)	2	(0.8)	0	(0.0)	4	(1.5)
	頭痛	9	(3.4)	4	(1.5)	0	(0.0)	13	(4.9)
	過眠症	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	感覚鈍麻	1	(0.4)	1	(0.4)	0	(0.0)	2	(0.8)
	嗜眠	2	(0.8)	0	(0.0)	0	(0.0)	2	(0.8)
	片頭痛	1	(0.4)	1	(0.4)	0	(0.0)	2	(0.8)
	錯感覚	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	パーキンソニズム	2	(0.8)	0	(0.0)	0	(0.0)	2	(0.8)
	精神運動亢進	0	(0.0)	1	(0.4)	0	(0.0)	1	(0.4)
	坐骨神経痛	0	(0.0)	1	(0.4)	0	(0.0)	1	(0.4)
	鎮静	2	(0.8)	0	(0.0)	0	(0.0)	2	(0.8)
	傾眠	5	(1.9)	2	(0.8)	0	(0.0)	7	(2.6)
	失神	0	(0.0)	1	(0.4)	0	(0.0)	1	(0.4)
	遅発性ジスキネジア	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)
	一過性脳虚血発作	0	(0.0)	0	(0.0)	1	(0.4)	1	(0.4)
	振戦	4	(1.5)	1	(0.4)	0	(0.0)	5	(1.9)
	下肢静止不能症候群	1	(0.4)	1	(0.4)	0	(0.0)	2	(0.8)
	脳損傷	0	(0.0)	0	(0.0)	1	(0.4)	1	(0.4)
眼障害	眼痛	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
眼障害	羞明	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	霧視	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	心房細動	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	第一度房室ブロック	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	徐脈	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心肺停止	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	高血圧	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)	0 (0.0)	3 (2.3)
呼吸器、胸郭および縦隔障害	喘息	1 (0.8)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	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)
	アレルギー性副鼻腔炎	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気道うっ血	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	口腔咽頭痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部膨満	1 (0.8)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
眼障害	羞明	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	霧視	3 (1.1)	0 (0.0)	0 (0.0)	3 (1.1)
耳および迷路障害	耳鳴	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
心臓障害	心房細動	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	第一度房室ブロック	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	徐脈	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	心肺停止	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
血管障害	本態性高血圧症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	高血圧	2 (0.8)	2 (0.8)	0 (0.0)	4 (1.5)
呼吸器、胸郭および縦隔障害	喘息	1 (0.4)	0 (0.0)	1 (0.4)	2 (0.8)
	咳嗽	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	呼吸不全	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 (0.4)	0 (0.0)	1 (0.4)
	気道うっ血	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	口腔咽頭痛	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
胃腸障害	腹部膨満	1 (0.4)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
胃腸障害	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	上腹部痛	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)
	便秘	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)
	齲歯	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	下痢	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)
	口内乾燥	2 (1.5)	2 (1.5)	0 (0.0)	4 (3.0)	1 (0.8)	2 (1.5)	0 (0.0)	3 (2.3)
	消化不良	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)
	食中毒	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	悪心	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)	4 (3.0)	2 (1.5)	0 (0.0)	6 (4.5)
	口腔内不快感	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	舌腫脹	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)
	嘔吐	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)	2 (1.5)	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)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	痔出血	1 (0.8)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
胃腸障害	腹痛	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	上腹部痛	2 (0.8)	1 (0.4)	0 (0.0)	3 (1.1)
	潰瘍性大腸炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	便秘	8 (3.0)	0 (0.0)	0 (0.0)	8 (3.0)
	齲歯	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	下痢	5 (1.9)	0 (0.0)	0 (0.0)	5 (1.9)
	口内乾燥	3 (1.1)	4 (1.5)	0 (0.0)	7 (2.6)
	消化不良	5 (1.9)	0 (0.0)	0 (0.0)	5 (1.9)
	食中毒	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	歯肉痛	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	血便排泄	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	悪心	6 (2.3)	3 (1.1)	0 (0.0)	9 (3.4)
	口腔内不快感	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	流涎過多	5 (1.9)	1 (0.4)	0 (0.0)	6 (2.3)
	歯の知覚過敏	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	舌腫脹	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	歯痛	2 (0.8)	2 (0.8)	0 (0.0)	4 (1.5)
	嘔吐	3 (1.1)	1 (0.4)	0 (0.0)	4 (1.5)
	腹壁嚢胞	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	痔出血	1 (0.4)	0 (0.0)	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.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
肝胆道系障害	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
皮膚および皮下組織障害	ざ瘡	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	皮膚炎	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	接触性皮膚炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	寝汗	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	粃糠疹	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	発疹	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	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 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)	0 (0.0)	3 (2.3)
	関節炎	0 (0.0)	2 (1.5)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)
	筋肉内出血	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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 (VERSION 19.0) PREFERRED TERM.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
肝胆道系障害	脂肪肝	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
皮膚および皮下組織障害	ざ瘡	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	皮膚炎	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	接触性皮膚炎	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	皮膚乾燥	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	湿疹	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	紅斑	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	多汗症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	寝汗	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	粃糠疹	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	そう痒症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	発疹	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
筋骨格系および結合組織障害	関節痛	1 (0.4)	3 (1.1)	0 (0.0)	4 (1.5)
	関節炎	0 (0.0)	2 (0.8)	0 (0.0)	2 (0.8)
	背部痛	6 (2.3)	1 (0.4)	0 (0.0)	7 (2.6)
	筋肉内出血	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	筋痙縮	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	筋攣縮	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	筋力低下	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
筋骨格系および結合組織障害	筋骨格痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	頚部痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	肩回旋筋腱板症候群	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	開口障害	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	筋浮腫	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	緊張性膀胱	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎結石症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
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)	0 (0.0)	0 (0.0)	1 (0.8)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	射精遅延	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	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 (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
筋骨格系および結合組織障害	筋骨格痛	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	筋肉痛	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	頚部痛	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	四肢痛	4 (1.5)	0 (0.0)	0 (0.0)	4 (1.5)
	顎痛	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	足底筋膜炎	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	肩回旋筋腱板症候群	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	顎関節症候群	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	開口障害	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	筋骨格硬直	2 (0.8)	1 (0.4)	0 (0.0)	3 (1.1)
	筋浮腫	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
腎および尿路障害	排尿困難	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	緊張性膀胱	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	腎結石症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	夜間頻尿	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
生殖系および乳房障害	子宮頚部嚢胞	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	月経困難症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	射精遅延	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	射精障害	1 (0.4)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
生殖系および乳房障害	月経過多	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	卵巣嚢胞	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	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)	1 (0.8)	0 (0.0)	1 (0.8)
	性機能不全	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	勃起不全	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	3 (2.3)	2 (1.5)	0 (0.0)	5 (3.8)
	注射部位疼痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	末梢性浮腫	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	非心臓性胸痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)	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)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	2 (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 (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
生殖系および乳房障害	月経過多	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	不規則月経	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	卵巣嚢胞	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	骨盤癒着症	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	性機能不全	0 (0.0)	2 (0.8)	0 (0.0)	2 (0.8)
	陰茎分泌物	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	勃起不全	2 (0.8)	1 (0.4)	0 (0.0)	3 (1.1)
一般・全身障害および投与部位の状態	無力症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	疲労	6 (2.3)	3 (1.1)	0 (0.0)	9 (3.4)
	注射部位疼痛	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	注射部位そう痒感	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	倦怠感	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	末梢性浮腫	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	不活発	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	非心臓性胸痛	1 (0.4)	0 (0.0)	0 (0.0)	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	3 (1.1)	0 (0.0)	0 (0.0)	3 (1.1)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (0.8)	0 (0.0)	0 (0.0)	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.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
臨床検査	血中クレアチンホスホキナーゼ増加	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	血中インスリン増加	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	2 (1.5)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	血圧上昇	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	心電図ＳＴ部分下降	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (4.5)	0 (0.0)	0 (0.0)	6 (4.5)
	体重増加	24 (18.2)	7 (5.3)	0 (0.0)	31 (23.5)	18 (13.5)	6 (4.5)	0 (0.0)	24 (18.0)
	肝機能検査値上昇	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	足骨折	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	裂傷	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	挫傷	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸部損傷	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	1 (0.8)	0 (0.0)	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
臨床検査	血中クレアチンホスホキナーゼ増加	4 (1.5)	0 (0.0)	0 (0.0)	4 (1.5)
	血中ブドウ糖増加	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	血中インスリン増加	3 (1.1)	0 (0.0)	0 (0.0)	3 (1.1)
	血中カリウム減少	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	血圧上昇	1 (0.4)	2 (0.8)	0 (0.0)	3 (1.1)
	心電図ＳＴ部分下降	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	グリコヘモグロビン増加	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	体重減少	6 (2.3)	0 (0.0)	0 (0.0)	6 (2.3)
	体重増加	42 (15.8)	13 (4.9)	0 (0.0)	55 (20.8)
	肝機能検査値上昇	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	転倒	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	足骨折	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	裂傷	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	靭帯捻挫	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	橈骨骨折	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	挫傷	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	胸部損傷	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	歯牙破折	1 (0.4)	0 (0.0)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
傷害、中毒および処置合併症	処置による疼痛	1 (0.8)	3 (2.3)	0 (0.0)	4 (3.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	脊柱損傷	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射に伴う反応	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	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)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-31　重症度別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events 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 (%)
傷害、中毒および処置合併症	処置による疼痛	1 (0.4)	4 (1.5)	0 (0.0)	5 (1.9)
	脊柱損傷	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	注射に伴う反応	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	外傷後頚部症候群	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
社会環境	個人衛生不良	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: ADAE2AAC.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-8.2.3　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.3 より作成＞

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
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)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	尿路感染	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白血球減少症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	好中球減少症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
代謝および栄養障害	高血糖	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
精神障害	激越	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	2 (1.5)	0 (0.0)	2 (1.5)
	不安	3 (2.3)	3 (2.3)	0 (0.0)	6 (4.5)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	無感情	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	うつ病	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	初期不眠症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	2 (1.5)	2 (1.5)	0 (0.0)	4 (3.0)	4 (3.0)	2 (1.5)	0 (0.0)	6 (4.5)

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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
感染症および寄生虫症	鼻咽頭炎	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	鼻炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	尿路感染	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
血液およびリンパ系障害	貧血	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	白血球減少症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	好中球減少症	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
代謝および栄養障害	高血糖	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	食欲亢進	5 (1.9)	0 (0.0)	0 (0.0)	5 (1.9)
	高インスリン血症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
精神障害	激越	1 (0.4)	2 (0.8)	0 (0.0)	3 (1.1)
	不安	4 (1.5)	4 (1.5)	0 (0.0)	8 (3.0)
	無感情	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	双極１型障害	0 (0.0)	1 (0.4)	1 (0.4)	2 (0.8)
	歯ぎしり	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	抑うつ気分	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	うつ病	4 (1.5)	1 (0.4)	0 (0.0)	5 (1.9)
	初期不眠症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	不眠症	6 (2.3)	4 (1.5)	0 (0.0)	10 (3.8)

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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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	リビドー減退	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	躁病	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	3 (2.3)	1 (0.8)	4 (3.0)
	中期不眠症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	落ち着きのなさ	2 (1.5)	2 (1.5)	0 (0.0)	4 (3.0)	4 (3.0)	1 (0.8)	0 (0.0)	5 (3.8)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	夢遊症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	ディスフェミア	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)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	2 (1.5)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
神経系障害	アカシジア	15 (11.4)	11 (8.3)	1 (0.8)	27 (20.5)	11 (8.3)	6 (4.5)	0 (0.0)	17 (12.8)
	運動緩慢	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	ジスキネジア	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	錐体外路障害	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	過眠症	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	1 (0.8)	0 (0.0)	1 (0.8)
	嗜眠	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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 (VERSION 19.0) PREFERRED TERM. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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	リビドー減退	4 (1.5)	0 (0.0)	0 (0.0)	4 (1.5)
	躁病	1 (0.4)	3 (1.1)	1 (0.4)	5 (1.9)
	中期不眠症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	神経過敏	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	落ち着きのなさ	6 (2.3)	3 (1.1)	0 (0.0)	9 (3.4)
	睡眠障害	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	夢遊症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	緊張	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	ディスフェミア	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	双極性障害	0 (0.0)	1 (0.4)	2 (0.8)	3 (1.1)
	精神活動過多	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	26 (9.8)	17 (6.4)	1 (0.4)	44 (16.6)
	運動緩慢	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	浮動性めまい	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	ジスキネジア	4 (1.5)	0 (0.0)	0 (0.0)	4 (1.5)
	錐体外路障害	1 (0.4)	2 (0.8)	0 (0.0)	3 (1.1)
	頭痛	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	過眠症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	感覚鈍麻	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	嗜眠	2 (0.8)	0 (0.0)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
神経系障害	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	錯感覚	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	鎮静	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	3 (2.3)	2 (1.5)	0 (0.0)	5 (3.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	遅発性ジスキネジア	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
眼障害	羞明	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	霧視	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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	1 (0.8)	0 (0.0)	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	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	2 (1.5)	0 (0.0)	2 (1.5)
胃腸障害	便秘	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	口内乾燥	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)	1 (0.8)	2 (1.5)	0 (0.0)	3 (2.3)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)

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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
神経系障害	片頭痛	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	錯感覚	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	パーキンソニズム	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	鎮静	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	傾眠	4 (1.5)	2 (0.8)	0 (0.0)	6 (2.3)
	遅発性ジスキネジア	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	振戦	4 (1.5)	1 (0.4)	0 (0.0)	5 (1.9)
	下肢静止不能症候群	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
眼障害	羞明	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	霧視	3 (1.1)	0 (0.0)	0 (0.0)	3 (1.1)
耳および迷路障害	耳鳴	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
心臓障害	第一度房室ブロック	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
血管障害	高血圧	1 (0.4)	2 (0.8)	0 (0.0)	3 (1.1)
胃腸障害	便秘	3 (1.1)	0 (0.0)	0 (0.0)	3 (1.1)
	口内乾燥	2 (0.8)	3 (1.1)	0 (0.0)	5 (1.9)
	消化不良	1 (0.4)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
胃腸障害	悪心	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	流涎過多	2 (1.5)	1 (0.8)	0 (0.0)	3 (2.3)	3 (2.3)	0 (0.0)	0 (0.0)	3 (2.3)
	嘔吐	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
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)
	皮膚炎	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
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)	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)
	筋骨格痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	開口障害	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
生殖系および乳房障害	射精遅延	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経過多	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	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)	2 (1.5)	0 (0.0)	0 (0.0)	2 (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 (VERSION 19.0) PREFERRED TERM. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
胃腸障害	悪心	2 (0.8)	1 (0.4)	0 (0.0)	3 (1.1)
	流涎過多	5 (1.9)	1 (0.4)	0 (0.0)	6 (2.3)
	嘔吐	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
皮膚および皮下組織障害	ざ瘡	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	皮膚炎	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	多汗症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	そう痒症	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
筋骨格系および結合組織障害	筋攣縮	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	筋骨格痛	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	顎痛	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	顎関節症候群	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	開口障害	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
腎および尿路障害	夜間頻尿	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
生殖系および乳房障害	射精遅延	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	月経過多	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	不規則月経	2 (0.8)	0 (0.0)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
生殖系および乳房障害	卵巣嚢胞	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	勃起不全	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	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	3 (2.3)	1 (0.8)	0 (0.0)	4 (3.0)	2 (1.5)	2 (1.5)	0 (0.0)	4 (3.0)
	注射部位疼痛	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	不活発	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
臨床検査	血中クレアチンホスホキナーゼ増加	2 (1.5)	0 (0.0)	0 (0.0)	2 (1.5)	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)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
	血中インスリン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.5)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.0)	0 (0.0)	0 (0.0)	4 (3.0)
	体重増加	23 (17.4)	7 (5.3)	0 (0.0)	30 (22.7)	16 (12.0)	5 (3.8)	0 (0.0)	21 (15.8)
傷害、中毒および処置合併症	挫傷	1 (0.8)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
生殖系および乳房障害	卵巣嚢胞	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	性機能不全	0 (0.0)	2 (0.8)	0 (0.0)	2 (0.8)
	勃起不全	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
一般・全身障害および投与部位の状態	疲労	5 (1.9)	3 (1.1)	0 (0.0)	8 (3.0)
	注射部位疼痛	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	注射部位そう痒感	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	倦怠感	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	不活発	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
臨床検査	血中クレアチンホスホキナーゼ増加	2 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)
	血中ブドウ糖増加	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	血中インスリン増加	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
	グリコヘモグロビン増加	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.8)
	体重減少	4 (1.5)	0 (0.0)	0 (0.0)	4 (1.5)
	体重増加	39 (14.7)	12 (4.5)	0 (0.0)	51 (19.2)
傷害、中毒および処置合併症	挫傷	1 (0.4)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3

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

		ARIP IMD (N=132)				PLACEBO (N=133)			
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	注射に伴う反応	1 (0.8)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.3　FINAL

表 2.7.4.7-32　重症度別副作用［二重盲検試験の二重盲検期（Phase D）］

CT-8.3.3
Incidence of Potentially Drug-related Treatment-emergent Adverse Events 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 (%)
傷害、中毒および処置合併症	注射に伴う反応	1 (0.4)	0 (0.0)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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＜資料番号 5.3.5.1-01：CT-8.3.3 より作成＞

表 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
感染症および寄生虫症	膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	細菌性膣症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	乳房蜂巣炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	気管支炎	2 (0.5)	2 (0.6)	2 (0.9)	0 (0.0)	0 (0.0)	5 (1.2)
	蜂巣炎	1 (0.2)	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)	3 (0.7)
	真菌感染	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	胃腸炎	3 (0.7)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
	ウイルス性胃腸炎	1 (0.2)	0 (0.0)	2 (0.9)	1 (0.6)	0 (0.0)	3 (0.7)
	ヘルペスウイルス感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	麦粒腫	1 (0.2)	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)	3 (0.7)
	インフルエンザ	3 (0.7)	2 (0.6)	0 (0.0)	1 (0.6)	0 (0.0)	6 (1.4)
	喉頭炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	下気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻咽頭炎	18 (4.2)	10 (2.9)	1 (0.4)	3 (1.8)	1 (0.8)	31 (7.3)
	外耳炎	1 (0.2)	0 (0.0)	2 (0.9)	0 (0.0)	1 (0.8)	3 (0.7)
	中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (0.5)
	急性中耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	爪囲炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	咽頭炎	2 (0.5)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	3 (0.7)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
感染症および寄生虫症	レンサ球菌性咽頭炎	2 (0.5)	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)	4 (0.9)
	腎盂腎炎	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	敗血症	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	性行為感染症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔炎	3 (0.7)	4 (1.1)	1 (0.4)	1 (0.6)	1 (0.8)	10 (2.4)
	須毛瘡	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	足部白癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.2)
	歯膿瘍	2 (0.5)	1 (0.3)	1 (0.4)	1 (0.6)	0 (0.0)	5 (1.2)
	トリコモナス症	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	上気道感染	11 (2.6)	6 (1.7)	1 (0.4)	1 (0.6)	1 (0.8)	19 (4.5)
	尿路感染	2 (0.5)	2 (0.6)	2 (0.9)	0 (0.0)	0 (0.0)	6 (1.4)
	ウイルス性上気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	外陰部膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	外陰部腟炎	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	歯感染	2 (0.5)	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)	4 (0.9)
	無症候性細菌尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	ブドウ球菌感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	クラミジア感染	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	真菌性口腔咽頭炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
感染症および寄生虫症	ウイルス性気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	気道感染	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	ダニ皮膚炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	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 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	子宮平滑筋腫	1 (0.2)	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.6)	2 (0.5)
	白血球減少症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	好中球減少症	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
免疫系障害	季節性アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	高血糖	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	食欲亢進	8 (1.9)	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)	10 (2.4)
	鉄欠乏	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=425) n	(%)	3-6 MONTHS (N=350) n	(%)	6-9 MONTHS (N=232) n	(%)	9-12 MONTHS (N=165) n	(%)	>12 MONTHS (N=126) n	(%)	TOTAL (N=425) n	(%)
代謝および栄養障害	食欲減退	4	(0.9)	1	(0.3)	0	(0.0)	1	(0.6)	1	(0.8)	7	(1.6)
精神障害	異常な夢	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	激越	7	(1.6)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	8	(1.9)
	不安	19	(4.5)	5	(1.4)	2	(0.9)	0	(0.0)	0	(0.0)	24	(5.6)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.2)
	双極１型障害	4	(0.9)	2	(0.6)	0	(0.0)	1	(0.6)	0	(0.0)	7	(1.6)
	錯乱状態	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	抑うつ気分	4	(0.9)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	4	(0.9)
	うつ病	16	(3.8)	7	(2.0)	0	(0.0)	1	(0.6)	0	(0.0)	22	(5.2)
	幻聴	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	軽躁	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	2	(0.5)
	初期不眠症	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	不眠症	24	(5.6)	8	(2.3)	3	(1.3)	2	(1.2)	1	(0.8)	37	(8.7)
	易刺激性	1	(0.2)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	2	(0.5)
	リビドー減退	3	(0.7)	3	(0.9)	1	(0.4)	0	(0.0)	0	(0.0)	7	(1.6)
	躁病	5	(1.2)	1	(0.3)	3	(1.3)	0	(0.0)	0	(0.0)	9	(2.1)
	気分動揺	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	悪夢	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	パニック発作	1	(0.2)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	2	(0.5)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
		<=3 MONTHS		3-6 MONTHS		6-9 MONTHS		9-12 MONTHS		>12 MONTHS		TOTAL	
	ADVERSE EVENT	(N=425)		(N=350)		(N=232)		(N=165)		(N=126)		(N=425)	
SYSTEM ORGAN CLASS	(MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
精神障害	精神運動制止遅滞	0	(0.0)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.2)
	落ち着きのなさ	10	(2.4)	2	(0.6)	2	(0.9)	1	(0.6)	0	(0.0)	15	(3.5)
	社会逃避行動	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	夢遊症	1	(0.2)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	2	(0.5)
	自殺念慮	6	(1.4)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	7	(1.6)
	自殺企図	1	(0.2)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	2	(0.5)
	せっかち	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	抑うつ症状	6	(1.4)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	6	(1.4)
	感情不安定	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.2)
	ディスフェミア	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	双極性障害	2	(0.5)	4	(1.1)	0	(0.0)	1	(0.6)	1	(0.8)	8	(1.9)
	大うつ病	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	自傷行動	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	精神活動過多	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
神経系障害	アカシジア	30	(7.1)	6	(1.7)	1	(0.4)	3	(1.8)	2	(1.6)	39	(9.2)
	運動緩慢	0	(0.0)	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	意識レベルの低下	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	糖尿病性ニューロパチー	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注意力障害	0	(0.0)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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-3.3　FINAL

表 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
		<=3 MONTHS		3-6 MONTHS		6-9 MONTHS		9-12 MONTHS		>12 MONTHS		TOTAL	
	ADVERSE EVENT	(N=425)		(N=350)		(N=232)		(N=165)		(N=126)		(N=425)	
SYSTEM ORGAN CLASS	(MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
神経系障害	浮動性めまい	5	(1.2)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	6	(1.4)
	よだれ	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	ジスキネジア	2	(0.5)	0	(0.0)	0	(0.0)	1	(0.6)	2	(1.6)	4	(0.9)
	ジストニア	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	錐体外路障害	4	(0.9)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	5	(1.2)
	顔面麻痺	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	頭痛	11	(2.6)	2	(0.6)	2	(0.9)	0	(0.0)	0	(0.0)	15	(3.5)
	過眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.2)
	感覚鈍麻	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	3	(0.7)
	嗜眠	5	(1.2)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	6	(1.4)
	記憶障害	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	片頭痛	3	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)
	ミオクローヌス	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.2)
	パーキンソニズム	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)
	精神運動亢進	3	(0.7)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	3	(0.7)
	神経根障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	坐骨神経痛	1	(0.2)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.2)
	鎮静	7	(1.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(1.6)
	痙攣発作	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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-3.3　FINAL

表 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
		<=3 MONTHS		3-6 MONTHS		6-9 MONTHS		9-12 MONTHS		>12 MONTHS		TOTAL	
	ADVERSE EVENT	(N=425)		(N=350)		(N=232)		(N=165)		(N=126)		(N=425)	
SYSTEM ORGAN CLASS	(MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
神経系障害	副鼻腔炎に伴う頭痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	傾眠	11	(2.6)	1	(0.3)	1	(0.4)	0	(0.0)	0	(0.0)	12	(2.8)
	失神	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	遅発性ジスキネジア	3	(0.7)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	3	(0.7)
	一過性脳虚血発作	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	振戦	6	(1.4)	3	(0.9)	2	(0.9)	0	(0.0)	1	(0.8)	10	(2.4)
	下肢静止不能症候群	3	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)
	慢性多発ニューロパチー	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	脳損傷	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.2)
眼障害	羞明	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	霧視	1	(0.2)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
心臓障害	急性心筋梗塞	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	心房細動	0	(0.0)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.2)
	徐脈	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.2)
	心肺停止	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.2)
血管障害	潮紅	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血腫	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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-3.3　FINAL

表 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
血管障害	高血圧	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
	低血圧	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血栓症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
呼吸器、胸郭および縦隔障害	喘息	2 (0.5)	1 (0.3)	0 (0.0)	1 (0.6)	0 (0.0)	4 (0.9)
	咳嗽	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	呼吸困難	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	しゃっくり	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻閉	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.7)
	鼻中隔弯曲	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	呼吸不全	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	鼻漏	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔うっ血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	睡眠時無呼吸症候群	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	くしゃみ	1 (0.2)	0 (0.0)	0 (0.0)	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)	1 (0.6)	0 (0.0)	1 (0.2)
	気道うっ血	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	2 (0.5)
	口腔咽頭痛	4 (0.9)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.2)
胃腸障害	腹部膨満	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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-3.3　FINAL

表 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
胃腸障害	腹痛	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.7)
	上腹部痛	1 (0.2)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.7)
	アフタ性潰瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	便秘	4 (0.9)	1 (0.3)	1 (0.4)	1 (0.6)	0 (0.0)	7 (1.6)
	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.2)
	下痢	14 (3.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	15 (3.5)
	口内乾燥	5 (1.2)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.8)	7 (1.6)
	消化不良	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	鼓腸	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	食中毒	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	胃食道逆流性疾患	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.7)
	悪心	8 (1.9)	1 (0.3)	1 (0.4)	2 (1.2)	0 (0.0)	11 (2.6)
	口腔内不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.2)
	流涎過多	4 (0.9)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	5 (1.2)
	舌腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.2)
	歯痛	4 (0.9)	1 (0.3)	1 (0.4)	0 (0.0)	0 (0.0)	6 (1.4)
	嘔吐	6 (1.4)	3 (0.9)	1 (0.4)	1 (0.6)	0 (0.0)	9 (2.1)
	痔出血	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	口の感覚鈍麻	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	腹部ヘルニア	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
		<=3 MONTHS		3-6 MONTHS		6-9 MONTHS		9-12 MONTHS		>12 MONTHS		TOTAL	
	ADVERSE EVENT	(N=425)		(N=350)		(N=232)		(N=165)		(N=126)		(N=425)	
SYSTEM ORGAN CLASS	(MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
肝胆道系障害	胆嚢炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	脂肪肝	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
皮膚および皮下組織障害	ざ瘡	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	皮膚炎	1	(0.2)	0	(0.0)	2	(0.9)	0	(0.0)	0	(0.0)	3	(0.7)
	接触性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.2)
	寝汗	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.2)
	粃糠疹	0	(0.0)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.2)
	そう痒症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	発疹	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	2	(0.5)
	皮膚病変	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	顔面腫脹	2	(0.5)	0	(0.0)	0	(0.0)	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	7	(1.6)	1	(0.3)	1	(0.4)	0	(0.0)	0	(0.0)	9	(2.1)
	関節炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.8)	2	(0.5)
	背部痛	10	(2.4)	5	(1.4)	0	(0.0)	0	(0.0)	1	(0.8)	14	(3.3)
	筋肉内出血	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	筋痙縮	0	(0.0)	1	(0.3)	1	(0.4)	0	(0.0)	0	(0.0)	2	(0.5)
	筋骨格痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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-3.3　FINAL

表 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
筋骨格系および結合組織障害	筋肉痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	頚部痛	2 (0.5)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	3 (0.7)
	四肢痛	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.7)
	顎痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	横紋筋融解症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	肩回旋筋腱板症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	開口障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	関節可動域低下	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	頚部腫瘤	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	椎間板突出	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	筋骨格系胸痛	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	筋骨格硬直	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	3 (0.7)
	筋浮腫	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
腎および尿路障害	排尿困難	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	緊張性膀胱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	腎結石症	0 (0.0)	0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	2 (0.5)
	夜間頻尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	頻尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	腎尿細管壊死	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
		<=3 MONTHS		3-6 MONTHS		6-9 MONTHS		9-12 MONTHS		>12 MONTHS		TOTAL	
	ADVERSE EVENT	(N=425)		(N=350)		(N=232)		(N=165)		(N=126)		(N=425)	
SYSTEM ORGAN CLASS	(MedDRA PREFERRED TERM)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
腎および尿路障害	急性腎障害	0	(0.0)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	1	(0.2)
生殖系および乳房障害	無月経	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	月経困難症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	射精遅延	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	乳汁漏出症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	月経過多	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	卵巣嚢胞	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	性機能不全	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	子宮ポリープ	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	勃起不全	3	(0.7)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	3	(0.7)
一般・全身障害および投与部位の状態	無力症	3	(0.7)	0	(0.0)	1	(0.4)	0	(0.0)	0	(0.0)	4	(0.9)
	悪寒	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	疲労	14	(3.3)	2	(0.6)	0	(0.0)	0	(0.0)	1	(0.8)	16	(3.8)
	インフルエンザ様疾患	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注射部位硬結	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注射部位疼痛	19	(4.5)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	19	(4.5)
	末梢性浮腫	1	(0.2)	1	(0.3)	0	(0.0)	1	(0.6)	1	(0.8)	3	(0.7)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
一般・全身障害および投与部位の状態	疼痛	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	発熱	5 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.2)
	不活発	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	活力増進	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	カテーテル留置部位疼痛	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位腫脹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	非心臓性胸痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.8)	2 (0.5)
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)	0 (0.0)	1 (0.8)	1 (0.2)
	血中クレアチンホスホキナーゼ増加	1 (0.2)	1 (0.3)	0 (0.0)	1 (0.6)	0 (0.0)	3 (0.7)
	血中ブドウ糖増加	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	血中インスリン増加	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	拡張期血圧上昇	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	血圧上昇	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.8)	2 (0.5)
	血中プロラクチン増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	心電図ＳＴ部分下降	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	心電図Ｔ波振幅減少	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

		ARIP IMD 400/300MG											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=425) n	(%)	3-6 MONTHS (N=350) n	(%)	6-9 MONTHS (N=232) n	(%)	9-12 MONTHS (N=165) n	(%)	>12 MONTHS (N=126) n	(%)	TOTAL (N=425) n	(%)
臨床検査	γ－グルタミルトランスフェラーゼ増加	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	ヘモグロビン減少	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血小板数減少	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	体重減少	7	(1.6)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	8	(1.9)
	体重増加	29	(6.8)	6	(1.7)	4	(1.7)	2	(1.2)	1	(0.8)	42	(9.9)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	節足動物咬傷	2	(0.5)	1	(0.3)	1	(0.4)	0	(0.0)	1	(0.8)	2	(0.5)
	転倒	4	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.9)
	足骨折	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	2	(0.5)
	頭部損傷	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	裂傷	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.2)
	靱帯捻挫	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	脛骨骨折	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	擦過傷	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	肉離れ	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	挫傷	3	(0.7)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.9)
	肛門損傷	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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 2.7.4.7-33　初回発現時期別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）及び二重盲検期（Phase D）］

CT-3.3
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Aripiprazole IM Depot Injection in Trial 31-08-250 Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample or Phase D Safety Sample Aripiprazole Treated Subjects)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG <=3 MONTHS (N=425) n (%)	3-6 MONTHS (N=350) n (%)	6-9 MONTHS (N=232) n (%)	9-12 MONTHS (N=165) n (%)	>12 MONTHS (N=126) n (%)	TOTAL (N=425) n (%)
傷害、中毒および処置合併症	胸部損傷	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
	歯牙破折	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	3 (0.7)
	処置による疼痛	2 (0.5)	0 (0.0)	1 (0.4)	2 (1.2)	1 (0.8)	6 (1.4)
	脊柱損傷	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.2)
	注射に伴う反応	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	外傷後頚部症候群	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	処置後挫傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
社会環境	個人衛生不良	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
TOTAL1)		253 (59.5)	84 (24.0)	46 (19.8)	33 (20.0)	23 (18.3)	278 (65.4)

NOTE: All adverse events started after first injection in Aripiprazole IM Depot stabilization 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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＜資料番号 5.3.5.3-01：SCS CT-3.3 より作成＞

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

ARIP IMD (N=132)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. 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)	1 (0.8)
	気管支炎	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	1 (0.8)	0 (0.0)	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)	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)
	胃腸炎	1 (0.8)	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	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	喉頭炎	1 (0.8)	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)	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)
	鼻咽頭炎	5 (3.8)	4 (3.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	外耳炎	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	咽頭炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	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)

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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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	副鼻腔炎	2	(1.5)	1	(0.8)	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
	足部白癬	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯膿瘍	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	トリコモナス症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道感染	3	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿路感染	2	(1.5)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯感染	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	無症候性細菌尿	1	(0.8)	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	1	(0.8)	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)	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)	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)	0	(0.0)	0	(0.0)
	気道感染	0	(0.0)	1	(0.8)	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)	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)
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	(0.8)	0	(0.0)	2	(1.5)
	白血球減少症	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(0.8)	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　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)
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)
	高血糖	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.8)
	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)
	食欲減退	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	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)
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)
	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)
	激越	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)
	不安	2	(1.5)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)	2	(1.5)	0	(0.0)	3	(2.3)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	双極１型障害	0	(0.0)	1	(0.8)	1	(0.8)	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)
	抑うつ気分	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	うつ病	1	(0.8)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	軽躁	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	初期不眠症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不眠症	3	(2.3)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	3	(2.3)
	易刺激性	1	(0.8)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	2	(1.5)
	躁病	2	(1.5)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	悪夢	1	(0.8)	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	1	(0.8)	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)	1	(0.8)
	落ち着きのなさ	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	3	(2.3)
	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)
	社会逃避行動	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺企図	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	感情不安定	0	(0.0)	1	(0.8)	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)	1	(0.8)
	双極性障害	2	(1.5)	1	(0.8)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	アカシジア	0	(0.0)	5	(3.8)	2	(1.5)	1	(0.8)	0	(0.0)	3	(2.3)	2	(1.5)	15	(11.4)
	運動緩慢	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	注意力障害	0	(0.0)	1	(0.8)	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)	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)	0	(0.0)	0	(0.0)
	ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	錐体外路障害	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	頭痛	4	(3.0)	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)	1	(0.8)	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)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	錯感覚	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	精神運動亢進	1	(0.8)	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	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鎮静	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	2	(1.5)
	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)
	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)	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 OTHER THAN RECOVERED/LONGEST DURATION 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. 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)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	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)
	脳損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	羞明	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
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)	1 (0.8)
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)	1 (0.8)
	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)	1 (0.8)
	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	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)	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)
	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
呼吸器、胸郭および縦隔障害	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)	1 (0.8)
	アレルギー性副鼻腔炎	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気道うっ血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔咽頭痛	1 (0.8)	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)	1 (0.8)
	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)
	上腹部痛	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	便秘	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	下痢	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	1 (0.8)
	消化不良	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食中毒	1 (0.8)	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)	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)
	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)
	悪心	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)	1 (0.8)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	2 (1.5)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
胃腸障害	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)
	舌腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	歯痛	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	痔出血	1 (0.8)	0 (0.0)	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)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	皮膚炎	1 (0.8)	1 (0.8)	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 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)	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)
	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)
	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)
	寝汗	1 (0.8)	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)	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)	0 (0.0)	0 (0.0)
	発疹	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	0	(0.0)	0	(0.0)	1	(0.8)
	関節炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	背部痛	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋肉内出血	0	(0.0)	1	(0.8)	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)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	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)
	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)
	筋骨格痛	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頚部痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)
	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)
	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)	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)	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)	1	(0.8)
	筋骨格硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋浮腫	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	緊張性膀胱	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
腎および尿路障害	腎結石症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
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)
	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)
	射精遅延	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)
	月経過多	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)
	卵巣嚢胞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	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)	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)
	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)	2	(1.5)
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)	1	(0.8)
	疲労	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	注射部位疼痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	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)	2	(1.5)
	不活発	0	(0.0)	1	(0.8)	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)	1	(0.8)	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	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	血中クレアチンホスホキナーゼ増加	1	(0.8)	1	(0.8)	0	(0.0)	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)	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)	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)	0	(0.0)	0	(0.0)
	血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	心電図ＳＴ部分下降	0	(0.0)	0	(0.0)	1	(0.8)	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)
	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)
	体重増加	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	27	(20.5)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	1	(0.8)
	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)
	足骨折	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	裂傷	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)
	挫傷	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸部損傷	1	(0.8)	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)	1	(0.8)
	処置による疼痛	1	(0.8)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	脊柱損傷	1	(0.8)	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	1	(0.8)	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)	1	(0.8)	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	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
TOTAL1)		6	(4.5)	11	(8.3)	9	(6.8)	2	(1.5)	3	(2.3)	9	(6.8)	2	(1.5)	59	(44.7)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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)
	気管支炎	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	結膜炎	1	(0.8)	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	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性胃腸炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	インフルエンザ	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	シラミ寄生	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	限局性感染	1	(0.8)	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	9	(6.8)	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	精巣炎	0	(0.0)	1	(0.8)	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)	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)
	咽頭炎	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	レンサ球菌性咽頭炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肺炎	2	(1.5)	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)	1	(0.8)

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5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	副鼻腔炎	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	足部白癬	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯膿瘍	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	トリコモナス症	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道感染	4	(3.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿路感染	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)	0	(0.0)	0	(0.0)
	歯感染	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)
	ウイルス性耳感染	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性気道感染	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口腔ヘルペス	1	(0.8)	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)	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)	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)
	好中球減少症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	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)	0	(0.0)	0	(0.0)	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)
	食欲亢進	0	(0.0)	0	(0.0)	0	(0.0)	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)	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)	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)	1	(0.8)
	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)	1	(0.8)
精神障害	感情障害	1	(0.8)	0	(0.0)	1	(0.8)	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)	1	(0.8)
	激越	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	2	(1.5)
	不安	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	2	(1.5)
	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)
	双極１型障害	0	(0.0)	4	(3.0)	4	(3.0)	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)	1	(0.8)
	抑うつ気分	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	うつ病	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	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)
	不眠症	2	(1.5)	1	(0.8)	2	(1.5)	1	(0.8)	1	(0.8)	1	(0.8)	0	(0.0)	2	(1.5)
	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)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)
	躁病	6	(4.5)	2	(1.5)	1	(0.8)	1	(0.8)	2	(1.5)	1	(0.8)	0	(0.0)	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)
	神経過敏	1	(0.8)	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)	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)
	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)
	落ち着きのなさ	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)	0	(0.0)	1	(0.8)
	睡眠障害	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	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)
	自殺企図	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	緊張	1	(0.8)	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	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)
	双極性障害	1	(0.8)	2	(1.5)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	大うつ病	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	精神活動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

PLACEBO (N=133)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
神経系障害	アカシジア	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	4 (3.0)	1 (0.8)	10 (7.5)
	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)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	浮動性めまい	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	錐体外路障害	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	6 (4.5)	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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)	1 (0.8)
	嗜眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	片頭痛	1 (0.8)	1 (0.8)	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)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	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)
	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)
	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)
	傾眠	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	失神	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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)	0	(0.0)	0	(0.0)
	振戦	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	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)	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)	0	(0.0)	0	(0.0)
眼障害	眼痛	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	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)	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)
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)
	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)
	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)
	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)
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)	1	(0.8)
	高血圧	0	(0.0)	1	(0.8)	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	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)
	咳嗽	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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.
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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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
呼吸器、胸郭および縦隔障害	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)
	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)
	気道うっ血	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
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)
	腹痛	1	(0.8)	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	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	潰瘍性大腸炎	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	0	(0.0)	1	(0.8)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	齲歯	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	下痢	4	(3.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	1	(0.8)
	消化不良	3	(2.3)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)	1	(0.8)
	歯肉痛	2	(1.5)	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	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪心	2	(1.5)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	2	(1.5)
	口腔内不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	流涎過多	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	歯の知覚過敏	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	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)
	歯痛	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	嘔吐	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腹壁嚢胞	0	(0.0)	0	(0.0)	1	(0.8)	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)	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)	0	(0.0)	0	(0.0)	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)	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)
	接触性皮膚炎	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮膚乾燥	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	湿疹	1	(0.8)	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)	1	(0.8)	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)	1	(0.8)
	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)
	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)
	そう痒症	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	1	(0.8)	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 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	背部痛	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	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)
	筋攣縮	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)
	筋力低下	0	(0.0)	0	(0.0)	1	(0.8)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	頚部痛	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢痛	2	(1.5)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	顎痛	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)	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)	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)	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)	0	(0.0)	0	(0.0)
	筋骨格硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	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)
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)	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)	0	(0.0)	0	(0.0)

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表 2.7.4.7-34　　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
腎および尿路障害	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)
	夜間頻尿	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(0.8)
	月経困難症	1	(0.8)	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)	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)	0	(0.0)	1	(0.8)
	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)
	不規則月経	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	骨盤癒着症	0	(0.0)	1	(0.8)	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)	0	(0.0)	1	(0.8)
	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)	1	(0.8)
	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)	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)	0	(0.0)	0	(0.0)
	疲労	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	2	(1.5)
	注射部位疼痛	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位そう痒感	1	(0.8)	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)	1	(0.8)	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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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5　FINAL

表 2.7.4.7-34　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	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)
	不活発	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	血中クレアチンホスホキナーゼ増加	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	血中インスリン増加	1	(0.8)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.8)
	血圧上昇	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	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)	2	(1.5)
	体重減少	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	4	(3.0)
	体重増加	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	6	(4.5)	2	(1.5)	15	(11.3)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

表 2.7.4.7-34　　持続期間別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-5
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)
	転倒	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	裂傷	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	靱帯捻挫	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	橈骨骨折	1	(0.8)	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)	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)
	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)
	処置による疼痛	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)
	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)
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)
TOTAL1)		14	(10.5)	11	(8.3)	7	(5.3)	5	(3.8)	1	(0.8)	13	(9.8)	1	(0.8)	55	(41.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-5＞

表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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)
	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)
	尿路感染	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)
	白血球減少症	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
代謝および栄養障害	高血糖	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	3	(2.3)	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)
精神障害	激越	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)
	不安	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	2	(1.5)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	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)
	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)
	うつ病	2	(1.5)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	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 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	不眠症	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	躁病	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	1	(0.8)
	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)
	落ち着きのなさ	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.8)
	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)
	夢遊症	0	(0.0)	1	(0.8)	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)	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)	1	(0.8)
	双極性障害	0	(0.0)	1	(0.8)	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)
神経系障害	アカシジア	0	(0.0)	4	(3.0)	2	(1.5)	1	(0.8)	0	(0.0)	3	(2.3)	2	(1.5)	15	(11.4)
	運動緩慢	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	浮動性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	錐体外路障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	過眠症	0	(0.0)	1	(0.8)	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)	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 OTHER THAN RECOVERED/LONGEST DURATION 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-7　FINAL

表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	嗜眠	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	錯感覚	0	(0.0)	1	(0.8)	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)	0	(0.0)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.8)	1	(0.8)	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)	0	(0.0)	1	(0.8)
	振戦	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
眼障害	羞明	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)
	霧視	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
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)	1	(0.8)
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)	1	(0.8)
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)	0	(0.0)
胃腸障害	便秘	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	口内乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)

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表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	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)
	悪心	1	(0.8)	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)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	2	(1.5)
	嘔吐	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮膚炎	1	(0.8)	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)
	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)
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)
	筋骨格痛	1	(0.8)	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)
	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)
	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)	1	(0.8)
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)
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)	1	(0.8)	0	(0.0)
	月経過多	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)

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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 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
生殖系および乳房障害	卵巣嚢胞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)
	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)	2	(1.5)
一般・全身障害および投与部位の状態	疲労	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	注射部位疼痛	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)
	不活発	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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	1	(0.8)	0	(0.0)	0	(0.0)	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)	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)
	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)
	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)
	体重増加	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	2	(1.5)	0	(0.0)	26	(19.7)
傷害、中毒および処置合併症	挫傷	0	(0.0)	1	(0.8)	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	1	(0.8)	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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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
TOTAL1)		4	(3.0)	8	(6.1)	5	(3.8)	2	(1.5)	4	(3.0)	11	(8.3)	2	(1.5)	46	(34.8)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	鼻咽頭炎	1	(0.8)	1	(0.8)	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)	1	(0.8)
	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)
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)
	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)
	好中球減少症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
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)
	食欲亢進	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
精神障害	激越	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	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)
	双極１型障害	0	(0.0)	1	(0.8)	1	(0.8)	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)	1	(0.8)
	抑うつ気分	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	うつ病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-7　FINAL

表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	不眠症	1	(0.8)	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)	0	(0.0)	2	(1.5)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)
	躁病	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	神経過敏	1	(0.8)	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	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)	0	(0.0)	1	(0.8)
	睡眠障害	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)
	緊張	1	(0.8)	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)
	双極性障害	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)
神経系障害	アカシジア	0	(0.0)	1	(0.8)	1	(0.8)	1	(0.8)	0	(0.0)	4	(3.0)	1	(0.8)	9	(6.8)
	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)
	浮動性めまい	0	(0.0)	0	(0.0)	1	(0.8)	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	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	錐体外路障害	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頭痛	2	(1.5)	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)	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)	0	(0.0)	1	(0.8)

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表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	嗜眠	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)
	片頭痛	0	(0.0)	1	(0.8)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
	傾眠	0	(0.0)	0	(0.0)	0	(0.0)	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)
	振戦	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)
眼障害	羞明	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	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)
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)
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)
胃腸障害	便秘	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(0.8)	1	(0.8)

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表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	消化不良	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	流涎過多	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	1	(0.8)
	嘔吐	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	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)
	多汗症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	そう痒症	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)
	顎痛	0	(0.0)	0	(0.0)	0	(0.0)	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)	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)	0	(0.0)	0	(0.0)
腎および尿路障害	夜間頻尿	0	(0.0)	0	(0.0)	1	(0.8)	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)	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)
	不規則月経	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)

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表 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
生殖系および乳房障害	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)
	性機能不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	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)
一般・全身障害および投与部位の状態	疲労	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	1	(0.8)
	注射部位疼痛	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位そう痒感	1	(0.8)	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)	1	(0.8)	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)	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)
	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)	1	(0.8)
	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)	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)	0	(0.0)	2	(1.5)
	体重減少	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	2	(1.5)
	体重増加	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	6	(4.5)	2	(1.5)	12	(9.0)
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)
	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)

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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 2.7.4.7-35　持続期間別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-7

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Placebo-controlled Randomization Phase (Phase D Safety Sample)

		PLACEBO (N=133)											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
TOTAL1)		3 (2.3)	3 (2.3)	2 (1.5)	4 (3.0)	1 (0.8)	17 (12.8)	3 (2.3)	34 (25.6)

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 OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BC.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-7　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-7＞

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気管支炎	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	1 (0.8)	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)	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)	0 (0.0)
	ウイルス性胃腸炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	喉頭炎	1 (0.8)	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)	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	10 (7.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外耳炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	4 (3.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	須毛瘡	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	足部白癬	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	トリコモナス症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無症候性細菌尿	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	クラミジア感染	1 (0.8)	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)	0 (0.0)	0 (0.0)
	真菌性口腔咽頭炎	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	気道感染	1 (0.8)	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)	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)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
血液およびリンパ系障害	貧血	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	白血球減少症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	好中球減少症	1 (0.8)	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)	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)	0 (0.0)
	食欲亢進	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	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)
	食欲減退	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	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)
	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	6 (4.5)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	無感情	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	2 (1.5)	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)
	抑うつ気分	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	7 (5.3)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	1 (0.8)	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)	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)	0 (0.0)
	パニック発作	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	3 (2.3)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	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)
	社会逃避行動	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	夢遊症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺企図	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	感情不安定	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	5 (3.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	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)
神経系障害	アカシジア	13 (9.8)	7 (5.3)	8 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)
	運動緩慢	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	1 (0.8)	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)	1 (0.8)	0 (0.0)	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)
	ジスキネジア	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	嗜眠	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	錯感覚	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	精神運動亢進	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	4 (3.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	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	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	一過性脳虚血発作	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	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)
	脳損傷	0 (0.0)	0 (0.0)	0 (0.0)	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)
	羞明	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
耳および迷路障害	耳鳴	0 (0.0)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	第一度房室ブロック	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	徐脈	0 (0.0)	1 (0.8)	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)	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	高血圧	1 (0.8)	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	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	アレルギー性副鼻腔炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気道うっ血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔咽頭痛	1 (0.8)	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)	1 (0.8)	0 (0.0)	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)

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表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	上腹部痛	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	2 (1.5)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食中毒	1 (0.8)	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)	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	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔内不快感	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	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)
	舌腫脹	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	痔出血	1 (0.8)	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)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	接触性皮膚炎	1 (0.8)	0 (0.0)	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)	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)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	寝汗	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	粃糠疹	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)
	発疹	1 (0.8)	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	関節痛	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	関節炎	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	筋肉内出血	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	2 (1.5)	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)	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)	0 (0.0)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頚部痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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 (0.8)	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)
	開口障害	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	筋浮腫	1 (0.8)	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)	0 (0.0)	0 (0.0)
	緊張性膀胱	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎結石症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
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(Phase D Safety Sample)

		ARIP IMD (N=132)					
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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)
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)
	射精遅延	1 (0.8)	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)
	月経過多	1 (0.8)	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)
	卵巣嚢胞	1 (0.8)	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	1 (0.8)	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)	0 (0.0)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	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	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	非心臓性胸痛	1 (0.8)	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	血中クレアチンホスホキナーゼ増加	3 (2.3)	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)	0 (0.0)	0 (0.0)
	血中インスリン増加	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	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)
	血圧上昇	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心電図ＳＴ部分下降	1 (0.8)	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)
	体重減少	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 WORST OUTCOME 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　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	体重増加	4 (3.0)	4 (3.0)	23 (17.4)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	1 (0.8)	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 (0.8)	0 (0.0)	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)
	足骨折	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	裂傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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)	0 (0.0)
	胸部損傷	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	脊柱損傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射に伴う反応	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	1 (0.8)	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
TOTAL1)		42 (31.8)	13 (9.8)	44 (33.3)	0 (0.0)	1 (0.8)	1 (0.8)

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表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	結膜炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	真菌感染	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	1 (0.8)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	インフルエンザ	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	限局性感染	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	12 (9.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	精巣炎	1 (0.8)	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)	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	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

PLACEBO (N=133)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	肺炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	足部白癬	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	トリコモナス症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	6 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	歯感染	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性気道感染	1 (0.8)	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)	0 (0.0)	0 (0.0)
	口腔ヘルペス	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)
	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)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
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)	0 (0.0)
	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)
	高脂血症	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	２型糖尿病	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	感情障害	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	攻撃性	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	2 (1.5)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	4 (3.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	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	8 (6.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	8 (6.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	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	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	13 (9.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	1 (0.8)	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)	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	4 (3.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	睡眠障害	1 (0.8)	0 (0.0)	1 (0.8)	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)	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)
	自殺企図	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	緊張	1 (0.8)	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)	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)
	双極性障害	4 (3.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	精神活動過多	1 (0.8)	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	7 (5.3)	3 (2.3)	7 (5.3)	0 (0.0)	0 (0.0)	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)
	注意力障害	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	9 (6.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	嗜眠	1 (0.8)	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)	0 (0.0)
	錯感覚	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)	1 (0.8)	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	1 (0.8)	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)	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)
	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	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.8)	0 (0.0)	1 (0.8)	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)	0 (0.0)
眼障害	眼痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	羞明	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)
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)
	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)
	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)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	高血圧	2 (1.5)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咳嗽	1 (0.8)	1 (0.8)	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)	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
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)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	上腹部痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	潰瘍性大腸炎	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	胃食道逆流性疾患	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉痛	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血便排泄	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	4 (3.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	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)
	流涎過多	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹壁嚢胞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	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	1 (0.8)	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)	0 (0.0)
	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	湿疹	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	紅斑	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	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)
	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	1 (0.8)	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	関節痛	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	関節炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	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)	0 (0.0)
	筋力低下	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	頚部痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	顎痛	1 (0.8)	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)	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	顎関節症候群	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	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)
	筋骨格硬直	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	1 (0.8)	0 (0.0)	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)
	腎結石症	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
腎および尿路障害	夜間頻尿	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	月経困難症	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	射精障害	0 (0.0)	0 (0.0)	1 (0.8)	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)
	不規則月経	1 (0.8)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)
	骨盤癒着症	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	陰茎分泌物	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	0 (0.0)	1 (0.8)	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	3 (2.3)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位そう痒感	1 (0.8)	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 WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	倦怠感	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.8)	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)
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)	0 (0.0)	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)	1 (0.8)	1 (0.8)	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)	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)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	血中インスリン増加	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	血中カリウム減少	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	2 (1.5)	0 (0.0)	4 (3.0)	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 WORST OUTCOME 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　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	体重増加	9 (6.8)	2 (1.5)	13 (9.8)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	1 (0.8)	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)	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)	0 (0.0)
	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	裂傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靱帯捻挫	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	橈骨骨折	1 (0.8)	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)	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)	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)
	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)

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 WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

表 2.7.4.7-36　転帰別有害事象［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-9
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
TOTAL1)		52 (39.1)	9 (6.8)	45 (33.8)	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]2C[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]2C[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-9＞

表 2.7.4.7-37　　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	1 (0.8)	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白血球減少症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	好中球減少症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	高血糖	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
精神障害	激越	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	4 (3.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	無感情	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)	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)
	抑うつ気分	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 WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11　FINAL

表 2.7.4.7-37　　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	うつ病	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	3 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	3 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	夢遊症	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	ディスフェミア	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	1 (0.8)	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)
神経系障害	アカシジア	12 (9.1)	7 (5.3)	8 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)
	運動緩慢	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11　FINAL

表 2.7.4.7-37　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	錐体外路障害	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	1 (0.8)	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	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	錯感覚	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	4 (3.0)	0 (0.0)	1 (0.8)	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 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	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)
眼障害	羞明	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	2 (1.5)	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-37　　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
心臓障害	第一度房室ブロック	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	高血圧	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	便秘	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	悪心	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	1 (0.8)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	1 (0.8)	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)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.8)	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)
	そう痒症	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)
	筋骨格痛	1 (0.8)	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)

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表 2.7.4.7-37　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	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 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
生殖系および乳房障害	射精遅延	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経過多	1 (0.8)	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)
	卵巣嚢胞	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	1 (0.8)	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)	1 (0.8)	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	疲労	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-37　　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		ARIP IMD (N=132)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	血中クレアチンホスホキナーゼ増加	2 (1.5)	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)	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)
	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 (3.0)	22 (16.7)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	挫傷	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射に伴う反応	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		36 (27.3)	9 (6.8)	36 (27.3)	0 (0.0)	1 (0.8)	0 (0.0)

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表 2.7.4.7-37　　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	鼻咽頭炎	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	1 (0.8)	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)	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)
	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)	1 (0.8)	0 (0.0)	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)
	食欲亢進	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高インスリン血症	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	激越	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	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	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	うつ病	0 (0.0)	1 (0.8)	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	4 (3.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	4 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	4 (3.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	睡眠障害	1 (0.8)	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)
	緊張	1 (0.8)	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)
	双極性障害	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神活動過多	1 (0.8)	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	8 (6.0)	3 (2.3)	6 (4.5)	0 (0.0)	0 (0.0)	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)
	浮動性めまい	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	1 (0.8)	0 (0.0)	1 (0.8)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11　FINAL

表 2.7.4.7-37　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	錐体外路障害	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	2 (1.5)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	1 (0.8)	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	1 (0.8)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.8)	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)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	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)

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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11　FINAL

表 2.7.4.7-37　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)
血管障害	高血圧	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	便秘	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	2 (1.5)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)
	流涎過多	2 (1.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	1 (0.8)	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)	0 (0.0)
	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒症	1 (0.8)	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	2 (1.5)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	顎痛	1 (0.8)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11　FINAL

表 2.7.4.7-37　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	顎関節症候群	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	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)
腎および尿路障害	夜間頻尿	1 (0.8)	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)	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)
	不規則月経	1 (0.8)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	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	3 (2.3)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位そう痒感	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.8)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11　FINAL

表 2.7.4.7-37　転帰別副作用［二重盲検試験の二重盲検期（Phase D）］

5.3.5.3-11

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Placebo-controlled Randomization Phase
(Phase D Safety Sample)

		PLACEBO (N=133)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	血中インスリン増加	0 (0.0)	0 (0.0)	1 (0.8)	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)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	2 (1.5)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	9 (6.8)	2 (1.5)	10 (7.5)	0 (0.0)	0 (0.0)	0 (0.0)
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)
	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)
TOTAL1)		33 (24.8)	6 (4.5)	27 (20.3)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-11＞

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
感染症および寄生虫症	乳房蜂巣炎	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	気管支炎	3 (3.4)	0 (0.0)	3 (2.3)	2 (2.4)	0 (0.0)	2 (1.5)	5 (2.9)	0 (0.0)	5 (1.9)
	蜂巣炎	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	胃腸炎	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	ウイルス性胃腸炎	1 (1.1)	1 (2.3)	2 (1.5)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	1 (1.1)	3 (1.1)
	麦粒腫	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	インフルエンザ	2 (2.3)	1 (2.3)	3 (2.3)	2 (2.4)	0 (0.0)	2 (1.5)	4 (2.3)	1 (1.1)	5 (1.9)
	喉頭炎	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	鼻咽頭炎	8 (9.1)	2 (4.5)	10 (7.6)	9 (10.6)	4 (8.3)	13 (9.8)	17 (9.8)	6 (6.5)	23 (8.7)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	外耳炎	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	中耳炎	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	咽頭炎	1 (1.1)	0 (0.0)	1 (0.8)	2 (2.4)	0 (0.0)	2 (1.5)	3 (1.7)	0 (0.0)	3 (1.1)
	レンサ球菌性咽頭炎	2 (2.3)	0 (0.0)	2 (1.5)	1 (1.2)	0 (0.0)	1 (0.8)	3 (1.7)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AD.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)						PLACEBO (N=133)						TOTAL (N=265)					
		< 45 YEARS OLD (N=88)		>= 45 YEARS OLD (N=44)		TOTAL (N=132)		< 45 YEARS OLD (N=85)		>= 45 YEARS OLD (N=48)		TOTAL (N=133)		< 45 YEARS OLD (N=173)		>= 45 YEARS OLD (N=92)		TOTAL (N=265)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
感染症および寄生虫症	肺炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	1	(2.1)	2	(1.5)	1	(0.6)	1	(1.1)	2	(0.8)
	鼻炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.8)	1	(0.6)	0	(0.0)	1	(0.4)
	副鼻腔炎	5	(5.7)	0	(0.0)	5	(3.8)	1	(1.2)	0	(0.0)	1	(0.8)	6	(3.5)	0	(0.0)	6	(2.3)
	須毛瘡	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	足部白癬	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	1	(2.1)	1	(0.8)	1	(0.6)	1	(1.1)	2	(0.8)
	歯膿瘍	1	(1.1)	0	(0.0)	1	(0.8)	1	(1.2)	0	(0.0)	1	(0.8)	2	(1.2)	0	(0.0)	2	(0.8)
	トリコモナス症	1	(1.1)	0	(0.0)	1	(0.8)	1	(1.2)	0	(0.0)	1	(0.8)	2	(1.2)	0	(0.0)	2	(0.8)
	上気道感染	3	(3.4)	1	(2.3)	4	(3.0)	5	(5.9)	1	(2.1)	6	(4.5)	8	(4.6)	2	(2.2)	10	(3.8)
	尿路感染	3	(3.4)	1	(2.3)	4	(3.0)	2	(2.4)	0	(0.0)	2	(1.5)	5	(2.9)	1	(1.1)	6	(2.3)
	ウイルス性上気道感染	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.8)	1	(0.6)	0	(0.0)	1	(0.4)
	歯感染	1	(1.1)	0	(0.0)	1	(0.8)	2	(2.4)	0	(0.0)	2	(1.5)	3	(1.7)	0	(0.0)	3	(1.1)
	無症候性細菌尿	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	クラミジア感染	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	ウイルス性耳感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.1)	1	(0.8)	0	(0.0)	1	(1.1)	1	(0.4)
	真菌性口腔咽頭炎	0	(0.0)	1	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.1)	1	(0.4)
	ウイルス性気道感染	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.8)	1	(0.6)	0	(0.0)	1	(0.4)
	気道感染	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	口腔ヘルペス	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.1)	1	(0.8)	0	(0.0)	1	(1.1)	1	(0.4)
	カンジダ感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.1)	1	(0.8)	0	(0.0)	1	(1.1)	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: ADAE21AD.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
血液およびリンパ系障害	貧血	3 (3.4)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	3 (1.1)
	白血球減少症	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	好中球減少症	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	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 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	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)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	高血糖	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	食欲亢進	1 (1.1)	3 (6.8)	4 (3.0)	0 (0.0)	1 (2.1)	1 (0.8)	1 (0.6)	4 (4.3)	5 (1.9)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	食欲減退	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (2.1)	2 (1.5)	1 (0.6)	1 (1.1)	2 (0.8)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	激越	0 (0.0)	1 (2.3)	1 (0.8)	2 (2.4)	2 (4.2)	4 (3.0)	2 (1.2)	3 (3.3)	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.

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)						PLACEBO (N=133)						TOTAL (N=265)					
		< 45 YEARS OLD (N=88)		>= 45 YEARS OLD (N=44)		TOTAL (N=132)		< 45 YEARS OLD (N=85)		>= 45 YEARS OLD (N=48)		TOTAL (N=133)		< 45 YEARS OLD (N=173)		>= 45 YEARS OLD (N=92)		TOTAL (N=265)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
精神障害	不安	5	(5.7)	4	(9.1)	9	(6.8)	2	(2.4)	4	(8.3)	6	(4.5)	7	(4.0)	8	(8.7)	15	(5.7)
	無感情	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	双極１型障害	1	(1.1)	1	(2.3)	2	(1.5)	5	(5.9)	3	(6.3)	8	(6.0)	6	(3.5)	4	(4.3)	10	(3.8)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.1)	1	(0.8)	0	(0.0)	1	(1.1)	1	(0.4)
	抑うつ気分	1	(1.1)	0	(0.0)	1	(0.8)	1	(1.2)	1	(2.1)	2	(1.5)	2	(1.2)	1	(1.1)	3	(1.1)
	うつ病	3	(3.4)	1	(2.3)	4	(3.0)	2	(2.4)	1	(2.1)	3	(2.3)	5	(2.9)	2	(2.2)	7	(2.6)
	軽躁	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	初期不眠症	0	(0.0)	1	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.1)	1	(0.4)
	不眠症	7	(8.0)	3	(6.8)	10	(7.6)	5	(5.9)	5	(10.4)	10	(7.5)	12	(6.9)	8	(8.7)	20	(7.5)
	易刺激性	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	リビドー減退	1	(1.1)	2	(4.5)	3	(2.3)	2	(2.4)	0	(0.0)	2	(1.5)	3	(1.7)	2	(2.2)	5	(1.9)
	躁病	2	(2.3)	1	(2.3)	3	(2.3)	9	(10.6)	5	(10.4)	14	(10.5)	11	(6.4)	6	(6.5)	17	(6.4)
	中期不眠症	0	(0.0)	1	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.1)	1	(0.4)
	神経過敏	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.8)	1	(0.6)	0	(0.0)	1	(0.4)
	悪夢	0	(0.0)	1	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.1)	1	(0.4)
	パニック発作	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	精神運動制止遅滞	1	(1.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	0	(0.0)	1	(0.4)
	落ち着きのなさ	3	(3.4)	3	(6.8)	6	(4.5)	3	(3.5)	2	(4.2)	5	(3.8)	6	(3.5)	5	(5.4)	11	(4.2)
	睡眠障害	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)	2	(1.5)	2	(1.2)	0	(0.0)	2	(0.8)
	社会逃避行動	0	(0.0)	1	(2.3)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.1)	1	(0.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
精神障害	夢遊症	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	自殺企図	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	感情不安定	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	ディスフェミア	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	双極性障害	3 (3.4)	2 (4.5)	5 (3.8)	3 (3.5)	2 (4.2)	5 (3.8)	6 (3.5)	4 (4.3)	10 (3.8)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (2.1)	2 (1.5)	1 (0.6)	1 (1.1)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	20 (22.7)	8 (18.2)	28 (21.2)	10 (11.8)	7 (14.6)	17 (12.8)	30 (17.3)	15 (16.3)	45 (17.0)
	運動緩慢	0 (0.0)	2 (4.5)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.2)	2 (0.8)
	注意力障害	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
	浮動性めまい	1 (1.1)	0 (0.0)	1 (0.8)	2 (2.4)	0 (0.0)	2 (1.5)	3 (1.7)	0 (0.0)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	ジスキネジア	1 (1.1)	1 (2.3)	2 (1.5)	2 (2.4)	0 (0.0)	2 (1.5)	3 (1.7)	1 (1.1)	4 (1.5)
	錐体外路障害	1 (1.1)	1 (2.3)	2 (1.5)	1 (1.2)	1 (2.1)	2 (1.5)	2 (1.2)	2 (2.2)	4 (1.5)
	頭痛	3 (3.4)	1 (2.3)	4 (3.0)	6 (7.1)	3 (6.3)	9 (6.8)	9 (5.2)	4 (4.3)	13 (4.9)
	過眠症	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	感覚鈍麻	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	2 (2.2)	2 (0.8)
	嗜眠	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)

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CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
神経系障害	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	錯感覚	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	パーキンソニズム	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	2 (2.2)	2 (0.8)
	精神運動亢進	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	坐骨神経痛	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	鎮静	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	傾眠	3 (3.4)	3 (6.8)	6 (4.5)	1 (1.2)	0 (0.0)	1 (0.8)	4 (2.3)	3 (3.3)	7 (2.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	遅発性ジスキネジア	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	一過性脳虚血発作	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	振戦	2 (2.3)	1 (2.3)	3 (2.3)	2 (2.4)	0 (0.0)	2 (1.5)	4 (2.3)	1 (1.1)	5 (1.9)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	1 (2.1)	2 (1.5)	1 (0.6)	1 (1.1)	2 (0.8)
	脳損傷	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
眼障害	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	羞明	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	2 (2.2)	2 (0.8)
	霧視	3 (3.4)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.7)	0 (0.0)	3 (1.1)
耳および迷路障害	耳鳴	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	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.

FILE: ADAE21AD.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
		< 45 YEARS OLD	>= 45 YEARS OLD	TOTAL	< 45 YEARS OLD	>= 45 YEARS OLD	TOTAL	< 45 YEARS OLD	>= 45 YEARS OLD	TOTAL
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	(N=88) n %	(N=44) n %	(N=132) n %	(N=85) n %	(N=48) n %	(N=133) n %	(N=173) n %	(N=92) n %	(N=265) n %
心臓障害	心房細動	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	第一度房室ブロック	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	徐脈	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	心肺停止	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	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)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	高血圧	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	3 (6.3)	3 (2.3)	0 (0.0)	4 (4.3)	4 (1.5)
呼吸器、胸郭および縦隔障害	喘息	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	呼吸不全	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	アレルギー性副鼻腔炎	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	気道うっ血	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	1 (0.6)	1 (1.1)	2 (0.8)
	口腔咽頭痛	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
胃腸障害	腹部膨満	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	上腹部痛	1 (1.1)	1 (2.3)	2 (1.5)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	1 (1.1)	3 (1.1)

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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-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	便秘	4 (4.5)	0 (0.0)	4 (3.0)	2 (2.4)	2 (4.2)	4 (3.0)	6 (3.5)	2 (2.2)	8 (3.0)
	齲歯	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
	下痢	0 (0.0)	1 (2.3)	1 (0.8)	1 (1.2)	3 (6.3)	4 (3.0)	1 (0.6)	4 (4.3)	5 (1.9)
	口内乾燥	2 (2.3)	2 (4.5)	4 (3.0)	2 (2.4)	1 (2.1)	3 (2.3)	4 (2.3)	3 (3.3)	7 (2.6)
	消化不良	1 (1.1)	0 (0.0)	1 (0.8)	3 (3.5)	1 (2.1)	4 (3.0)	4 (2.3)	1 (1.1)	5 (1.9)
	食中毒	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	悪心	3 (3.4)	0 (0.0)	3 (2.3)	4 (4.7)	2 (4.2)	6 (4.5)	7 (4.0)	2 (2.2)	9 (3.4)
	口腔内不快感	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	流涎過多	2 (2.3)	1 (2.3)	3 (2.3)	0 (0.0)	3 (6.3)	3 (2.3)	2 (1.2)	4 (4.3)	6 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	舌腫脹	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	歯痛	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	2 (4.2)	3 (2.3)	2 (1.2)	2 (2.2)	4 (1.5)
	嘔吐	2 (2.3)	0 (0.0)	2 (1.5)	2 (2.4)	0 (0.0)	2 (1.5)	4 (2.3)	0 (0.0)	4 (1.5)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	痔出血	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)

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表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
肝胆道系障害	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
皮膚および皮下組織障害	ざ瘡	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
	皮膚炎	2 (2.3)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	2 (0.8)
	接触性皮膚炎	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	寝汗	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	粃糠疹	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	発疹	0 (0.0)	1 (2.3)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	1 (1.1)	2 (0.8)
筋骨格系および結合組織障害	関節痛	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	2 (4.2)	3 (2.3)	2 (1.2)	2 (2.2)	4 (1.5)
	関節炎	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	背部痛	2 (2.3)	1 (2.3)	3 (2.3)	3 (3.5)	1 (2.1)	4 (3.0)	5 (2.9)	2 (2.2)	7 (2.6)
	筋肉内出血	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)

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表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
筋骨格系および結合組織障害	筋痙縮	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (1.1)	2 (0.8)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	筋骨格痛	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	頚部痛	0 (0.0)	1 (2.3)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	1 (1.1)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	3 (6.3)	4 (3.0)	1 (0.6)	3 (3.3)	4 (1.5)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	肩回旋筋腱板症候群	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	開口障害	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	筋骨格硬直	0 (0.0)	1 (2.3)	1 (0.8)	1 (1.2)	1 (2.1)	2 (1.5)	1 (0.6)	2 (2.2)	3 (1.1)
	筋浮腫	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	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 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	緊張性膀胱	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	1 (0.4)
	腎結石症	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AD.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	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)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	射精遅延	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	月経過多	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	卵巣嚢胞	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	性機能不全	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	2 (2.2)	2 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	勃起不全	1 (1.1)	1 (2.3)	2 (1.5)	0 (0.0)	1 (2.1)	1 (0.8)	1 (0.6)	2 (2.2)	3 (1.1)
一般・全身障害および投与部位の状態	無力症	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	疲労	2 (2.3)	2 (4.5)	4 (3.0)	2 (2.4)	3 (6.3)	5 (3.8)	4 (2.3)	5 (5.4)	9 (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 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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
一般・全身障害および投与部位の状態	注射部位疼痛	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	末梢性浮腫	0 (0.0)	2 (4.5)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.2)	2 (0.8)
	不活発	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	2 (2.2)	2 (0.8)
	非心臓性胸痛	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	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	1 (1.1)	0 (0.0)	1 (0.8)	2 (2.4)	0 (0.0)	2 (1.5)	3 (1.7)	0 (0.0)	3 (1.1)
	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 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	血中クレアチンホスホキナーゼ増加	1 (1.1)	2 (4.5)	3 (2.3)	0 (0.0)	1 (2.1)	1 (0.8)	1 (0.6)	3 (3.3)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	血中インスリン増加	0 (0.0)	1 (2.3)	1 (0.8)	1 (1.2)	1 (2.1)	2 (1.5)	1 (0.6)	2 (2.2)	3 (1.1)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	血圧上昇	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	2 (4.2)	2 (1.5)	0 (0.0)	3 (3.3)	3 (1.1)
	心電図ＳＴ部分下降	0 (0.0)	1 (2.3)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.1)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) 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)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	3 (3.5)	3 (6.3)	6 (4.5)	3 (1.7)	3 (3.3)	6 (2.3)
	体重増加	20 (22.7)	11 (25.0)	31 (23.5)	20 (23.5)	4 (8.3)	24 (18.0)	40 (23.1)	15 (16.3)	55 (20.8)
	肝機能検査値上昇	1 (1.1)	0 (0.0)	1 (0.8)	1 (1.2)	0 (0.0)	1 (0.8)	2 (1.2)	0 (0.0)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (0.8)	1 (0.6)	0 (0.0)	1 (0.4)
	足骨折	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	裂傷	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	1 (2.1)	1 (0.8)	1 (0.6)	1 (1.1)	2 (0.8)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)	0 (0.0)	2 (1.5)	2 (1.2)	0 (0.0)	2 (0.8)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.1)	1 (0.8)	0 (0.0)	1 (1.1)	1 (0.4)
	挫傷	2 (2.3)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	0 (0.0)	2 (0.8)
	胸部損傷	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	歯牙破折	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	処置による疼痛	3 (3.4)	1 (2.3)	4 (3.0)	1 (1.2)	0 (0.0)	1 (0.8)	4 (2.3)	1 (1.1)	5 (1.9)
	脊柱損傷	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	注射に伴う反応	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
	外傷後頚部症候群	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-38　年齢別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.4
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Age Group
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	< 45 YEARS OLD (N=88) n %	>= 45 YEARS OLD (N=44) n %	TOTAL (N=132) n %	< 45 YEARS OLD (N=85) n %	>= 45 YEARS OLD (N=48) n %	TOTAL (N=133) n %	< 45 YEARS OLD (N=173) n %	>= 45 YEARS OLD (N=92) n %	TOTAL (N=265) n %
社会環境	個人衛生不良	1 (1.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	0 (0.0)	1 (0.4)
TOTAL1)		65 (73.9)	36 (81.8)	101 (76.5)	68 (80.0)	39 (81.3)	107 (80.5)	133 (76.9)	75 (81.5)	208 (78.5)

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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.4　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.6.4 より作成＞

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) n %	TOTAL (N=265) n %
感染症および寄生虫症	乳房蜂巣炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	気管支炎	2 (4.0)	1 (1.2)	3 (2.3)	2 (3.2)	0 (0.0)	2 (1.5)	4 (3.5)	1 (0.7)	5 (1.9)
	蜂巣炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	胃腸炎	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	ウイルス性胃腸炎	0 (0.0)	2 (2.4)	2 (1.5)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	2 (1.3)	3 (1.1)
	麦粒腫	0 (0.0)	2 (2.4)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.3)	2 (0.8)
	インフルエンザ	0 (0.0)	3 (3.7)	3 (2.3)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	4 (2.6)	5 (1.9)
	喉頭炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	鼻咽頭炎	2 (4.0)	8 (9.8)	10 (7.6)	7 (11.1)	6 (8.6)	13 (9.8)	9 (8.0)	14 (9.2)	23 (8.7)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	外耳炎	0 (0.0)	2 (2.4)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.3)	2 (0.8)
	中耳炎	0 (0.0)	2 (2.4)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.3)	2 (0.8)
	咽頭炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	3 (2.0)	3 (1.1)
	レンサ球菌性咽頭炎	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	1 (1.4)	1 (0.8)	1 (0.9)	2 (1.3)	3 (1.1)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	1 (0.7)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AB.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) 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 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	副鼻腔炎	1 (2.0)	4 (4.9)	5 (3.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	4 (2.6)	6 (2.3)
	須毛瘡	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	足部白癬	0 (0.0)	1 (1.2)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
	歯膿瘍	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	2 (0.8)
	トリコモナス症	0 (0.0)	1 (1.2)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
	上気道感染	1 (2.0)	3 (3.7)	4 (3.0)	2 (3.2)	4 (5.7)	6 (4.5)	3 (2.7)	7 (4.6)	10 (3.8)
	尿路感染	0 (0.0)	4 (4.9)	4 (3.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	6 (3.9)	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 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	歯感染	1 (2.0)	0 (0.0)	1 (0.8)	2 (3.2)	0 (0.0)	2 (1.5)	3 (2.7)	0 (0.0)	3 (1.1)
	無症候性細菌尿	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	クラミジア感染	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	真菌性口腔咽頭炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	気道感染	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) MALE (N=50) n	%	ARIP IMD (N=132) FEMALE (N=82) n	%	ARIP IMD (N=132) TOTAL (N=132) n	%	PLACEBO (N=133) MALE (N=63) n	%	PLACEBO (N=133) FEMALE (N=70) n	%	PLACEBO (N=133) TOTAL (N=133) n	%	TOTAL (N=265) MALE (N=113) n	%	TOTAL (N=265) FEMALE (N=152) n	%	TOTAL (N=265) TOTAL (N=265) n	%
血液およびリンパ系障害	貧血	0	(0.0)	3	(3.7)	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.0)	3	(1.1)
	白血球減少症	0	(0.0)	1	(1.2)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.7)	1	(0.4)
	好中球減少症	0	(0.0)	1	(1.2)	1	(0.8)	0	(0.0)	1	(1.4)	1	(0.8)	0	(0.0)	2	(1.3)	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	(1.6)	0	(0.0)	1	(0.8)	1	(0.9)	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	(1.4)	1	(0.8)	0	(0.0)	1	(0.7)	1	(0.4)
	高血糖	1	(2.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	1	(0.4)
	食欲亢進	3	(6.0)	1	(1.2)	4	(3.0)	1	(1.6)	0	(0.0)	1	(0.8)	4	(3.5)	1	(0.7)	5	(1.9)
	高インスリン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	1	(0.8)	0	(0.0)	1	(0.7)	1	(0.4)
	食欲減退	0	(0.0)	2	(2.4)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.3)	2	(0.8)
	高脂血症	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.6)	0	(0.0)	1	(0.8)	1	(0.9)	0	(0.0)	1	(0.4)
	２型糖尿病	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.6)	0	(0.0)	1	(0.8)	1	(0.9)	0	(0.0)	1	(0.4)
精神障害	感情障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.9)	2	(1.5)	0	(0.0)	2	(1.3)	2	(0.8)
	攻撃性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.4)	1	(0.8)	0	(0.0)	1	(0.7)	1	(0.4)
	激越	1	(2.0)	0	(0.0)	1	(0.8)	4	(6.3)	0	(0.0)	4	(3.0)	5	(4.4)	0	(0.0)	5	(1.9)
	不安	4	(8.0)	5	(6.1)	9	(6.8)	2	(3.2)	4	(5.7)	6	(4.5)	6	(5.3)	9	(5.9)	15	(5.7)
	無感情	1	(2.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.9)	0	(0.0)	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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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) n %	TOTAL (N=265) n %
精神障害	双極１型障害	0 (0.0)	2 (2.4)	2 (1.5)	4 (6.3)	4 (5.7)	8 (6.0)	4 (3.5)	6 (3.9)	10 (3.8)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	抑うつ気分	0 (0.0)	1 (1.2)	1 (0.8)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	2 (1.3)	3 (1.1)
	うつ病	1 (2.0)	3 (3.7)	4 (3.0)	2 (3.2)	1 (1.4)	3 (2.3)	3 (2.7)	4 (2.6)	7 (2.6)
	軽躁	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	初期不眠症	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	不眠症	3 (6.0)	7 (8.5)	10 (7.6)	4 (6.3)	6 (8.6)	10 (7.5)	7 (6.2)	13 (8.6)	20 (7.5)
	易刺激性	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	リビドー減退	2 (4.0)	1 (1.2)	3 (2.3)	2 (3.2)	0 (0.0)	2 (1.5)	4 (3.5)	1 (0.7)	5 (1.9)
	躁病	1 (2.0)	2 (2.4)	3 (2.3)	6 (9.5)	8 (11.4)	14 (10.5)	7 (6.2)	10 (6.6)	17 (6.4)
	中期不眠症	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	悪夢	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	パニック発作	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	精神運動制止遅滞	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	落ち着きのなさ	2 (4.0)	4 (4.9)	6 (4.5)	3 (4.8)	2 (2.9)	5 (3.8)	5 (4.4)	6 (3.9)	11 (4.2)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	1 (0.7)	2 (0.8)
	社会逃避行動	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	夢遊症	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	自殺企図	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	2 (1.3)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	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-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
		MALE (N=50)	FEMALE (N=82)	TOTAL (N=132)	MALE (N=63)	FEMALE (N=70)	TOTAL (N=133)	MALE (N=113)	FEMALE (N=152)	TOTAL (N=265)
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n %	n %	n %	n %	n %	n %	n %	n %	n %
精神障害	感情不安定	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	ディスフェミア	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	双極性障害	3 (6.0)	2 (2.4)	5 (3.8)	2 (3.2)	3 (4.3)	5 (3.8)	5 (4.4)	5 (3.3)	10 (3.8)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	10 (20.0)	18 (22.0)	28 (21.2)	9 (14.3)	8 (11.4)	17 (12.8)	19 (16.8)	26 (17.1)	45 (17.0)
	運動緩慢	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	2 (0.8)
	注意力障害	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	2 (1.3)	2 (0.8)
	浮動性めまい	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	3 (2.0)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	ジスキネジア	0 (0.0)	2 (2.4)	2 (1.5)	2 (3.2)	0 (0.0)	2 (1.5)	2 (1.8)	2 (1.3)	4 (1.5)
	錐体外路障害	0 (0.0)	2 (2.4)	2 (1.5)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	4 (2.6)	4 (1.5)
	頭痛	1 (2.0)	3 (3.7)	4 (3.0)	4 (6.3)	5 (7.1)	9 (6.8)	5 (4.4)	8 (5.3)	13 (4.9)
	過眠症	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	感覚鈍麻	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	2 (0.8)
	嗜眠	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	2 (0.8)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	錯感覚	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	パーキンソニズム	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	2 (0.8)
	精神運動亢進	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)

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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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
		MALE (N=50)	FEMALE (N=82)	TOTAL (N=132)	MALE (N=63)	FEMALE (N=70)	TOTAL (N=133)	MALE (N=113)	FEMALE (N=152)	TOTAL (N=265)
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n %	n %	n %	n %	n %	n %	n %	n %	n %
神経系障害	坐骨神経痛	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	鎮静	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	2 (0.8)
	傾眠	2 (4.0)	4 (4.9)	6 (4.5)	0 (0.0)	1 (1.4)	1 (0.8)	2 (1.8)	5 (3.3)	7 (2.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	遅発性ジスキネジア	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	一過性脳虚血発作	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	振戦	2 (4.0)	1 (1.2)	3 (2.3)	1 (1.6)	1 (1.4)	2 (1.5)	3 (2.7)	2 (1.3)	5 (1.9)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	1 (0.7)	2 (0.8)
	脳損傷	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
眼障害	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	羞明	0 (0.0)	1 (1.2)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
	霧視	1 (2.0)	2 (2.4)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (1.3)	3 (1.1)
耳および迷路障害	耳鳴	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
心臓障害	心房細動	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	第一度房室ブロック	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	徐脈	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	心肺停止	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
		MALE (N=50)	FEMALE (N=82)	TOTAL (N=132)	MALE (N=63)	FEMALE (N=70)	TOTAL (N=133)	MALE (N=113)	FEMALE (N=152)	TOTAL (N=265)
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n %	n %	n %	n %	n %	n %	n %	n %	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 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	高血圧	0 (0.0)	1 (1.2)	1 (0.8)	1 (1.6)	2 (2.9)	3 (2.3)	1 (0.9)	3 (2.0)	4 (1.5)
呼吸器、胸郭および縦隔障害	喘息	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	2 (0.8)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	呼吸不全	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	アレルギー性副鼻腔炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	気道うっ血	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	2 (0.8)
	口腔咽頭痛	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
胃腸障害	腹部膨満	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	上腹部痛	1 (2.0)	1 (1.2)	2 (1.5)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	1 (0.7)	3 (1.1)
	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	便秘	1 (2.0)	3 (3.7)	4 (3.0)	1 (1.6)	3 (4.3)	4 (3.0)	2 (1.8)	6 (3.9)	8 (3.0)
	齲歯	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	2 (1.3)	2 (0.8)
	下痢	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	3 (4.3)	4 (3.0)	2 (1.8)	3 (2.0)	5 (1.9)
	口内乾燥	2 (4.0)	2 (2.4)	4 (3.0)	2 (3.2)	1 (1.4)	3 (2.3)	4 (3.5)	3 (2.0)	7 (2.6)
	消化不良	0 (0.0)	1 (1.2)	1 (0.8)	1 (1.6)	3 (4.3)	4 (3.0)	1 (0.9)	4 (2.6)	5 (1.9)

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表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
		MALE (N=50)	FEMALE (N=82)	TOTAL (N=132)	MALE (N=63)	FEMALE (N=70)	TOTAL (N=133)	MALE (N=113)	FEMALE (N=152)	TOTAL (N=265)
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n %	n %	n %	n %	n %	n %	n %	n %	n %
胃腸障害	食中毒	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	悪心	0 (0.0)	3 (3.7)	3 (2.3)	3 (4.8)	3 (4.3)	6 (4.5)	3 (2.7)	6 (3.9)	9 (3.4)
	口腔内不快感	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	流涎過多	2 (4.0)	1 (1.2)	3 (2.3)	1 (1.6)	2 (2.9)	3 (2.3)	3 (2.7)	3 (2.0)	6 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	舌腫脹	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	歯痛	0 (0.0)	1 (1.2)	1 (0.8)	3 (4.8)	0 (0.0)	3 (2.3)	3 (2.7)	1 (0.7)	4 (1.5)
	嘔吐	0 (0.0)	2 (2.4)	2 (1.5)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	3 (2.0)	4 (1.5)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	痔出血	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
肝胆道系障害	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
皮膚および皮下組織障害	ざ瘡	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
	皮膚炎	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	2 (0.8)
	接触性皮膚炎	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	2 (1.3)	2 (0.8)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)

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表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
		MALE (N=50)	FEMALE (N=82)	TOTAL (N=132)	MALE (N=63)	FEMALE (N=70)	TOTAL (N=133)	MALE (N=113)	FEMALE (N=152)	TOTAL (N=265)
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n %	n %	n %	n %	n %	n %	n %	n %	n %
皮膚および皮下組織障害	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	寝汗	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	粃糠疹	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	発疹	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
筋骨格系および結合組織障害	関節痛	1 (2.0)	0 (0.0)	1 (0.8)	2 (3.2)	1 (1.4)	3 (2.3)	3 (2.7)	1 (0.7)	4 (1.5)
	関節炎	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	2 (0.8)
	背部痛	3 (6.0)	0 (0.0)	3 (2.3)	0 (0.0)	4 (5.7)	4 (3.0)	3 (2.7)	4 (2.6)	7 (2.6)
	筋肉内出血	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	筋痙縮	0 (0.0)	2 (2.4)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.3)	2 (0.8)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.2)	0 (0.0)	2 (1.5)	2 (1.8)	0 (0.0)	2 (0.8)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	筋骨格痛	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	頚部痛	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	2 (1.3)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	3 (4.3)	4 (3.0)	1 (0.9)	3 (2.0)	4 (1.5)

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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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) 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)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	肩回旋筋腱板症候群	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	開口障害	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	筋骨格硬直	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	1 (1.4)	2 (1.5)	2 (1.8)	1 (0.7)	3 (1.1)
	筋浮腫	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	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 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	緊張性膀胱	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	腎結石症	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	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 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	射精遅延	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	月経過多	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)

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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-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) 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 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	卵巣嚢胞	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	性機能不全	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	2 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	勃起不全	2 (4.0)	0 (0.0)	2 (1.5)	1 (1.6)	0 (0.0)	1 (0.8)	3 (2.7)	0 (0.0)	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 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	疲労	3 (6.0)	1 (1.2)	4 (3.0)	3 (4.8)	2 (2.9)	5 (3.8)	6 (5.3)	3 (2.0)	9 (3.4)
	注射部位疼痛	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)
	末梢性浮腫	1 (2.0)	1 (1.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	1 (0.7)	2 (0.8)
	不活発	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	1 (0.9)	1 (0.7)	2 (0.8)
	非心臓性胸痛	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	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	1 (2.0)	0 (0.0)	1 (0.8)	2 (3.2)	0 (0.0)	2 (1.5)	3 (2.7)	0 (0.0)	3 (1.1)

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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-8.2.6.2　FINAL

表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) 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 (3.2)	0 (0.0)	2 (1.5)	2 (1.8)	0 (0.0)	2 (0.8)
	血中クレアチンホスホキナーゼ増加	3 (6.0)	0 (0.0)	3 (2.3)	1 (1.6)	0 (0.0)	1 (0.8)	4 (3.5)	0 (0.0)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	1 (0.7)	2 (0.8)
	血中インスリン増加	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	1 (1.4)	2 (1.5)	2 (1.8)	1 (0.7)	3 (1.1)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	血圧上昇	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	1 (1.4)	2 (1.5)	2 (1.8)	1 (0.7)	3 (1.1)
	心電図ＳＴ部分下降	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (1.4)	2 (1.5)	1 (0.9)	1 (0.7)	2 (0.8)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.2)	4 (5.7)	6 (4.5)	2 (1.8)	4 (2.6)	6 (2.3)
	体重増加	8 (16.0)	23 (28.0)	31 (23.5)	12 (19.0)	12 (17.1)	24 (18.0)	20 (17.7)	35 (23.0)	55 (20.8)
	肝機能検査値上昇	1 (2.0)	0 (0.0)	1 (0.8)	1 (1.6)	0 (0.0)	1 (0.8)	2 (1.8)	0 (0.0)	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 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	1 (0.7)	1 (0.4)
	足骨折	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	裂傷	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	1 (1.4)	1 (0.8)	0 (0.0)	2 (1.3)	2 (0.8)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.9)	2 (1.5)	0 (0.0)	2 (1.3)	2 (0.8)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	0 (0.0)	1 (0.8)	1 (0.9)	0 (0.0)	1 (0.4)

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表 2.7.4.7-39　性別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.2
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Gender
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	MALE (N=50) n %	FEMALE (N=82) n %	TOTAL (N=132) n %	MALE (N=63) n %	FEMALE (N=70) n %	TOTAL (N=133) n %	MALE (N=113) n %	FEMALE (N=152) n %	TOTAL (N=265) n %
傷害、中毒および処置合併症	挫傷	0 (0.0)	2 (2.4)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.3)	2 (0.8)
	胸部損傷	1 (2.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	1 (0.4)
	歯牙破折	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	処置による疼痛	2 (4.0)	2 (2.4)	4 (3.0)	0 (0.0)	1 (1.4)	1 (0.8)	2 (1.8)	3 (2.0)	5 (1.9)
	脊柱損傷	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	注射に伴う反応	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
	外傷後頚部症候群	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
社会環境	個人衛生不良	0 (0.0)	1 (1.2)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.4)
TOTAL1)		38 (76.0)	63 (76.8)	101 (76.5)	51 (81.0)	56 (80.0)	107 (80.5)	89 (78.8)	119 (78.3)	208 (78.5)

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＜資料番号 5.3.5.1-01：CT-8.2.6.2 より作成＞

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) BMI <= 28 kg/m2 (N=45) n	%	ARIP IMD (N=132) BMI > 28 kg/m2 (N=87) n	%	ARIP IMD (N=132) TOTAL (N=132) n	%	PLACEBO (N=133) BMI <= 28 kg/m2 (N=58) n	%	PLACEBO (N=133) BMI > 28 kg/m2 (N=75) n	%	PLACEBO (N=133) TOTAL (N=133) n	%	TOTAL (N=265) BMI <= 28 kg/m2 (N=103) n	%	TOTAL (N=265) BMI > 28 kg/m2 (N=162) n	%	TOTAL (N=265) TOTAL (N=265) n	%
感染症および寄生虫症	乳房蜂巣炎	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	気管支炎	1	(2.2)	2	(2.3)	3	(2.3)	2	(3.4)	0	(0.0)	2	(1.5)	3	(2.9)	2	(1.2)	5	(1.9)
	蜂巣炎	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	結膜炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	真菌感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	胃腸炎	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	ウイルス性胃腸炎	1	(2.2)	1	(1.1)	2	(1.5)	0	(0.0)	1	(1.3)	1	(0.8)	1	(1.0)	2	(1.2)	3	(1.1)
	麦粒腫	2	(4.4)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.9)	0	(0.0)	2	(0.8)
	インフルエンザ	1	(2.2)	2	(2.3)	3	(2.3)	2	(3.4)	0	(0.0)	2	(1.5)	3	(2.9)	2	(1.2)	5	(1.9)
	喉頭炎	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	シラミ寄生	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	限局性感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	鼻咽頭炎	4	(8.9)	6	(6.9)	10	(7.6)	8	(13.8)	5	(6.7)	13	(9.8)	12	(11.7)	11	(6.8)	23	(8.7)
	精巣炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
	外耳炎	1	(2.2)	1	(1.1)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	1	(0.6)	2	(0.8)
	中耳炎	1	(2.2)	1	(1.1)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	1	(0.6)	2	(0.8)
	咽頭炎	1	(2.2)	0	(0.0)	1	(0.8)	1	(1.7)	1	(1.3)	2	(1.5)	2	(1.9)	1	(0.6)	3	(1.1)
	レンサ球菌性咽頭炎	1	(2.2)	1	(1.1)	2	(1.5)	0	(0.0)	1	(1.3)	1	(0.8)	1	(1.0)	2	(1.2)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AF.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) 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)	2 (2.7)	2 (1.5)	0 (0.0)	2 (1.2)	2 (0.8)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	副鼻腔炎	1 (2.2)	4 (4.6)	5 (3.8)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	5 (3.1)	6 (2.3)
	須毛瘡	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	足部白癬	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	歯膿瘍	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	トリコモナス症	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	2 (1.2)	2 (0.8)
	上気道感染	1 (2.2)	3 (3.4)	4 (3.0)	2 (3.4)	4 (5.3)	6 (4.5)	3 (2.9)	7 (4.3)	10 (3.8)
	尿路感染	2 (4.4)	2 (2.3)	4 (3.0)	1 (1.7)	1 (1.3)	2 (1.5)	3 (2.9)	3 (1.9)	6 (2.3)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	歯感染	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	2 (2.7)	2 (1.5)	0 (0.0)	3 (1.9)	3 (1.1)
	無症候性細菌尿	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	クラミジア感染	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	真菌性口腔咽頭炎	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	気道感染	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) BMI <= 28 kg/m2 (N=45) n	%	ARIP IMD (N=132) BMI > 28 kg/m2 (N=87) n	%	ARIP IMD (N=132) TOTAL (N=132) n	%	PLACEBO (N=133) BMI <= 28 kg/m2 (N=58) n	%	PLACEBO (N=133) BMI > 28 kg/m2 (N=75) n	%	PLACEBO (N=133) TOTAL (N=133) n	%	TOTAL (N=265) BMI <= 28 kg/m2 (N=103) n	%	TOTAL (N=265) BMI > 28 kg/m2 (N=162) n	%	TOTAL (N=265) TOTAL (N=265) n	%
血液およびリンパ系障害	貧血	1	(2.2)	2	(2.3)	3	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	2	(1.2)	3	(1.1)
	白血球減少症	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	好中球減少症	1	(2.2)	0	(0.0)	1	(0.8)	1	(1.7)	0	(0.0)	1	(0.8)	2	(1.9)	0	(0.0)	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	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	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)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
	高血糖	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	食欲亢進	4	(8.9)	0	(0.0)	4	(3.0)	1	(1.7)	0	(0.0)	1	(0.8)	5	(4.9)	0	(0.0)	5	(1.9)
	高インスリン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	食欲減退	1	(2.2)	1	(1.1)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	1	(0.6)	2	(0.8)
	高脂血症	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
	２型糖尿病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
精神障害	感情障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	1	(1.3)	2	(1.5)	1	(1.0)	1	(0.6)	2	(0.8)
	攻撃性	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
	激越	0	(0.0)	1	(1.1)	1	(0.8)	2	(3.4)	2	(2.7)	4	(3.0)	2	(1.9)	3	(1.9)	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) BMI <= 28 kg/m2 (N=45) n	%	ARIP IMD (N=132) BMI > 28 kg/m2 (N=87) n	%	ARIP IMD (N=132) TOTAL (N=132) n	%	PLACEBO (N=133) BMI <= 28 kg/m2 (N=58) n	%	PLACEBO (N=133) BMI > 28 kg/m2 (N=75) n	%	PLACEBO (N=133) TOTAL (N=133) n	%	TOTAL (N=265) BMI <= 28 kg/m2 (N=103) n	%	TOTAL (N=265) BMI > 28 kg/m2 (N=162) n	%	TOTAL (N=265) TOTAL (N=265) n	%
精神障害	不安	4	(8.9)	5	(5.7)	9	(6.8)	3	(5.2)	3	(4.0)	6	(4.5)	7	(6.8)	8	(4.9)	15	(5.7)
	無感情	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	双極１型障害	0	(0.0)	2	(2.3)	2	(1.5)	7	(12.1)	1	(1.3)	8	(6.0)	7	(6.8)	3	(1.9)	10	(3.8)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
	抑うつ気分	1	(2.2)	0	(0.0)	1	(0.8)	1	(1.7)	1	(1.3)	2	(1.5)	2	(1.9)	1	(0.6)	3	(1.1)
	うつ病	2	(4.4)	2	(2.3)	4	(3.0)	0	(0.0)	3	(4.0)	3	(2.3)	2	(1.9)	5	(3.1)	7	(2.6)
	軽躁	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	初期不眠症	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	不眠症	3	(6.7)	7	(8.0)	10	(7.6)	5	(8.6)	5	(6.7)	10	(7.5)	8	(7.8)	12	(7.4)	20	(7.5)
	易刺激性	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	リビドー減退	2	(4.4)	1	(1.1)	3	(2.3)	1	(1.7)	1	(1.3)	2	(1.5)	3	(2.9)	2	(1.2)	5	(1.9)
	躁病	2	(4.4)	1	(1.1)	3	(2.3)	8	(13.8)	6	(8.0)	14	(10.5)	10	(9.7)	7	(4.3)	17	(6.4)
	中期不眠症	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	神経過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	悪夢	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	パニック発作	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	精神運動制止遅滞	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	落ち着きのなさ	2	(4.4)	4	(4.6)	6	(4.5)	2	(3.4)	3	(4.0)	5	(3.8)	4	(3.9)	7	(4.3)	11	(4.2)
	睡眠障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.7)	2	(1.5)	0	(0.0)	2	(1.2)	2	(0.8)
	社会逃避行動	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) n %
精神障害	夢遊症	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	自殺企図	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	2 (1.2)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	感情不安定	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	ディスフェミア	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	双極性障害	0 (0.0)	5 (5.7)	5 (3.8)	3 (5.2)	2 (2.7)	5 (3.8)	3 (2.9)	7 (4.3)	10 (3.8)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	1 (0.6)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	12 (26.7)	16 (18.4)	28 (21.2)	7 (12.1)	10 (13.3)	17 (12.8)	19 (18.4)	26 (16.0)	45 (17.0)
	運動緩慢	2 (4.4)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.9)	0 (0.0)	2 (0.8)
	注意力障害	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	浮動性めまい	1 (2.2)	0 (0.0)	1 (0.8)	1 (1.7)	1 (1.3)	2 (1.5)	2 (1.9)	1 (0.6)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	ジスキネジア	1 (2.2)	1 (1.1)	2 (1.5)	2 (3.4)	0 (0.0)	2 (1.5)	3 (2.9)	1 (0.6)	4 (1.5)
	錐体外路障害	0 (0.0)	2 (2.3)	2 (1.5)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	3 (1.9)	4 (1.5)
	頭痛	2 (4.4)	2 (2.3)	4 (3.0)	4 (6.9)	5 (6.7)	9 (6.8)	6 (5.8)	7 (4.3)	13 (4.9)
	過眠症	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	感覚鈍麻	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	嗜眠	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AF.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) n %
神経系障害	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.4)	0 (0.0)	2 (1.5)	2 (1.9)	0 (0.0)	2 (0.8)
	錯感覚	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	パーキンソニズム	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	精神運動亢進	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	坐骨神経痛	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	鎮静	0 (0.0)	2 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	2 (0.8)
	傾眠	1 (2.2)	5 (5.7)	6 (4.5)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	6 (3.7)	7 (2.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	遅発性ジスキネジア	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	一過性脳虚血発作	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	振戦	1 (2.2)	2 (2.3)	3 (2.3)	1 (1.7)	1 (1.3)	2 (1.5)	2 (1.9)	3 (1.9)	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 (2.7)	2 (1.5)	0 (0.0)	2 (1.2)	2 (0.8)
	脳損傷	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
眼障害	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	羞明	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	霧視	0 (0.0)	3 (3.4)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.9)	3 (1.1)
耳および迷路障害	耳鳴	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	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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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)						PLACEBO (N=133)						TOTAL (N=265)					
		BMI <= 28 kg/m2 (N=45)		BMI > 28 kg/m2 (N=87)		TOTAL (N=132)		BMI <= 28 kg/m2 (N=58)		BMI > 28 kg/m2 (N=75)		TOTAL (N=133)		BMI <= 28 kg/m2 (N=103)		BMI > 28 kg/m2 (N=162)		TOTAL (N=265)	
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
心臓障害	心房細動	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	第一度房室ブロック	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	徐脈	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	心肺停止	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	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)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	高血圧	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	3	(4.0)	3	(2.3)	0	(0.0)	4	(2.5)	4	(1.5)
呼吸器、胸郭および縦隔障害	喘息	1	(2.2)	1	(1.1)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	1	(0.6)	2	(0.8)
	咳嗽	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	1	(1.3)	2	(1.5)	1	(1.0)	1	(0.6)	2	(0.8)
	呼吸不全	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	アレルギー性副鼻腔炎	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	気道うっ血	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	1	(1.3)	1	(0.8)	1	(1.0)	1	(0.6)	2	(0.8)
	口腔咽頭痛	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
胃腸障害	腹部膨満	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	腹痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	上腹部痛	1	(2.2)	1	(1.1)	2	(1.5)	1	(1.7)	0	(0.0)	1	(0.8)	2	(1.9)	1	(0.6)	3	(1.1)

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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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) n %
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	便秘	2 (4.4)	2 (2.3)	4 (3.0)	2 (3.4)	2 (2.7)	4 (3.0)	4 (3.9)	4 (2.5)	8 (3.0)
	齲歯	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	下痢	1 (2.2)	0 (0.0)	1 (0.8)	1 (1.7)	3 (4.0)	4 (3.0)	2 (1.9)	3 (1.9)	5 (1.9)
	口内乾燥	1 (2.2)	3 (3.4)	4 (3.0)	1 (1.7)	2 (2.7)	3 (2.3)	2 (1.9)	5 (3.1)	7 (2.6)
	消化不良	0 (0.0)	1 (1.1)	1 (0.8)	2 (3.4)	2 (2.7)	4 (3.0)	2 (1.9)	3 (1.9)	5 (1.9)
	食中毒	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	1 (0.6)	2 (0.8)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	悪心	0 (0.0)	3 (3.4)	3 (2.3)	4 (6.9)	2 (2.7)	6 (4.5)	4 (3.9)	5 (3.1)	9 (3.4)
	口腔内不快感	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	流涎過多	2 (4.4)	1 (1.1)	3 (2.3)	1 (1.7)	2 (2.7)	3 (2.3)	3 (2.9)	3 (1.9)	6 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	舌腫脹	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	歯痛	1 (2.2)	0 (0.0)	1 (0.8)	2 (3.4)	1 (1.3)	3 (2.3)	3 (2.9)	1 (0.6)	4 (1.5)
	嘔吐	0 (0.0)	2 (2.3)	2 (1.5)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	3 (1.9)	4 (1.5)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	痔出血	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)

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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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) BMI <= 28 kg/m2 (N=45) n	%	ARIP IMD (N=132) BMI > 28 kg/m2 (N=87) n	%	ARIP IMD (N=132) TOTAL n	%	PLACEBO (N=133) BMI <= 28 kg/m2 (N=58) n	%	PLACEBO (N=133) BMI > 28 kg/m2 (N=75) n	%	PLACEBO (N=133) TOTAL n	%	TOTAL (N=265) BMI <= 28 kg/m2 (N=103) n	%	TOTAL (N=265) BMI > 28 kg/m2 (N=162) n	%	TOTAL (N=265) TOTAL n	%
肝胆道系障害	脂肪肝	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
皮膚および皮下組織障害	ざ瘡	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	2	(1.2)	2	(0.8)
	皮膚炎	2	(4.4)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.9)	0	(0.0)	2	(0.8)
	接触性皮膚炎	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	2	(1.2)	2	(0.8)
	皮膚乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	湿疹	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(0.4)
	紅斑	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	多汗症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	寝汗	1	(2.2)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(0.4)
	粃糠疹	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)
	そう痒症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.3)	1	(0.8)	0	(0.0)	1	(0.6)	1	(0.4)
	発疹	0	(0.0)	1	(1.1)	1	(0.8)	1	(1.7)	0	(0.0)	1	(0.8)	1	(1.0)	1	(0.6)	2	(0.8)
筋骨格系および結合組織障害	関節痛	0	(0.0)	1	(1.1)	1	(0.8)	1	(1.7)	2	(2.7)	3	(2.3)	1	(1.0)	3	(1.9)	4	(1.5)
	関節炎	0	(0.0)	2	(2.3)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.2)	2	(0.8)
	背部痛	1	(2.2)	2	(2.3)	3	(2.3)	2	(3.4)	2	(2.7)	4	(3.0)	3	(2.9)	4	(2.5)	7	(2.6)
	筋肉内出血	0	(0.0)	1	(1.1)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)	1	(0.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) n %
筋骨格系および結合組織障害	筋痙縮	1 (2.2)	1 (1.1)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (0.6)	2 (0.8)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	2 (1.5)	0 (0.0)	2 (1.2)	2 (0.8)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	筋骨格痛	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	1 (0.6)	2 (0.8)
	頚部痛	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	3 (4.0)	4 (3.0)	1 (1.0)	3 (1.9)	4 (1.5)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	肩回旋筋腱板症候群	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	開口障害	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	筋骨格硬直	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	2 (1.2)	3 (1.1)
	筋浮腫	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	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 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	緊張性膀胱	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	腎結石症	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)

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表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) n %
腎および尿路障害	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	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 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	射精遅延	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	月経過多	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (1.3)	2 (1.5)	1 (1.0)	1 (0.6)	2 (0.8)
	卵巣嚢胞	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	性機能不全	0 (0.0)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	勃起不全	1 (2.2)	1 (1.1)	2 (1.5)	1 (1.7)	0 (0.0)	1 (0.8)	2 (1.9)	1 (0.6)	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 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	疲労	3 (6.7)	1 (1.1)	4 (3.0)	2 (3.4)	3 (4.0)	5 (3.8)	5 (4.9)	4 (2.5)	9 (3.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) 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)	1 (1.1)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.4)
	末梢性浮腫	0 (0.0)	2 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	2 (0.8)
	不活発	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	1 (0.6)	2 (0.8)
	非心臓性胸痛	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	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	1 (2.2)	0 (0.0)	1 (0.8)	2 (3.4)	0 (0.0)	2 (1.5)	3 (2.9)	0 (0.0)	3 (1.1)
	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 (3.4)	0 (0.0)	2 (1.5)	2 (1.9)	0 (0.0)	2 (0.8)
	血中クレアチンホスホキナーゼ増加	2 (4.4)	1 (1.1)	3 (2.3)	0 (0.0)	1 (1.3)	1 (0.8)	2 (1.9)	2 (1.2)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	2 (1.5)	0 (0.0)	2 (1.2)	2 (0.8)
	血中インスリン増加	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	2 (2.7)	2 (1.5)	0 (0.0)	3 (1.9)	3 (1.1)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	血圧上昇	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	2 (2.7)	2 (1.5)	0 (0.0)	3 (1.9)	3 (1.1)
	心電図ＳＴ部分下降	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)

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表 2.7.4.7-40　BMI別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.6
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by BMI
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) 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)	2 (2.7)	2 (1.5)	0 (0.0)	2 (1.2)	2 (0.8)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	3 (5.2)	3 (4.0)	6 (4.5)	3 (2.9)	3 (1.9)	6 (2.3)
	体重増加	8 (17.8)	23 (26.4)	31 (23.5)	9 (15.5)	15 (20.0)	24 (18.0)	17 (16.5)	38 (23.5)	55 (20.8)
	肝機能検査値上昇	1 (2.2)	0 (0.0)	1 (0.8)	1 (1.7)	0 (0.0)	1 (0.8)	2 (1.9)	0 (0.0)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	足骨折	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	裂傷	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	2 (1.2)	2 (0.8)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.4)	0 (0.0)	2 (1.5)	2 (1.9)	0 (0.0)	2 (0.8)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.3)	1 (0.8)	0 (0.0)	1 (0.6)	1 (0.4)
	挫傷	0 (0.0)	2 (2.3)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.2)	2 (0.8)
	胸部損傷	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	歯牙破折	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
	処置による疼痛	1 (2.2)	3 (3.4)	4 (3.0)	0 (0.0)	1 (1.3)	1 (0.8)	1 (1.0)	4 (2.5)	5 (1.9)
	脊柱損傷	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	注射に伴う反応	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)
	外傷後頚部症候群	0 (0.0)	1 (1.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.6)	1 (0.4)

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		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	BMI <= 28 kg/m2 (N=45) n %	BMI > 28 kg/m2 (N=87) n %	TOTAL (N=132) n %	BMI <= 28 kg/m2 (N=58) n %	BMI > 28 kg/m2 (N=75) n %	TOTAL (N=133) n %	BMI <= 28 kg/m2 (N=103) n %	BMI > 28 kg/m2 (N=162) n %	TOTAL (N=265) n %
社会環境	個人衛生不良	1 (2.2)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.4)
TOTAL1)		33 (73.3)	68 (78.2)	101 (76.5)	47 (81.0)	60 (80.0)	107 (80.5)	80 (77.7)	128 (79.0)	208 (78.5)

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: ADAE21AF.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.6　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.6.6 より作成＞

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
感染症および寄生虫症	乳房蜂巣炎	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	気管支炎	2	(2.9)	1	(2.6)	0	(0.0)	0	(0.0)	3	(2.3)
	蜂巣炎	1	(1.4)	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)
	真菌感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胃腸炎	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	ウイルス性胃腸炎	2	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	麦粒腫	2	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	インフルエンザ	1	(1.4)	1	(2.6)	0	(0.0)	1	(25.0)	3	(2.3)
	喉頭炎	1	(1.4)	0	(0.0)	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)
	限局性感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻咽頭炎	5	(7.1)	3	(7.7)	2	(10.5)	0	(0.0)	10	(7.6)
	精巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外耳炎	1	(1.4)	1	(2.6)	0	(0.0)	0	(0.0)	2	(1.5)
	中耳炎	1	(1.4)	1	(2.6)	0	(0.0)	0	(0.0)	2	(1.5)
	咽頭炎	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.8)
	レンサ球菌性咽頭炎	1	(1.4)	1	(2.6)	0	(0.0)	0	(0.0)	2	(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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	PLACEBO (N=133) CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) 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)
	気管支炎	1	(1.4)	0	(0.0)	1	(5.6)	0	(0.0)	2	(1.5)
	蜂巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	結膜炎	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	真菌感染	0	(0.0)	1	(2.9)	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)
	ウイルス性胃腸炎	0	(0.0)	1	(2.9)	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)
	インフルエンザ	1	(1.4)	0	(0.0)	1	(5.6)	0	(0.0)	2	(1.5)
	喉頭炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	シラミ寄生	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	限局性感染	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	鼻咽頭炎	1	(1.4)	3	(8.6)	9	(50.0)	0	(0.0)	13	(9.8)
	精巣炎	1	(1.4)	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)
	中耳炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽頭炎	0	(0.0)	1	(2.9)	1	(5.6)	0	(0.0)	2	(1.5)
	レンサ球菌性咽頭炎	1	(1.4)	0	(0.0)	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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
感染症および寄生虫症	乳房蜂巣炎	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	気管支炎	3 (2.1)	1 (1.4)	1 (2.7)	0 (0.0)	5 (1.9)
	蜂巣炎	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	結膜炎	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	真菌感染	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	胃腸炎	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	ウイルス性胃腸炎	2 (1.4)	1 (1.4)	0 (0.0)	0 (0.0)	3 (1.1)
	麦粒腫	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	インフルエンザ	2 (1.4)	1 (1.4)	1 (2.7)	1 (10.0)	5 (1.9)
	喉頭炎	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	シラミ寄生	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	限局性感染	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	鼻咽頭炎	6 (4.2)	6 (8.1)	11 (29.7)	0 (0.0)	23 (8.7)
	精巣炎	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	外耳炎	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	中耳炎	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	咽頭炎	0 (0.0)	1 (1.4)	2 (5.4)	0 (0.0)	3 (1.1)
	レンサ球菌性咽頭炎	2 (1.4)	1 (1.4)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) 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)
	鼻炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	副鼻腔炎	3	(4.3)	2	(5.1)	0	(0.0)	0	(0.0)	5	(3.8)
	須毛瘡	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.8)
	足部白癬	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯膿瘍	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	トリコモナス症	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	上気道感染	3	(4.3)	1	(2.6)	0	(0.0)	0	(0.0)	4	(3.0)
	尿路感染	4	(5.7)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)
	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)
	歯感染	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	無症候性細菌尿	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	クラミジア感染	1	(1.4)	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)
	真菌性口腔咽頭炎	1	(1.4)	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)
	気道感染	1	(1.4)	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)
	カンジダ感染	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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
感染症および寄生虫症	肺炎	2	(2.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	鼻炎	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	副鼻腔炎	1	(1.4)	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)
	足部白癬	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	歯膿瘍	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	トリコモナス症	0	(0.0)	1	(2.9)	0	(0.0)	0	(0.0)	1	(0.8)
	上気道感染	4	(5.4)	1	(2.9)	0	(0.0)	1	(16.7)	6	(4.5)
	尿路感染	2	(2.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	ウイルス性上気道感染	0	(0.0)	1	(2.9)	0	(0.0)	0	(0.0)	1	(0.8)
	歯感染	1	(1.4)	0	(0.0)	0	(0.0)	1	(16.7)	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)
	クラミジア感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性耳感染	1	(1.4)	0	(0.0)	0	(0.0)	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)
	ウイルス性気道感染	1	(1.4)	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)
	口腔ヘルペス	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	カンジダ感染	1	(1.4)	0	(0.0)	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.
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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
感染症および寄生虫症	肺炎	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	鼻炎	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	副鼻腔炎	4 (2.8)	2 (2.7)	0 (0.0)	0 (0.0)	6 (2.3)
	須毛瘡	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	足部白癬	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	2 (0.8)
	歯膿瘍	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	トリコモナス症	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	上気道感染	7 (4.9)	2 (2.7)	0 (0.0)	1 (10.0)	10 (3.8)
	尿路感染	6 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	6 (2.3)
	ウイルス性上気道感染	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	歯感染	1 (0.7)	1 (1.4)	0 (0.0)	1 (10.0)	3 (1.1)
	無症候性細菌尿	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	クラミジア感染	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	ウイルス性耳感染	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	真菌性口腔咽頭炎	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	ウイルス性気道感染	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	気道感染	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	口腔ヘルペス	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	カンジダ感染	1 (0.7)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
血液およびリンパ系障害	貧血	1	(1.4)	1	(2.6)	1	(5.3)	0	(0.0)	3	(2.3)
	白血球減少症	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.8)
	好中球減少症	0	(0.0)	0	(0.0)	1	(5.3)	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)
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)
	高血糖	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	食欲亢進	2	(2.9)	2	(5.1)	0	(0.0)	0	(0.0)	4	(3.0)
	高インスリン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食欲減退	2	(2.9)	0	(0.0)	0	(0.0)	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)
	２型糖尿病	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)
	攻撃性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	激越	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	不安	7	(10.0)	1	(2.6)	1	(5.3)	0	(0.0)	9	(6.8)

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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n %	BLACK/ AFRICAN AMERICAN (N=35) n %	ASIAN (N=18) n %	OTHER (N=6) n %	TOTAL (N=133) 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)
	白血球減少症	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)	1 (5.6)	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)	1 (5.6)	0 (0.0)	1 (0.8)
代謝および栄養障害	脱水	0 (0.0)	1 (2.9)	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)
	食欲亢進	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (0.8)
	高インスリン血症	0 (0.0)	1 (2.9)	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)
	高脂血症	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (0.8)
	２型糖尿病	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
精神障害	感情障害	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	攻撃性	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	激越	4 (5.4)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.0)
	不安	2 (2.7)	1 (2.9)	3 (16.7)	0 (0.0)	6 (4.5)

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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
血液およびリンパ系障害	貧血	1 (0.7)	1 (1.4)	1 (2.7)	0 (0.0)	3 (1.1)
	白血球減少症	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	好中球減少症	0 (0.0)	0 (0.0)	2 (5.4)	0 (0.0)	2 (0.8)
内分泌障害	高プロラクチン血症	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
代謝および栄養障害	脱水	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	高血糖	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	食欲亢進	2 (1.4)	3 (4.1)	0 (0.0)	0 (0.0)	5 (1.9)
	高インスリン血症	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	食欲減退	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	高脂血症	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	２型糖尿病	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
精神障害	感情障害	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	攻撃性	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	激越	5 (3.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.9)
	不安	9 (6.3)	2 (2.7)	4 (10.8)	0 (0.0)	15 (5.7)

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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
精神障害	無感情	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	双極１型障害	2	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	抑うつ気分	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	うつ病	1	(1.4)	1	(2.6)	2	(10.5)	0	(0.0)	4	(3.0)
	軽躁	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.8)
	初期不眠症	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	不眠症	6	(8.6)	3	(7.7)	1	(5.3)	0	(0.0)	10	(7.6)
	易刺激性	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	リビドー減退	3	(4.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	躁病	1	(1.4)	0	(0.0)	2	(10.5)	0	(0.0)	3	(2.3)
	中期不眠症	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	神経過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪夢	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	パニック発作	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	精神運動制止遅滞	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	落ち着きのなさ	3	(4.3)	2	(5.1)	1	(5.3)	0	(0.0)	6	(4.5)
	睡眠障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	社会逃避行動	1	(1.4)	0	(0.0)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
精神障害	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	双極１型障害	7	(9.5)	0	(0.0)	1	(5.6)	0	(0.0)	8	(6.0)
	歯ぎしり	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	抑うつ気分	0	(0.0)	0	(0.0)	1	(5.6)	1	(16.7)	2	(1.5)
	うつ病	1	(1.4)	0	(0.0)	0	(0.0)	2	(33.3)	3	(2.3)
	軽躁	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)
	不眠症	4	(5.4)	2	(5.7)	4	(22.2)	0	(0.0)	10	(7.5)
	易刺激性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	リビドー減退	0	(0.0)	1	(2.9)	1	(5.6)	0	(0.0)	2	(1.5)
	躁病	5	(6.8)	3	(8.6)	5	(27.8)	1	(16.7)	14	(10.5)
	中期不眠症	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	(16.7)	1	(0.8)
	悪夢	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)
	精神運動制止遅滞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	落ち着きのなさ	4	(5.4)	0	(0.0)	0	(0.0)	1	(16.7)	5	(3.8)
	睡眠障害	0	(0.0)	0	(0.0)	1	(5.6)	1	(16.7)	2	(1.5)
	社会逃避行動	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 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n	%	BLACK/ AFRICAN AMERICAN (N=74) n	%	ASIAN (N=37) n	%	OTHER (N=10) n	%	TOTAL (N=265) n	%
精神障害	無感情	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	双極１型障害	9	(6.3)	0	(0.0)	1	(2.7)	0	(0.0)	10	(3.8)
	歯ぎしり	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	抑うつ気分	1	(0.7)	0	(0.0)	1	(2.7)	1	(10.0)	3	(1.1)
	うつ病	2	(1.4)	1	(1.4)	2	(5.4)	2	(20.0)	7	(2.6)
	軽躁	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	初期不眠症	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	不眠症	10	(6.9)	5	(6.8)	5	(13.5)	0	(0.0)	20	(7.5)
	易刺激性	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	リビドー減退	3	(2.1)	1	(1.4)	1	(2.7)	0	(0.0)	5	(1.9)
	躁病	6	(4.2)	3	(4.1)	7	(18.9)	1	(10.0)	17	(6.4)
	中期不眠症	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	神経過敏	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	1	(0.4)
	悪夢	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	パニック発作	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	精神運動制止遅滞	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	落ち着きのなさ	7	(4.9)	2	(2.7)	1	(2.7)	1	(10.0)	11	(4.2)
	睡眠障害	0	(0.0)	0	(0.0)	1	(2.7)	1	(10.0)	2	(0.8)
	社会逃避行動	1	(0.7)	0	(0.0)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	BLACK/ AFRICAN AMERICAN (N=39) n %	ASIAN (N=19) n %	OTHER (N=4) n %	TOTAL (N=132) n %
精神障害	夢遊症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	自殺企図	0 (0.0)	1 (2.6)	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)
	感情不安定	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	1 (0.8)
	ディスフェミア	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	双極性障害	4 (5.7)	1 (2.6)	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)
	精神活動過多	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	16 (22.9)	9 (23.1)	2 (10.5)	1 (25.0)	28 (21.2)
	運動緩慢	1 (1.4)	1 (2.6)	0 (0.0)	0 (0.0)	2 (1.5)
	注意力障害	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	浮動性めまい	1 (1.4)	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)
	ジスキネジア	1 (1.4)	1 (2.6)	0 (0.0)	0 (0.0)	2 (1.5)
	錐体外路障害	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	頭痛	2 (2.9)	1 (2.6)	1 (5.3)	0 (0.0)	4 (3.0)
	過眠症	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	感覚鈍麻	0 (0.0)	1 (2.6)	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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n %	BLACK/ AFRICAN AMERICAN (N=35) n %	ASIAN (N=18) n %	OTHER (N=6) n %	TOTAL (N=133) n %
精神障害	夢遊症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺企図	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (16.7)	1 (0.8)
	感情不安定	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)
	双極性障害	2 (2.7)	2 (5.7)	1 (5.6)	0 (0.0)	5 (3.8)
	大うつ病	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	精神活動過多	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
神経系障害	アカシジア	8 (10.8)	5 (14.3)	4 (22.2)	0 (0.0)	17 (12.8)
	運動緩慢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	浮動性めまい	1 (1.4)	0 (0.0)	1 (5.6)	0 (0.0)	2 (1.5)
	構語障害	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	1 (0.8)
	ジスキネジア	0 (0.0)	0 (0.0)	2 (11.1)	0 (0.0)	2 (1.5)
	錐体外路障害	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	頭痛	5 (6.8)	2 (5.7)	2 (11.1)	0 (0.0)	9 (6.8)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (1.4)	0 (0.0)	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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
精神障害	夢遊症	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	自殺企図	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	1 (0.4)
	感情不安定	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	ディスフェミア	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	双極性障害	6 (4.2)	3 (4.1)	1 (2.7)	0 (0.0)	10 (3.8)
	大うつ病	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	精神活動過多	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	24 (16.7)	14 (18.9)	6 (16.2)	1 (10.0)	45 (17.0)
	運動緩慢	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	注意力障害	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	浮動性めまい	2 (1.4)	0 (0.0)	1 (2.7)	0 (0.0)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (0.4)
	ジスキネジア	1 (0.7)	1 (1.4)	2 (5.4)	0 (0.0)	4 (1.5)
	錐体外路障害	4 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.5)
	頭痛	7 (4.9)	3 (4.1)	3 (8.1)	0 (0.0)	13 (4.9)
	過眠症	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	感覚鈍麻	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
神経系障害	嗜眠	1	(1.4)	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)
	錯感覚	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	パーキンソニズム	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	精神運動亢進	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	坐骨神経痛	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	鎮静	1	(1.4)	1	(2.6)	0	(0.0)	0	(0.0)	2	(1.5)
	傾眠	2	(2.9)	4	(10.3)	0	(0.0)	0	(0.0)	6	(4.5)
	失神	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	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	一過性脳虚血発作	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	振戦	2	(2.9)	0	(0.0)	1	(5.3)	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)
	脳損傷	0	(0.0)	1	(2.6)	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)
	羞明	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	霧視	1	(1.4)	2	(5.1)	0	(0.0)	0	(0.0)	3	(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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
神経系障害	嗜眠	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	片頭痛	1	(1.4)	0	(0.0)	1	(5.6)	0	(0.0)	2	(1.5)
	錯感覚	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)	1	(5.6)	0	(0.0)	1	(0.8)
	精神運動亢進	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)
	鎮静	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	失神	0	(0.0)	1	(2.9)	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)
	一過性脳虚血発作	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	振戦	1	(1.4)	0	(0.0)	1	(5.6)	0	(0.0)	2	(1.5)
	下肢静止不能症候群	1	(1.4)	0	(0.0)	1	(5.6)	0	(0.0)	2	(1.5)
	脳損傷	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)	1	(5.6)	0	(0.0)	1	(0.8)
	羞明	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	霧視	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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		TOTAL (N=265)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=144) n	%	BLACK/ AFRICAN AMERICAN (N=74) n	%	ASIAN (N=37) n	%	OTHER (N=10) n	%	TOTAL (N=265) n	%
神経系障害	嗜眠	2	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	片頭痛	1	(0.7)	0	(0.0)	1	(2.7)	0	(0.0)	2	(0.8)
	錯感覚	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	パーキンソニズム	0	(0.0)	1	(1.4)	1	(2.7)	0	(0.0)	2	(0.8)
	精神運動亢進	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	坐骨神経痛	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	鎮静	1	(0.7)	1	(1.4)	0	(0.0)	0	(0.0)	2	(0.8)
	傾眠	3	(2.1)	4	(5.4)	0	(0.0)	0	(0.0)	7	(2.6)
	失神	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	遅発性ジスキネジア	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	一過性脳虚血発作	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	振戦	3	(2.1)	0	(0.0)	2	(5.4)	0	(0.0)	5	(1.9)
	下肢静止不能症候群	1	(0.7)	0	(0.0)	1	(2.7)	0	(0.0)	2	(0.8)
	脳損傷	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
眼障害	眼痛	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	羞明	2	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	霧視	1	(0.7)	2	(2.7)	0	(0.0)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
耳および迷路障害	耳鳴	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
心臓障害	心房細動	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	第一度房室ブロック	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.8)
	徐脈	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	心肺停止	0	(0.0)	1	(2.6)	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)
	高血圧	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
呼吸器、胸郭および縦隔障害	喘息	1	(1.4)	1	(2.6)	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)
	呼吸不全	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	アレルギー性副鼻腔炎	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	気道うっ血	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	口腔咽頭痛	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
胃腸障害	腹部膨満	0	(0.0)	1	(2.6)	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)

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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) 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)
心臓障害	心房細動	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)
	徐脈	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)
血管障害	本態性高血圧症	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	高血圧	2	(2.7)	1	(2.9)	0	(0.0)	0	(0.0)	3	(2.3)
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)
	咳嗽	2	(2.7)	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)
	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)
	気道うっ血	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	口腔咽頭痛	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)
	腹痛	1	(1.4)	0	(0.0)	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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		TOTAL (N=265)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=144) n	%	BLACK/ AFRICAN AMERICAN (N=74) n	%	ASIAN (N=37) n	%	OTHER (N=10) n	%	TOTAL (N=265) n	%
耳および迷路障害	耳鳴	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
心臓障害	心房細動	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	第一度房室ブロック	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	徐脈	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	心肺停止	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
血管障害	本態性高血圧症	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	高血圧	3	(2.1)	1	(1.4)	0	(0.0)	0	(0.0)	4	(1.5)
呼吸器、胸郭および縦隔障害	喘息	1	(0.7)	1	(1.4)	0	(0.0)	0	(0.0)	2	(0.8)
	咳嗽	2	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	呼吸不全	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	アレルギー性副鼻腔炎	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	気道うっ血	1	(0.7)	1	(1.4)	0	(0.0)	0	(0.0)	2	(0.8)
	口腔咽頭痛	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
胃腸障害	腹部膨満	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	腹痛	1	(0.7)	0	(0.0)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
胃腸障害	上腹部痛	2	(2.9)	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)
	便秘	1	(1.4)	1	(2.6)	2	(10.5)	0	(0.0)	4	(3.0)
	齲歯	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	下痢	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	口内乾燥	2	(2.9)	2	(5.1)	0	(0.0)	0	(0.0)	4	(3.0)
	消化不良	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	食中毒	1	(1.4)	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)
	歯肉痛	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)
	悪心	3	(4.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	口腔内不快感	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	流涎過多	2	(2.9)	1	(2.6)	0	(0.0)	0	(0.0)	3	(2.3)
	歯の知覚過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌腫脹	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯痛	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	嘔吐	2	(2.9)	0	(0.0)	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)

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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
胃腸障害	上腹部痛	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	潰瘍性大腸炎	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	便秘	1	(1.4)	0	(0.0)	3	(16.7)	0	(0.0)	4	(3.0)
	齲歯	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	下痢	3	(4.1)	0	(0.0)	1	(5.6)	0	(0.0)	4	(3.0)
	口内乾燥	3	(4.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	消化不良	1	(1.4)	0	(0.0)	3	(16.7)	0	(0.0)	4	(3.0)
	食中毒	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	(2.9)	0	(0.0)	0	(0.0)	1	(0.8)
	歯肉痛	1	(1.4)	0	(0.0)	1	(5.6)	0	(0.0)	2	(1.5)
	血便排泄	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	悪心	4	(5.4)	0	(0.0)	2	(11.1)	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)
	流涎過多	3	(4.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	歯の知覚過敏	1	(1.4)	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)
	歯痛	1	(1.4)	2	(5.7)	0	(0.0)	0	(0.0)	3	(2.3)
	嘔吐	2	(2.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	腹壁嚢胞	1	(1.4)	0	(0.0)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
胃腸障害	上腹部痛	2 (1.4)	0 (0.0)	1 (2.7)	0 (0.0)	3 (1.1)
	潰瘍性大腸炎	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	便秘	2 (1.4)	1 (1.4)	5 (13.5)	0 (0.0)	8 (3.0)
	齲歯	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	2 (0.8)
	下痢	4 (2.8)	0 (0.0)	1 (2.7)	0 (0.0)	5 (1.9)
	口内乾燥	5 (3.5)	2 (2.7)	0 (0.0)	0 (0.0)	7 (2.6)
	消化不良	2 (1.4)	0 (0.0)	3 (8.1)	0 (0.0)	5 (1.9)
	食中毒	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	歯肉痛	1 (0.7)	0 (0.0)	1 (2.7)	0 (0.0)	2 (0.8)
	血便排泄	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	悪心	7 (4.9)	0 (0.0)	2 (5.4)	0 (0.0)	9 (3.4)
	口腔内不快感	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	流涎過多	5 (3.5)	1 (1.4)	0 (0.0)	0 (0.0)	6 (2.3)
	歯の知覚過敏	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	舌腫脹	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	歯痛	2 (1.4)	2 (2.7)	0 (0.0)	0 (0.0)	4 (1.5)
	嘔吐	4 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.5)
	腹壁嚢胞	1 (0.7)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
胃腸障害	痔出血	0	(0.0)	1	(2.6)	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)
皮膚および皮下組織障害	ざ瘡	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	皮膚炎	1	(1.4)	0	(0.0)	1	(5.3)	0	(0.0)	2	(1.5)
	接触性皮膚炎	1	(1.4)	0	(0.0)	0	(0.0)	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)
	湿疹	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)
	多汗症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	寝汗	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	粃糠疹	1	(1.4)	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)
	発疹	0	(0.0)	1	(2.6)	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	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	関節炎	1	(1.4)	1	(2.6)	0	(0.0)	0	(0.0)	2	(1.5)
	背部痛	1	(1.4)	1	(2.6)	1	(5.3)	0	(0.0)	3	(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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
胃腸障害	痔出血	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)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
皮膚および皮下組織障害	ざ瘡	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	皮膚炎	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)	1	(5.6)	0	(0.0)	1	(0.8)
	皮膚乾燥	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	湿疹	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	紅斑	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	多汗症	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	寝汗	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)
	そう痒症	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	発疹	0	(0.0)	1	(2.9)	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	(2.7)	1	(2.9)	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)
	背部痛	2	(2.7)	1	(2.9)	1	(5.6)	0	(0.0)	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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n	%	BLACK/ AFRICAN AMERICAN (N=74) n	%	ASIAN (N=37) n	%	OTHER (N=10) n	%	TOTAL (N=265) n	%
胃腸障害	痔出血	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
肝胆道系障害	脂肪肝	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
皮膚および皮下組織障害	ざ瘡	1	(0.7)	0	(0.0)	1	(2.7)	0	(0.0)	2	(0.8)
	皮膚炎	1	(0.7)	0	(0.0)	1	(2.7)	0	(0.0)	2	(0.8)
	接触性皮膚炎	1	(0.7)	0	(0.0)	1	(2.7)	0	(0.0)	2	(0.8)
	皮膚乾燥	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	湿疹	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	紅斑	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	多汗症	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	寝汗	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	粃糠疹	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	そう痒症	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	発疹	0	(0.0)	2	(2.7)	0	(0.0)	0	(0.0)	2	(0.8)
筋骨格系および結合組織障害	関節痛	2	(1.4)	2	(2.7)	0	(0.0)	0	(0.0)	4	(1.5)
	関節炎	1	(0.7)	1	(1.4)	0	(0.0)	0	(0.0)	2	(0.8)
	背部痛	3	(2.1)	2	(2.7)	2	(5.4)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) n	%
筋骨格系および結合組織障害	筋肉内出血	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋痙縮	2	(2.9)	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)
	筋力低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	1	(1.4)	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)
	頚部痛	1	(1.4)	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)
	顎痛	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)
	肩回旋筋腱板症候群	1	(1.4)	0	(0.0)	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)
	開口障害	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	筋骨格硬直	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	筋浮腫	1	(1.4)	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)
	緊張性膀胱	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	腎結石症	1	(1.4)	0	(0.0)	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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
筋骨格系および結合組織障害	筋肉内出血	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)
	筋攣縮	0	(0.0)	2	(5.7)	0	(0.0)	0	(0.0)	2	(1.5)
	筋力低下	1	(1.4)	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)
	筋肉痛	2	(2.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	頚部痛	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	四肢痛	2	(2.7)	0	(0.0)	1	(5.6)	1	(16.7)	4	(3.0)
	顎痛	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	足底筋膜炎	1	(1.4)	0	(0.0)	0	(0.0)	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)
	顎関節症候群	0	(0.0)	0	(0.0)	1	(5.6)	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)
	筋骨格硬直	0	(0.0)	1	(2.9)	1	(5.6)	0	(0.0)	2	(1.5)
	筋浮腫	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)	1	(5.6)	0	(0.0)	1	(0.8)
	緊張性膀胱	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)

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-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n	%	BLACK/ AFRICAN AMERICAN (N=74) n	%	ASIAN (N=37) n	%	OTHER (N=10) n	%	TOTAL (N=265) n	%
筋骨格系および結合組織障害	筋肉内出血	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋痙縮	2	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	筋攣縮	0	(0.0)	2	(2.7)	0	(0.0)	0	(0.0)	2	(0.8)
	筋力低下	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋骨格痛	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋肉痛	2	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	頚部痛	1	(0.7)	0	(0.0)	1	(2.7)	0	(0.0)	2	(0.8)
	四肢痛	2	(1.4)	0	(0.0)	1	(2.7)	1	(10.0)	4	(1.5)
	顎痛	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	足底筋膜炎	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	肩回旋筋腱板症候群	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	顎関節症候群	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	開口障害	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	筋骨格硬直	0	(0.0)	2	(2.7)	1	(2.7)	0	(0.0)	3	(1.1)
	筋浮腫	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
腎および尿路障害	排尿困難	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	緊張性膀胱	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	腎結石症	1	(0.7)	0	(0.0)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n	%	BLACK/ AFRICAN AMERICAN (N=39) n	%	ASIAN (N=19) n	%	OTHER (N=4) n	%	TOTAL (N=132) 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)
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)
	月経困難症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	射精遅延	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	射精障害	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)	1	(5.3)	0	(0.0)	1	(0.8)
	不規則月経	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	卵巣嚢胞	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	骨盤癒着症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	性機能不全	1	(1.4)	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)	0	(0.0)	0	(0.0)
	勃起不全	0	(0.0)	2	(5.1)	0	(0.0)	0	(0.0)	2	(1.5)
一般・全身障害および投与部位の状態	無力症	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	疲労	2	(2.9)	2	(5.1)	0	(0.0)	0	(0.0)	4	(3.0)
	注射部位疼痛	1	(1.4)	0	(0.0)	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)
	倦怠感	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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n	%	BLACK/ AFRICAN AMERICAN (N=35) n	%	ASIAN (N=18) n	%	OTHER (N=6) n	%	TOTAL (N=133) n	%
腎および尿路障害	夜間頻尿	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
生殖系および乳房障害	子宮頚部嚢胞	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	月経困難症	0	(0.0)	0	(0.0)	1	(5.6)	0	(0.0)	1	(0.8)
	射精遅延	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)	1	(5.6)	0	(0.0)	1	(0.8)
	月経過多	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)	2	(11.1)	0	(0.0)	2	(1.5)
	卵巣嚢胞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨盤癒着症	0	(0.0)	1	(2.9)	0	(0.0)	0	(0.0)	1	(0.8)
	性機能不全	0	(0.0)	1	(2.9)	0	(0.0)	0	(0.0)	1	(0.8)
	陰茎分泌物	0	(0.0)	1	(2.9)	0	(0.0)	0	(0.0)	1	(0.8)
	勃起不全	1	(1.4)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疲労	5	(6.8)	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.8)
	注射部位疼痛	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	注射部位そう痒感	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	倦怠感	0	(0.0)	0	(0.0)	1	(5.6)	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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		TOTAL (N=265)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=144) n	%	BLACK/ AFRICAN AMERICAN (N=74) n	%	ASIAN (N=37) n	%	OTHER (N=10) n	%	TOTAL (N=265) n	%
腎および尿路障害	夜間頻尿	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
生殖系および乳房障害	子宮頚部嚢胞	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	月経困難症	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	射精遅延	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	射精障害	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	月経過多	0	(0.0)	0	(0.0)	1	(2.7)	0	(0.0)	1	(0.4)
	不規則月経	0	(0.0)	0	(0.0)	2	(5.4)	0	(0.0)	2	(0.8)
	卵巣嚢胞	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	骨盤癒着症	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	性機能不全	1	(0.7)	1	(1.4)	0	(0.0)	0	(0.0)	2	(0.8)
	陰茎分泌物	0	(0.0)	1	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	勃起不全	1	(0.7)	2	(2.7)	0	(0.0)	0	(0.0)	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	(1.4)	0	(0.0)	0	(0.0)	1	(0.4)
	疲労	7	(4.9)	2	(2.7)	0	(0.0)	0	(0.0)	9	(3.4)
	注射部位疼痛	2	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	注射部位そう痒感	1	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	倦怠感	0	(0.0)	0	(0.0)	1	(2.7)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)									
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70)		BLACK/ AFRICAN AMERICAN (N=39)		ASIAN (N=19)		OTHER (N=4)		TOTAL (N=132)	
		n	%	n	%	n	%	n	%	n	%
一般・全身障害および投与部位の状態	末梢性浮腫	0	(0.0)	2	(5.1)	0	(0.0)	0	(0.0)	2	(1.5)
	不活発	1	(1.4)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	非心臓性胸痛	0	(0.0)	0	(0.0)	0	(0.0)	1	(25.0)	1	(0.8)
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	(5.3)	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)
	血中クレアチンホスホキナーゼ増加	0	(0.0)	2	(5.1)	1	(5.3)	0	(0.0)	3	(2.3)
	血中ブドウ糖増加	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	(1.4)	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)
	血圧上昇	0	(0.0)	1	(2.6)	0	(0.0)	0	(0.0)	1	(0.8)
	心電図ＳＴ部分下降	1	(1.4)	0	(0.0)	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)
	体重減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	体重増加	16	(22.9)	12	(30.8)	3	(15.8)	0	(0.0)	31	(23.5)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.8)
傷害、中毒および処置合併症	節足動物咬傷	1	(1.4)	0	(0.0)	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.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n %	BLACK/ AFRICAN AMERICAN (N=35) n %	ASIAN (N=18) n %	OTHER (N=6) n %	TOTAL (N=133) n %
一般・全身障害および投与部位の状態	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (0.8)
	非心臓性胸痛	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	0 (0.0)	0 (0.0)	2 (11.1)	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)	2 (11.1)	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)	1 (2.9)	0 (0.0)	0 (0.0)	1 (0.8)
	血中ブドウ糖増加	0 (0.0)	1 (2.9)	0 (0.0)	1 (16.7)	2 (1.5)
	血中インスリン増加	0 (0.0)	2 (5.7)	0 (0.0)	0 (0.0)	2 (1.5)
	血中カリウム減少	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	1 (0.8)
	血圧上昇	2 (2.7)	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)
	グリコヘモグロビン増加	1 (1.4)	1 (2.9)	0 (0.0)	0 (0.0)	2 (1.5)
	体重減少	2 (2.7)	3 (8.6)	1 (5.6)	0 (0.0)	6 (4.5)
	体重増加	13 (17.6)	4 (11.4)	5 (27.8)	2 (33.3)	24 (18.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)	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)

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-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
一般・全身障害および投与部位の状態	末梢性浮腫	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)	2 (0.8)
	不活発	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	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)	0 (0.0)	3 (8.1)	0 (0.0)	3 (1.1)
	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)	2 (5.4)	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 (4.1)	1 (2.7)	0 (0.0)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	1 (1.4)	0 (0.0)	1 (10.0)	2 (0.8)
	血中インスリン増加	1 (0.7)	2 (2.7)	0 (0.0)	0 (0.0)	3 (1.1)
	血中カリウム減少	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	血圧上昇	2 (1.4)	1 (1.4)	0 (0.0)	0 (0.0)	3 (1.1)
	心電図ＳＴ部分下降	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	グリコヘモグロビン増加	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	体重減少	2 (1.4)	3 (4.1)	1 (2.7)	0 (0.0)	6 (2.3)
	体重増加	29 (20.1)	16 (21.6)	8 (21.6)	2 (20.0)	55 (20.8)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	2 (5.4)	0 (0.0)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (0.7)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		ARIP IMD (N=132)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	BLACK/ AFRICAN AMERICAN (N=39) n %	ASIAN (N=19) n %	OTHER (N=4) n %	TOTAL (N=132) n %
傷害、中毒および処置合併症	転倒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	足骨折	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	裂傷	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	靱帯捻挫	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)
	挫傷	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	胸部損傷	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	歯牙破折	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	処置による疼痛	2 (2.9)	2 (5.1)	0 (0.0)	0 (0.0)	4 (3.0)
	脊柱損傷	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	注射に伴う反応	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
	外傷後頚部症候群	0 (0.0)	1 (2.6)	0 (0.0)	0 (0.0)	1 (0.8)
社会環境	個人衛生不良	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
TOTAL1)		55 (78.6)	32 (82.1)	11 (57.9)	3 (75.0)	101 (76.5)

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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

		PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=74) n %	BLACK/ AFRICAN AMERICAN (N=35) n %	ASIAN (N=18) n %	OTHER (N=6) n %	TOTAL (N=133) n %
傷害、中毒および処置合併症	転倒	1 (1.4)	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)
	裂傷	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	靱帯捻挫	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	橈骨骨折	1 (1.4)	0 (0.0)	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)
	胸部損傷	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)
	処置による疼痛	0 (0.0)	1 (2.9)	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)
	注射に伴う反応	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)
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)
TOTAL1)		60 (81.1)	27 (77.1)	15 (83.3)	5 (83.3)	107 (80.5)

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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

表 2.7.4.7-41　人種別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.3
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) CAUCASIAN (N=144) n %	BLACK/ AFRICAN AMERICAN (N=74) n %	ASIAN (N=37) n %	OTHER (N=10) n %	TOTAL (N=265) n %
傷害、中毒および処置合併症	転倒	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	足骨折	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	裂傷	1 (0.7)	1 (1.4)	0 (0.0)	0 (0.0)	2 (0.8)
	靱帯捻挫	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	橈骨骨折	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	挫傷	2 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	胸部損傷	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	歯牙破折	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	処置による疼痛	2 (1.4)	3 (4.1)	0 (0.0)	0 (0.0)	5 (1.9)
	脊柱損傷	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	注射に伴う反応	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
	外傷後頸部症候群	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (0.4)
社会環境	個人衛生不良	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
TOTAL1)		115 (79.9)	59 (79.7)	26 (70.3)	8 (80.0)	208 (78.5)

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: ADAE21AC.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.3　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.6.3 より作成＞

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
感染症および寄生虫症	乳房蜂巣炎	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	気管支炎	2 (2.9)	1 (1.6)	3 (2.3)	1 (1.4)	1 (1.7)	2 (1.5)	3 (2.1)	2 (1.7)	5 (1.9)
	蜂巣炎	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	胃腸炎	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	ウイルス性胃腸炎	2 (2.9)	0 (0.0)	2 (1.5)	0 (0.0)	1 (1.7)	1 (0.8)	2 (1.4)	1 (0.8)	3 (1.1)
	麦粒腫	2 (2.9)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	2 (0.8)
	インフルエンザ	1 (1.4)	2 (3.2)	3 (2.3)	1 (1.4)	1 (1.7)	2 (1.5)	2 (1.4)	3 (2.5)	5 (1.9)
	喉頭炎	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	鼻咽頭炎	5 (7.1)	5 (8.1)	10 (7.6)	1 (1.4)	12 (20.3)	13 (9.8)	6 (4.2)	17 (14.0)	23 (8.7)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	外耳炎	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	中耳炎	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	咽頭炎	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	3 (2.5)	3 (1.1)
	レンサ球菌性咽頭炎	1 (1.4)	1 (1.6)	2 (1.5)	1 (1.4)	0 (0.0)	1 (0.8)	2 (1.4)	1 (0.8)	3 (1.1)

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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.

FILE: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) 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)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	0 (0.0)	2 (0.8)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	副鼻腔炎	3 (4.3)	2 (3.2)	5 (3.8)	1 (1.4)	0 (0.0)	1 (0.8)	4 (2.8)	2 (1.7)	6 (2.3)
	須毛瘡	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	足部白癬	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	歯膿瘍	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	2 (1.4)	0 (0.0)	2 (0.8)
	トリコモナス症	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	上気道感染	3 (4.3)	1 (1.6)	4 (3.0)	4 (5.4)	2 (3.4)	6 (4.5)	7 (4.9)	3 (2.5)	10 (3.8)
	尿路感染	4 (5.7)	0 (0.0)	4 (3.0)	2 (2.7)	0 (0.0)	2 (1.5)	6 (4.2)	0 (0.0)	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 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	歯感染	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.4)	1 (1.7)	2 (1.5)	1 (0.7)	2 (1.7)	3 (1.1)
	無症候性細菌尿	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	クラミジア感染	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	真菌性口腔咽頭炎	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	気道感染	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
血液およびリンパ系障害	貧血	1 (1.4)	2 (3.2)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	2 (1.7)	3 (1.1)
	白血球減少症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	好中球減少症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	2 (1.7)	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)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	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 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	高血糖	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	食欲亢進	2 (2.9)	2 (3.2)	4 (3.0)	0 (0.0)	1 (1.7)	1 (0.8)	2 (1.4)	3 (2.5)	5 (1.9)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	食欲減退	2 (2.9)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	2 (0.8)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	0 (0.0)	2 (0.8)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	激越	1 (1.4)	0 (0.0)	1 (0.8)	4 (5.4)	0 (0.0)	4 (3.0)	5 (3.5)	0 (0.0)	5 (1.9)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
精神障害	不安	7 (10.0)	2 (3.2)	9 (6.8)	2 (2.7)	4 (6.8)	6 (4.5)	9 (6.3)	6 (5.0)	15 (5.7)
	無感情	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	双極１型障害	2 (2.9)	0 (0.0)	2 (1.5)	7 (9.5)	1 (1.7)	8 (6.0)	9 (6.3)	1 (0.8)	10 (3.8)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	抑うつ気分	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	2 (3.4)	2 (1.5)	1 (0.7)	2 (1.7)	3 (1.1)
	うつ病	1 (1.4)	3 (4.8)	4 (3.0)	1 (1.4)	2 (3.4)	3 (2.3)	2 (1.4)	5 (4.1)	7 (2.6)
	軽躁	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	初期不眠症	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	不眠症	6 (8.6)	4 (6.5)	10 (7.6)	4 (5.4)	6 (10.2)	10 (7.5)	10 (6.9)	10 (8.3)	20 (7.5)
	易刺激性	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	リビドー減退	3 (4.3)	0 (0.0)	3 (2.3)	0 (0.0)	2 (3.4)	2 (1.5)	3 (2.1)	2 (1.7)	5 (1.9)
	躁病	1 (1.4)	2 (3.2)	3 (2.3)	5 (6.8)	9 (15.3)	14 (10.5)	6 (4.2)	11 (9.1)	17 (6.4)
	中期不眠症	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	悪夢	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	パニック発作	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	精神運動制止遅滞	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	落ち着きのなさ	3 (4.3)	3 (4.8)	6 (4.5)	4 (5.4)	1 (1.7)	5 (3.8)	7 (4.9)	4 (3.3)	11 (4.2)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	2 (1.7)	2 (0.8)
	社会逃避行動	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)

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表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
精神障害	夢遊症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	自殺企図	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	感情不安定	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	ディスフェミア	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	双極性障害	4 (5.7)	1 (1.6)	5 (3.8)	2 (2.7)	3 (5.1)	5 (3.8)	6 (4.2)	4 (3.3)	10 (3.8)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	0 (0.0)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	16 (22.9)	12 (19.4)	28 (21.2)	8 (10.8)	9 (15.3)	17 (12.8)	24 (16.7)	21 (17.4)	45 (17.0)
	運動緩慢	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	注意力障害	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	浮動性めまい	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	1 (1.7)	2 (1.5)	2 (1.4)	1 (0.8)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	ジスキネジア	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	2 (3.4)	2 (1.5)	1 (0.7)	3 (2.5)	4 (1.5)
	錐体外路障害	2 (2.9)	0 (0.0)	2 (1.5)	2 (2.7)	0 (0.0)	2 (1.5)	4 (2.8)	0 (0.0)	4 (1.5)
	頭痛	2 (2.9)	2 (3.2)	4 (3.0)	5 (6.8)	4 (6.8)	9 (6.8)	7 (4.9)	6 (5.0)	13 (4.9)
	過眠症	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	感覚鈍麻	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	嗜眠	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	2 (1.4)	0 (0.0)	2 (0.8)

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表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
神経系障害	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.7)	2 (1.5)	1 (0.7)	1 (0.8)	2 (0.8)
	錯感覚	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	パーキンソニズム	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	2 (1.7)	2 (0.8)
	精神運動亢進	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	坐骨神経痛	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	鎮静	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	傾眠	2 (2.9)	4 (6.5)	6 (4.5)	1 (1.4)	0 (0.0)	1 (0.8)	3 (2.1)	4 (3.3)	7 (2.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	遅発性ジスキネジア	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	一過性脳虚血発作	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	振戦	2 (2.9)	1 (1.6)	3 (2.3)	1 (1.4)	1 (1.7)	2 (1.5)	3 (2.1)	2 (1.7)	5 (1.9)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.7)	2 (1.5)	1 (0.7)	1 (0.8)	2 (0.8)
	脳損傷	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
眼障害	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	羞明	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	2 (1.4)	0 (0.0)	2 (0.8)
	霧視	1 (1.4)	2 (3.2)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	2 (1.7)	3 (1.1)
耳および迷路障害	耳鳴	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)

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表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
心臓障害	心房細動	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	第一度房室ブロック	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	徐脈	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	心肺停止	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
血管障害	本態性高血圧症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	高血圧	1 (1.4)	0 (0.0)	1 (0.8)	2 (2.7)	1 (1.7)	3 (2.3)	3 (2.1)	1 (0.8)	4 (1.5)
呼吸器、胸郭および縦隔障害	喘息	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	0 (0.0)	2 (0.8)
	呼吸不全	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	アレルギー性副鼻腔炎	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	気道うっ血	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	口腔咽頭痛	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
胃腸障害	腹部膨満	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	上腹部痛	2 (2.9)	0 (0.0)	2 (1.5)	0 (0.0)	1 (1.7)	1 (0.8)	2 (1.4)	1 (0.8)	3 (1.1)

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FILE: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	便秘	1 (1.4)	3 (4.8)	4 (3.0)	1 (1.4)	3 (5.1)	4 (3.0)	2 (1.4)	6 (5.0)	8 (3.0)
	齲歯	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	下痢	1 (1.4)	0 (0.0)	1 (0.8)	3 (4.1)	1 (1.7)	4 (3.0)	4 (2.8)	1 (0.8)	5 (1.9)
	口内乾燥	2 (2.9)	2 (3.2)	4 (3.0)	3 (4.1)	0 (0.0)	3 (2.3)	5 (3.5)	2 (1.7)	7 (2.6)
	消化不良	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	3 (5.1)	4 (3.0)	2 (1.4)	3 (2.5)	5 (1.9)
	食中毒	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	1 (1.7)	2 (1.5)	1 (0.7)	1 (0.8)	2 (0.8)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	悪心	3 (4.3)	0 (0.0)	3 (2.3)	4 (5.4)	2 (3.4)	6 (4.5)	7 (4.9)	2 (1.7)	9 (3.4)
	口腔内不快感	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	流涎過多	2 (2.9)	1 (1.6)	3 (2.3)	3 (4.1)	0 (0.0)	3 (2.3)	5 (3.5)	1 (0.8)	6 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	舌腫脹	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	歯痛	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	2 (3.4)	3 (2.3)	2 (1.4)	2 (1.7)	4 (1.5)
	嘔吐	2 (2.9)	0 (0.0)	2 (1.5)	2 (2.7)	0 (0.0)	2 (1.5)	4 (2.8)	0 (0.0)	4 (1.5)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	痔出血	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
肝胆道系障害	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
皮膚および皮下組織障害	ざ瘡	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	皮膚炎	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	接触性皮膚炎	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	湿疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	寝汗	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	粃糠疹	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	発疹	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	2 (1.7)	2 (0.8)
筋骨格系および結合組織障害	関節痛	0 (0.0)	1 (1.6)	1 (0.8)	2 (2.7)	1 (1.7)	3 (2.3)	2 (1.4)	2 (1.7)	4 (1.5)
	関節炎	1 (1.4)	1 (1.6)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)	2 (0.8)
	背部痛	1 (1.4)	2 (3.2)	3 (2.3)	2 (2.7)	2 (3.4)	4 (3.0)	3 (2.1)	4 (3.3)	7 (2.6)
	筋肉内出血	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
筋骨格系および結合組織障害	筋痙縮	2 (2.9)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	2 (0.8)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	2 (1.7)	2 (0.8)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	筋骨格痛	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	0 (0.0)	2 (0.8)
	頚部痛	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	2 (3.4)	4 (3.0)	2 (1.4)	2 (1.7)	4 (1.5)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	肩回旋筋腱板症候群	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	開口障害	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	筋骨格硬直	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	3 (2.5)	3 (1.1)
	筋浮腫	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
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 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	緊張性膀胱	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	腎結石症	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)

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表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) 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)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	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)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	射精遅延	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	月経過多	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	2 (1.7)	2 (0.8)
	卵巣嚢胞	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	性機能不全	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	勃起不全	0 (0.0)	2 (3.2)	2 (1.5)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	2 (1.7)	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 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	疲労	2 (2.9)	2 (3.2)	4 (3.0)	5 (6.8)	0 (0.0)	5 (3.8)	7 (4.9)	2 (1.7)	9 (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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
一般・全身障害および投与部位の状態	注射部位疼痛	1 (1.4)	0 (0.0)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	2 (1.4)	0 (0.0)	2 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	末梢性浮腫	0 (0.0)	2 (3.2)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.7)	2 (0.8)
	不活発	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	非心臓性胸痛	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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 (1.6)	1 (0.8)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	3 (2.5)	3 (1.1)
	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)	2 (3.4)	2 (1.5)	0 (0.0)	2 (1.7)	2 (0.8)
	血中クレアチンホスホキナーゼ増加	0 (0.0)	3 (4.8)	3 (2.3)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	4 (3.3)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.4)	2 (1.5)	0 (0.0)	2 (1.7)	2 (0.8)
	血中インスリン増加	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	2 (3.4)	2 (1.5)	1 (0.7)	2 (1.7)	3 (1.1)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.4)
	血圧上昇	0 (0.0)	1 (1.6)	1 (0.8)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	1 (0.8)	3 (1.1)
	心電図ＳＴ部分下降	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) 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 (1.4)	1 (1.7)	2 (1.5)	1 (0.7)	1 (0.8)	2 (0.8)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	4 (6.8)	6 (4.5)	2 (1.4)	4 (3.3)	6 (2.3)
	体重増加	16 (22.9)	15 (24.2)	31 (23.5)	13 (17.6)	11 (18.6)	24 (18.0)	29 (20.1)	26 (21.5)	55 (20.8)
	肝機能検査値上昇	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	1 (1.7)	1 (0.8)	0 (0.0)	2 (1.7)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	足骨折	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	裂傷	0 (0.0)	1 (1.6)	1 (0.8)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	1 (0.8)	2 (0.8)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.7)	0 (0.0)	2 (1.5)	2 (1.4)	0 (0.0)	2 (0.8)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	1 (0.8)	1 (0.7)	0 (0.0)	1 (0.4)
	挫傷	2 (2.9)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	0 (0.0)	2 (0.8)
	胸部損傷	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	歯牙破折	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	処置による疼痛	2 (2.9)	2 (3.2)	4 (3.0)	0 (0.0)	1 (1.7)	1 (0.8)	2 (1.4)	3 (2.5)	5 (1.9)
	脊柱損傷	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
	注射に伴う反応	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.4)
	外傷後頚部症候群	0 (0.0)	1 (1.6)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

表 2.7.4.7-42　人種別有害事象（白人，白人以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.9

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Race (Caucasian vs Non-Caucasian)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	CAUCASIAN (N=70) n %	NON-CAUCASIAN (N=62) n %	TOTAL (N=132) n %	CAUCASIAN (N=74) n %	NON-CAUCASIAN (N=59) n %	TOTAL (N=133) n %	CAUCASIAN (N=144) n %	NON-CAUCASIAN (N=121) n %	TOTAL (N=265) n %
社会環境	**個人衛生不良**	1 (1.4)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)	1 (0.4)
TOTAL1)		55 (78.6)	46 (74.2)	101 (76.5)	60 (81.1)	47 (79.7)	107 (80.5)	115 (79.9)	93 (76.9)	208 (78.5)

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: ADAE21AH.LIS, RUN: [redacted]20[redacted] 10:49
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.9　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.6.9 より作成＞

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	5 (2.0)	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	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	1 (12.5)	1 (0.8)	2 (1.5)	0 (0.0)	1 (0.8)	1 (0.8)	1 (5.3)	2 (0.8)	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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	5 (2.0)	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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	鼻咽頭炎	1 (12.5)	9 (7.3)	10 (7.6)	1 (9.1)	12 (9.8)	13 (9.8)	2 (10.5)	21 (8.5)	23 (8.7)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	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	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)

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: ADAE21AE.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5

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

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
感染症および寄生虫症	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)
	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 (4.0)	5 (3.8)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	6 (2.4)	6 (2.3)
	須毛瘡	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)
	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	1 (12.5)	3 (2.4)	4 (3.0)	1 (9.1)	5 (4.1)	6 (4.5)	2 (10.5)	8 (3.3)	10 (3.8)
	尿路感染	0 (0.0)	4 (3.2)	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)	1 (9.1)	1 (0.8)	2 (1.5)	1 (5.3)	2 (0.8)	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)

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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.

FILE: ADAE21AE.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
感染症および寄生虫症	口腔ヘルペス	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)
	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)
血液およびリンパ系障害	貧血	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)
	白血球減少症	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)
	好中球減少症	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)
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 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	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 (3.2)	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	1 (12.5)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	1 (0.4)	2 (0.8)
	高脂血症	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)
	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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5

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

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (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)
	激越	1 (12.5)	0 (0.0)	1 (0.8)	1 (9.1)	3 (2.5)	4 (3.0)	2 (10.5)	3 (1.2)	5 (1.9)
	不安	1 (12.5)	8 (6.5)	9 (6.8)	0 (0.0)	6 (4.9)	6 (4.5)	1 (5.3)	14 (5.7)	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)
	双極１型障害	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	8 (6.6)	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 (9.1)	1 (0.8)	2 (1.5)	1 (5.3)	2 (0.8)	3 (1.1)
	うつ病	0 (0.0)	4 (3.2)	4 (3.0)	1 (9.1)	2 (1.6)	3 (2.3)	1 (5.3)	6 (2.4)	7 (2.6)
	軽躁	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)
	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	1 (12.5)	9 (7.3)	10 (7.6)	0 (0.0)	10 (8.2)	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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	5 (2.0)	5 (1.9)
	躁病	0 (0.0)	3 (2.4)	3 (2.3)	1 (9.1)	13 (10.7)	14 (10.5)	1 (5.3)	16 (6.5)	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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
精神障害	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	0 (0.0)	6 (4.8)	6 (4.5)	2 (18.2)	3 (2.5)	5 (3.8)	2 (10.5)	9 (3.7)	11 (4.2)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	1 (0.8)	2 (1.5)	1 (5.3)	1 (0.4)	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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
	感情不安定	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)
	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 (4.0)	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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	4 (50.0)	24 (19.4)	28 (21.2)	1 (9.1)	16 (13.1)	17 (12.8)	5 (26.3)	40 (16.3)	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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (1.2)	3 (1.1)
	構語障害	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)

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表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
神経系障害	ジスキネジア	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)
	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 (3.2)	4 (3.0)	1 (9.1)	8 (6.6)	9 (6.8)	1 (5.3)	12 (4.9)	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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	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)
	坐骨神経痛	1 (12.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	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 (4.8)	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	1 (12.5)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	5 (2.0)	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)

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

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
眼障害	眼痛	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)
	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	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)
	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)
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	1 (12.5)	0 (0.0)	1 (0.8)	1 (9.1)	2 (1.6)	3 (2.3)	2 (10.5)	2 (0.8)	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)

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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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
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)
	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	3 (1.2)	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	0 (0.0)	4 (3.2)	4 (3.0)	0 (0.0)	4 (3.3)	4 (3.0)	0 (0.0)	8 (3.3)	8 (3.0)
	齲歯	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)
	下痢	0 (0.0)	1 (0.8)	1 (0.8)	1 (9.1)	3 (2.5)	4 (3.0)	1 (5.3)	4 (1.6)	5 (1.9)
	口内乾燥	0 (0.0)	4 (3.2)	4 (3.0)	0 (0.0)	3 (2.5)	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)
	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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	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)

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表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
胃腸障害	悪心	0 (0.0)	3 (2.4)	3 (2.3)	0 (0.0)	6 (4.9)	6 (4.5)	0 (0.0)	9 (3.7)	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 (2.5)	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 (2.5)	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	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	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)
	接触性皮膚炎	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)
	湿疹	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)
	紅斑	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 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

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

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
皮膚および皮下組織障害	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 (2.5)	3 (2.3)	0 (0.0)	4 (1.6)	4 (1.5)
	関節炎	1 (12.5)	1 (0.8)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.3)	1 (0.4)	2 (0.8)
	背部痛	0 (0.0)	3 (2.4)	3 (2.3)	1 (9.1)	3 (2.5)	4 (3.0)	1 (5.3)	6 (2.4)	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	1 (12.5)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	3 (2.5)	4 (3.0)	1 (5.3)	3 (1.2)	4 (1.5)

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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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (1.2)	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	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)

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: ADAE21AE.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
生殖系および乳房障害	射精障害	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)
	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)
	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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	2 (0.8)	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 (3.2)	4 (3.0)	1 (9.1)	4 (3.3)	5 (3.8)	1 (5.3)	8 (3.3)	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	1 (0.4)	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)

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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-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) HISPANIC/LATINO (N=8) n %	ARIP IMD (N=132) NOT HISPANIC/LATINO (N=124) n %	ARIP IMD (N=132) TOTAL (N=132) n %	PLACEBO (N=133) HISPANIC/LATINO (N=11) n %	PLACEBO (N=133) NOT HISPANIC/LATINO (N=122) n %	PLACEBO (N=133) TOTAL (N=133) n %	TOTAL (N=265) HISPANIC/LATINO (N=19) n %	TOTAL (N=265) NOT HISPANIC/LATINO (N=246) n %	TOTAL (N=265) TOTAL (N=265) n %
一般・全身障害および投与部位の状態	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)	0 (0.0)	2 (1.6)	2 (1.5)	0 (0.0)	3 (1.2)	3 (1.1)
	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)	2 (1.6)	2 (1.5)	0 (0.0)	2 (0.8)	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)	1 (9.1)	1 (0.8)	2 (1.5)	1 (5.3)	1 (0.4)	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)	0 (0.0)	6 (4.9)	6 (4.5)	0 (0.0)	6 (2.4)	6 (2.3)
	体重増加	4 (50.0)	27 (21.8)	31 (23.5)	1 (9.1)	23 (18.9)	24 (18.0)	5 (26.3)	50 (20.3)	55 (20.8)
	肝機能検査値上昇	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)

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-8.2.6.5　FINAL

表 2.7.4.7-43　民族別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.5
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Ethnicity
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	HISPANIC/ LATINO (N=8) n %	NOT HISPANIC/ LATINO (N=124) n %	TOTAL (N=132) n %	HISPANIC/ LATINO (N=11) n %	NOT HISPANIC/ LATINO (N=122) n %	TOTAL (N=133) n %	HISPANIC/ LATINO (N=19) n %	NOT HISPANIC/ LATINO (N=246) n %	TOTAL (N=265) n %
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)	1 (9.1)	0 (0.0)	1 (0.8)	1 (5.3)	1 (0.4)	2 (0.8)
	靭帯捻挫	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)
	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 (3.2)	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)
	外傷後頚部症候群	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 (75.0)	95 (76.6)	101 (76.5)	7 (63.6)	100 (82.0)	107 (80.5)	13 (68.4)	195 (79.3)	208 (78.5)

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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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＜資料番号 5.3.5.1-01：CT-8.2.6.5 より作成＞

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD (N=132) US (N=100) n %	ARIP IMD (N=132) NON-US (N=32) n %	ARIP IMD (N=132) TOTAL (N=132) n %	PLACEBO (N=133) US (N=102) n %	PLACEBO (N=133) NON-US (N=31) n %	PLACEBO (N=133) TOTAL (N=133) n %	TOTAL (N=265) US (N=202) n %	TOTAL (N=265) NON-US (N=63) n %	TOTAL (N=265) TOTAL (N=265) n %
感染症および寄生虫症	乳房蜂巣炎	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	気管支炎	3 (3.0)	0 (0.0)	3 (2.3)	1 (1.0)	1 (3.2)	2 (1.5)	4 (2.0)	1 (1.6)	5 (1.9)
	蜂巣炎	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	結膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	真菌感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	胃腸炎	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	ウイルス性胃腸炎	2 (2.0)	0 (0.0)	2 (1.5)	1 (1.0)	0 (0.0)	1 (0.8)	3 (1.5)	0 (0.0)	3 (1.1)
	麦粒腫	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	インフルエンザ	2 (2.0)	1 (3.1)	3 (2.3)	1 (1.0)	1 (3.2)	2 (1.5)	3 (1.5)	2 (3.2)	5 (1.9)
	喉頭炎	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	シラミ寄生	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	限局性感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	鼻咽頭炎	8 (8.0)	2 (6.3)	10 (7.6)	4 (3.9)	9 (29.0)	13 (9.8)	12 (5.9)	11 (17.5)	23 (8.7)
	精巣炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	外耳炎	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	中耳炎	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	咽頭炎	0 (0.0)	1 (3.1)	1 (0.8)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	2 (3.2)	3 (1.1)
	レンサ球菌性咽頭炎	2 (2.0)	0 (0.0)	2 (1.5)	1 (1.0)	0 (0.0)	1 (0.8)	3 (1.5)	0 (0.0)	3 (1.1)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)

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表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) 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 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	副鼻腔炎	5 (5.0)	0 (0.0)	5 (3.8)	1 (1.0)	0 (0.0)	1 (0.8)	6 (3.0)	0 (0.0)	6 (2.3)
	須毛瘡	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	足部白癬	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	歯膿瘍	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	トリコモナス症	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	上気道感染	4 (4.0)	0 (0.0)	4 (3.0)	6 (5.9)	0 (0.0)	6 (4.5)	10 (5.0)	0 (0.0)	10 (3.8)
	尿路感染	3 (3.0)	1 (3.1)	4 (3.0)	2 (2.0)	0 (0.0)	2 (1.5)	5 (2.5)	1 (1.6)	6 (2.3)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	歯感染	1 (1.0)	0 (0.0)	1 (0.8)	2 (2.0)	0 (0.0)	2 (1.5)	3 (1.5)	0 (0.0)	3 (1.1)
	無症候性細菌尿	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	クラミジア感染	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	ウイルス性耳感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	真菌性口腔咽頭炎	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	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 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	気道感染	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	カンジダ感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	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: ADAE21AA.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) n %	TOTAL (N=265) n %
血液およびリンパ系障害	貧血	2 (2.0)	1 (3.1)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	1 (1.6)	3 (1.1)
	白血球減少症	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	好中球減少症	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	2 (3.2)	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)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
代謝および栄養障害	脱水	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	高血糖	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	食欲亢進	4 (4.0)	0 (0.0)	4 (3.0)	1 (1.0)	0 (0.0)	1 (0.8)	5 (2.5)	0 (0.0)	5 (1.9)
	高インスリン血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	食欲減退	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	高脂血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
精神障害	感情障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	1 (1.6)	2 (0.8)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	激越	1 (1.0)	0 (0.0)	1 (0.8)	4 (3.9)	0 (0.0)	4 (3.0)	5 (2.5)	0 (0.0)	5 (1.9)
	不安	8 (8.0)	1 (3.1)	9 (6.8)	3 (2.9)	3 (9.7)	6 (4.5)	11 (5.4)	4 (6.3)	15 (5.7)
	無感情	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	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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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) n %	TOTAL (N=265) n %
精神障害	双極１型障害	0 (0.0)	2 (6.3)	2 (1.5)	0 (0.0)	8 (25.8)	8 (6.0)	0 (0.0)	10 (15.9)	10 (3.8)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	抑うつ気分	0 (0.0)	1 (3.1)	1 (0.8)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	2 (3.2)	3 (1.1)
	うつ病	2 (2.0)	2 (6.3)	4 (3.0)	3 (2.9)	0 (0.0)	3 (2.3)	5 (2.5)	2 (3.2)	7 (2.6)
	軽躁	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	初期不眠症	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	不眠症	8 (8.0)	2 (6.3)	10 (7.6)	6 (5.9)	4 (12.9)	10 (7.5)	14 (6.9)	6 (9.5)	20 (7.5)
	易刺激性	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	リビドー減退	3 (3.0)	0 (0.0)	3 (2.3)	1 (1.0)	1 (3.2)	2 (1.5)	4 (2.0)	1 (1.6)	5 (1.9)
	躁病	1 (1.0)	2 (6.3)	3 (2.3)	8 (7.8)	6 (19.4)	14 (10.5)	9 (4.5)	8 (12.7)	17 (6.4)
	中期不眠症	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	神経過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	悪夢	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	パニック発作	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	精神運動制止遅滞	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	落ち着きのなさ	5 (5.0)	1 (3.1)	6 (4.5)	5 (4.9)	0 (0.0)	5 (3.8)	10 (5.0)	1 (1.6)	11 (4.2)
	睡眠障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	1 (1.6)	2 (0.8)
	社会逃避行動	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	夢遊症	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	自殺企図	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	緊張	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	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 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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) n %	TOTAL (N=265) n %
精神障害	感情不安定	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	ディスフェミア	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	双極性障害	4 (4.0)	1 (3.1)	5 (3.8)	3 (2.9)	2 (6.5)	5 (3.8)	7 (3.5)	3 (4.8)	10 (3.8)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (6.5)	2 (1.5)	0 (0.0)	2 (3.2)	2 (0.8)
	精神活動過多	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
神経系障害	アカシジア	26 (26.0)	2 (6.3)	28 (21.2)	13 (12.7)	4 (12.9)	17 (12.8)	39 (19.3)	6 (9.5)	45 (17.0)
	運動緩慢	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	注意力障害	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	浮動性めまい	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	1 (3.2)	2 (1.5)	2 (1.0)	1 (1.6)	3 (1.1)
	構語障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	ジスキネジア	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	2 (6.5)	2 (1.5)	2 (1.0)	2 (3.2)	4 (1.5)
	錐体外路障害	1 (1.0)	1 (3.1)	2 (1.5)	0 (0.0)	2 (6.5)	2 (1.5)	1 (0.5)	3 (4.8)	4 (1.5)
	頭痛	3 (3.0)	1 (3.1)	4 (3.0)	7 (6.9)	2 (6.5)	9 (6.8)	10 (5.0)	3 (4.8)	13 (4.9)
	過眠症	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	感覚鈍麻	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	嗜眠	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	1 (1.6)	2 (0.8)
	錯感覚	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	パーキンソニズム	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	精神運動亢進	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)

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表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) n %	TOTAL (N=265) n %
神経系障害	坐骨神経痛	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	鎮静	1 (1.0)	1 (3.1)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	1 (1.6)	2 (0.8)
	傾眠	6 (6.0)	0 (0.0)	6 (4.5)	1 (1.0)	0 (0.0)	1 (0.8)	7 (3.5)	0 (0.0)	7 (2.6)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	遅発性ジスキネジア	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	一過性脳虚血発作	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	振戦	2 (2.0)	1 (3.1)	3 (2.3)	1 (1.0)	1 (3.2)	2 (1.5)	3 (1.5)	2 (3.2)	5 (1.9)
	下肢静止不能症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	1 (1.6)	2 (0.8)
	脳損傷	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
眼障害	眼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	羞明	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	霧視	3 (3.0)	0 (0.0)	3 (2.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.5)	0 (0.0)	3 (1.1)
耳および迷路障害	耳鳴	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
心臓障害	心房細動	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	第一度房室ブロック	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	徐脈	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	心肺停止	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	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.

FILE: ADAE21AA.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) 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 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	高血圧	1 (1.0)	0 (0.0)	1 (0.8)	3 (2.9)	0 (0.0)	3 (2.3)	4 (2.0)	0 (0.0)	4 (1.5)
呼吸器、胸郭および縦隔障害	喘息	1 (1.0)	1 (3.1)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	1 (1.6)	2 (0.8)
	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)
	呼吸不全	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	アレルギー性副鼻腔炎	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	気道うっ血	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	口腔咽頭痛	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
胃腸障害	腹部膨満	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	腹痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	上腹部痛	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	1 (3.2)	1 (0.8)	2 (1.0)	1 (1.6)	3 (1.1)
	潰瘍性大腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	便秘	2 (2.0)	2 (6.3)	4 (3.0)	1 (1.0)	3 (9.7)	4 (3.0)	3 (1.5)	5 (7.9)	8 (3.0)
	齲歯	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	下痢	1 (1.0)	0 (0.0)	1 (0.8)	3 (2.9)	1 (3.2)	4 (3.0)	4 (2.0)	1 (1.6)	5 (1.9)
	口内乾燥	4 (4.0)	0 (0.0)	4 (3.0)	3 (2.9)	0 (0.0)	3 (2.3)	7 (3.5)	0 (0.0)	7 (2.6)
	消化不良	0 (0.0)	1 (3.1)	1 (0.8)	1 (1.0)	3 (9.7)	4 (3.0)	1 (0.5)	4 (6.3)	5 (1.9)

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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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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) n %	TOTAL (N=265) n %
胃腸障害	食中毒	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	歯肉痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	1 (3.2)	2 (1.5)	1 (0.5)	1 (1.6)	2 (0.8)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	悪心	2 (2.0)	1 (3.1)	3 (2.3)	4 (3.9)	2 (6.5)	6 (4.5)	6 (3.0)	3 (4.8)	9 (3.4)
	口腔内不快感	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	流涎過多	3 (3.0)	0 (0.0)	3 (2.3)	3 (2.9)	0 (0.0)	3 (2.3)	6 (3.0)	0 (0.0)	6 (2.3)
	歯の知覚過敏	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	舌腫脹	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	歯痛	1 (1.0)	0 (0.0)	1 (0.8)	3 (2.9)	0 (0.0)	3 (2.3)	4 (2.0)	0 (0.0)	4 (1.5)
	嘔吐	2 (2.0)	0 (0.0)	2 (1.5)	2 (2.0)	0 (0.0)	2 (1.5)	4 (2.0)	0 (0.0)	4 (1.5)
	腹壁嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	痔出血	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
肝胆道系障害	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
皮膚および皮下組織障害	ざ瘡	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	皮膚炎	1 (1.0)	1 (3.1)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	1 (1.6)	2 (0.8)
	接触性皮膚炎	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) 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)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	多汗症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	寝汗	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	粃糠疹	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	そう痒症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	発疹	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
筋骨格系および結合組織障害	関節痛	1 (1.0)	0 (0.0)	1 (0.8)	3 (2.9)	0 (0.0)	3 (2.3)	4 (2.0)	0 (0.0)	4 (1.5)
	関節炎	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	背部痛	2 (2.0)	1 (3.1)	3 (2.3)	3 (2.9)	1 (3.2)	4 (3.0)	5 (2.5)	2 (3.2)	7 (2.6)
	筋肉内出血	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	筋痙縮	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	筋攣縮	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)
	筋力低下	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	筋骨格痛	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)
	頚部痛	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.9)	1 (3.2)	4 (3.0)	3 (1.5)	1 (1.6)	4 (1.5)

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表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) 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)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	足底筋膜炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	肩回旋筋腱板症候群	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	開口障害	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	筋骨格硬直	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	1 (3.2)	2 (1.5)	2 (1.0)	1 (1.6)	3 (1.1)
	筋浮腫	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
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 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	緊張性膀胱	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	腎結石症	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	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)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	射精遅延	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	射精障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	月経過多	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	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: ADAE21AA.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) 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 (6.5)	2 (1.5)	0 (0.0)	2 (3.2)	2 (0.8)
	卵巣嚢胞	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	骨盤癒着症	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	性機能不全	0 (0.0)	1 (3.1)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	1 (1.6)	2 (0.8)
	陰茎分泌物	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	勃起不全	2 (2.0)	0 (0.0)	2 (1.5)	1 (1.0)	0 (0.0)	1 (0.8)	3 (1.5)	0 (0.0)	3 (1.1)
一般・全身障害および投与部位の状態	無力症	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	疲労	4 (4.0)	0 (0.0)	4 (3.0)	5 (4.9)	0 (0.0)	5 (3.8)	9 (4.5)	0 (0.0)	9 (3.4)
	注射部位疼痛	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	注射部位そう痒感	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	倦怠感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	1 (1.6)	1 (0.4)
	末梢性浮腫	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	不活発	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	非心臓性胸痛	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	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 (3.1)	1 (0.8)	0 (0.0)	2 (6.5)	2 (1.5)	0 (0.0)	3 (4.8)	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 PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.1　FINAL

表 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) 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)	0 (0.0)	2 (6.5)	2 (1.5)	0 (0.0)	2 (3.2)	2 (0.8)
	血中クレアチンホスホキナーゼ増加	2 (2.0)	1 (3.1)	3 (2.3)	1 (1.0)	0 (0.0)	1 (0.8)	3 (1.5)	1 (1.6)	4 (1.5)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)
	血中インスリン増加	1 (1.0)	0 (0.0)	1 (0.8)	2 (2.0)	0 (0.0)	2 (1.5)	3 (1.5)	0 (0.0)	3 (1.1)
	血中カリウム減少	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	血圧上昇	1 (1.0)	0 (0.0)	1 (0.8)	2 (2.0)	0 (0.0)	2 (1.5)	3 (1.5)	0 (0.0)	3 (1.1)
	心電図ＳＴ部分下降	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.6)	1 (0.4)
	グリコヘモグロビン増加	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.9)	1 (3.2)	6 (4.5)	5 (2.5)	1 (1.6)	6 (2.3)
	体重増加	27 (27.0)	4 (12.5)	31 (23.5)	18 (17.6)	6 (19.4)	24 (18.0)	45 (22.3)	10 (15.9)	55 (20.8)
	肝機能検査値上昇	0 (0.0)	1 (3.1)	1 (0.8)	0 (0.0)	1 (3.2)	1 (0.8)	0 (0.0)	2 (3.2)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	転倒	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)
	足骨折	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	裂傷	1 (1.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (0.8)	2 (1.0)	0 (0.0)	2 (0.8)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	2 (1.5)	2 (1.0)	0 (0.0)	2 (0.8)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	1 (0.8)	1 (0.5)	0 (0.0)	1 (0.4)

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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 2.7.4.7-44　地域別有害事象（米国，米国以外）［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.1
Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Region (US vs Non-US)
(Phase D Safety Sample)

		ARIP IMD (N=132)			PLACEBO (N=133)			TOTAL (N=265)		
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	US (N=100) n %	NON-US (N=32) n %	TOTAL (N=132) n %	US (N=102) n %	NON-US (N=31) n %	TOTAL (N=133) n %	US (N=202) n %	NON-US (N=63) n %	TOTAL (N=265) n %
傷害、中毒および処置合併症	挫傷	2 (2.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.0)	0 (0.0)	2 (0.8)
	胸部損傷	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	歯牙破折	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	処置による疼痛	4 (4.0)	0 (0.0)	4 (3.0)	1 (1.0)	0 (0.0)	1 (0.8)	5 (2.5)	0 (0.0)	5 (1.9)
	脊柱損傷	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	注射に伴う反応	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
	外傷後頚部症候群	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
社会環境	個人衛生不良	1 (1.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.5)	0 (0.0)	1 (0.4)
TOTAL1)		83 (83.0)	18 (56.3)	101 (76.5)	79 (77.5)	28 (90.3)	107 (80.5)	162 (80.2)	46 (73.0)	208 (78.5)

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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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＜資料番号 5.3.5.1-01：CT-8.2.6.1 より作成＞

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
感染症および寄生虫症	乳房蜂巣炎	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	気管支炎	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)
	蜂巣炎	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	真菌感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	胃腸炎	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性胃腸炎	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	麦粒腫	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	インフルエンザ	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)
	喉頭炎	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	鼻咽頭炎	8	(7.8)	0	(0.0)	2	(22.2)	0	(0.0)	10	(7.6)	4	(3.9)	0	(0.0)	6	(60.0)	3	(37.5)	13	(9.8)
	精巣炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	外耳炎	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	中耳炎	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽頭炎	0	(0.0)	0	(0.0)	1	(11.1)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
感染症および寄生虫症	乳房蜂巣炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	気管支炎	4	(2.0)	0	(0.0)	1	(5.3)	0	(0.0)	5	(1.9)
	蜂巣炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	結膜炎	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	真菌感染	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	胃腸炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	ウイルス性胃腸炎	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
	麦粒腫	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	インフルエンザ	4	(2.0)	0	(0.0)	1	(5.3)	0	(0.0)	5	(1.9)
	喉頭炎	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	シラミ寄生	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	限局性感染	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	鼻咽頭炎	12	(5.9)	0	(0.0)	8	(42.1)	3	(17.6)	23	(8.7)
	精巣炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	外耳炎	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	中耳炎	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	咽頭炎	1	(0.5)	0	(0.0)	2	(10.5)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)									PLACEBO (N=133)								
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	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	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	肺炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	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)	1	(12.5)	1	(0.8)
	副鼻腔炎	5	(4.9)	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	須毛瘡	0	(0.0)	0	(0.0)	1	(11.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	足部白癬	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	1	(0.8)
	歯膿瘍	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	トリコモナス症	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	上気道感染	4	(3.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)	6	(5.9)	0	(0.0)	0	(0.0)	0	(0.0)	6	(4.5)
	尿路感染	3	(2.9)	1	(8.3)	0	(0.0)	0	(0.0)	4	(3.0)	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	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	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯感染	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	無症候性細菌尿	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	クラミジア感染	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	真菌性口腔咽頭炎	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(7.7)	0	(0.0)	0	(0.0)	1	(0.8)
	気道感染	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	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-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
感染症および寄生虫症	レンサ球菌性咽頭炎	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
	肺炎	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	鼻炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.9)	1	(0.4)
	副鼻腔炎	6	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	6	(2.3)
	須毛瘡	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	足部白癬	1	(0.5)	0	(0.0)	0	(0.0)	1	(5.9)	2	(0.8)
	歯膿瘍	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	トリコモナス症	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	上気道感染	10	(4.9)	0	(0.0)	0	(0.0)	0	(0.0)	10	(3.8)
	尿路感染	5	(2.5)	1	(4.0)	0	(0.0)	0	(0.0)	6	(2.3)
	ウイルス性上気道感染	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	歯感染	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
	無症候性細菌尿	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	クラミジア感染	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	ウイルス性耳感染	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	真菌性口腔咽頭炎	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	ウイルス性気道感染	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	気道感染	0	(0.0)	1	(4.0)	0	(0.0)	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 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-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
感染症および寄生虫症	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)	1	(10.0)	0	(0.0)	1	(0.8)
	カンジダ感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(7.7)	0	(0.0)	0	(0.0)	1	(0.8)
血液およびリンパ系障害	貧血	2	(2.0)	0	(0.0)	1	(11.1)	0	(0.0)	3	(2.3)	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)	1	(11.1)	0	(0.0)	1	(0.8)	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)	1	(11.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	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)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
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)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	高血糖	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食欲亢進	4	(3.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	高インスリン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	食欲減退	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	２型糖尿病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	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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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
感染症および寄生虫症	口腔ヘルペス	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	カンジダ感染	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
血液およびリンパ系障害	貧血	2	(1.0)	0	(0.0)	1	(5.3)	0	(0.0)	3	(1.1)
	白血球減少症	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	好中球減少症	0	(0.0)	0	(0.0)	1	(5.3)	1	(5.9)	2	(0.8)
内分泌障害	高プロラクチン血症	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
代謝および栄養障害	脱水	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	高血糖	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	食欲亢進	5	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.9)
	高インスリン血症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	食欲減退	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	高脂血症	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	２型糖尿病	1	(0.5)	0	(0.0)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)					PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102) n %	EUROPE (N=12) n %	JAPAN (N=9) n %	OTHER ASIAN COUNTRIES (N=9) n %	TOTAL (N=132) n %	NORTH AMERICA (N=102) n %	EUROPE (N=13) n %	JAPAN (N=10) n %	OTHER ASIAN COUNTRIES (N=8) n %	TOTAL (N=133) 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 (1.0)	1 (7.7)	0 (0.0)	0 (0.0)	2 (1.5)
	攻撃性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)	0 (0.0)	0 (0.0)	1 (0.8)
	激越	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	4 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.0)
	不安	8 (7.8)	0 (0.0)	1 (11.1)	0 (0.0)	9 (6.8)	3 (2.9)	0 (0.0)	2 (20.0)	1 (12.5)	6 (4.5)
	無感情	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	0 (0.0)	2 (16.7)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	7 (53.8)	0 (0.0)	1 (12.5)	8 (6.0)
	歯ぎしり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	抑うつ気分	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	1 (10.0)	0 (0.0)	2 (1.5)
	うつ病	2 (2.0)	0 (0.0)	1 (11.1)	1 (11.1)	4 (3.0)	3 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)
	軽躁	0 (0.0)	0 (0.0)	1 (11.1)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	8 (7.8)	1 (8.3)	0 (0.0)	1 (11.1)	10 (7.6)	6 (5.9)	0 (0.0)	1 (10.0)	3 (37.5)	10 (7.5)
	易刺激性	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	3 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 (2.3)	1 (1.0)	0 (0.0)	1 (10.0)	0 (0.0)	2 (1.5)
	躁病	1 (1.0)	0 (0.0)	1 (11.1)	1 (11.1)	3 (2.3)	8 (7.8)	1 (7.7)	3 (30.0)	2 (25.0)	14 (10.5)
	中期不眠症	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	悪夢	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
精神障害	感情障害	1	(0.5)	1	(4.0)	0	(0.0)	0	(0.0)	2	(0.8)
	攻撃性	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	激越	5	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.9)
	不安	11	(5.4)	0	(0.0)	3	(15.8)	1	(5.9)	15	(5.7)
	無感情	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	双極１型障害	0	(0.0)	9	(36.0)	0	(0.0)	1	(5.9)	10	(3.8)
	歯ぎしり	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	抑うつ気分	2	(1.0)	0	(0.0)	1	(5.3)	0	(0.0)	3	(1.1)
	うつ病	5	(2.5)	0	(0.0)	1	(5.3)	1	(5.9)	7	(2.6)
	軽躁	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	初期不眠症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	不眠症	14	(6.9)	1	(4.0)	1	(5.3)	4	(23.5)	20	(7.5)
	易刺激性	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	リビドー減退	4	(2.0)	0	(0.0)	1	(5.3)	0	(0.0)	5	(1.9)
	躁病	9	(4.4)	1	(4.0)	4	(21.1)	3	(17.6)	17	(6.4)
	中期不眠症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	神経過敏	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	悪夢	1	(0.5)	0	(0.0)	0	(0.0)	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 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-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
精神障害	パニック発作	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	精神運動制止遅滞	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	落ち着きのなさ	5	(4.9)	0	(0.0)	1	(11.1)	0	(0.0)	6	(4.5)	5	(4.9)	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.8)
	睡眠障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	1	(12.5)	2	(1.5)
	社会逃避行動	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	夢遊症	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺企図	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	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)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	感情不安定	0	(0.0)	0	(0.0)	1	(11.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ディスフェミア	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	双極性障害	4	(3.9)	1	(8.3)	0	(0.0)	0	(0.0)	5	(3.8)	3	(2.9)	1	(7.7)	0	(0.0)	1	(12.5)	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)	2	(15.4)	0	(0.0)	0	(0.0)	2	(1.5)
	精神活動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
神経系障害	アカシジア	26	(25.5)	1	(8.3)	0	(0.0)	1	(11.1)	28	(21.2)	13	(12.7)	0	(0.0)	2	(20.0)	2	(25.0)	17	(12.8)
	運動緩慢	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注意力障害	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	浮動性めまい	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)
	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)	1	(10.0)	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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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
精神障害	パニック発作	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	精神運動制止遅滞	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	落ち着きのなさ	10	(4.9)	0	(0.0)	1	(5.3)	0	(0.0)	11	(4.2)
	睡眠障害	1	(0.5)	0	(0.0)	0	(0.0)	1	(5.9)	2	(0.8)
	社会逃避行動	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	夢遊症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	自殺企図	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	緊張	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	感情不安定	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	ディスフェミア	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	双極性障害	7	(3.4)	2	(8.0)	0	(0.0)	1	(5.9)	10	(3.8)
	大うつ病	0	(0.0)	2	(8.0)	0	(0.0)	0	(0.0)	2	(0.8)
	精神活動過多	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
神経系障害	アカシジア	39	(19.1)	1	(4.0)	2	(10.5)	3	(17.6)	45	(17.0)
	運動緩慢	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	注意力障害	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	浮動性めまい	2	(1.0)	0	(0.0)	1	(5.3)	0	(0.0)	3	(1.1)
	構語障害	0	(0.0)	0	(0.0)	1	(5.3)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
神経系障害	ジスキネジア	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	2	(20.0)	0	(0.0)	2	(1.5)
	錐体外路障害	1	(1.0)	1	(8.3)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	2	(15.4)	0	(0.0)	0	(0.0)	2	(1.5)
	頭痛	3	(2.9)	0	(0.0)	0	(0.0)	1	(11.1)	4	(3.0)	7	(6.9)	0	(0.0)	2	(20.0)	0	(0.0)	9	(6.8)
	過眠症	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	感覚鈍麻	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	嗜眠	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	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)	1	(1.0)	0	(0.0)	0	(0.0)	1	(12.5)	2	(1.5)
	錯感覚	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	パーキンソニズム	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	1	(0.8)
	精神運動亢進	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	坐骨神経痛	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鎮静	1	(1.0)	1	(8.3)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	6	(5.9)	0	(0.0)	0	(0.0)	0	(0.0)	6	(4.5)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	失神	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	遅発性ジスキネジア	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	一過性脳虚血発作	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	振戦	2	(2.0)	0	(0.0)	0	(0.0)	1	(11.1)	3	(2.3)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)
	下肢静止不能症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	1	(12.5)	2	(1.5)
	脳損傷	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
神経系障害	ジスキネジア	2	(1.0)	0	(0.0)	2	(10.5)	0	(0.0)	4	(1.5)
	錐体外路障害	1	(0.5)	3	(12.0)	0	(0.0)	0	(0.0)	4	(1.5)
	頭痛	10	(4.9)	0	(0.0)	2	(10.5)	1	(5.9)	13	(4.9)
	過眠症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	感覚鈍麻	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	嗜眠	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	片頭痛	1	(0.5)	0	(0.0)	0	(0.0)	1	(5.9)	2	(0.8)
	錯感覚	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	パーキンソニズム	1	(0.5)	0	(0.0)	0	(0.0)	1	(5.9)	2	(0.8)
	精神運動亢進	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	坐骨神経痛	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	鎮静	1	(0.5)	1	(4.0)	0	(0.0)	0	(0.0)	2	(0.8)
	傾眠	7	(3.4)	0	(0.0)	0	(0.0)	0	(0.0)	7	(2.6)
	失神	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	遅発性ジスキネジア	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	一過性脳虚血発作	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	振戦	3	(1.5)	0	(0.0)	1	(5.3)	1	(5.9)	5	(1.9)
	下肢静止不能症候群	1	(0.5)	0	(0.0)	0	(0.0)	1	(5.9)	2	(0.8)
	脳損傷	1	(0.5)	0	(0.0)	0	(0.0)	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 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-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
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)	1	(10.0)	0	(0.0)	1	(0.8)
	羞明	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	霧視	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)	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	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
心臓障害	心房細動	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(11.1)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	徐脈	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心肺停止	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(7.7)	0	(0.0)	0	(0.0)	1	(0.8)
	高血圧	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
呼吸器、胸郭および縦隔障害	喘息	1	(1.0)	1	(8.3)	0	(0.0)	0	(0.0)	2	(1.5)	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)	0	(0.0)	0	(0.0)	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
眼障害	眼痛	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	羞明	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	霧視	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
耳および迷路障害	耳鳴	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
心臓障害	心房細動	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	第一度房室ブロック	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	徐脈	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	心肺停止	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
血管障害	本態性高血圧症	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	高血圧	4	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.5)
呼吸器、胸郭および縦隔障害	喘息	1	(0.5)	1	(4.0)	0	(0.0)	0	(0.0)	2	(0.8)
	咳嗽	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
呼吸器、胸郭および縦隔障害	呼吸不全	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	気道うっ血	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	口腔咽頭痛	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
胃腸障害	腹部膨満	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	上腹部痛	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	潰瘍性大腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	便秘	2	(2.0)	0	(0.0)	1	(11.1)	1	(11.1)	4	(3.0)	1	(1.0)	0	(0.0)	1	(10.0)	2	(25.0)	4	(3.0)
	齲歯	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	下痢	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	3	(2.9)	0	(0.0)	1	(10.0)	0	(0.0)	4	(3.0)
	口内乾燥	4	(3.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	消化不良	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	0	(0.0)	3	(37.5)	4	(3.0)
	食中毒	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	歯肉痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)
	血便排泄	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	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.
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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
呼吸器、胸郭および縦隔障害	呼吸不全	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	アレルギー性副鼻腔炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	気道うっ血	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	口腔咽頭痛	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
胃腸障害	腹部膨満	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	腹痛	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	上腹部痛	2	(1.0)	0	(0.0)	1	(5.3)	0	(0.0)	3	(1.1)
	潰瘍性大腸炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	便秘	3	(1.5)	0	(0.0)	2	(10.5)	3	(17.6)	8	(3.0)
	齲歯	1	(0.5)	0	(0.0)	1	(5.3)	0	(0.0)	2	(0.8)
	下痢	4	(2.0)	0	(0.0)	1	(5.3)	0	(0.0)	5	(1.9)
	口内乾燥	7	(3.4)	0	(0.0)	0	(0.0)	0	(0.0)	7	(2.6)
	消化不良	1	(0.5)	1	(4.0)	0	(0.0)	3	(17.6)	5	(1.9)
	食中毒	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	胃食道逆流性疾患	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	歯肉痛	1	(0.5)	0	(0.0)	1	(5.3)	0	(0.0)	2	(0.8)
	血便排泄	1	(0.5)	0	(0.0)	0	(0.0)	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 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_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
胃腸障害	悪心	2	(2.0)	1	(8.3)	0	(0.0)	0	(0.0)	3	(2.3)	4	(3.9)	0	(0.0)	2	(20.0)	0	(0.0)	6	(4.5)
	口腔内不快感	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	流涎過多	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	歯の知覚過敏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	舌腫脹	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯痛	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	嘔吐	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	2	(2.0)	0	(0.0)	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)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	痔出血	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
皮膚および皮下組織障害	ざ瘡	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(12.5)	1	(0.8)
	皮膚炎	1	(1.0)	0	(0.0)	1	(11.1)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	接触性皮膚炎	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(10.0)	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)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	湿疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	紅斑	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
胃腸障害	悪心	6	(2.9)	1	(4.0)	2	(10.5)	0	(0.0)	9	(3.4)
	口腔内不快感	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	流涎過多	6	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	6	(2.3)
	歯の知覚過敏	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	舌腫脹	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	歯痛	4	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.5)
	嘔吐	4	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.5)
	腹壁嚢胞	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	痔出血	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
肝胆道系障害	脂肪肝	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
皮膚および皮下組織障害	ざ瘡	1	(0.5)	0	(0.0)	0	(0.0)	1	(5.9)	2	(0.8)
	皮膚炎	1	(0.5)	0	(0.0)	1	(5.3)	0	(0.0)	2	(0.8)
	接触性皮膚炎	1	(0.5)	0	(0.0)	1	(5.3)	0	(0.0)	2	(0.8)
	皮膚乾燥	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	湿疹	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	紅斑	0	(0.0)	0	(0.0)	1	(5.3)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
皮膚および皮下組織障害	多汗症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	寝汗	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	粃糠疹	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	発疹	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	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	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	3	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.3)
	関節炎	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	背部痛	2	(2.0)	0	(0.0)	1	(11.1)	0	(0.0)	3	(2.3)	3	(2.9)	0	(0.0)	1	(10.0)	0	(0.0)	4	(3.0)
	筋肉内出血	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋痙縮	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	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)	0	(0.0)	0	(0.0)	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	筋力低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	筋骨格痛	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)
	頚部痛	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	四肢痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(2.9)	0	(0.0)	0	(0.0)	1	(12.5)	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.
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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
皮膚および皮下組織障害	多汗症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	寝汗	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	粃糠疹	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	そう痒症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	発疹	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
筋骨格系および結合組織障害	関節痛	4	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.5)
	関節炎	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	背部痛	5	(2.5)	0	(0.0)	2	(10.5)	0	(0.0)	7	(2.6)
	筋肉内出血	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋痙縮	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	筋攣縮	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	筋力低下	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋骨格痛	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋肉痛	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	頚部痛	1	(0.5)	0	(0.0)	1	(5.3)	0	(0.0)	2	(0.8)
	四肢痛	3	(1.5)	0	(0.0)	0	(0.0)	1	(5.9)	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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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	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)	0	(0.0)	1	(1.0)	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)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	肩回旋筋腱板症候群	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(12.5)	1	(0.8)
	開口障害	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格硬直	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	1	(10.0)	0	(0.0)	2	(1.5)
	筋浮腫	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	緊張性膀胱	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎結石症	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	1	(12.5)	1	(0.8)
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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	射精遅延	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
筋骨格系および結合組織障害	顎痛	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	足底筋膜炎	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	肩回旋筋腱板症候群	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	顎関節症候群	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.9)	1	(0.4)
	開口障害	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	筋骨格硬直	2	(1.0)	0	(0.0)	1	(5.3)	0	(0.0)	3	(1.1)
	筋浮腫	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
腎および尿路障害	排尿困難	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	緊張性膀胱	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	腎結石症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	夜間頻尿	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.9)	1	(0.4)
生殖系および乳房障害	子宮頚部嚢胞	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	月経困難症	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	射精遅延	1	(0.5)	0	(0.0)	0	(0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)								PLACEBO (N=133)							
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102)		EUROPE (N=12)		JAPAN (N=9)		OTHER ASIAN COUNTRIES (N=9)		TOTAL (N=132)		NORTH AMERICA (N=102)		EUROPE (N=13)		JAPAN (N=10)		OTHER ASIAN COUNTRIES (N=8)		TOTAL (N=133)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
生殖系および乳房障害	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)	1	(10.0)	0	(0.0)	1	(0.8)
	月経過多	0	(0.0)	0	(0.0)	0	(0.0)	1	(11.1)	1	(0.8)	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)	0	(0.0)	0	(0.0)	2	(25.0)	2	(1.5)
	卵巣嚢胞	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	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)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	性機能不全	0	(0.0)	1	(8.3)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	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)	0	(0.0)	0	(0.0)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	勃起不全	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	1	(1.0)	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	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疲労	4	(3.9)	0	(0.0)	0	(0.0)	0	(0.0)	4	(3.0)	5	(4.9)	0	(0.0)	0	(0.0)	0	(0.0)	5	(3.8)
	注射部位疼痛	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	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)	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)
	倦怠感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(10.0)	0	(0.0)	1	(0.8)
	末梢性浮腫	2	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不活発	1	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.8)	1	(1.0)	0	(0.0)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
生殖系および乳房障害	射精障害	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	月経過多	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.9)	1	(0.4)
	不規則月経	0	(0.0)	0	(0.0)	0	(0.0)	2	(11.8)	2	(0.8)
	卵巣嚢胞	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	骨盤癒着症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	性機能不全	1	(0.5)	1	(4.0)	0	(0.0)	0	(0.0)	2	(0.8)
	陰茎分泌物	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	勃起不全	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
一般・全身障害および投与部位の状態	無力症	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	疲労	9	(4.4)	0	(0.0)	0	(0.0)	0	(0.0)	9	(3.4)
	注射部位疼痛	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	注射部位そう痒感	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	倦怠感	0	(0.0)	0	(0.0)	1	(5.3)	0	(0.0)	1	(0.4)
	末梢性浮腫	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	不活発	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)

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表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)					PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102) n %	EUROPE (N=12) n %	JAPAN (N=9) n %	OTHER ASIAN COUNTRIES (N=9) n %	TOTAL (N=132) n %	NORTH AMERICA (N=102) n %	EUROPE (N=13) n %	JAPAN (N=10) n %	OTHER ASIAN COUNTRIES (N=8) n %	TOTAL (N=133) n %
一般・全身障害および投与部位の状態	非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (0.8)	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	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (0.8)	0 (0.0)	0 (0.0)	2 (20.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (20.0)	0 (0.0)	2 (1.5)
	血中クレアチンホスホキナーゼ増加	2 (2.0)	0 (0.0)	0 (0.0)	1 (11.1)	3 (2.3)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	血中インスリン増加	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (2.0)	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)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	血圧上昇	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	心電図ＳＴ部分下降	0 (0.0)	1 (8.3)	0 (0.0)	0 (0.0)	1 (0.8)	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)	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (4.9)	0 (0.0)	1 (10.0)	0 (0.0)	6 (4.5)

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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 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n	%	EUROPE (N=25) n	%	JAPAN (N=19) n	%	OTHER ASIAN COUNTRIES (N=17) n	%	TOTAL (N=265) n	%
一般・全身障害および投与部位の状態	非心臓性胸痛	0	(0.0)	0	(0.0)	0	(0.0)	1	(5.9)	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)	0	(0.0)	2	(10.5)	1	(5.9)	3	(1.1)
	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)	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	3	(1.5)	0	(0.0)	0	(0.0)	1	(5.9)	4	(1.5)
	血中ブドウ糖増加	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	血中インスリン増加	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
	血中カリウム減少	1	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)
	血圧上昇	3	(1.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.1)
	心電図ＳＴ部分下降	0	(0.0)	1	(4.0)	0	(0.0)	0	(0.0)	1	(0.4)
	グリコヘモグロビン増加	2	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.8)
	体重減少	5	(2.5)	0	(0.0)	1	(5.3)	0	(0.0)	6	(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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)					PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102) n %	EUROPE (N=12) n %	JAPAN (N=9) n %	OTHER ASIAN COUNTRIES (N=9) n %	TOTAL (N=132) n %	NORTH AMERICA (N=102) n %	EUROPE (N=13) n %	JAPAN (N=10) n %	OTHER ASIAN COUNTRIES (N=8) n %	TOTAL (N=133) n %
臨床検査	体重増加	27 (26.5)	2 (16.7)	1 (11.1)	1 (11.1)	31 (23.5)	18 (17.6)	1 (7.7)	3 (30.0)	2 (25.0)	24 (18.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (0.8)	0 (0.0)	0 (0.0)	1 (10.0)	0 (0.0)	1 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	足骨折	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	裂傷	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	靱帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)
	橈骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	挫傷	2 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸部損傷	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	4 (3.9)	0 (0.0)	0 (0.0)	0 (0.0)	4 (3.0)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)
	脊柱損傷	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射に伴う反応	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外傷後頚部症候群	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.8)	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: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

TOTAL (N=265)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=204) n %	EUROPE (N=25) n %	JAPAN (N=19) n %	OTHER ASIAN COUNTRIES (N=17) n %	TOTAL (N=265) n %
臨床検査	体重増加	45 (22.1)	3 (12.0)	4 (21.1)	3 (17.6)	55 (20.8)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	1 (5.3)	1 (5.9)	2 (0.8)
傷害、中毒および処置合併症	節足動物咬傷	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	転倒	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	足骨折	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	裂傷	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	靱帯捻挫	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	橈骨骨折	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	挫傷	2 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)
	胸部損傷	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	歯牙破折	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	処置による疼痛	5 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.9)
	脊柱損傷	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	注射に伴う反応	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
	外傷後頸部症候群	1 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)
社会環境	個人衛生不良	1 (0.5)	0 (0.0)	0 (0.0)	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 PREFERRED TERM.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

		ARIP IMD (N=132)					PLACEBO (N=133)				
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	NORTH AMERICA (N=102) n %	EUROPE (N=12) n %	JAPAN (N=9) n %	OTHER ASIAN COUNTRIES (N=9) n %	TOTAL (N=132) n %	NORTH AMERICA (N=102) n %	EUROPE (N=13) n %	JAPAN (N=10) n %	OTHER ASIAN COUNTRIES (N=8) n %	TOTAL (N=133) n %
TOTAL1)		84 (82.4)	6 (50.0)	6 (66.7)	5 (55.6)	101 (76.5)	79 (77.5)	13(100.0)	8 (80.0)	7 (87.5)	107 (80.5)

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: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

表 2.7.4.7-45　地域別有害事象［二重盲検試験の二重盲検期（Phase D）］

CT-8.2.6.8

Incidence of Treatment-emergent Adverse Events in Phase D by System Organ Class and MedDRA Preferred Term by Stratified Region
(Phase D Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=265) NORTH AMERICA (N=204) n %	EUROPE (N=25) n %	JAPAN (N=19) n %	OTHER ASIAN COUNTRIES (N=17) n %	TOTAL (N=265) n %
TOTAL1)		163 (79.9)	19 (76.0)	14 (73.7)	12 (70.6)	208 (78.5)

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: ADAE21AG.LIS, RUN: [redacted]20[redacted] 10:49; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE21.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.6.8　FINAL

＜資料番号 5.3.5.1-01：CT-8.2.6.8 より作成＞

表 2.7.4.7-46　器官別大分類別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.1
Incidence of 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	37	(6.0)	67	(15.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1	(0.2)	2	(0.5)
血液およびリンパ系障害	4	(0.7)	2	(0.5)
免疫系障害	0	(0.0)	1	(0.2)
内分泌障害	1	(0.2)	0	(0.0)
代謝および栄養障害	25	(4.1)	27	(6.4)
精神障害	122	(19.9)	125	(29.4)
神経系障害	183	(29.8)	136	(32.0)
眼障害	19	(3.1)	8	(1.9)
耳および迷路障害	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 ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BAA.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-21.2.1　FINAL

表 2.7.4.7-46　器官別大分類別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.1
Incidence of 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	(%)
心臓障害	4	(0.7)	5	(1.2)
血管障害	3	(0.5)	8	(1.9)
呼吸器、胸郭および縦隔障害	8	(1.3)	17	(4.0)
胃腸障害	69	(11.2)	56	(13.2)
肝胆道系障害	2	(0.3)	2	(0.5)
皮膚および皮下組織障害	7	(1.1)	8	(1.9)
筋骨格系および結合組織障害	29	(4.7)	31	(7.3)
腎および尿路障害	2	(0.3)	4	(0.9)
生殖系および乳房障害	8	(1.3)	14	(3.3)
一般・全身障害および投与部位の状態	26	(4.2)	61	(14.4)
臨床検査	38	(6.2)	67	(15.8)

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 ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BAA.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-21.2.1　FINAL

表 2.7.4.7-46　器官別大分類別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.1
Incidence of 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	(%)
傷害、中毒および処置合併症	16	(2.6)	20	(4.7)
TOTAL1)	355	(57.8)	291	(68.5)

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: ADAE2BAA.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-21.2.1　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.1 より作成＞

表 2.7.4.7-47　器官別大分類別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.1
Incidence of Potentially Drug-related 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	1	(0.2)	1	(0.2)
血液およびリンパ系障害	2	(0.3)	2	(0.5)
代謝および栄養障害	23	(3.7)	21	(4.9)
精神障害	76	(12.4)	80	(18.8)
神経系障害	169	(27.5)	123	(28.9)
眼障害	16	(2.6)	8	(1.9)
耳および迷路障害	2	(0.3)	1	(0.2)
心臓障害	3	(0.5)	3	(0.7)
血管障害	1	(0.2)	4	(0.9)
呼吸器、胸郭および縦隔障害	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BBA.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-21.3.1　FINAL

表 2.7.4.7-47　器官別大分類別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.1
Incidence of Potentially Drug-related 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	(%)
胃腸障害	50	(8.1)	28	(6.6)
皮膚および皮下組織障害	3	(0.5)	3	(0.7)
筋骨格系および結合組織障害	10	(1.6)	9	(2.1)
腎および尿路障害	1	(0.2)	3	(0.7)
生殖系および乳房障害	4	(0.7)	9	(2.1)
一般・全身障害および投与部位の状態	23	(3.7)	49	(11.5)
臨床検査	28	(4.6)	57	(13.4)
TOTAL1)	283	(46.1)	238	(56.0)

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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-21.3.1　FINAL

＜資料番号 5.3.5.1-01：CT-21.3.1 より作成＞

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	膿瘍	0	(0.0)	1	(0.2)
	細菌性膣症	1	(0.2)	1	(0.2)
	気管支炎	5	(0.8)	2	(0.5)
	蜂巣炎	0	(0.0)	2	(0.5)
	結膜炎	1	(0.2)	0	(0.0)
	真菌感染	0	(0.0)	1	(0.2)
	胃腸炎	1	(0.2)	3	(0.7)
	ウイルス性胃腸炎	1	(0.2)	1	(0.2)
	単純ヘルペス	1	(0.2)	0	(0.0)
	ヘルペスウイルス感染	0	(0.0)	1	(0.2)
	麦粒腫	0	(0.0)	1	(0.2)
	インフルエンザ	2	(0.3)	3	(0.7)
	下気道感染	0	(0.0)	1	(0.2)
	鼻咽頭炎	11	(1.8)	22	(5.2)
	外耳炎	0	(0.0)	1	(0.2)
	急性中耳炎	0	(0.0)	1	(0.2)
	爪囲炎	0	(0.0)	1	(0.2)
	耳下腺炎	1	(0.2)	0	(0.0)
	咽頭炎	0	(0.0)	2	(0.5)
	レンサ球菌性咽頭炎	1	(0.2)	2	(0.5)
	腎盂腎炎	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	鼻炎	0	(0.0)	1	(0.2)
	敗血症	0	(0.0)	1	(0.2)
	性行為感染症	0	(0.0)	1	(0.2)
	副鼻腔炎	1	(0.2)	5	(1.2)
	皮膚感染	1	(0.2)	0	(0.0)
	歯膿瘍	2	(0.3)	4	(0.9)
	トリコモナス症	1	(0.2)	1	(0.2)
	上気道感染	7	(1.1)	15	(3.5)
	尿路感染	1	(0.2)	3	(0.7)
	ウイルス性上気道感染	2	(0.3)	1	(0.2)
	外陰部膿瘍	0	(0.0)	1	(0.2)
	外陰部腟炎	0	(0.0)	1	(0.2)
	歯感染	0	(0.0)	3	(0.7)
	腟膿瘍	1	(0.2)	0	(0.0)
	ブドウ球菌感染	0	(0.0)	1	(0.2)
	ウイルス性気道感染	0	(0.0)	1	(0.2)
	ダニ皮膚炎	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)
	脂肪腫	1	(0.2)	0	(0.0)
	子宮平滑筋腫	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
血液およびリンパ系障害	貧血	1	(0.2)	1	(0.2)
	鉄欠乏性貧血	1	(0.2)	0	(0.0)
	リンパ節症	1	(0.2)	0	(0.0)
	好中球減少症	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)
内分泌障害	甲状腺機能低下症	1	(0.2)	0	(0.0)
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)
	耐糖能障害	1	(0.2)	0	(0.0)
	痛風	1	(0.2)	0	(0.0)
	過食	1	(0.2)	0	(0.0)
	食欲亢進	19	(3.1)	19	(4.5)
	鉄欠乏	0	(0.0)	1	(0.2)
	食欲減退	2	(0.3)	6	(1.4)
	高脂血症	1	(0.2)	1	(0.2)
精神障害	異常な夢	1	(0.2)	2	(0.5)
	激越	7	(1.1)	11	(2.6)
	無オルガズム症	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	24	(3.9)	30	(7.1)
	無感情	1	(0.2)	1	(0.2)
	双極１型障害	3	(0.5)	5	(1.2)
	歯ぎしり	2	(0.3)	2	(0.5)
	錯乱状態	0	(0.0)	1	(0.2)
	抑うつ気分	1	(0.2)	4	(0.9)
	うつ病	9	(1.5)	18	(4.2)
	不快気分	1	(0.2)	0	(0.0)
	感情の平板化	1	(0.2)	0	(0.0)
	幻聴	0	(0.0)	1	(0.2)
	軽躁	0	(0.0)	1	(0.2)
	不眠症	35	(5.7)	41	(9.6)
	易刺激性	1	(0.2)	1	(0.2)
	リビドー減退	2	(0.3)	6	(1.4)
	リビドー亢進	1	(0.2)	0	(0.0)
	躁病	18	(2.9)	7	(1.6)
	中期不眠症	1	(0.2)	1	(0.2)
	気分動揺	0	(0.0)	1	(0.2)
	悪夢	1	(0.2)	0	(0.0)
	パニック発作	1	(0.2)	1	(0.2)
	妄想症	1	(0.2)	0	(0.0)
	落ち着きのなさ	32	(5.2)	24	(5.6)

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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 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	睡眠障害	1	(0.2)	0	(0.0)
	夢遊症	0	(0.0)	1	(0.2)
	自殺念慮	4	(0.7)	7	(1.6)
	自殺企図	2	(0.3)	1	(0.2)
	緊張	1	(0.2)	0	(0.0)
	せっかち	0	(0.0)	1	(0.2)
	抑うつ症状	5	(0.8)	6	(1.4)
	ディスフェミア	0	(0.0)	1	(0.2)
	双極性障害	3	(0.5)	3	(0.7)
	大うつ病	1	(0.2)	1	(0.2)
	自傷行動	0	(0.0)	1	(0.2)
	精神活動過多	2	(0.3)	1	(0.2)
神経系障害	アカシジア	95	(15.5)	74	(17.4)
	意識レベルの低下	0	(0.0)	1	(0.2)
	糖尿病性ニューロパチー	0	(0.0)	1	(0.2)
	浮動性めまい	8	(1.3)	5	(1.2)
	体位性めまい	1	(0.2)	0	(0.0)
	よだれ	3	(0.5)	1	(0.2)
	構語障害	1	(0.2)	0	(0.0)
	ジスキネジア	3	(0.5)	2	(0.5)
	ジストニア	2	(0.3)	2	(0.5)

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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-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	錐体外路障害	4	(0.7)	6	(1.4)
	顔面麻痺	0	(0.0)	1	(0.2)
	頭痛	13	(2.1)	12	(2.8)
	過眠症	4	(0.7)	1	(0.2)
	感覚鈍麻	0	(0.0)	2	(0.5)
	嗜眠	6	(1.0)	7	(1.6)
	記憶障害	1	(0.2)	1	(0.2)
	精神的機能障害	1	(0.2)	0	(0.0)
	片頭痛	0	(0.0)	3	(0.7)
	ミオクローヌス	0	(0.0)	1	(0.2)
	神経圧迫	1	(0.2)	0	(0.0)
	神経痛	1	(0.2)	0	(0.0)
	錯感覚	2	(0.3)	0	(0.0)
	パーキンソニズム	0	(0.0)	3	(0.7)
	精神運動亢進	4	(0.7)	4	(0.9)
	神経根障害	0	(0.0)	1	(0.2)
	坐骨神経痛	1	(0.2)	1	(0.2)
	鎮静	20	(3.3)	12	(2.8)
	痙攣発作	0	(0.0)	1	(0.2)
	副鼻腔炎に伴う頭痛	0	(0.0)	1	(0.2)
	傾眠	27	(4.4)	16	(3.8)
	会話障害	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

CT-21.2.2
Incidence of 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	失神	1	(0.2)	1	(0.2)
	遅発性ジスキネジア	1	(0.2)	3	(0.7)
	振戦	6	(1.0)	8	(1.9)
	平衡障害	1	(0.2)	0	(0.0)
	認知障害	1	(0.2)	0	(0.0)
	下肢静止不能症候群	1	(0.2)	3	(0.7)
	大脳動脈狭窄	1	(0.2)	1	(0.2)
	慢性多発ニューロパチー	0	(0.0)	1	(0.2)
	口下顎ジストニア	1	(0.2)	0	(0.0)
眼障害	眼部腫脹	1	(0.2)	0	(0.0)
	散瞳	1	(0.2)	0	(0.0)
	羞明	1	(0.2)	2	(0.5)
	霧視	14	(2.3)	6	(1.4)
	瞬目過多	2	(0.3)	0	(0.0)
耳および迷路障害	耳鳴	2	(0.3)	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)
	第一度房室ブロック	2	(0.3)	2	(0.5)
	心筋梗塞	1	(0.2)	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 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
心臓障害	洞性頻脈	1	(0.2)	1	(0.2)
血管障害	潮紅	0	(0.0)	1	(0.2)
	血腫	0	(0.0)	1	(0.2)
	高血圧	2	(0.3)	4	(0.9)
	低血圧	0	(0.0)	1	(0.2)
	起立性低血圧	1	(0.2)	0	(0.0)
	血栓症	0	(0.0)	1	(0.2)
呼吸器、胸郭および縦隔障害	喘息	1	(0.2)	2	(0.5)
	咳嗽	2	(0.3)	2	(0.5)
	呼吸困難	1	(0.2)	1	(0.2)
	しゃっくり	0	(0.0)	1	(0.2)
	鼻閉	1	(0.2)	3	(0.7)
	鼻中隔弯曲	0	(0.0)	1	(0.2)
	アレルギー性鼻炎	1	(0.2)	0	(0.0)
	鼻漏	0	(0.0)	1	(0.2)
	副鼻腔うっ血	1	(0.2)	1	(0.2)
	睡眠時無呼吸症候群	0	(0.0)	2	(0.5)
	くしゃみ	0	(0.0)	1	(0.2)
	気道うっ血	0	(0.0)	1	(0.2)
	口腔咽頭痛	1	(0.2)	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: ADAE2BAB.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-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
胃腸障害	腹部不快感	2	(0.3)	0	(0.0)
	腹痛	2	(0.3)	3	(0.7)
	上腹部痛	0	(0.0)	1	(0.2)
	アフタ性潰瘍	0	(0.0)	1	(0.2)
	便秘	10	(1.6)	6	(1.4)
	齲歯	1	(0.2)	0	(0.0)
	下痢	11	(1.8)	14	(3.3)
	口内乾燥	16	(2.6)	11	(2.6)
	消化不良	2	(0.3)	0	(0.0)
	鼓腸	1	(0.2)	1	(0.2)
	食中毒	1	(0.2)	0	(0.0)
	胃炎	1	(0.2)	0	(0.0)
	胃食道逆流性疾患	1	(0.2)	4	(0.9)
	悪心	14	(2.3)	9	(2.1)
	口腔内不快感	1	(0.2)	0	(0.0)
	流涎過多	4	(0.7)	7	(1.6)
	舌障害	2	(0.3)	0	(0.0)
	舌の運動障害	1	(0.2)	0	(0.0)
	歯痛	5	(0.8)	5	(1.2)
	嘔吐	6	(1.0)	9	(2.1)
	口の感覚鈍麻	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
胃腸障害	腹部ヘルニア	0	(0.0)	1	(0.2)
肝胆道系障害	胆嚢炎	0	(0.0)	1	(0.2)
	慢性胆嚢炎	1	(0.2)	0	(0.0)
	胆石症	1	(0.2)	0	(0.0)
	胆汁うっ滞	1	(0.2)	0	(0.0)
	脂肪肝	0	(0.0)	1	(0.2)
皮膚および皮下組織障害	皮膚炎	0	(0.0)	1	(0.2)
	多汗症	2	(0.3)	2	(0.5)
	過角化	1	(0.2)	0	(0.0)
	そう痒症	1	(0.2)	1	(0.2)
	発疹	0	(0.0)	1	(0.2)
	斑状丘疹状皮疹	1	(0.2)	0	(0.0)
	皮膚病変	1	(0.2)	1	(0.2)
	顔面腫脹	0	(0.0)	2	(0.5)
	蕁麻疹	1	(0.2)	0	(0.0)
筋骨格系および結合組織障害	関節痛	5	(0.8)	8	(1.9)
	関節炎	1	(0.2)	1	(0.2)
	背部痛	4	(0.7)	12	(2.8)
	尾骨痛	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
筋骨格系および結合組織障害	筋固縮	1	(0.2)	0	(0.0)
	筋痙縮	3	(0.5)	0	(0.0)
	筋攣縮	2	(0.3)	0	(0.0)
	筋肉痛	0	(0.0)	1	(0.2)
	頚部痛	1	(0.2)	2	(0.5)
	変形性関節症	1	(0.2)	0	(0.0)
	四肢痛	4	(0.7)	3	(0.7)
	顎痛	0	(0.0)	1	(0.2)
	横紋筋融解症	0	(0.0)	1	(0.2)
	開口障害	2	(0.3)	0	(0.0)
	線維筋痛	1	(0.2)	1	(0.2)
	関節可動域低下	0	(0.0)	1	(0.2)
	頚部腫瘤	0	(0.0)	1	(0.2)
	椎間板突出	0	(0.0)	1	(0.2)
	筋骨格系胸痛	1	(0.2)	2	(0.5)
	筋骨格硬直	4	(0.7)	2	(0.5)
	足変形	1	(0.2)	0	(0.0)
腎および尿路障害	排尿困難	0	(0.0)	1	(0.2)
	尿意切迫	1	(0.2)	0	(0.0)
	腎結石症	0	(0.0)	1	(0.2)
	夜間頻尿	0	(0.0)	1	(0.2)

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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-21.2.2　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
腎および尿路障害	頻尿	0	(0.0)	1	(0.2)
	多尿	1	(0.2)	0	(0.0)
	腎尿細管壊死	0	(0.0)	1	(0.2)
	急性腎障害	0	(0.0)	1	(0.2)
生殖系および乳房障害	無月経	0	(0.0)	1	(0.2)
	乳房圧痛	1	(0.2)	0	(0.0)
	月経困難症	0	(0.0)	1	(0.2)
	射精遅延	0	(0.0)	1	(0.2)
	乳汁漏出症	0	(0.0)	1	(0.2)
	月経過多	0	(0.0)	2	(0.5)
	不規則月経	2	(0.3)	1	(0.2)
	卵巣嚢胞	0	(0.0)	2	(0.5)
	頻発月経	1	(0.2)	1	(0.2)
	性機能不全	1	(0.2)	2	(0.5)
	子宮ポリープ	0	(0.0)	1	(0.2)
	腟出血	1	(0.2)	0	(0.0)
	外陰腟乾燥	1	(0.2)	0	(0.0)
	子宮付属器痛	1	(0.2)	0	(0.0)
	勃起不全	1	(0.2)	3	(0.7)
一般・全身障害および投与部位の状態	無力症	1	(0.2)	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.
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　FINAL

表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	(%)
一般・全身障害および投与部位の状態	悪寒	0	(0.0)	1	(0.2)
	嚢胞	1	(0.2)	0	(0.0)
	疲労	19	(3.1)	22	(5.2)
	インフルエンザ様疾患	0	(0.0)	1	(0.2)
	注射部位硬結	0	(0.0)	1	(0.2)
	注射部位疼痛	2	(0.3)	21	(4.9)
	倦怠感	1	(0.2)	1	(0.2)
	浮腫	1	(0.2)	0	(0.0)
	末梢性浮腫	0	(0.0)	1	(0.2)
	疼痛	1	(0.2)	2	(0.5)
	発熱	0	(0.0)	5	(1.2)
	不活発	0	(0.0)	1	(0.2)
	活力増進	0	(0.0)	1	(0.2)
	末梢腫脹	1	(0.2)	0	(0.0)
	カテーテル留置部位疼痛	0	(0.0)	1	(0.2)
	注射部位腫脹	0	(0.0)	1	(0.2)
	非心臓性胸痛	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	(0.3)	1	(0.2)
	アスパラギン酸アミノトランスフェラーゼ増加	2	(0.3)	1	(0.2)

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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-21.2.2　FINAL

CT-21.2.2
Incidence of 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	(%)
臨床検査	血中クレアチンホスホキナーゼ増加	2	(0.3)	2	(0.5)
	血中ブドウ糖増加	2	(0.3)	2	(0.5)
	血中インスリン増加	3	(0.5)	1	(0.2)
	拡張期血圧上昇	0	(0.0)	2	(0.5)
	血圧上昇	2	(0.3)	2	(0.5)
	血中プロラクチン増加	0	(0.0)	1	(0.2)
	血中トリグリセリド増加	1	(0.2)	1	(0.2)
	心電図Ｔ波振幅減少	0	(0.0)	1	(0.2)
	γ－グルタミルトランスフェラーゼ増加	0	(0.0)	1	(0.2)
	ヘマトクリット減少	1	(0.2)	0	(0.0)
	ヘモグロビン減少	1	(0.2)	1	(0.2)
	心拍数増加	1	(0.2)	0	(0.0)
	高比重リポ蛋白減少	1	(0.2)	1	(0.2)
	血小板数減少	0	(0.0)	1	(0.2)
	体重減少	1	(0.2)	8	(1.9)
	体重増加	22	(3.6)	47	(11.1)
	白血球数増加	1	(0.2)	0	(0.0)
	血小板数増加	1	(0.2)	1	(0.2)
	肝酵素上昇	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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.2　FINAL

CT-21.2.2
Incidence of 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	偶発的過量投与	1	(0.2)	1	(0.2)
	動物による引っかき傷	1	(0.2)	0	(0.0)
	節足動物咬傷	0	(0.0)	2	(0.5)
	転倒	2	(0.3)	4	(0.9)
	足骨折	0	(0.0)	1	(0.2)
	頭部損傷	0	(0.0)	1	(0.2)
	裂傷	1	(0.2)	0	(0.0)
	靱帯捻挫	4	(0.7)	1	(0.2)
	交通事故	1	(0.2)	0	(0.0)
	脛骨骨折	0	(0.0)	1	(0.2)
	尺骨神経損傷	1	(0.2)	0	(0.0)
	擦過傷	0	(0.0)	2	(0.5)
	肉離れ	3	(0.5)	2	(0.5)
	挫傷	2	(0.3)	2	(0.5)
	熱傷	1	(0.2)	0	(0.0)
	肛門損傷	0	(0.0)	1	(0.2)
	関節損傷	1	(0.2)	0	(0.0)
	四肢損傷	1	(0.2)	0	(0.0)
	上肢骨折	1	(0.2)	0	(0.0)
	歯牙破折	0	(0.0)	2	(0.5)
	処置による疼痛	0	(0.0)	2	(0.5)
	皮膚擦過傷	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.

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表 2.7.4.7-48　すべての有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.2
Incidence of 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	処置後挫傷	0	(0.0)	1	(0.2)
TOTAL1)		355	(57.8)	291	(68.5)

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: ADAE2BAB.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-21.2.2　FINAL

＜資料番号 5.3.5.1-01：CT-21.2.2 より作成＞

表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	鼻咽頭炎	1	(0.2)	0	(0.0)
	尿路感染	0	(0.0)	1	(0.2)
血液およびリンパ系障害	貧血	1	(0.2)	1	(0.2)
	好中球減少症	1	(0.2)	1	(0.2)
代謝および栄養障害	耐糖能障害	1	(0.2)	0	(0.0)
	食欲亢進	19	(3.1)	18	(4.2)
	食欲減退	2	(0.3)	3	(0.7)
	高脂血症	1	(0.2)	1	(0.2)
精神障害	異常な夢	1	(0.2)	1	(0.2)
	激越	4	(0.7)	7	(1.6)
	無オルガズム症	1	(0.2)	0	(0.0)
	不安	14	(2.3)	15	(3.5)
	無感情	1	(0.2)	1	(0.2)
	歯ぎしり	2	(0.3)	2	(0.5)
	錯乱状態	0	(0.0)	1	(0.2)
	抑うつ気分	0	(0.0)	2	(0.5)
	うつ病	2	(0.3)	7	(1.6)

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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-21.3.2　FINAL

表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	感情の平板化	1	(0.2)	0	(0.0)
	幻聴	0	(0.0)	1	(0.2)
	軽躁	0	(0.0)	1	(0.2)
	不眠症	24	(3.9)	26	(6.1)
	易刺激性	1	(0.2)	1	(0.2)
	リビドー減退	2	(0.3)	6	(1.4)
	リビドー亢進	1	(0.2)	0	(0.0)
	躁病	1	(0.2)	0	(0.0)
	中期不眠症	1	(0.2)	1	(0.2)
	気分動揺	0	(0.0)	1	(0.2)
	悪夢	1	(0.2)	0	(0.0)
	妄想症	1	(0.2)	0	(0.0)
	落ち着きのなさ	29	(4.7)	24	(5.6)
	睡眠障害	1	(0.2)	0	(0.0)
	緊張	1	(0.2)	0	(0.0)
	せっかち	0	(0.0)	1	(0.2)
	抑うつ症状	0	(0.0)	3	(0.7)
	ディスフェミア	0	(0.0)	1	(0.2)
	双極性障害	0	(0.0)	1	(0.2)
	精神活動過多	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.
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POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-21.3.2　FINAL

表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	アカシジア	95	(15.5)	74	(17.4)
	浮動性めまい	3	(0.5)	4	(0.9)
	よだれ	3	(0.5)	1	(0.2)
	構語障害	1	(0.2)	0	(0.0)
	ジスキネジア	3	(0.5)	2	(0.5)
	ジストニア	2	(0.3)	1	(0.2)
	錐体外路障害	4	(0.7)	6	(1.4)
	頭痛	7	(1.1)	2	(0.5)
	過眠症	4	(0.7)	1	(0.2)
	感覚鈍麻	0	(0.0)	2	(0.5)
	嗜眠	6	(1.0)	7	(1.6)
	記憶障害	1	(0.2)	1	(0.2)
	精神的機能障害	1	(0.2)	0	(0.0)
	片頭痛	0	(0.0)	1	(0.2)
	ミオクローヌス	0	(0.0)	1	(0.2)
	錯感覚	2	(0.3)	0	(0.0)
	パーキンソニズム	0	(0.0)	3	(0.7)
	精神運動亢進	3	(0.5)	2	(0.5)
	鎮静	19	(3.1)	12	(2.8)
	傾眠	27	(4.4)	14	(3.3)
	会話障害	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-21.3.2　FINAL

表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	遅発性ジスキネジア	1	(0.2)	3	(0.7)
	振戦	5	(0.8)	8	(1.9)
	平衡障害	1	(0.2)	0	(0.0)
	下肢静止不能症候群	1	(0.2)	3	(0.7)
	大脳動脈狭窄	1	(0.2)	1	(0.2)
	口下顎ジストニア	1	(0.2)	0	(0.0)
眼障害	散瞳	1	(0.2)	0	(0.0)
	羞明	1	(0.2)	2	(0.5)
	霧視	12	(2.0)	6	(1.4)
	瞬目過多	2	(0.3)	0	(0.0)
耳および迷路障害	耳鳴	2	(0.3)	1	(0.2)
心臓障害	第一度房室ブロック	2	(0.3)	2	(0.5)
	洞性頻脈	1	(0.2)	1	(0.2)
血管障害	潮紅	0	(0.0)	1	(0.2)
	高血圧	0	(0.0)	3	(0.7)
	起立性低血圧	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.3.2　FINAL

表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	(%)
呼吸器、胸郭および縦隔障害	副鼻腔うっ血	1	(0.2)	0	(0.0)
胃腸障害	腹部不快感	1	(0.2)	0	(0.0)
	腹痛	0	(0.0)	1	(0.2)
	便秘	6	(1.0)	3	(0.7)
	下痢	7	(1.1)	3	(0.7)
	口内乾燥	16	(2.6)	10	(2.4)
	消化不良	1	(0.2)	0	(0.0)
	鼓腸	1	(0.2)	0	(0.0)
	胃食道逆流性疾患	1	(0.2)	2	(0.5)
	悪心	12	(2.0)	3	(0.7)
	口腔内不快感	1	(0.2)	0	(0.0)
	流涎過多	4	(0.7)	7	(1.6)
	舌障害	2	(0.3)	0	(0.0)
	舌の運動障害	1	(0.2)	0	(0.0)
	嘔吐	5	(0.8)	2	(0.5)
皮膚および皮下組織障害	多汗症	2	(0.3)	2	(0.5)
	斑状丘疹状皮疹	1	(0.2)	0	(0.0)
	顔面腫脹	0	(0.0)	1	(0.2)

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表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	(%)
筋骨格系および結合組織障害	関節痛	1	(0.2)	3	(0.7)
	関節炎	1	(0.2)	1	(0.2)
	背部痛	0	(0.0)	1	(0.2)
	筋固縮	1	(0.2)	0	(0.0)
	筋痙縮	1	(0.2)	0	(0.0)
	筋攣縮	1	(0.2)	0	(0.0)
	筋肉痛	0	(0.0)	1	(0.2)
	四肢痛	0	(0.0)	1	(0.2)
	開口障害	1	(0.2)	0	(0.0)
	線維筋痛	1	(0.2)	1	(0.2)
	筋骨格硬直	4	(0.7)	2	(0.5)
腎および尿路障害	排尿困難	0	(0.0)	1	(0.2)
	尿意切迫	1	(0.2)	0	(0.0)
	夜間頻尿	0	(0.0)	1	(0.2)
	頻尿	0	(0.0)	1	(0.2)
生殖系および乳房障害	射精遅延	0	(0.0)	1	(0.2)
	月経過多	0	(0.0)	1	(0.2)
	不規則月経	1	(0.2)	1	(0.2)
	卵巣嚢胞	0	(0.0)	1	(0.2)

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表 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	(%)
生殖系および乳房障害	頻発月経	1	(0.2)	1	(0.2)
	性機能不全	1	(0.2)	2	(0.5)
	外陰腟乾燥	1	(0.2)	0	(0.0)
	勃起不全	0	(0.0)	3	(0.7)
一般・全身障害および投与部位の状態	無力症	1	(0.2)	3	(0.7)
	疲労	18	(2.9)	21	(4.9)
	注射部位硬結	0	(0.0)	1	(0.2)
	注射部位疼痛	2	(0.3)	21	(4.9)
	倦怠感	1	(0.2)	1	(0.2)
	浮腫	1	(0.2)	0	(0.0)
	疼痛	0	(0.0)	1	(0.2)
	不活発	0	(0.0)	1	(0.2)
	注射部位腫脹	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	(0.2)	1	(0.2)
	アスパラギン酸アミノトランスフェラーゼ増加	1	(0.2)	1	(0.2)
	血中クレアチンホスホキナーゼ増加	1	(0.2)	1	(0.2)
	血中インスリン増加	2	(0.3)	1	(0.2)

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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 2.7.4.7-49　すべての副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.2
Incidence of Potentially Drug-related 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	(%)
臨床検査	拡張期血圧上昇	0	(0.0)	1	(0.2)
	血中プロラクチン増加	0	(0.0)	1	(0.2)
	血中トリグリセリド増加	1	(0.2)	1	(0.2)
	心拍数増加	1	(0.2)	0	(0.0)
	高比重リポ蛋白減少	1	(0.2)	1	(0.2)
	体重減少	0	(0.0)	4	(0.9)
	体重増加	21	(3.4)	47	(11.1)
	血小板数増加	1	(0.2)	1	(0.2)
	肝酵素上昇	1	(0.2)	0	(0.0)
TOTAL1)		283	(46.1)	238	(56.0)

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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2BBB.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-21.3.2　FINAL

＜資料番号 5.3.5.1-01：CT-21.3.2 より作成＞

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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	膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	細菌性膣症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	気管支炎	1 (0.2)	4 (0.7)	0 (0.0)	5 (0.8)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	蜂巣炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	結膜炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	1 (0.2)
	胃腸炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	ウイルス性胃腸炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	単純ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘルペスウイルス感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	麦粒腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	インフルエンザ	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	下気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻咽頭炎	10 (1.6)	1 (0.2)	0 (0.0)	11 (1.8)	19 (4.5)	3 (0.7)	0 (0.0)	22 (5.2)
	外耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	急性中耳炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	爪囲炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	耳下腺炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	レンサ球菌性咽頭炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	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)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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FILE: ADAE2BAC.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-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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	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)
	性行為感染症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.2)
	皮膚感染	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	4 (0.9)	0 (0.0)	4 (0.9)
	トリコモナス症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	上気道感染	3 (0.5)	4 (0.7)	0 (0.0)	7 (1.1)	7 (1.6)	8 (1.9)	0 (0.0)	15 (3.5)
	尿路感染	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	ウイルス性上気道感染	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	0 (0.0)	1 (0.2)	0 (0.0)	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)
	外陰部腟炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	歯感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.2)	3 (0.7)
	腟膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ブドウ球菌感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	ウイルス性気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
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)
	脂肪腫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮平滑筋腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
血液およびリンパ系障害	貧血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鉄欠乏性貧血	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リンパ節症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	好中球減少症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	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	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)
代謝および栄養障害	コントロール不良の糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	耐糖能障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痛風	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過食	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	16 (2.6)	3 (0.5)	0 (0.0)	19 (3.1)	17 (4.0)	2 (0.5)	0 (0.0)	19 (4.5)
	鉄欠乏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	食欲減退	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	3 (0.7)	3 (0.7)	0 (0.0)	6 (1.4)
	高脂血症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
精神障害	異常な夢	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	激越	0 (0.0)	5 (0.8)	2 (0.3)	7 (1.1)	5 (1.2)	5 (1.2)	1 (0.2)	11 (2.6)
	無オルガズム症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
精神障害	不安	13 (2.1)	9 (1.5)	2 (0.3)	24 (3.9)	14 (3.3)	12 (2.8)	4 (0.9)	30 (7.1)
	無感情	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	双極１型障害	2 (0.3)	1 (0.2)	0 (0.0)	3 (0.5)	0 (0.0)	2 (0.5)	3 (0.7)	5 (1.2)
	歯ぎしり	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	錯乱状態	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	抑うつ気分	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	うつ病	1 (0.2)	8 (1.3)	0 (0.0)	9 (1.5)	4 (0.9)	11 (2.6)	3 (0.7)	18 (4.2)
	不快気分	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	幻聴	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	不眠症	18 (2.9)	17 (2.8)	0 (0.0)	35 (5.7)	19 (4.5)	22 (5.2)	0 (0.0)	41 (9.6)
	易刺激性	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	リビドー減退	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	4 (0.9)	2 (0.5)	0 (0.0)	6 (1.4)
	リビドー亢進	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)	17 (2.8)	1 (0.2)	18 (2.9)	0 (0.0)	3 (0.7)	4 (0.9)	7 (1.6)
	中期不眠症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	気分動揺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	悪夢	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パニック発作	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	妄想症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	22 (3.6)	9 (1.5)	1 (0.2)	32 (5.2)	18 (4.2)	5 (1.2)	1 (0.2)	24 (5.6)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
精神障害	睡眠障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夢遊症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	自殺念慮	0 (0.0)	4 (0.7)	0 (0.0)	4 (0.7)	5 (1.2)	2 (0.5)	0 (0.0)	7 (1.6)
	自殺企図	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.3)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	緊張	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せっかち	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)	3 (0.5)	2 (0.3)	5 (0.8)	5 (1.2)	0 (0.0)	1 (0.2)	6 (1.4)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	双極性障害	0 (0.0)	2 (0.3)	1 (0.2)	3 (0.5)	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)
	自傷行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	精神活動過多	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
神経系障害	アカシジア	60 (9.8)	32 (5.2)	3 (0.5)	95 (15.5)	48 (11.3)	24 (5.6)	2 (0.5)	74 (17.4)
	意識レベルの低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	糖尿病性ニューロパチー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	浮動性めまい	8 (1.3)	0 (0.0)	0 (0.0)	8 (1.3)	3 (0.7)	2 (0.5)	0 (0.0)	5 (1.2)
	体位性めまい	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)
	ジスキネジア	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	ジストニア	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)

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FILE: ADAE2BAC.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-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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	錐体外路障害	1 (0.2)	3 (0.5)	0 (0.0)	4 (0.7)	3 (0.7)	3 (0.7)	0 (0.0)	6 (1.4)
	顔面麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	頭痛	7 (1.1)	5 (0.8)	1 (0.2)	13 (2.1)	8 (1.9)	4 (0.9)	0 (0.0)	12 (2.8)
	過眠症	3 (0.5)	1 (0.2)	0 (0.0)	4 (0.7)	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	2 (0.5)
	嗜眠	4 (0.7)	2 (0.3)	0 (0.0)	6 (1.0)	4 (0.9)	3 (0.7)	0 (0.0)	7 (1.6)
	記憶障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	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)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	ミオクローヌス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	神経圧迫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錯感覚	2 (0.3)	0 (0.0)	0 (0.0)	2 (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)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	精神運動亢進	2 (0.3)	2 (0.3)	0 (0.0)	4 (0.7)	3 (0.7)	1 (0.2)	0 (0.0)	4 (0.9)
	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)
	坐骨神経痛	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鎮静	13 (2.1)	7 (1.1)	0 (0.0)	20 (3.3)	9 (2.1)	3 (0.7)	0 (0.0)	12 (2.8)
	痙攣発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔炎に伴う頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	傾眠	16 (2.6)	10 (1.6)	1 (0.2)	27 (4.4)	11 (2.6)	3 (0.7)	2 (0.5)	16 (3.8)
	会話障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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	失神	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	遅発性ジスキネジア	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	振戦	5 (0.8)	1 (0.2)	0 (0.0)	6 (1.0)	5 (1.2)	3 (0.7)	0 (0.0)	8 (1.9)
	平衡障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	認知障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	大脳動脈狭窄	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	慢性多発ニューロパチー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	口下顎ジストニア	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼部腫脹	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	散瞳	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	羞明	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	霧視	8 (1.3)	6 (1.0)	0 (0.0)	14 (2.3)	5 (1.2)	1 (0.2)	0 (0.0)	6 (1.4)
	瞬目過多	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	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)
	第一度房室ブロック	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	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)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
心臓障害	洞性頻脈	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
血管障害	潮紅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	高血圧	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	3 (0.7)	1 (0.2)	0 (0.0)	4 (0.9)
	低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)
呼吸器、胸郭および縦隔障害	喘息	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	咳嗽	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	呼吸困難	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	しゃっくり	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻閉	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	2 (0.5)	0 (0.0)	3 (0.7)
	鼻中隔弯曲	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アレルギー性鼻炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻漏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔うっ血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	睡眠時無呼吸症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	くしゃみ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	気道うっ血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
呼吸器、胸郭および縦隔障害	口腔咽頭痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
胃腸障害	腹部不快感	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.5)	1 (0.2)	3 (0.7)
	上腹部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	アフタ性潰瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	便秘	7 (1.1)	3 (0.5)	0 (0.0)	10 (1.6)	3 (0.7)	3 (0.7)	0 (0.0)	6 (1.4)
	齲歯	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	9 (1.5)	2 (0.3)	0 (0.0)	11 (1.8)	10 (2.4)	3 (0.7)	1 (0.2)	14 (3.3)
	口内乾燥	13 (2.1)	3 (0.5)	0 (0.0)	16 (2.6)	8 (1.9)	3 (0.7)	0 (0.0)	11 (2.6)
	消化不良	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼓腸	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	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)
	胃炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	2 (0.5)	2 (0.5)	0 (0.0)	4 (0.9)
	悪心	9 (1.5)	5 (0.8)	0 (0.0)	14 (2.3)	6 (1.4)	3 (0.7)	0 (0.0)	9 (2.1)
	口腔内不快感	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	2 (0.3)	2 (0.3)	0 (0.0)	4 (0.7)	4 (0.9)	3 (0.7)	0 (0.0)	7 (1.6)
	舌障害	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	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)
	歯痛	3 (0.5)	2 (0.3)	0 (0.0)	5 (0.8)	2 (0.5)	3 (0.7)	0 (0.0)	5 (1.2)

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FILE: ADAE2BAC.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-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
胃腸障害	嘔吐	4 (0.7)	2 (0.3)	0 (0.0)	6 (1.0)	5 (1.2)	4 (0.9)	0 (0.0)	9 (2.1)
	口の感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	腹部ヘルニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
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 (0.2)	0 (0.0)	1 (0.2)
	慢性胆嚢炎	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胆石症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	脂肪肝	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
皮膚および皮下組織障害	皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	多汗症	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	過角化	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)
	皮膚病変	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	蕁麻疹	0 (0.0)	1 (0.2)	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	関節痛	2 (0.3)	3 (0.5)	0 (0.0)	5 (0.8)	6 (1.4)	1 (0.2)	1 (0.2)	8 (1.9)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
筋骨格系および結合組織障害	関節炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	背部痛	2 (0.3)	2 (0.3)	0 (0.0)	4 (0.7)	7 (1.6)	3 (0.7)	2 (0.5)	12 (2.8)
	尾骨痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋固縮	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋攣縮	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	頚部痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	変形性関節症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	1 (0.2)	3 (0.5)	0 (0.0)	4 (0.7)	2 (0.5)	0 (0.0)	1 (0.2)	3 (0.7)
	顎痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	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)
	開口障害	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	線維筋痛	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	関節可動域低下	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	頚部腫瘤	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	椎間板突出	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	筋骨格系胸痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.5)
	筋骨格硬直	2 (0.3)	2 (0.3)	0 (0.0)	4 (0.7)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	足変形	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
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 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	尿意切迫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)
	多尿	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
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)
	乳房圧痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経困難症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	不規則月経	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	頻発月経	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	性機能不全	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	子宮ポリープ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	膣出血	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰膣乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
生殖系および乳房障害	子宮付属器痛	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
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)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	悪寒	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	11 (1.8)	6 (1.0)	2 (0.3)	19 (3.1)	11 (2.6)	10 (2.4)	1 (0.2)	22 (5.2)
	インフルエンザ様疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位疼痛	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	14 (3.3)	7 (1.6)	0 (0.0)	21 (4.9)
	倦怠感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	浮腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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)	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)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	発熱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.2)	0 (0.0)	0 (0.0)	5 (1.2)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	活力増進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	末梢腫脹	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	カテーテル留置部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	注射部位腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	非心臓性胸痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
臨床検査	アラニンアミノトランスフェラーゼ増加	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アスパラギン酸アミノトランスフェラーゼ増加	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	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)	1 (0.2)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	血中ブドウ糖増加	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.3)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	血中インスリン増加	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	拡張期血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	血圧上昇	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	血中プロラクチン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	血中トリグリセリド増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	心電図Ｔ波振幅減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	γ－グルタミルトランスフェラーゼ増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ヘマトクリット減少	1 (0.2)	0 (0.0)	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	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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)
	高比重リポ蛋白減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血小板数減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	体重減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	8 (1.9)	0 (0.0)	0 (0.0)	8 (1.9)
	体重増加	15 (2.4)	7 (1.1)	0 (0.0)	22 (3.6)	36 (8.5)	11 (2.6)	0 (0.0)	47 (11.1)

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FILE: ADAE2BAC.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-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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 (%)
臨床検査	白血球数増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血小板数増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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)
	動物による引っかき傷	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	節足動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	転倒	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	2 (0.5)	2 (0.5)	0 (0.0)	4 (0.9)
	足骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	裂傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靭帯捻挫	1 (0.2)	3 (0.5)	0 (0.0)	4 (0.7)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	交通事故	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脛骨骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	尺骨神経損傷	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	肉離れ	2 (0.3)	1 (0.2)	0 (0.0)	3 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	挫傷	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
	熱傷	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	関節損傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL

表 2.7.4.7-50　重症度別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.2.3
Incidence of 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	四肢損傷	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上肢骨折	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	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)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	処置による疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	皮膚擦過傷	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置後挫傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.2.3　FINAL
＜資料番号 5.3.5.1-01：CT-21.2.3 より作成＞

表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3

Incidence of Potentially Drug-related 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	鼻咽頭炎	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	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	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
血液およびリンパ系障害	貧血	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	好中球減少症	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食欲亢進	16	(2.6)	3	(0.5)	0	(0.0)	19	(3.1)	17	(4.0)	1	(0.2)	0	(0.0)	18	(4.2)
	食欲減退	2	(0.3)	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.5)	1	(0.2)	0	(0.0)	3	(0.7)
	高脂血症	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
精神障害	異常な夢	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	激越	0	(0.0)	3	(0.5)	1	(0.2)	4	(0.7)	3	(0.7)	4	(0.9)	0	(0.0)	7	(1.6)
	無オルガズム症	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	6	(1.0)	6	(1.0)	2	(0.3)	14	(2.3)	6	(1.4)	6	(1.4)	3	(0.7)	15	(3.5)
	無感情	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	歯ぎしり	2	(0.3)	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.5)	0	(0.0)	0	(0.0)	2	(0.5)
	錯乱状態	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	抑うつ気分	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	2	(0.5)
	うつ病	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.3)	1	(0.2)	4	(0.9)	2	(0.5)	7	(1.6)
	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)

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FILE: ADAE2BBC.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-21.3.3　FINAL

表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3

Incidence of Potentially Drug-related 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 (%)
精神障害	幻聴	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	不眠症	11 (1.8)	13 (2.1)	0 (0.0)	24 (3.9)	11 (2.6)	15 (3.5)	0 (0.0)	26 (6.1)
	易刺激性	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	リビドー減退	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	4 (0.9)	2 (0.5)	0 (0.0)	6 (1.4)
	リビドー亢進	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)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	気分動揺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	悪夢	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	19 (3.1)	9 (1.5)	1 (0.2)	29 (4.7)	18 (4.2)	5 (1.2)	1 (0.2)	24 (5.6)
	睡眠障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	緊張	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せっかち	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)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	1 (0.2)	3 (0.7)
	ディスフェミア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	双極性障害	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	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
神経系障害	アカシジア	60 (9.8)	32 (5.2)	3 (0.5)	95 (15.5)	48 (11.3)	24 (5.6)	2 (0.5)	74 (17.4)

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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.3.3　FINAL

表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3

Incidence of Potentially Drug-related 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	浮動性めまい	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	3 (0.7)	1 (0.2)	0 (0.0)	4 (0.9)
	よだれ	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)
	ジスキネジア	3 (0.5)	0 (0.0)	0 (0.0)	3 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	ジストニア	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	錐体外路障害	1 (0.2)	3 (0.5)	0 (0.0)	4 (0.7)	3 (0.7)	3 (0.7)	0 (0.0)	6 (1.4)
	頭痛	3 (0.5)	4 (0.7)	0 (0.0)	7 (1.1)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	過眠症	3 (0.5)	1 (0.2)	0 (0.0)	4 (0.7)	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	2 (0.5)
	嗜眠	4 (0.7)	2 (0.3)	0 (0.0)	6 (1.0)	4 (0.9)	3 (0.7)	0 (0.0)	7 (1.6)
	記憶障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	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)
	片頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	ミオクローヌス	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	2 (0.3)	0 (0.0)	0 (0.0)	2 (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)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	精神運動亢進	1 (0.2)	2 (0.3)	0 (0.0)	3 (0.5)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	鎮静	13 (2.1)	6 (1.0)	0 (0.0)	19 (3.1)	9 (2.1)	3 (0.7)	0 (0.0)	12 (2.8)
	傾眠	16 (2.6)	10 (1.6)	1 (0.2)	27 (4.4)	11 (2.6)	1 (0.2)	2 (0.5)	14 (3.3)
	会話障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	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)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.3.3　FINAL

表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3
Incidence of Potentially Drug-related 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	4 (0.7)	1 (0.2)	0 (0.0)	5 (0.8)	5 (1.2)	3 (0.7)	0 (0.0)	8 (1.9)
	平衡障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	大脳動脈狭窄	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	口下顎ジストニア	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	散瞳	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	羞明	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	霧視	6 (1.0)	6 (1.0)	0 (0.0)	12 (2.0)	5 (1.2)	1 (0.2)	0 (0.0)	6 (1.4)
	瞬目過多	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳鳴	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
心臓障害	第一度房室ブロック	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	洞性頻脈	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
血管障害	潮紅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	高血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	3 (0.7)
	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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-21.3.3　FINAL

表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3

Incidence of Potentially Drug-related 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 (%)
呼吸器、胸郭および縦隔障害	副鼻腔うっ血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部不快感	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	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)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	便秘	3 (0.5)	3 (0.5)	0 (0.0)	6 (1.0)	1 (0.2)	2 (0.5)	0 (0.0)	3 (0.7)
	下痢	5 (0.8)	2 (0.3)	0 (0.0)	7 (1.1)	2 (0.5)	0 (0.0)	1 (0.2)	3 (0.7)
	口内乾燥	13 (2.1)	3 (0.5)	0 (0.0)	16 (2.6)	7 (1.6)	3 (0.7)	0 (0.0)	10 (2.4)
	消化不良	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼓腸	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	悪心	8 (1.3)	4 (0.7)	0 (0.0)	12 (2.0)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	口腔内不快感	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	2 (0.3)	2 (0.3)	0 (0.0)	4 (0.7)	4 (0.9)	3 (0.7)	0 (0.0)	7 (1.6)
	舌障害	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	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)
	嘔吐	3 (0.5)	2 (0.3)	0 (0.0)	5 (0.8)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚および皮下組織障害	多汗症	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)
	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)
	顔面腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3

Incidence of Potentially Drug-related 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 (%)
筋骨格系および結合組織障害	関節痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	関節炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	背部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋固縮	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋攣縮	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)
	四肢痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	開口障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	線維筋痛	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	筋骨格硬直	2 (0.3)	2 (0.3)	0 (0.0)	4 (0.7)	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)
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 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	尿意切迫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)
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)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3

Incidence of Potentially Drug-related 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 (%)
生殖系および乳房障害	卵巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	頻発月経	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	性機能不全	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.5)
	外陰腟乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
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)	3 (0.7)	0 (0.0)	0 (0.0)	3 (0.7)
	疲労	10 (1.6)	6 (1.0)	2 (0.3)	18 (2.9)	10 (2.4)	10 (2.4)	1 (0.2)	21 (4.9)
	注射部位硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位疼痛	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	14 (3.3)	7 (1.6)	0 (0.0)	21 (4.9)
	倦怠感	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	浮腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	不活発	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位腫脹	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 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アスパラギン酸アミノトランスフェラーゼ増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2BBC.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-21.3.3　FINAL

表 2.7.4.7-51　重症度別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

CT-21.3.3
Incidence of Potentially Drug-related 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 (%)
臨床検査	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)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	血中インスリン増加	2 (0.3)	0 (0.0)	0 (0.0)	2 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	拡張期血圧上昇	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)
	血中トリグリセリド増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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)
	高比重リポ蛋白減少	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	体重減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	体重増加	14 (2.3)	7 (1.1)	0 (0.0)	21 (3.4)	36 (8.5)	11 (2.6)	0 (0.0)	47 (11.1)
	血小板数増加	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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＜資料番号 5.3.5.1-01：CT-21.3.3 より作成＞

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	膿瘍	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	細菌性膣症	1	(0.2)	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	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	蜂巣炎	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	真菌感染	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胃腸炎	3	(0.7)	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	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ヘルペスウイルス感染	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	麦粒腫	1	(0.2)	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	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	下気道感染	1	(0.2)	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	17	(4.0)	5	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外耳炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	急性中耳炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	爪囲炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽頭炎	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	レンサ球菌性咽頭炎	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎盂腎炎	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	敗血症	1	(0.2)	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 OTHER THAN RECOVERED/LONGEST DURATION 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	性行為感染症	1	(0.2)	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	2	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	歯膿瘍	3	(0.7)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	トリコモナス症	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道感染	10	(2.4)	1	(0.2)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	尿路感染	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性上気道感染	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰部膿瘍	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	外陰部腟炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯感染	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	ブドウ球菌感染	1	(0.2)	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	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ダニ皮膚炎	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	子宮平滑筋腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	0	(0.0)	1	(0.2)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
免疫系障害	季節性アレルギー	1	(0.2)	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	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)	0	(0.0)	1	(0.2)	0	(0.0)
	食欲亢進	2	(0.5)	4	(0.9)	6	(1.4)	2	(0.5)	0	(0.0)	3	(0.7)	1	(0.2)	1	(0.2)
	鉄欠乏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	食欲減退	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)
	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)	1	(0.2)
精神障害	異常な夢	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)
	激越	1	(0.2)	0	(0.0)	2	(0.5)	1	(0.2)	1	(0.2)	2	(0.5)	0	(0.0)	4	(0.9)
	不安	7	(1.6)	1	(0.2)	2	(0.5)	3	(0.7)	3	(0.7)	5	(1.2)	0	(0.0)	9	(2.1)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	双極１型障害	2	(0.5)	1	(0.2)	1	(0.2)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	錯乱状態	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	抑うつ気分	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	うつ病	4	(0.9)	1	(0.2)	5	(1.2)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	6	(1.4)
	幻聴	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	軽躁	1	(0.2)	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 OTHER THAN RECOVERED/LONGEST DURATION 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　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG (N=425) <=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	不眠症	8	(1.9)	7	(1.6)	5	(1.2)	3	(0.7)	0	(0.0)	3	(0.7)	3	(0.7)	12	(2.8)
	易刺激性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	リビドー減退	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.2)	2	(0.5)
	躁病	1	(0.2)	0	(0.0)	2	(0.5)	1	(0.2)	2	(0.5)	0	(0.0)	0	(0.0)	1	(0.2)
	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)	1	(0.2)
	気分動揺	1	(0.2)	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	1	(0.2)	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	3	(0.7)	4	(0.9)	2	(0.5)	4	(0.9)	1	(0.2)	3	(0.7)	3	(0.7)	4	(0.9)
	夢遊症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	自殺念慮	7	(1.6)	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	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	せっかち	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	抑うつ症状	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	2	(0.5)
	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)	1	(0.2)
	双極性障害	0	(0.0)	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	大うつ病	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自傷行動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	精神活動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
神経系障害	アカシジア	4	(0.9)	7	(1.6)	10	(2.4)	6	(1.4)	1	(0.2)	7	(1.6)	6	(1.4)	33	(7.8)
	意識レベルの低下	1	(0.2)	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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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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG (N=425) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-196DAYS n (%)	197<= DAYS n (%)	DAYS NOT RECOV. n (%)
神経系障害	糖尿病性ニューロパチー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	浮動性めまい	3 (0.7)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	よだれ	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	ジストニア	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	錐体外路障害	1 (0.2)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	顔面麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	頭痛	8 (1.9)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	嗜眠	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	2 (0.5)
	記憶障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	2 (0.5)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ミオクローヌス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	パーキンソニズム	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	精神運動亢進	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	神経根障害	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	3 (0.7)	1 (0.2)	4 (0.9)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	1 (0.2)
	痙攣発作	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	1 (0.2)	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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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　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG (N=425) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-196DAYS n (%)	197<= DAYS n (%)	NOT RECOV. n (%)
神経系障害	傾眠	5 (1.2)	4 (0.9)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	2 (0.5)
	失神	1 (0.2)	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	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	振戦	2 (0.5)	2 (0.5)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	下肢静止不能症候群	1 (0.2)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大脳動脈狭窄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	慢性多発ニューロパチー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
眼障害	羞明	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	霧視	1 (0.2)	0 (0.0)	3 (0.7)	0 (0.0)	0 (0.0)	1 (0.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
心臓障害	急性心筋梗塞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心房細動	1 (0.2)	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)	2 (0.5)
	洞性頻脈	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	潮紅	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)

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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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
血管障害	低血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血栓症	0	(0.0)	1	(0.2)	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	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咳嗽	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	呼吸困難	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.2)	0	(0.0)
	鼻閉	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻中隔弯曲	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	鼻漏	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	副鼻腔うっ血	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	睡眠時無呼吸症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	くしゃみ	1	(0.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	口腔咽頭痛	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	3	(0.7)
	上腹部痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	アフタ性潰瘍	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	4	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	下痢	10	(2.4)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)

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表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	口内乾燥	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	1	(0.2)	2	(0.5)	3	(0.7)	3	(0.7)
	鼓腸	1	(0.2)	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	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)
	悪心	6	(1.4)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	流涎過多	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	4	(0.9)
	歯痛	2	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	嘔吐	8	(1.9)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口の感覚鈍麻	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	腹部ヘルニア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
肝胆道系障害	胆嚢炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂肪肝	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
皮膚および皮下組織障害	皮膚炎	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	多汗症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	そう痒症	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮膚病変	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	顔面腫脹	1	(0.2)	1	(0.2)	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	関節痛	4	(0.9)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	関節炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	背部痛	6	(1.4)	1	(0.2)	3	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	筋肉痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頚部痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	四肢痛	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	顎痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	横紋筋融解症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	線維筋痛	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節可動域低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	頚部腫瘤	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	椎間板突出	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格系胸痛	2	(0.5)	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	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
腎および尿路障害	排尿困難	1	(0.2)	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)	1	(0.2)
	夜間頻尿	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頻尿	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎尿細管壊死	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	急性腎障害	1	(0.2)	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 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG (N=425) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-196DAYS n (%)	197<= DAYS n (%)	NOT RECOV. n (%)
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)	0 (0.0)	0 (0.0)	1 (0.2)
	月経困難症	1 (0.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
	乳汁漏出症	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	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)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	頻発月経	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮ポリープ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	勃起不全	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	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	無力症	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪寒	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	3 (0.7)	1 (0.2)	5 (1.2)	0 (0.0)	1 (0.2)	3 (0.7)	2 (0.5)	7 (1.6)
	インフルエンザ様疾患	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	19 (4.5)	2 (0.5)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	1 (0.2)	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 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	疼痛	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発熱	4	(0.9)	1	(0.2)	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	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	活力増進	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	カテーテル留置部位疼痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫脹	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	非心臓性胸痛	1	(0.2)	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	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)
	血中ブドウ糖増加	1	(0.2)	1	(0.2)	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)	1	(0.2)
	拡張期血圧上昇	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血圧上昇	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中トリグリセリド増加	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
臨床検査	心電図Ｔ波振幅減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	ヘモグロビン減少	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高比重リポ蛋白減少	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血小板数減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	体重減少	0	(0.0)	0	(0.0)	3	(0.7)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.9)
	体重増加	0	(0.0)	0	(0.0)	2	(0.5)	4	(0.9)	1	(0.2)	3	(0.7)	5	(1.2)	32	(7.5)
	血小板数増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	節足動物咬傷	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	転倒	4	(0.9)	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	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頭部損傷	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	靱帯捻挫	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脛骨骨折	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	擦過傷	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肉離れ	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	挫傷	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肛門損傷	1	(0.2)	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 OTHER THAN RECOVERED/LONGEST DURATION 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-6　FINAL

表 2.7.4.7-52　持続期間別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-6
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG (N=425) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-196DAYS n (%)	197<= DAYS n (%)	NOT RECOV. n (%)
傷害、中毒および処置合併症	歯牙破折	2 (0.5)	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	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置後挫傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		47 (11.1)	21 (4.9)	23 (5.4)	21 (4.9)	14 (3.3)	21 (4.9)	20 (4.7)	124 (29.2)

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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　5.3.5.3-6　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-6＞

表 2.7.4.7-53　　持続期間別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-8

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	尿路感染	0	(0.0)	1	(0.2)	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)	1	(0.2)	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)	0	(0.0)	1	(0.2)
代謝および栄養障害	食欲亢進	2	(0.5)	3	(0.7)	6	(1.4)	2	(0.5)	0	(0.0)	3	(0.7)	1	(0.2)	1	(0.2)
	食欲減退	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	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)	1	(0.2)
精神障害	異常な夢	1	(0.2)	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	(0.2)	1	(0.2)	2	(0.5)	0	(0.0)	3	(0.7)
	不安	1	(0.2)	0	(0.0)	0	(0.0)	3	(0.7)	3	(0.7)	3	(0.7)	0	(0.0)	5	(1.2)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	錯乱状態	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	抑うつ気分	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	うつ病	1	(0.2)	1	(0.2)	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	幻聴	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	軽躁	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不眠症	4	(0.9)	3	(0.7)	4	(0.9)	3	(0.7)	0	(0.0)	3	(0.7)	1	(0.2)	8	(1.9)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-8　FINAL

表 2.7.4.7-53　　持続期間別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-8

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	易刺激性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	リビドー減退	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.2)	2	(0.5)
	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)	1	(0.2)
	気分動揺	1	(0.2)	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	3	(0.7)	4	(0.9)	2	(0.5)	4	(0.9)	1	(0.2)	3	(0.7)	3	(0.7)	4	(0.9)
	せっかち	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	抑うつ症状	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	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)	1	(0.2)
	双極性障害	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
神経系障害	アカシジア	4	(0.9)	7	(1.6)	10	(2.4)	6	(1.4)	1	(0.2)	7	(1.6)	6	(1.4)	33	(7.8)
	浮動性めまい	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	よだれ	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	ジストニア	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	錐体外路障害	1	(0.2)	1	(0.2)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	頭痛	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	過眠症	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	感覚鈍麻	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	嗜眠	1	(0.2)	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.5)

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表 2.7.4.7-53　持続期間別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-8

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	記憶障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	片頭痛	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ミオクローヌス	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	パーキンソニズム	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	精神運動亢進	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	鎮静	3	(0.7)	1	(0.2)	4	(0.9)	0	(0.0)	2	(0.5)	1	(0.2)	0	(0.0)	1	(0.2)
	傾眠	3	(0.7)	4	(0.9)	1	(0.2)	1	(0.2)	1	(0.2)	1	(0.2)	1	(0.2)	2	(0.5)
	遅発性ジスキネジア	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	振戦	2	(0.5)	2	(0.5)	0	(0.0)	2	(0.5)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	下肢静止不能症候群	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	大脳動脈狭窄	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
眼障害	羞明	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)
	霧視	1	(0.2)	0	(0.0)	3	(0.7)	0	(0.0)	0	(0.0)	1	(0.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
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)	2	(0.5)
	洞性頻脈	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
血管障害	潮紅	1	(0.2)	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 2.7.4.7-53　　持続期間別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-8

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
血管障害	高血圧	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)
胃腸障害	腹痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	便秘	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	下痢	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	口内乾燥	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	2	(0.5)	3	(0.7)	3	(0.7)
	胃食道逆流性疾患	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	悪心	3	(0.7)	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	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	4	(0.9)
	嘔吐	1	(0.2)	1	(0.2)	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	多汗症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	顔面腫脹	1	(0.2)	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	関節痛	3	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節炎	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	背部痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢痛	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	線維筋痛	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格硬直	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	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 OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BD.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-8　FINAL

表 2.7.4.7-53　持続期間別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-8

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	ARIP IMD 400/300MG (N=425) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-196DAYS n (%)	197<= DAYS n (%)	DAYS NOT RECOV. n (%)
腎および尿路障害	排尿困難	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	0 (0.0)	1 (0.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
	月経過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	不規則月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	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)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	頻発月経	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	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	無力症	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	3 (0.7)	1 (0.2)	5 (1.2)	0 (0.0)	1 (0.2)	2 (0.5)	2 (0.5)	7 (1.6)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	19 (4.5)	2 (0.5)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	1 (0.2)	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 (0.2)	0 (0.0)	0 (0.0)	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　5.3.5.3-8　FINAL

表 2.7.4.7-53　　持続期間別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-8

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-196DAYS n	(%)	197<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	注射部位腫脹	1	(0.2)	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	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	1	(0.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)
	拡張期血圧上昇	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中トリグリセリド増加	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高比重リポ蛋白減少	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)
	体重増加	0	(0.0)	0	(0.0)	2	(0.5)	4	(0.9)	1	(0.2)	3	(0.7)	5	(1.2)	32	(7.5)
	血小板数増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
TOTAL1)		26	(6.1)	18	(4.2)	19	(4.5)	18	(4.2)	14	(3.3)	22	(5.2)	18	(4.2)	103	(24.2)

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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　　5.3.5.3-8　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-8＞

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	細菌性膣症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気管支炎	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	真菌感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘルペスウイルス感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	22 (5.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性中耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	爪囲炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎盂腎炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	鼻炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	敗血症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性行為感染症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	トリコモナス症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	13 (3.1)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
	尿路感染	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰部膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	外陰部腟炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	2 (0.5)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ブドウ球菌感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	1 (0.2)	0 (0.0)	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)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-10　FINAL

表 2.7.4.7-54　　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
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(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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）	子宮平滑筋腫	0 (0.0)	1 (0.2)	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	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	季節性アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	コントロール不良の糖尿病	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	18 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
	鉄欠乏	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	3 (0.7)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	異常な夢	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	7 (1.6)	0 (0.0)	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	21 (4.9)	5 (1.2)	4 (0.9)	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 WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	無感情	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	5 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錯乱状態	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	3 (0.7)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	12 (2.8)	3 (0.7)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	幻聴	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	29 (6.8)	3 (0.7)	8 (1.9)	0 (0.0)	1 (0.2)	0 (0.0)
	易刺激性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	4 (0.9)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	6 (1.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気分動揺	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パニック発作	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	20 (4.7)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	夢遊症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	7 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺企図	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	せっかち	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	4 (0.9)	2 (0.5)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自傷行動	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	精神活動過多	1 (0.2)	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	41 (9.6)	13 (3.1)	20 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)
	意識レベルの低下	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性ニューロパチー	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	4 (0.9)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	顔面麻痺	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	12 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	感覚鈍麻	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	5 (1.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	記憶障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ミオクローヌス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
	パーキンソニズム	1 (0.2)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	精神運動亢進	3 (0.7)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経根障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	11 (2.6)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痙攣発作	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	14 (3.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	失神	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	7 (1.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大脳動脈狭窄	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性多発ニューロパチー	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
眼障害	羞明	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	5 (1.2)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	急性心筋梗塞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心房細動	1 (0.2)	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)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	洞性頻脈	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	潮紅	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高血圧	3 (0.7)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	低血圧	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血栓症	1 (0.2)	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	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咳嗽	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-10
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		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
呼吸器、胸郭および縦隔障害	呼吸困難	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻閉	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻中隔弯曲	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻漏	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔うっ血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	睡眠時無呼吸症候群	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	くしゃみ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気道うっ血	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔咽頭痛	3 (0.7)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹痛	0 (0.0)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	上腹部痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	アフタ性潰瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	4 (0.9)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	12 (2.8)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	8 (1.9)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	鼓腸	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	1 (0.2)	0 (0.0)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	悪心	8 (1.9)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	3 (0.7)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	9 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の感覚鈍麻	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹部ヘルニア	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	胆嚢炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脂肪肝	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚病変	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	顔面腫脹	2 (0.5)	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	関節痛	6 (1.4)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	関節炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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FILE: ADAE24CB.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	背部痛	10 (2.4)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頚部痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	2 (0.5)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	顎痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	横紋筋融解症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	線維筋痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節可動域低下	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	頚部腫瘤	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板突出	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格系胸痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	1 (0.2)	1 (0.2)	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 (0.2)	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)	1 (0.2)	0 (0.0)
	夜間頻尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎尿細管壊死	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性腎障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-10　FINAL

表 2.7.4.7-54　転帰別有害事象［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-10
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
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生殖系および乳房障害	無月経	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	月経困難症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	射精遅延	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乳汁漏出症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経過多	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻発月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮ポリープ	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
一般・全身障害および投与部位の状態	無力症	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪寒	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	15 (3.5)	0 (0.0)	7 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ様疾患	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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一般・全身障害および投与部位の状態	注射部位疼痛	21 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	5 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	活力増進	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	カテーテル留置部位疼痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	非心臓性胸痛	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	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	1 (0.2)	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	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-10
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臨床検査	血中インスリン増加	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	拡張期血圧上昇	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心電図Ｔ波振幅減少	1 (0.2)	0 (0.0)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘモグロビン減少	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高比重リポ蛋白減少	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血小板数減少	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	4 (0.9)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	15 (3.5)	6 (1.4)	26 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)
	血小板数増加	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	偶発的過量投与	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	節足動物咬傷	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	転倒	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	足骨折	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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傷害、中毒および処置合併症	頭部損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靱帯捻挫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脛骨骨折	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	擦過傷	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	挫傷	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	処置後挫傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		167 (39.3)	26 (6.1)	91 (21.4)	2 (0.5)	5 (1.2)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-10　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-10＞

表 2.7.4.7-55　転帰別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-12
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	尿路感染	1 (0.2)	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	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	食欲亢進	17 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
	食欲減退	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	異常な夢	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	4 (0.9)	0 (0.0)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	10 (2.4)	2 (0.5)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錯乱状態	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	5 (1.2)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	幻聴	1 (0.2)	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 WORST OUTCOME 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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-12　FINAL

表 2.7.4.7-55　　転帰別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-12
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	軽躁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	18 (4.2)	1 (0.2)	6 (1.4)	0 (0.0)	1 (0.2)	0 (0.0)
	易刺激性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	4 (0.9)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	中期不眠症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気分動揺	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	20 (4.7)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	せっかち	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	2 (0.5)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神活動過多	1 (0.2)	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	41 (9.6)	13 (3.1)	20 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	3 (0.7)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	4 (0.9)	0 (0.0)	2 (0.5)	0 (0.0)	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¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-12　FINAL

表 2.7.4.7-55　転帰別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-12
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	頭痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	5 (1.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	記憶障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ミオクローヌス	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
	パーキンソニズム	1 (0.2)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	精神運動亢進	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	11 (2.6)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	12 (2.8)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	7 (1.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大脳動脈狭窄	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	羞明	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	5 (1.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-55　転帰別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-12
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
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耳および迷路障害	耳鳴	0 (0.0)	1 (0.2)	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)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	洞性頻脈	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	潮紅	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高血圧	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹痛	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	7 (1.6)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	3 (0.7)	1 (0.2)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	2 (0.5)	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	多汗症	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	顔面腫脹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-55　転帰別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-12
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in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	関節痛	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	線維筋痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	1 (0.2)	1 (0.2)	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 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経過多	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻発月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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(Phase C Safety Sample)

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生殖系および乳房障害	勃起不全	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)
一般・全身障害および投与部位の状態	無力症	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	14 (3.3)	0 (0.0)	7 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	21 (4.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不活発	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	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	1 (0.2)	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 (0.2)	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)	1 (0.2)	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 WORST OUTCOME 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: ADAE24CD.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-12　FINAL

表 2.7.4.7-55　転帰別副作用［二重盲検試験の IM デポ剤安定期（Phase C）］

5.3.5.3-12

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Aripiprazole IM Depot Stabilization Phase
(Phase C Safety Sample)

		ARIP IMD 400/300MG (N=425)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	拡張期血圧上昇	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高比重リポ蛋白減少	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	1 (0.2)	0 (0.0)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	15 (3.5)	6 (1.4)	26 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)
	血小板数増加	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		135 (31.8)	24 (5.6)	75 (17.6)	0 (0.0)	4 (0.9)	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 WORST OUTCOME 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: ADAE24CD.LIS, RUN: [redacted]20[redacted] 11:32; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-12　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-12＞

表 2.7.4.7-56　器官別大分類別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.1
Incidence of 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	121	(31.9)	15	(17.6)	136	(29.3)
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）	6	(1.6)	0	(0.0)	6	(1.3)
血液およびリンパ系障害	1	(0.3)	0	(0.0)	1	(0.2)
免疫系障害	5	(1.3)	1	(1.2)	6	(1.3)
内分泌障害	5	(1.3)	0	(0.0)	5	(1.1)
代謝および栄養障害	39	(10.3)	1	(1.2)	40	(8.6)
精神障害	138	(36.4)	10	(11.8)	148	(31.9)
神経系障害	158	(41.7)	18	(21.2)	176	(37.9)
眼障害	10	(2.6)	0	(0.0)	10	(2.2)
耳および迷路障害	2	(0.5)	1	(1.2)	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.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAA.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-8.2.1　FINAL

表 2.7.4.7-56　器官別大分類別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.1
Incidence of 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	(%)
心臓障害	9	(2.4)	0	(0.0)	9	(1.9)
血管障害	9	(2.4)	3	(3.5)	12	(2.6)
呼吸器、胸郭および縦隔障害	29	(7.7)	3	(3.5)	32	(6.9)
胃腸障害	90	(23.7)	6	(7.1)	96	(20.7)
肝胆道系障害	4	(1.1)	0	(0.0)	4	(0.9)
皮膚および皮下組織障害	33	(8.7)	1	(1.2)	34	(7.3)
筋骨格系および結合組織障害	54	(14.2)	6	(7.1)	60	(12.9)
腎および尿路障害	10	(2.6)	1	(1.2)	11	(2.4)
生殖系および乳房障害	13	(3.4)	1	(1.2)	14	(3.0)
先天性、家族性および遺伝性障害	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	76	(20.1)	6	(7.1)	82	(17.7)

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: ADAE2AAA.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-8.2.1　FINAL

表 2.7.4.7-56　器官別大分類別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-8.2.1
Incidence of 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	(%)
臨床検査	85	(22.4)	7	(8.2)	92	(19.8)
傷害、中毒および処置合併症	32	(8.4)	4	(4.7)	36	(7.8)
TOTAL1)	323	(85.2)	51	(60.0)	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.

FILE: ADAE2AAA.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-8.2.1　FINAL

＜資料番号 5.3.5.2-01：CT-8.2.1 より作成＞

表 2.7.4.7-57　器官別大分類別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.1
Incidence of Potentially Drug-related 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	7	(1.8)	0	(0.0)	7	(1.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1	(0.3)	0	(0.0)	1	(0.2)
免疫系障害	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	27	(7.1)	1	(1.2)	28	(6.0)
精神障害	90	(23.7)	4	(4.7)	94	(20.3)
神経系障害	136	(35.9)	13	(15.3)	149	(32.1)
眼障害	8	(2.1)	0	(0.0)	8	(1.7)
耳および迷路障害	1	(0.3)	0	(0.0)	1	(0.2)
心臓障害	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABA.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-8.3.1　FINAL

表 2.7.4.7-57　器官別大分類別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.1
Incidence of Potentially Drug-related 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	(%)
血管障害	4	(1.1)	0	(0.0)	4	(0.9)
呼吸器、胸郭および縦隔障害	5	(1.3)	0	(0.0)	5	(1.1)
胃腸障害	35	(9.2)	0	(0.0)	35	(7.5)
肝胆道系障害	2	(0.5)	0	(0.0)	2	(0.4)
皮膚および皮下組織障害	11	(2.9)	0	(0.0)	11	(2.4)
筋骨格系および結合組織障害	19	(5.0)	1	(1.2)	20	(4.3)
腎および尿路障害	2	(0.5)	0	(0.0)	2	(0.4)
生殖系および乳房障害	10	(2.6)	1	(1.2)	11	(2.4)
一般・全身障害および投与部位の状態	61	(16.1)	4	(4.7)	65	(14.0)
臨床検査	62	(16.4)	6	(7.1)	68	(14.7)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABA.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-8.3.1　FINAL

表 2.7.4.7-57　器官別大分類別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.1
Incidence of Potentially Drug-related 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)	237	(62.5)	26	(30.6)	263	(56.7)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABA.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-8.3.1　FINAL

＜資料番号 5.3.5.2-01：CT-8.3.1 より作成＞

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	気管支炎	9	(2.4)	2	(2.4)	11	(2.4)
	蜂巣炎	1	(0.3)	1	(1.2)	2	(0.4)
	膀胱炎	3	(0.8)	0	(0.0)	3	(0.6)
	耳感染	3	(0.8)	1	(1.2)	4	(0.9)
	毛包炎	1	(0.3)	0	(0.0)	1	(0.2)
	せつ	0	(0.0)	1	(1.2)	1	(0.2)
	胃腸炎	1	(0.3)	0	(0.0)	1	(0.2)
	ウイルス性胃腸炎	11	(2.9)	0	(0.0)	11	(2.4)
	歯肉炎	1	(0.3)	0	(0.0)	1	(0.2)
	単純ヘルペス	1	(0.3)	0	(0.0)	1	(0.2)
	帯状疱疹	0	(0.0)	1	(1.2)	1	(0.2)
	麦粒腫	2	(0.5)	0	(0.0)	2	(0.4)
	感染	1	(0.3)	0	(0.0)	1	(0.2)
	インフルエンザ	7	(1.8)	1	(1.2)	8	(1.7)
	腎感染	1	(0.3)	0	(0.0)	1	(0.2)
	限局性感染	1	(0.3)	0	(0.0)	1	(0.2)
	下気道感染	1	(0.3)	0	(0.0)	1	(0.2)
	鼻咽頭炎	48	(12.7)	8	(9.4)	56	(12.1)
	外耳炎	1	(0.3)	0	(0.0)	1	(0.2)
	中耳炎	1	(0.3)	0	(0.0)	1	(0.2)
	歯周炎	1	(0.3)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	咽頭炎	5	(1.3)	1	(1.2)	6	(1.3)
	レンサ球菌性咽頭炎	2	(0.5)	0	(0.0)	2	(0.4)
	毛巣嚢胞	1	(0.3)	0	(0.0)	1	(0.2)
	肺炎	1	(0.3)	0	(0.0)	1	(0.2)
	マイコプラズマ性肺炎	1	(0.3)	0	(0.0)	1	(0.2)
	腎盂腎炎	1	(0.3)	0	(0.0)	1	(0.2)
	鼻炎	1	(0.3)	0	(0.0)	1	(0.2)
	副鼻腔炎	5	(1.3)	1	(1.2)	6	(1.3)
	皮下組織膿瘍	1	(0.3)	0	(0.0)	1	(0.2)
	歯膿瘍	3	(0.8)	1	(1.2)	4	(0.9)
	上気道感染	22	(5.8)	2	(2.4)	24	(5.2)
	尿路感染	11	(2.9)	0	(0.0)	11	(2.4)
	ウイルス性上気道感染	1	(0.3)	0	(0.0)	1	(0.2)
	歯感染	3	(0.8)	0	(0.0)	3	(0.6)
	白癬感染	1	(0.3)	0	(0.0)	1	(0.2)
	ダニ皮膚炎	3	(0.8)	0	(0.0)	3	(0.6)
	外陰腟真菌感染	1	(0.3)	0	(0.0)	1	(0.2)
	口腔ヘルペス	1	(0.3)	0	(0.0)	1	(0.2)
	ノロウイルス性胃腸炎	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）	基底細胞癌	1	(0.3)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) 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	1	(0.3)	0	(0.0)	1	(0.2)
	脂肪腫	1	(0.3)	0	(0.0)	1	(0.2)
	皮膚の新生物	1	(0.3)	0	(0.0)	1	(0.2)
	扁平上皮癌	1	(0.3)	0	(0.0)	1	(0.2)
	子宮平滑筋腫	1	(0.3)	0	(0.0)	1	(0.2)
	肛門性器疣贅	1	(0.3)	0	(0.0)	1	(0.2)
血液およびリンパ系障害	貧血	1	(0.3)	0	(0.0)	1	(0.2)
免疫系障害	動物アレルギー	1	(0.3)	0	(0.0)	1	(0.2)
	食物アレルギー	1	(0.3)	0	(0.0)	1	(0.2)
	季節性アレルギー	3	(0.8)	1	(1.2)	4	(0.9)
内分泌障害	高プロラクチン血症	3	(0.8)	0	(0.0)	3	(0.6)
	甲状腺機能低下症	2	(0.5)	0	(0.0)	2	(0.4)
代謝および栄養障害	糖尿病	4	(1.1)	1	(1.2)	5	(1.1)
	コントロール不良の糖尿病	1	(0.3)	1	(1.2)	2	(0.4)
	体液貯留	1	(0.3)	0	(0.0)	1	(0.2)
	耐糖能障害	1	(0.3)	0	(0.0)	1	(0.2)
	痛風	1	(0.3)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	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	高血糖	2	(0.5)	0	(0.0)	2	(0.4)
	低カリウム血症	1	(0.3)	0	(0.0)	1	(0.2)
	食欲亢進	16	(4.2)	0	(0.0)	16	(3.4)
	肥満	2	(0.5)	0	(0.0)	2	(0.4)
	食欲減退	7	(1.8)	0	(0.0)	7	(1.5)
	高脂血症	2	(0.5)	0	(0.0)	2	(0.4)
	過小食	1	(0.3)	0	(0.0)	1	(0.2)
	２型糖尿病	3	(0.8)	0	(0.0)	3	(0.6)
精神障害	異常な夢	4	(1.1)	2	(2.4)	6	(1.3)
	急性ストレス反応	1	(0.3)	0	(0.0)	1	(0.2)
	攻撃性	1	(0.3)	0	(0.0)	1	(0.2)
	激越	8	(2.1)	0	(0.0)	8	(1.7)
	広場恐怖症	1	(0.3)	0	(0.0)	1	(0.2)
	不安	43	(11.3)	3	(3.5)	46	(9.9)
	無感情	1	(0.3)	0	(0.0)	1	(0.2)
	注意喚起行動	1	(0.3)	0	(0.0)	1	(0.2)
	双極１型障害	18	(4.7)	0	(0.0)	18	(3.9)
	情動鈍麻	1	(0.3)	0	(0.0)	1	(0.2)
	歯ぎしり	3	(0.8)	0	(0.0)	3	(0.6)
	抑うつ気分	2	(0.5)	0	(0.0)	2	(0.4)
	うつ病	26	(6.9)	0	(0.0)	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.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
精神障害	不快気分	1	(0.3)	0	(0.0)	1	(0.2)
	感情の貧困	2	(0.5)	0	(0.0)	2	(0.4)
	軽躁	2	(0.5)	0	(0.0)	2	(0.4)
	衝動行為	1	(0.3)	0	(0.0)	1	(0.2)
	初期不眠症	1	(0.3)	0	(0.0)	1	(0.2)
	不眠症	49	(12.9)	2	(2.4)	51	(11.0)
	故意の自傷行為	1	(0.3)	0	(0.0)	1	(0.2)
	易刺激性	4	(1.1)	0	(0.0)	4	(0.9)
	リビドー減退	3	(0.8)	0	(0.0)	3	(0.6)
	躁病	3	(0.8)	1	(1.2)	4	(0.9)
	気分変化	2	(0.5)	0	(0.0)	2	(0.4)
	神経過敏	2	(0.5)	0	(0.0)	2	(0.4)
	悪夢	2	(0.5)	0	(0.0)	2	(0.4)
	パニック発作	1	(0.3)	0	(0.0)	1	(0.2)
	妄想症	1	(0.3)	0	(0.0)	1	(0.2)
	落ち着きのなさ	23	(6.1)	0	(0.0)	23	(5.0)
	睡眠障害	2	(0.5)	0	(0.0)	2	(0.4)
	社会逃避行動	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)
	抑うつ症状	2	(0.5)	1	(1.2)	3	(0.6)
	双極性障害	3	(0.8)	1	(1.2)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
精神障害	大うつ病	1	(0.3)	0	(0.0)	1	(0.2)
	異常行動	1	(0.3)	0	(0.0)	1	(0.2)
	自傷行動	3	(0.8)	0	(0.0)	3	(0.6)
	早朝覚醒型不眠症	1	(0.3)	0	(0.0)	1	(0.2)
神経系障害	アカシジア	60	(15.8)	8	(9.4)	68	(14.7)
	失語症	1	(0.3)	0	(0.0)	1	(0.2)
	自律神経失調	1	(0.3)	0	(0.0)	1	(0.2)
	運動緩慢	3	(0.8)	0	(0.0)	3	(0.6)
	注意力障害	3	(0.8)	0	(0.0)	3	(0.6)
	浮動性めまい	10	(2.6)	0	(0.0)	10	(2.2)
	体位性めまい	5	(1.3)	0	(0.0)	5	(1.1)
	よだれ	2	(0.5)	0	(0.0)	2	(0.4)
	構語障害	1	(0.3)	0	(0.0)	1	(0.2)
	味覚異常	1	(0.3)	0	(0.0)	1	(0.2)
	ジスキネジア	6	(1.6)	2	(2.4)	8	(1.7)
	ジストニア	4	(1.1)	0	(0.0)	4	(0.9)
	錐体外路障害	12	(3.2)	0	(0.0)	12	(2.6)
	頭痛	23	(6.1)	6	(7.1)	29	(6.3)
	運動過多	1	(0.3)	0	(0.0)	1	(0.2)
	過眠症	2	(0.5)	0	(0.0)	2	(0.4)
	感覚鈍麻	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.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
神経系障害	企図振戦	2	(0.5)	0	(0.0)	2	(0.4)
	嗜眠	4	(1.1)	0	(0.0)	4	(0.9)
	精神的機能障害	1	(0.3)	0	(0.0)	1	(0.2)
	片頭痛	3	(0.8)	0	(0.0)	3	(0.6)
	錯感覚	1	(0.3)	0	(0.0)	1	(0.2)
	パーキンソニズム	4	(1.1)	1	(1.2)	5	(1.1)
	坐骨神経痛	2	(0.5)	0	(0.0)	2	(0.4)
	鎮静	17	(4.5)	0	(0.0)	17	(3.7)
	感覚障害	0	(0.0)	1	(1.2)	1	(0.2)
	副鼻腔炎に伴う頭痛	1	(0.3)	0	(0.0)	1	(0.2)
	傾眠	20	(5.3)	0	(0.0)	20	(4.3)
	失神	1	(0.3)	0	(0.0)	1	(0.2)
	遅発性ジスキネジア	3	(0.8)	0	(0.0)	3	(0.6)
	振戦	27	(7.1)	1	(1.2)	28	(6.0)
	眉間反射異常	1	(0.3)	0	(0.0)	1	(0.2)
	下肢静止不能症候群	4	(1.1)	0	(0.0)	4	(0.9)
	微細運動機能障害	1	(0.3)	0	(0.0)	1	(0.2)
眼障害	眼瞼痙攣	4	(1.1)	0	(0.0)	4	(0.9)
	糖尿病性白内障	1	(0.3)	0	(0.0)	1	(0.2)
	霧視	2	(0.5)	0	(0.0)	2	(0.4)
	注視麻痺	1	(0.3)	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: ADAE2AAB.LIS, RUN: [redacted]20[redacted] 14:00; 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　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
眼障害	瞬目過多	2	(0.5)	0	(0.0)	2	(0.4)
耳および迷路障害	耳痛	0	(0.0)	1	(1.2)	1	(0.2)
	回転性めまい	2	(0.5)	0	(0.0)	2	(0.4)
心臓障害	急性心筋梗塞	1	(0.3)	0	(0.0)	1	(0.2)
	徐脈	1	(0.3)	0	(0.0)	1	(0.2)
	心停止	1	(0.3)	0	(0.0)	1	(0.2)
	心筋梗塞	1	(0.3)	0	(0.0)	1	(0.2)
	動悸	1	(0.3)	0	(0.0)	1	(0.2)
	プリンツメタル狭心症	1	(0.3)	0	(0.0)	1	(0.2)
	頻脈	4	(1.1)	0	(0.0)	4	(0.9)
血管障害	本態性高血圧症	0	(0.0)	1	(1.2)	1	(0.2)
	潮紅	1	(0.3)	0	(0.0)	1	(0.2)
	血腫	0	(0.0)	1	(1.2)	1	(0.2)
	高血圧	3	(0.8)	1	(1.2)	4	(0.9)
	起立性低血圧	5	(1.3)	0	(0.0)	5	(1.1)
呼吸器、胸郭および縦隔障害	喘息	0	(0.0)	1	(1.2)	1	(0.2)
	慢性閉塞性肺疾患	1	(0.3)	0	(0.0)	1	(0.2)
	咳嗽	7	(1.8)	0	(0.0)	7	(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 (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　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1	(0.3)	0	(0.0)	1	(0.2)
	呼吸困難	1	(0.3)	0	(0.0)	1	(0.2)
	鼻出血	2	(0.5)	0	(0.0)	2	(0.4)
	しゃっくり	1	(0.3)	0	(0.0)	1	(0.2)
	低酸素症	1	(0.3)	0	(0.0)	1	(0.2)
	肺障害	1	(0.3)	0	(0.0)	1	(0.2)
	鼻閉	3	(0.8)	0	(0.0)	3	(0.6)
	鼻乾燥	1	(0.3)	0	(0.0)	1	(0.2)
	胸膜炎	0	(0.0)	1	(1.2)	1	(0.2)
	鼻漏	2	(0.5)	0	(0.0)	2	(0.4)
	咽喉絞扼感	1	(0.3)	0	(0.0)	1	(0.2)
	アレルギー性副鼻腔炎	1	(0.3)	1	(1.2)	2	(0.4)
	上気道の炎症	1	(0.3)	0	(0.0)	1	(0.2)
	口腔咽頭痛	5	(1.3)	0	(0.0)	5	(1.1)
	咽頭反射亢進	1	(0.3)	0	(0.0)	1	(0.2)
胃腸障害	腹部不快感	3	(0.8)	1	(1.2)	4	(0.9)
	腹部膨満	1	(0.3)	0	(0.0)	1	(0.2)
	腹痛	5	(1.3)	1	(1.2)	6	(1.3)
	上腹部痛	4	(1.1)	1	(1.2)	5	(1.1)
	慢性胃炎	0	(0.0)	1	(1.2)	1	(0.2)
	便秘	10	(2.6)	0	(0.0)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
胃腸障害	齲歯	5	(1.3)	0	(0.0)	5	(1.1)
	下痢	19	(5.0)	2	(2.4)	21	(4.5)
	口内乾燥	8	(2.1)	0	(0.0)	8	(1.7)
	消化不良	3	(0.8)	0	(0.0)	3	(0.6)
	嚥下障害	2	(0.5)	0	(0.0)	2	(0.4)
	腸炎	1	(0.3)	0	(0.0)	1	(0.2)
	胃炎	2	(0.5)	0	(0.0)	2	(0.4)
	胃食道逆流性疾患	1	(0.3)	0	(0.0)	1	(0.2)
	消化器痛	1	(0.3)	0	(0.0)	1	(0.2)
	血便排泄	0	(0.0)	1	(1.2)	1	(0.2)
	痔核	1	(0.3)	0	(0.0)	1	(0.2)
	過敏性腸症候群	1	(0.3)	0	(0.0)	1	(0.2)
	悪心	15	(4.0)	0	(0.0)	15	(3.2)
	歯周病	1	(0.3)	0	(0.0)	1	(0.2)
	流涎過多	14	(3.7)	0	(0.0)	14	(3.0)
	歯の知覚過敏	1	(0.3)	0	(0.0)	1	(0.2)
	口内炎	1	(0.3)	0	(0.0)	1	(0.2)
	舌障害	2	(0.5)	0	(0.0)	2	(0.4)
	歯の脱落	1	(0.3)	0	(0.0)	1	(0.2)
	歯痛	14	(3.7)	1	(1.2)	15	(3.2)
	嘔吐	11	(2.9)	1	(1.2)	12	(2.6)
	心窩部不快感	1	(0.3)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
胃腸障害	口の錯感覚	1	(0.3)	0	(0.0)	1	(0.2)
肝胆道系障害	胆嚢炎	1	(0.3)	0	(0.0)	1	(0.2)
	急性胆嚢炎	1	(0.3)	0	(0.0)	1	(0.2)
	肝炎	1	(0.3)	0	(0.0)	1	(0.2)
	高ビリルビン血症	1	(0.3)	0	(0.0)	1	(0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	1	(0.3)	0	(0.0)	1	(0.2)
	水疱	1	(0.3)	0	(0.0)	1	(0.2)
	皮膚炎	1	(0.3)	0	(0.0)	1	(0.2)
	ざ瘡様皮膚炎	1	(0.3)	0	(0.0)	1	(0.2)
	接触性皮膚炎	1	(0.3)	0	(0.0)	1	(0.2)
	皮膚乾燥	2	(0.5)	0	(0.0)	2	(0.4)
	斑状出血	1	(0.3)	0	(0.0)	1	(0.2)
	湿疹	3	(0.8)	0	(0.0)	3	(0.6)
	紅斑	0	(0.0)	1	(1.2)	1	(0.2)
	多汗症	4	(1.1)	0	(0.0)	4	(0.9)
	嵌入爪	1	(0.3)	0	(0.0)	1	(0.2)
	寝汗	1	(0.3)	0	(0.0)	1	(0.2)
	光線過敏性反応	1	(0.3)	0	(0.0)	1	(0.2)
	そう痒症	5	(1.3)	0	(0.0)	5	(1.1)
	乾癬	1	(0.3)	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.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
皮膚および皮下組織障害	発疹	9	(2.4)	0	(0.0)	9	(1.9)
	斑状皮疹	1	(0.3)	0	(0.0)	1	(0.2)
	斑状丘疹状皮疹	1	(0.3)	0	(0.0)	1	(0.2)
	そう痒性皮疹	1	(0.3)	0	(0.0)	1	(0.2)
	脂漏性皮膚炎	1	(0.3)	0	(0.0)	1	(0.2)
	蕁麻疹	3	(0.8)	0	(0.0)	3	(0.6)
筋骨格系および結合組織障害	関節痛	11	(2.9)	0	(0.0)	11	(2.4)
	背部痛	12	(3.2)	3	(3.5)	15	(3.2)
	外骨腫	1	(0.3)	0	(0.0)	1	(0.2)
	肩径部痛	1	(0.3)	0	(0.0)	1	(0.2)
	関節硬直	1	(0.3)	0	(0.0)	1	(0.2)
	筋萎縮	1	(0.3)	0	(0.0)	1	(0.2)
	筋固縮	1	(0.3)	0	(0.0)	1	(0.2)
	筋痙縮	4	(1.1)	0	(0.0)	4	(0.9)
	筋攣縮	2	(0.5)	0	(0.0)	2	(0.4)
	筋骨格痛	3	(0.8)	1	(1.2)	4	(0.9)
	筋肉痛	3	(0.8)	1	(1.2)	4	(0.9)
	頚部痛	1	(0.3)	0	(0.0)	1	(0.2)
	骨端症	1	(0.3)	0	(0.0)	1	(0.2)
	骨壊死	1	(0.3)	0	(0.0)	1	(0.2)
	四肢痛	9	(2.4)	1	(1.2)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
筋骨格系および結合組織障害	滑液嚢腫	1	(0.3)	0	(0.0)	1	(0.2)
	顎関節症候群	0	(0.0)	1	(1.2)	1	(0.2)
	腱炎	1	(0.3)	0	(0.0)	1	(0.2)
	開口障害	1	(0.3)	0	(0.0)	1	(0.2)
	筋緊張	1	(0.3)	0	(0.0)	1	(0.2)
	椎間板突出	1	(0.3)	0	(0.0)	1	(0.2)
	筋骨格硬直	8	(2.1)	0	(0.0)	8	(1.7)
	項部硬直	1	(0.3)	0	(0.0)	1	(0.2)
	椎間板障害	1	(0.3)	0	(0.0)	1	(0.2)
	関節過伸展	1	(0.3)	0	(0.0)	1	(0.2)
	関節不安定	1	(0.3)	0	(0.0)	1	(0.2)
腎および尿路障害	血尿	1	(0.3)	0	(0.0)	1	(0.2)
	尿意切迫	1	(0.3)	0	(0.0)	1	(0.2)
	腎結石症	2	(0.5)	0	(0.0)	2	(0.4)
	夜間頻尿	1	(0.3)	0	(0.0)	1	(0.2)
	頻尿	2	(0.5)	0	(0.0)	2	(0.4)
	蛋白尿	1	(0.3)	0	(0.0)	1	(0.2)
	尿失禁	1	(0.3)	0	(0.0)	1	(0.2)
	尿管結石症	1	(0.3)	1	(1.2)	2	(0.4)
生殖系および乳房障害	無月経	1	(0.3)	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: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
生殖系および乳房障害	良性前立腺肥大症	1	(0.3)	0	(0.0)	1	(0.2)
	性器発疹	1	(0.3)	0	(0.0)	1	(0.2)
	月経障害	1	(0.3)	0	(0.0)	1	(0.2)
	月経遅延	1	(0.3)	0	(0.0)	1	(0.2)
	不規則月経	1	(0.3)	0	(0.0)	1	(0.2)
	不正子宮出血	1	(0.3)	0	(0.0)	1	(0.2)
	卵巣嚢胞	1	(0.3)	0	(0.0)	1	(0.2)
	性機能不全	1	(0.3)	0	(0.0)	1	(0.2)
	外陰腟乾燥	1	(0.3)	0	(0.0)	1	(0.2)
	勃起不全	5	(1.3)	1	(1.2)	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	(0.3)	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	1	(0.3)	0	(0.0)	1	(0.2)
	無力症	4	(1.1)	0	(0.0)	4	(0.9)
	胸部不快感	1	(0.3)	0	(0.0)	1	(0.2)
	胸痛	4	(1.1)	0	(0.0)	4	(0.9)
	嚢胞	1	(0.3)	0	(0.0)	1	(0.2)
	疲労	16	(4.2)	4	(4.7)	20	(4.3)
	異常感	1	(0.3)	0	(0.0)	1	(0.2)
	歩行障害	1	(0.3)	0	(0.0)	1	(0.2)
	インフルエンザ様疾患	3	(0.8)	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.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	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	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)
	倦怠感	3	(0.8)	0	(0.0)	3	(0.6)
	末梢性浮腫	2	(0.5)	0	(0.0)	2	(0.4)
	疼痛	1	(0.3)	0	(0.0)	1	(0.2)
	発熱	5	(1.3)	0	(0.0)	5	(1.1)
	口渇	1	(0.3)	0	(0.0)	1	(0.2)
	注射部位腫脹	4	(1.1)	0	(0.0)	4	(0.9)
	小結節	1	(0.3)	0	(0.0)	1	(0.2)
	非心臓性胸痛	1	(0.3)	1	(1.2)	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	3	(0.8)	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	3	(0.8)	0	(0.0)	3	(0.6)
	血中コレステロール増加	2	(0.5)	0	(0.0)	2	(0.4)
	血中クレアチンホスホキナーゼ増加	5	(1.3)	0	(0.0)	5	(1.1)
	血中ブドウ糖増加	4	(1.1)	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.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2AAB.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-8.2.2.1　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
臨床検査	血圧低下	2	(0.5)	0	(0.0)	2	(0.4)
	血圧上昇	4	(1.1)	0	(0.0)	4	(0.9)
	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)
	血中トリグリセリド増加	1	(0.3)	0	(0.0)	1	(0.2)
	血中尿酸増加	1	(0.3)	0	(0.0)	1	(0.2)
	心雑音	1	(0.3)	0	(0.0)	1	(0.2)
	γ－グルタミルトランスフェラーゼ増加	2	(0.5)	0	(0.0)	2	(0.4)
	尿中ブドウ糖陽性	1	(0.3)	0	(0.0)	1	(0.2)
	グリコヘモグロビン増加	1	(0.3)	0	(0.0)	1	(0.2)
	尿中血陽性	1	(0.3)	0	(0.0)	1	(0.2)
	心拍数増加	3	(0.8)	0	(0.0)	3	(0.6)
	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)
	尿中白血球陽性	2	(0.5)	0	(0.0)	2	(0.4)
	起立血圧上昇	1	(0.3)	0	(0.0)	1	(0.2)
	肝酵素上昇	1	(0.3)	0	(0.0)	1	(0.2)
	ビタミンD減少	1	(0.3)	0	(0.0)	1	(0.2)
	ヘリコバクター検査陽性	1	(0.3)	0	(0.0)	1	(0.2)
	肝機能検査値上昇	1	(0.3)	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: ADAE2AAB.LIS, RUN: [redacted]20[redacted] 14:00; 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　FINAL

表 2.7.4.7-58　すべての有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.2.1
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	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	足関節部骨折	1	(0.3)	0	(0.0)	1	(0.2)
	節足動物咬傷	2	(0.5)	0	(0.0)	2	(0.4)
	凍瘡	1	(0.3)	0	(0.0)	1	(0.2)
	転倒	2	(0.5)	0	(0.0)	2	(0.4)
	裂傷	4	(1.1)	0	(0.0)	4	(0.9)
	靭帯捻挫	8	(2.1)	1	(1.2)	9	(1.9)
	ストレス骨折	1	(0.3)	0	(0.0)	1	(0.2)
	肉離れ	1	(0.3)	1	(1.2)	2	(0.4)
	挫傷	1	(0.3)	0	(0.0)	1	(0.2)
	関節損傷	1	(0.3)	0	(0.0)	1	(0.2)
	四肢損傷	0	(0.0)	1	(1.2)	1	(0.2)
	胸部損傷	2	(0.5)	0	(0.0)	2	(0.4)
	歯牙破折	2	(0.5)	0	(0.0)	2	(0.4)
	処置による疼痛	6	(1.6)	1	(1.2)	7	(1.5)
	皮膚擦過傷	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL1)		323	(85.2)	51	(60.0)	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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＜資料番号 5.3.5.2-01：CT-8.2.2.1 より作成＞

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
感染症および寄生虫症	気管支炎	2	(0.5)	0	(0.0)	2	(0.4)
	ウイルス性胃腸炎	1	(0.3)	0	(0.0)	1	(0.2)
	鼻咽頭炎	1	(0.3)	0	(0.0)	1	(0.2)
	上気道感染	2	(0.5)	0	(0.0)	2	(0.4)
	尿路感染	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）	脂肪腫	1	(0.3)	0	(0.0)	1	(0.2)
免疫系障害	季節性アレルギー	1	(0.3)	0	(0.0)	1	(0.2)
内分泌障害	高プロラクチン血症	1	(0.3)	0	(0.0)	1	(0.2)
代謝および栄養障害	糖尿病	2	(0.5)	1	(1.2)	3	(0.6)
	コントロール不良の糖尿病	0	(0.0)	1	(1.2)	1	(0.2)
	耐糖能障害	1	(0.3)	0	(0.0)	1	(0.2)
	高血糖	1	(0.3)	0	(0.0)	1	(0.2)
	食欲亢進	16	(4.2)	0	(0.0)	16	(3.4)
	肥満	2	(0.5)	0	(0.0)	2	(0.4)
	食欲減退	4	(1.1)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	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	過小食	1	(0.3)	0	(0.0)	1	(0.2)
	２型糖尿病	1	(0.3)	0	(0.0)	1	(0.2)
精神障害	異常な夢	4	(1.1)	1	(1.2)	5	(1.1)
	激越	6	(1.6)	0	(0.0)	6	(1.3)
	広場恐怖症	1	(0.3)	0	(0.0)	1	(0.2)
	不安	23	(6.1)	1	(1.2)	24	(5.2)
	無感情	1	(0.3)	0	(0.0)	1	(0.2)
	双極１型障害	5	(1.3)	0	(0.0)	5	(1.1)
	歯ぎしり	3	(0.8)	0	(0.0)	3	(0.6)
	抑うつ気分	1	(0.3)	0	(0.0)	1	(0.2)
	うつ病	15	(4.0)	0	(0.0)	15	(3.2)
	感情の貧困	2	(0.5)	0	(0.0)	2	(0.4)
	軽躁	1	(0.3)	0	(0.0)	1	(0.2)
	衝動行為	1	(0.3)	0	(0.0)	1	(0.2)
	初期不眠症	1	(0.3)	0	(0.0)	1	(0.2)
	不眠症	29	(7.7)	2	(2.4)	31	(6.7)
	故意の自傷行為	1	(0.3)	0	(0.0)	1	(0.2)
	易刺激性	1	(0.3)	0	(0.0)	1	(0.2)
	リビドー減退	2	(0.5)	0	(0.0)	2	(0.4)
	躁病	1	(0.3)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
精神障害	神経過敏	2	(0.5)	0	(0.0)	2	(0.4)
	悪夢	1	(0.3)	0	(0.0)	1	(0.2)
	妄想症	1	(0.3)	0	(0.0)	1	(0.2)
	落ち着きのなさ	21	(5.5)	0	(0.0)	21	(4.5)
	睡眠障害	2	(0.5)	0	(0.0)	2	(0.4)
	自殺念慮	1	(0.3)	0	(0.0)	1	(0.2)
	抑うつ症状	1	(0.3)	0	(0.0)	1	(0.2)
	双極性障害	1	(0.3)	0	(0.0)	1	(0.2)
	大うつ病	1	(0.3)	0	(0.0)	1	(0.2)
	異常行動	1	(0.3)	0	(0.0)	1	(0.2)
神経系障害	アカシジア	60	(15.8)	8	(9.4)	68	(14.7)
	運動緩慢	3	(0.8)	0	(0.0)	3	(0.6)
	注意力障害	3	(0.8)	0	(0.0)	3	(0.6)
	浮動性めまい	6	(1.6)	0	(0.0)	6	(1.3)
	体位性めまい	5	(1.3)	0	(0.0)	5	(1.1)
	よだれ	2	(0.5)	0	(0.0)	2	(0.4)
	構語障害	1	(0.3)	0	(0.0)	1	(0.2)
	ジスキネジア	6	(1.6)	1	(1.2)	7	(1.5)
	ジストニア	4	(1.1)	0	(0.0)	4	(0.9)
	錐体外路障害	12	(3.2)	0	(0.0)	12	(2.6)

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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-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
神経系障害	頭痛	9	(2.4)	1	(1.2)	10	(2.2)
	運動過多	1	(0.3)	0	(0.0)	1	(0.2)
	過眠症	2	(0.5)	0	(0.0)	2	(0.4)
	企図振戦	1	(0.3)	0	(0.0)	1	(0.2)
	嗜眠	4	(1.1)	0	(0.0)	4	(0.9)
	精神的機能障害	1	(0.3)	0	(0.0)	1	(0.2)
	片頭痛	1	(0.3)	0	(0.0)	1	(0.2)
	パーキンソニズム	4	(1.1)	1	(1.2)	5	(1.1)
	坐骨神経痛	1	(0.3)	0	(0.0)	1	(0.2)
	鎮静	16	(4.2)	0	(0.0)	16	(3.4)
	感覚障害	0	(0.0)	1	(1.2)	1	(0.2)
	傾眠	17	(4.5)	0	(0.0)	17	(3.7)
	遅発性ジスキネジア	3	(0.8)	0	(0.0)	3	(0.6)
	振戦	24	(6.3)	1	(1.2)	25	(5.4)
	眉間反射異常	1	(0.3)	0	(0.0)	1	(0.2)
	下肢静止不能症候群	4	(1.1)	0	(0.0)	4	(0.9)
眼障害	眼瞼痙攣	3	(0.8)	0	(0.0)	3	(0.6)
	糖尿病性白内障	1	(0.3)	0	(0.0)	1	(0.2)
	霧視	1	(0.3)	0	(0.0)	1	(0.2)
	注視麻痺	1	(0.3)	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.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
眼障害	瞬目過多	2	(0.5)	0	(0.0)	2	(0.4)
耳および迷路障害	回転性めまい	1	(0.3)	0	(0.0)	1	(0.2)
心臓障害	動悸	1	(0.3)	0	(0.0)	1	(0.2)
	頻脈	4	(1.1)	0	(0.0)	4	(0.9)
血管障害	高血圧	1	(0.3)	0	(0.0)	1	(0.2)
	起立性低血圧	3	(0.8)	0	(0.0)	3	(0.6)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1	(0.3)	0	(0.0)	1	(0.2)
	呼吸困難	1	(0.3)	0	(0.0)	1	(0.2)
	鼻出血	1	(0.3)	0	(0.0)	1	(0.2)
	しゃっくり	1	(0.3)	0	(0.0)	1	(0.2)
	鼻乾燥	1	(0.3)	0	(0.0)	1	(0.2)
胃腸障害	腹部膨満	1	(0.3)	0	(0.0)	1	(0.2)
	腹痛	2	(0.5)	0	(0.0)	2	(0.4)
	便秘	5	(1.3)	0	(0.0)	5	(1.1)
	下痢	3	(0.8)	0	(0.0)	3	(0.6)
	口内乾燥	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
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-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
胃腸障害	消化不良	1	(0.3)	0	(0.0)	1	(0.2)
	嚥下障害	1	(0.3)	0	(0.0)	1	(0.2)
	胃食道逆流性疾患	1	(0.3)	0	(0.0)	1	(0.2)
	悪心	6	(1.6)	0	(0.0)	6	(1.3)
	流涎過多	13	(3.4)	0	(0.0)	13	(2.8)
	歯の知覚過敏	1	(0.3)	0	(0.0)	1	(0.2)
	舌障害	2	(0.5)	0	(0.0)	2	(0.4)
	嘔吐	3	(0.8)	0	(0.0)	3	(0.6)
	口の錯感覚	1	(0.3)	0	(0.0)	1	(0.2)
肝胆道系障害	肝炎	1	(0.3)	0	(0.0)	1	(0.2)
	高ビリルビン血症	1	(0.3)	0	(0.0)	1	(0.2)
皮膚および皮下組織障害	嚢胞性ざ瘡	1	(0.3)	0	(0.0)	1	(0.2)
	皮膚炎	1	(0.3)	0	(0.0)	1	(0.2)
	ざ瘡様皮膚炎	1	(0.3)	0	(0.0)	1	(0.2)
	皮膚乾燥	1	(0.3)	0	(0.0)	1	(0.2)
	多汗症	4	(1.1)	0	(0.0)	4	(0.9)
	寝汗	1	(0.3)	0	(0.0)	1	(0.2)
	発疹	4	(1.1)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABB.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-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
筋骨格系および結合組織障害	関節痛	1	(0.3)	0	(0.0)	1	(0.2)
	関節硬直	1	(0.3)	0	(0.0)	1	(0.2)
	筋萎縮	1	(0.3)	0	(0.0)	1	(0.2)
	筋固縮	1	(0.3)	0	(0.0)	1	(0.2)
	筋痙縮	2	(0.5)	0	(0.0)	2	(0.4)
	筋攣縮	2	(0.5)	0	(0.0)	2	(0.4)
	筋骨格痛	1	(0.3)	0	(0.0)	1	(0.2)
	筋肉痛	2	(0.5)	0	(0.0)	2	(0.4)
	四肢痛	3	(0.8)	0	(0.0)	3	(0.6)
	顎関節症候群	0	(0.0)	1	(1.2)	1	(0.2)
	開口障害	1	(0.3)	0	(0.0)	1	(0.2)
	筋緊張	1	(0.3)	0	(0.0)	1	(0.2)
	筋骨格硬直	4	(1.1)	0	(0.0)	4	(0.9)
	項部硬直	1	(0.3)	0	(0.0)	1	(0.2)
腎および尿路障害	血尿	1	(0.3)	0	(0.0)	1	(0.2)
	尿失禁	1	(0.3)	0	(0.0)	1	(0.2)
生殖系および乳房障害	無月経	1	(0.3)	0	(0.0)	1	(0.2)
	月経障害	1	(0.3)	0	(0.0)	1	(0.2)
	月経遅延	1	(0.3)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABB.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-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
生殖系および乳房障害	不規則月経	1	(0.3)	0	(0.0)	1	(0.2)
	不正子宮出血	1	(0.3)	0	(0.0)	1	(0.2)
	性機能不全	1	(0.3)	0	(0.0)	1	(0.2)
	外陰腟乾燥	1	(0.3)	0	(0.0)	1	(0.2)
	勃起不全	5	(1.3)	1	(1.2)	6	(1.3)
一般・全身障害および投与部位の状態	無菌膿瘍	1	(0.3)	0	(0.0)	1	(0.2)
	無力症	2	(0.5)	0	(0.0)	2	(0.4)
	疲労	15	(4.0)	3	(3.5)	18	(3.9)
	異常感	1	(0.3)	0	(0.0)	1	(0.2)
	歩行障害	1	(0.3)	0	(0.0)	1	(0.2)
	注射部位内出血	1	(0.3)	0	(0.0)	1	(0.2)
	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	32	(8.4)	0	(0.0)	32	(6.9)
	倦怠感	1	(0.3)	0	(0.0)	1	(0.2)
	末梢性浮腫	1	(0.3)	0	(0.0)	1	(0.2)
	発熱	2	(0.5)	0	(0.0)	2	(0.4)
	口渇	1	(0.3)	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.
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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-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	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	注射部位腫脹	4	(1.1)	0	(0.0)	4	(0.9)
	非心臓性胸痛	1	(0.3)	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	(0.3)	0	(0.0)	1	(0.2)
	アスパラギン酸アミノトランスフェラーゼ増加	1	(0.3)	0	(0.0)	1	(0.2)
	血中コレステロール増加	1	(0.3)	0	(0.0)	1	(0.2)
	血中クレアチンホスホキナーゼ増加	2	(0.5)	0	(0.0)	2	(0.4)
	血中ブドウ糖増加	2	(0.5)	0	(0.0)	2	(0.4)
	血圧低下	2	(0.5)	0	(0.0)	2	(0.4)
	血圧上昇	1	(0.3)	0	(0.0)	1	(0.2)
	血中プロラクチン減少	1	(0.3)	0	(0.0)	1	(0.2)
	血中トリグリセリド増加	1	(0.3)	0	(0.0)	1	(0.2)
	γ－グルタミルトランスフェラーゼ増加	2	(0.5)	0	(0.0)	2	(0.4)
	尿中血陽性	1	(0.3)	0	(0.0)	1	(0.2)
	心拍数増加	3	(0.8)	0	(0.0)	3	(0.6)
	体重減少	4	(1.1)	0	(0.0)	4	(0.9)
	体重増加	49	(12.9)	6	(7.1)	55	(11.9)
	起立血圧上昇	1	(0.3)	0	(0.0)	1	(0.2)
	肝酵素上昇	1	(0.3)	0	(0.0)	1	(0.2)

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1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABB.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.3.2　FINAL

表 2.7.4.7-59　すべての副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.2

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

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) n	(%)	ROLLOVER (N=85) n	(%)	TOTAL (N=464) n	(%)
臨床検査	肝機能検査値上昇	1	(0.3)	0	(0.0)	1	(0.2)
傷害、中毒および処置合併症	歯牙破折	1	(0.3)	0	(0.0)	1	(0.2)
TOTAL1)		237	(62.5)	26	(30.6)	263	(56.7)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.
1)SUBJECTS WITH ADVERSE EVENTS IN MULTIPLE SYSTEM ORGAN CLASSES WERE COUNTED ONLY ONCE TOWARDS THE TOTAL.

FILE: ADAE2ABB.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-8.3.2　FINAL

＜資料番号 5.3.5.2-01：CT-8.3.2 より作成＞

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	気管支炎	5 (1.3)	4 (1.1)	0 (0.0)	9 (2.4)	1 (1.2)	1 (1.2)	0 (0.0)	2 (2.4)
	蜂巣炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	膀胱炎	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳感染	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	毛包炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せつ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	胃腸炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	5 (1.3)	6 (1.6)	0 (0.0)	11 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	単純ヘルペス	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	帯状疱疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	麦粒腫	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感染	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	2 (0.5)	4 (1.1)	1 (0.3)	7 (1.8)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	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)
	限局性感染	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下気道感染	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	31 (8.2)	17 (4.5)	0 (0.0)	48 (12.7)	6 (7.1)	2 (2.4)	0 (0.0)	8 (9.4)
	外耳炎	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯周炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	5 (1.3)	0 (0.0)	0 (0.0)	5 (1.3)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3

Incidence of 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	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.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	レンサ球菌性咽頭炎	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	毛巣嚢胞	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	マイコプラズマ性肺炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎盂腎炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	3 (0.8)	2 (0.5)	0 (0.0)	5 (1.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	皮下組織膿瘍	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	1 (0.3)	1 (0.3)	1 (0.3)	3 (0.8)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	上気道感染	14 (3.7)	7 (1.8)	1 (0.3)	22 (5.8)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	尿路感染	6 (1.6)	5 (1.3)	0 (0.0)	11 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	0 (0.0)	3 (0.8)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白癬感染	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟真菌感染	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔ヘルペス	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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)	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）	基底細胞癌	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3

Incidence of 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	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)

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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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)
	脂肪腫	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚の新生物	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	扁平上皮癌	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮平滑筋腫	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門性器疣贅	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	動物アレルギー	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食物アレルギー	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	季節性アレルギー	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
内分泌障害	高プロラクチン血症	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	甲状腺機能低下症	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	糖尿病	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	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)	1 (1.2)	0 (0.0)	1 (1.2)
	体液貯留	0 (0.0)	1 (0.3)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3

Incidence of 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 (%)
代謝および栄養障害	耐糖能障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痛風	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高血糖	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	低カリウム血症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	11 (2.9)	4 (1.1)	1 (0.3)	16 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肥満	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	5 (1.3)	2 (0.5)	0 (0.0)	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	２型糖尿病	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	異常な夢	2 (0.5)	2 (0.5)	0 (0.0)	4 (1.1)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	急性ストレス反応	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	激越	5 (1.3)	3 (0.8)	0 (0.0)	8 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	20 (5.3)	22 (5.8)	1 (0.3)	43 (11.3)	2 (2.4)	1 (1.2)	0 (0.0)	3 (3.5)
	無感情	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意喚起行動	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	10 (2.6)	6 (1.6)	2 (0.5)	18 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	情動鈍麻	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	3 (0.8)	0 (0.0)	0 (0.0)	3 (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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
精神障害	抑うつ気分	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	9 (2.4)	16 (4.2)	1 (0.3)	26 (6.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不快気分	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	30 (7.9)	18 (4.7)	1 (0.3)	49 (12.9)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	故意の自傷行為	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	1 (0.3)	3 (0.8)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	1 (0.3)	2 (0.5)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	1 (0.3)	0 (0.0)	2 (0.5)	3 (0.8)	0 (0.0)	0 (0.0)	1 (1.2)	1 (1.2)
	気分変化	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パニック発作	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	13 (3.4)	10 (2.6)	0 (0.0)	23 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	睡眠障害	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	3 (0.8)	2 (0.5)	2 (0.5)	7 (1.8)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	自殺企図	2 (0.5)	0 (0.0)	1 (0.3)	3 (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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
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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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3

Incidence of 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 (%)
精神障害	抑うつ症状	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	双極性障害	0 (0.0)	2 (0.5)	1 (0.3)	3 (0.8)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	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)
	異常行動	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自傷行動	0 (0.0)	3 (0.8)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	早朝覚醒型不眠症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
神経系障害	アカシジア	38 (10.0)	21 (5.5)	1 (0.3)	60 (15.8)	7 (8.2)	1 (1.2)	0 (0.0)	8 (9.4)
	失語症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自律神経失調	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動緩慢	1 (0.3)	2 (0.5)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	7 (1.8)	3 (0.8)	0 (0.0)	10 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	5 (1.3)	0 (0.0)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	味覚異常	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	4 (1.1)	2 (0.5)	0 (0.0)	6 (1.6)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	ジストニア	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	7 (1.8)	4 (1.1)	1 (0.3)	12 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	13 (3.4)	10 (2.6)	0 (0.0)	23 (6.1)	4 (4.7)	2 (2.4)	0 (0.0)	6 (7.1)
	運動過多	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.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
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)

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¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	過眠症	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	企図振戦	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	2 (0.5)	1 (0.3)	1 (0.3)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	0 (0.0)	2 (0.5)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錯感覚	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	坐骨神経痛	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	4 (1.1)	11 (2.9)	2 (0.5)	17 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	副鼻腔炎に伴う頭痛	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	13 (3.4)	6 (1.6)	1 (0.3)	20 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	失神	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	1 (0.3)	1 (0.3)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	24 (6.3)	2 (0.5)	1 (0.3)	27 (7.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	眉間反射異常	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	微細運動機能障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性白内障	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3

Incidence of 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	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.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
眼障害	霧視	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	回転性めまい	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	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)
	徐脈	1 (0.3)	0 (0.0)	0 (0.0)	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)
	動悸	1 (0.3)	0 (0.0)	0 (0.0)	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)
	頻脈	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	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)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	潮紅	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	高血圧	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	起立性低血圧	5 (1.3)	0 (0.0)	0 (0.0)	5 (1.3)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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)

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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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 (1.2)	0 (0.0)	1 (1.2)
	慢性閉塞性肺疾患	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咳嗽	4 (1.1)	3 (0.8)	0 (0.0)	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉乾燥	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	鼻出血	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	低酸素症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺障害	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻閉	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	鼻漏	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉絞扼感	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	アレルギー性副鼻腔炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	上気道の炎症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔咽頭痛	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
胃腸障害	腹部不快感	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	腹部膨満	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3

Incidence of 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 (%)
胃腸障害	腹痛	1 (0.3)	4 (1.1)	0 (0.0)	5 (1.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	上腹部痛	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	便秘	8 (2.1)	2 (0.5)	0 (0.0)	10 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	17 (4.5)	2 (0.5)	0 (0.0)	19 (5.0)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	口内乾燥	7 (1.8)	1 (0.3)	0 (0.0)	8 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腸炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃炎	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	消化器痛	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	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)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	痔核	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過敏性腸症候群	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	12 (3.2)	2 (0.5)	1 (0.3)	15 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯周病	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	12 (3.2)	2 (0.5)	0 (0.0)	14 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	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¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
胃腸障害	歯の脱落	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	10 (2.6)	4 (1.1)	0 (0.0)	14 (3.7)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	嘔吐	11 (2.9)	0 (0.0)	0 (0.0)	11 (2.9)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	心窩部不快感	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	胆嚢炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	肝炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	嚢胞性ざ瘡	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	水疱	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ざ瘡様皮膚炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	接触性皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状出血	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	湿疹	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	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)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	多汗症	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嵌入爪	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	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　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
皮膚および皮下組織障害	寝汗	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	光線過敏性反応	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	そう痒症	5	(1.3)	0	(0.0)	0	(0.0)	5	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	乾癬	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	7	(1.8)	2	(0.5)	0	(0.0)	9	(2.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	斑状皮疹	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	斑状丘疹状皮疹	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	そう痒性皮疹	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂漏性皮膚炎	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	蕁麻疹	3	(0.8)	0	(0.0)	0	(0.0)	3	(0.8)	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	4	(1.1)	6	(1.6)	1	(0.3)	11	(2.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	背部痛	11	(2.9)	1	(0.3)	0	(0.0)	12	(3.2)	3	(3.5)	0	(0.0)	0	(0.0)	3	(3.5)
	外骨腫	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼡径部痛	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節硬直	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	筋固縮	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋痙縮	2	(0.5)	2	(0.5)	0	(0.0)	4	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋攣縮	2	(0.5)	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	3	(0.8)	0	(0.0)	0	(0.0)	3	(0.8)	0	(0.0)	1	(1.2)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
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.

FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
筋骨格系および結合組織障害	筋肉痛	1 (0.3)	0 (0.0)	2 (0.5)	3 (0.8)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	頚部痛	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨端症	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨壊死	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	9 (2.4)	0 (0.0)	0 (0.0)	9 (2.4)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	滑液嚢腫	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	腱炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	開口障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板突出	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	6 (1.6)	2 (0.5)	0 (0.0)	8 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節過伸展	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節不安定	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	血尿	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿意切迫	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎結石症	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
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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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
腎および尿路障害	頻尿	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蛋白尿	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿管結石症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
生殖系および乳房障害	無月経	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	良性前立腺肥大症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性器発疹	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟乾燥	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1 (0.3)	0 (0.0)	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	無菌膿瘍	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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	(%)
一般・全身障害および投与部位の状態	無力症	3	(0.8)	1	(0.3)	0	(0.0)	4	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸部不快感	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸痛	0	(0.0)	2	(0.5)	2	(0.5)	4	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	嚢胞	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疲労	10	(2.6)	6	(1.6)	0	(0.0)	16	(4.2)	3	(3.5)	1	(1.2)	0	(0.0)	4	(4.7)
	異常感	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歩行障害	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	インフルエンザ様疾患	3	(0.8)	0	(0.0)	0	(0.0)	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位内出血	2	(0.5)	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位紅斑	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位硬結	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫瘤	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	1	(1.2)	0	(0.0)	0	(0.0)	1	(1.2)
	注射部位疼痛	29	(7.7)	5	(1.3)	0	(0.0)	34	(9.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	倦怠感	3	(0.8)	0	(0.0)	0	(0.0)	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	末梢性浮腫	0	(0.0)	2	(0.5)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疼痛	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発熱	5	(1.3)	0	(0.0)	0	(0.0)	5	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口渇	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫脹	4	(1.1)	0	(0.0)	0	(0.0)	4	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	小結節	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	非心臓性胸痛	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	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: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	TOTAL (N=464) MILD n (%)	MOD n (%)	SEV n (%)	TOTAL 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　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
臨床検査	アラニンアミノトランスフェラーゼ増加	1 (0.3)	2 (0.5)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	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 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中コレステロール増加	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	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	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン増加	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中尿酸増加	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心雑音	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中ブドウ糖陽性	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	グリコヘモグロビン増加	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	6 (1.6)	6 (1.6)	0 (0.0)	12 (3.2)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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)

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表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class, MedDRA Preferred Term and Severity
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MEDDRA PREFERRED TERM)	DE NOVO (N=379) MILD n (%)	DE NOVO (N=379) MOD n (%)	DE NOVO (N=379) SEV n (%)	DE NOVO (N=379) TOTAL n (%)	ROLLOVER (N=85) MILD n (%)	ROLLOVER (N=85) MOD n (%)	ROLLOVER (N=85) SEV n (%)	ROLLOVER (N=85) TOTAL n (%)
臨床検査	体重増加	34 (9.0)	18 (4.7)	4 (1.1)	56 (14.8)	4 (4.7)	2 (2.4)	0 (0.0)	6 (7.1)
	尿中白血球陽性	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立血圧上昇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ビタミンＤ減少	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘリコバクター検査陽性	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
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 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	節足動物咬傷	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	凍瘡	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	転倒	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	裂傷	2 (0.5)	2 (0.5)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靱帯捻挫	5 (1.3)	3 (0.8)	0 (0.0)	8 (2.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	ストレス骨折	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	挫傷	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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 (1.2)	0 (0.0)	1 (1.2)
	胸部損傷	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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FILE: ADAE2AAC.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-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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: ADAE2AAC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
傷害、中毒および処置合併症	処置による疼痛	1 (0.3)	4 (1.1)	1 (0.3)	6 (1.6)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	皮膚擦過傷	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: ADAE2AAC.LIS, RUN: [redacted]20[redacted] 14:00; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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表 2.7.4.7-60　　重症度別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.3
Incidence of 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 (%)
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.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.3　FINAL

＜資料番号 5.3.5.2-01：CT-8.2.3 より作成＞

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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	気管支炎	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	鼻咽頭炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	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）	脂肪腫	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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 (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	1 (0.3)	0 (0.0)	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)	1 (0.3)	0 (0.0)	2 (0.5)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	耐糖能障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高血糖	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	11 (2.9)	4 (1.1)	1 (0.3)	16 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肥満	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	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 (VERSION 19.0) PREFERRED TERM.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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	気管支炎	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	ウイルス性胃腸炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鼻咽頭炎	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	上気道感染	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	尿路感染	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）	脂肪腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
免疫系障害	季節性アレルギー	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	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
代謝および栄養障害	糖尿病	1 (0.2)	1 (0.2)	1 (0.2)	3 (0.6)
	コントロール不良の糖尿病	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	耐糖能障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	高血糖	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)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
代謝および栄養障害	食欲減退	2 (0.5)	2 (0.5)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	２型糖尿病	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	異常な夢	2 (0.5)	2 (0.5)	0 (0.0)	4 (1.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	激越	3 (0.8)	3 (0.8)	0 (0.0)	6 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	8 (2.1)	14 (3.7)	1 (0.3)	23 (6.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	無感情	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	2 (0.5)	2 (0.5)	1 (0.3)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	7 (1.8)	8 (2.1)	0 (0.0)	15 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	15 (4.0)	14 (3.7)	0 (0.0)	29 (7.7)	2 (2.4)	0 (0.0)	0 (0.0)	2 (2.4)
	故意の自傷行為	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	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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POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
代謝および栄養障害	食欲減退	2 (0.4)	2 (0.4)	0 (0.0)	4 (0.9)
	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	3 (0.6)	2 (0.4)	0 (0.0)	5 (1.1)
	激越	3 (0.6)	3 (0.6)	0 (0.0)	6 (1.3)
	広場恐怖症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	不安	9 (1.9)	14 (3.0)	1 (0.2)	24 (5.2)
	無感情	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	双極１型障害	2 (0.4)	2 (0.4)	1 (0.2)	5 (1.1)
	歯ぎしり	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	抑うつ気分	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	うつ病	7 (1.5)	8 (1.7)	0 (0.0)	15 (3.2)
	感情の貧困	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	軽躁	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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	17 (3.7)	14 (3.0)	0 (0.0)	31 (6.7)
	故意の自傷行為	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	易刺激性	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	リビドー減退	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)

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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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
精神障害	躁病	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	11 (2.9)	10 (2.6)	0 (0.0)	21 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	睡眠障害	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	1 (0.3)	0 (0.0)	1 (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 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	1 (0.3)	0 (0.0)	0 (0.0)	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	38 (10.0)	21 (5.5)	1 (0.3)	60 (15.8)	7 (8.2)	1 (1.2)	0 (0.0)	8 (9.4)
	運動緩慢	1 (0.3)	2 (0.5)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	5 (1.3)	1 (0.3)	0 (0.0)	6 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	5 (1.3)	0 (0.0)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	4 (1.1)	2 (0.5)	0 (0.0)	6 (1.6)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	ジストニア	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
精神障害	躁病	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)
	神経過敏	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	悪夢	1 (0.2)	0 (0.0)	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	11 (2.4)	10 (2.2)	0 (0.0)	21 (4.5)
	睡眠障害	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	自殺念慮	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	抑うつ症状	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	双極性障害	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)
	異常行動	1 (0.2)	0 (0.0)	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)
	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	5 (1.1)	1 (0.2)	0 (0.0)	6 (1.3)
	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)
	ジスキネジア	5 (1.1)	2 (0.4)	0 (0.0)	7 (1.5)
	ジストニア	3 (0.6)	1 (0.2)	0 (0.0)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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	錐体外路障害	7 (1.8)	4 (1.1)	1 (0.3)	12 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	5 (1.3)	4 (1.1)	0 (0.0)	9 (2.4)	0 (0.0)	1 (1.2)	0 (0.0)	1 (1.2)
	運動過多	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	企図振戦	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	2 (0.5)	1 (0.3)	1 (0.3)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	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	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	坐骨神経痛	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	3 (0.8)	11 (2.9)	2 (0.5)	16 (4.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	傾眠	10 (2.6)	6 (1.6)	1 (0.3)	17 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	1 (0.3)	1 (0.3)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	21 (5.5)	2 (0.5)	1 (0.3)	24 (6.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	眉間反射異常	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性白内障	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	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.
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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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	錐体外路障害	7 (1.5)	4 (0.9)	1 (0.2)	12 (2.6)
	頭痛	5 (1.1)	5 (1.1)	0 (0.0)	10 (2.2)
	運動過多	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	過眠症	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	企図振戦	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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)	0 (0.0)	1 (0.2)	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	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	鎮静	3 (0.6)	11 (2.4)	2 (0.4)	16 (3.4)
	感覚障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	傾眠	10 (2.2)	6 (1.3)	1 (0.2)	17 (3.7)
	遅発性ジスキネジア	1 (0.2)	1 (0.2)	1 (0.2)	3 (0.6)
	振戦	22 (4.7)	2 (0.4)	1 (0.2)	25 (5.4)
	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)
眼障害	眼瞼痙攣	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	糖尿病性白内障	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)

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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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
眼障害	注視麻痺	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	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	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	動悸	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	高血圧	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立性低血圧	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	鼻出血	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部膨満	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	0 (0.0)	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
眼障害	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	回転性めまい	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
心臓障害	動悸	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	頻脈	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
血管障害	高血圧	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	起立性低血圧	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
呼吸器、胸郭および縦隔障害	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	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	しゃっくり	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻乾燥	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
胃腸障害	腹部膨満	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	腹痛	0 (0.0)	2 (0.4)	0 (0.0)	2 (0.4)
	便秘	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)

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FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
胃腸障害	下痢	2 (0.5)	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	4 (1.1)	1 (0.3)	1 (0.3)	6 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	11 (2.9)	2 (0.5)	0 (0.0)	13 (3.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	肝炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
皮膚および皮下組織障害	嚢胞性ざ瘡	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ざ瘡様皮膚炎	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	寝汗	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE2.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
胃腸障害	下痢	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)
	口内乾燥	4 (0.9)	1 (0.2)	0 (0.0)	5 (1.1)
	消化不良	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	嚥下障害	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	胃食道逆流性疾患	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	悪心	4 (0.9)	1 (0.2)	1 (0.2)	6 (1.3)
	流涎過多	11 (2.4)	2 (0.4)	0 (0.0)	13 (2.8)
	歯の知覚過敏	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)
	嘔吐	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	口の錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
肝胆道系障害	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)
	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)
	皮膚乾燥	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	多汗症	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	寝汗	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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
皮膚および皮下組織障害	発疹	3 (0.8)	1 (0.3)	0 (0.0)	4 (1.1)	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 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節硬直	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	筋固縮	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋攣縮	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	1 (0.3)	0 (0.0)	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	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 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	開口障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	2 (0.5)	2 (0.5)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	血尿	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
皮膚および皮下組織障害	発疹	3 (0.6)	1 (0.2)	0 (0.0)	4 (0.9)
筋骨格系および結合組織障害	関節痛	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)	0 (0.0)	0 (0.0)	2 (0.4)
	筋攣縮	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	筋骨格痛	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	筋肉痛	1 (0.2)	0 (0.0)	1 (0.2)	2 (0.4)
	四肢痛	3 (0.6)	0 (0.0)	0 (0.0)	3 (0.6)
	顎関節症候群	1 (0.2)	0 (0.0)	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)
	筋骨格硬直	2 (0.4)	2 (0.4)	0 (0.0)	4 (0.9)
	項部硬直	1 (0.2)	0 (0.0)	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)
	尿失禁	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)

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表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
生殖系および乳房障害	無月経	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟乾燥	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	4 (1.1)	1 (0.3)	0 (0.0)	5 (1.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
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)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	9 (2.4)	6 (1.6)	0 (0.0)	15 (4.0)	2 (2.4)	1 (1.2)	0 (0.0)	3 (3.5)
	異常感	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	1 (1.2)	0 (0.0)	0 (0.0)	1 (1.2)
	注射部位疼痛	27 (7.1)	5 (1.3)	0 (0.0)	32 (8.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
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)
	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)
	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)
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)
	無力症	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	疲労	11 (2.4)	7 (1.5)	0 (0.0)	18 (3.9)
	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)
	注射部位内出血	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	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	27 (5.8)	5 (1.1)	0 (0.0)	32 (6.9)
	倦怠感	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
一般・全身障害および投与部位の状態	末梢性浮腫	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	非心臓性胸痛	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	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	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	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	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	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)	1 (0.3)	0 (0.0)	1 (0.3)	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	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	2 (0.5)	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	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	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.5)	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
一般・全身障害および投与部位の状態	末梢性浮腫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	発熱	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	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)
	非心臓性胸痛	0 (0.0)	1 (0.2)	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 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	アスパラギン酸アミノトランスフェラーゼ増加	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	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	血中ブドウ糖増加	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	血圧低下	2 (0.4)	0 (0.0)	0 (0.0)	2 (0.4)
	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)
	血中トリグリセリド増加	0 (0.0)	1 (0.2)	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)

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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
臨床検査	尿中血陽性	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	3 (0.8)	0 (0.0)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	4 (1.1)	0 (0.0)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	29 (7.7)	16 (4.2)	4 (1.1)	49 (12.9)	4 (4.7)	2 (2.4)	0 (0.0)	6 (7.1)
	起立血圧上昇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
傷害、中毒および処置合併症	歯牙破折	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.
POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

表 2.7.4.7-61　　重症度別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.3.3

Incidence of Potentially Drug-related 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 (%)
臨床検査	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	4 (0.9)	0 (0.0)	0 (0.0)	4 (0.9)
	体重増加	33 (7.1)	18 (3.9)	4 (0.9)	55 (11.9)
	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)
	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	歯牙破折	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. POTENTIALLY DRUG-RELATED ADVERSE EVENTS INCLUDE THOSE CLASSIFIED AS DEFINITELY, POSSIBLY OR PROBABLY RELATED.

FILE: ADAE2ABC.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-8.3.3　FINAL

＜資料番号 5.3.5.2-01：CT-8.3.3 より作成＞

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
TOTAL1)		240 (63.3)	152 (44.1)	117 (39.3)	86 (33.5)	33 (14.3)	309 (81.5)
胃腸障害	悪心	7 (1.8)	6 (1.7)	1 (0.3)	2 (0.8)	0 (0.0)	15 (4.0)
	胃炎	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	下痢	10 (2.6)	1 (0.3)	3 (1.0)	4 (1.6)	1 (0.4)	19 (5.0)
	過敏性腸症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	血便排泄	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	口内乾燥	4 (1.1)	1 (0.3)	1 (0.3)	1 (0.4)	0 (0.0)	7 (1.8)
	歯の脱落	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歯の知覚過敏	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歯周病	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歯痛	7 (1.8)	3 (0.9)	4 (1.3)	2 (0.8)	0 (0.0)	14 (3.7)
	痔核	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	消化器痛	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.4)	0 (0.0)	1 (0.3)
	消化不良	0 (0.0)	0 (0.0)	2 (0.7)	1 (0.4)	0 (0.0)	3 (0.8)
	上腹部痛	1 (0.3)	1 (0.3)	3 (1.0)	1 (0.4)	0 (0.0)	4 (1.1)
	心窩部不快感	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	舌障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
TOTAL1)		30 (35.3)	21 (27.6)	12 (16.7)	3 (12.5)	1 (6.7)	50 (58.8)
胃腸障害	悪心	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	1 (1.2)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	2 (2.4)
	過敏性腸症候群	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)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	口内炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の脱落	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	歯周病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	消化器痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	上腹部痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	心窩部不快感	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	TOTAL 3-6 MONTHS (N=421) n (%)	TOTAL 6-9 MONTHS (N=370) n (%)	TOTAL 9-12 MONTHS (N=281) n (%)	TOTAL >12 MONTHS (N=245) n (%)	TOTAL TOTAL (N=464) n (%)
TOTAL1)		270 (58.2)	173 (41.1)	129 (34.9)	89 (31.7)	34 (13.9)	359 (77.4)
胃腸障害	悪心	7 (1.5)	6 (1.4)	1 (0.3)	2 (0.7)	0 (0.0)	15 (3.2)
	胃炎	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	下痢	11 (2.4)	1 (0.2)	4 (1.1)	4 (1.4)	1 (0.4)	21 (4.5)
	過敏性腸症候群	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	血便排泄	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	口内炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	口内乾燥	4 (0.9)	1 (0.2)	1 (0.3)	1 (0.4)	0 (0.0)	7 (1.5)
	歯の脱落	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯の知覚過敏	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯周病	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯痛	8 (1.7)	3 (0.7)	4 (1.1)	2 (0.7)	0 (0.0)	15 (3.2)
	痔核	0 (0.0)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	消化器痛	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.4)	0 (0.0)	1 (0.2)
	消化不良	0 (0.0)	0 (0.0)	2 (0.5)	1 (0.4)	0 (0.0)	3 (0.6)
	上腹部痛	2 (0.4)	1 (0.2)	3 (0.8)	1 (0.4)	0 (0.0)	5 (1.1)
	心窩部不快感	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	舌障害	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.7)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
胃腸障害	腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	腹痛	1 (0.3)	1 (0.3)	2 (0.7)	1 (0.4)	0 (0.0)	5 (1.3)
	腹部不快感	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
	便秘	6 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	7 (1.8)
	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	5 (1.3)	3 (0.9)	3 (1.0)	0 (0.0)	1 (0.4)	11 (2.9)
	嘔吐	6 (1.6)	1 (0.3)	4 (1.3)	0 (0.0)	0 (0.0)	10 (2.6)
	嚥下障害	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	齲歯	1 (0.3)	1 (0.3)	3 (1.0)	0 (0.0)	0 (0.0)	5 (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 (0.3)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
	胸痛	2 (0.5)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	4 (1.1)
	胸部不快感	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	倦怠感	1 (0.3)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.8)
	口渇	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	小結節	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	注射部位硬結	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	注射部位紅斑	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	注射部位腫脹	2 (0.5)	0 (0.0)	2 (0.7)	0 (0.0)	0 (0.0)	4 (1.1)
	注射部位腫瘤	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
胃腸障害	腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	腹部不快感	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.2)
	便秘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (1.2)
	流涎過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.2)
	嚥下障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	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	インフルエンザ様疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸部不快感	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)
	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	小結節	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
胃腸障害	腸炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	腹痛	1 (0.2)	2 (0.5)	2 (0.5)	1 (0.4)	0 (0.0)	6 (1.3)
	腹部不快感	3 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	便秘	6 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	7 (1.5)
	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	流涎過多	5 (1.1)	3 (0.7)	3 (0.8)	0 (0.0)	1 (0.4)	11 (2.4)
	嘔吐	6 (1.3)	2 (0.5)	5 (1.4)	0 (0.0)	0 (0.0)	11 (2.4)
	嚥下障害	1 (0.2)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	齲歯	1 (0.2)	1 (0.2)	3 (0.8)	0 (0.0)	0 (0.0)	5 (1.1)
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 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)
	胸痛	2 (0.4)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	胸部不快感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	倦怠感	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.6)
	口渇	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	小結節	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位硬結	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位紅斑	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位腫脹	2 (0.4)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	4 (0.9)
	注射部位腫瘤	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	DE NOVO <=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
一般・全身障害および投与部位の状態	注射部位内出血	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	注射部位疼痛	30 (7.9)	2 (0.6)	3 (1.0)	3 (1.2)	0 (0.0)	34 (9.0)
	嚢胞	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	発熱	1 (0.3)	1 (0.3)	1 (0.3)	2 (0.8)	0 (0.0)	5 (1.3)
	疲労	5 (1.3)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	8 (2.1)
	非心臓性胸痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歩行障害	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	末梢性浮腫	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	無菌膿瘍	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	無力症	2 (0.5)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	4 (1.1)
	疼痛	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
感染症および寄生虫症	せつ	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	2 (0.5)	2 (0.6)	4 (1.3)	1 (0.4)	0 (0.0)	7 (1.8)
	ウイルス性胃腸炎	4 (1.1)	2 (0.6)	3 (1.0)	3 (1.2)	0 (0.0)	11 (2.9)
	ウイルス性上気道感染	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	ダニ皮膚炎	2 (0.5)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
	ノロウイルス性胃腸炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	マイコプラズマ性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	レンサ球菌性咽頭炎	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) 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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	4 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.7)
	非心臓性胸痛	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.2)
	歩行障害	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)	0 (0.0)	0 (0.0)	0 (0.0)
	無菌膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
感染症および寄生虫症	せつ	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	インフルエンザ	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (1.2)
	ウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	0 (0.0)	0 (0.0)	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)	0 (0.0)
	マイコプラズマ性肺炎	0 (0.0)	0 (0.0)	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)	0 (0.0)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) 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	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	注射部位疼痛	30 (6.5)	2 (0.5)	3 (0.8)	3 (1.1)	0 (0.0)	34 (7.3)
	嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	発熱	1 (0.2)	1 (0.2)	1 (0.3)	2 (0.7)	0 (0.0)	5 (1.1)
	疲労	9 (1.9)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	12 (2.6)
	非心臓性胸痛	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	歩行障害	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	末梢性浮腫	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	無菌膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	無力症	2 (0.4)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	疼痛	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
感染症および寄生虫症	せつ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	インフルエンザ	2 (0.4)	2 (0.5)	4 (1.1)	2 (0.7)	0 (0.0)	8 (1.7)
	ウイルス性胃腸炎	4 (0.9)	2 (0.5)	3 (0.8)	3 (1.1)	0 (0.0)	11 (2.4)
	ウイルス性上気道感染	0 (0.0)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	ダニ皮膚炎	2 (0.4)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)
	ノロウイルス性胃腸炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	マイコプラズマ性肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	レンサ球菌性咽頭炎	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
感染症および寄生虫症	胃腸炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	咽頭炎	3 (0.8)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	5 (1.3)
	下気道感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	外陰腟真菌感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	外耳炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	気管支炎	2 (0.5)	1 (0.3)	3 (1.0)	2 (0.8)	0 (0.0)	8 (2.1)
	限局性感染	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	歯感染	0 (0.0)	1 (0.3)	2 (0.7)	0 (0.0)	0 (0.0)	3 (0.8)
	歯周炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歯肉炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歯膿瘍	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	耳感染	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	上気道感染	11 (2.9)	6 (1.7)	3 (1.0)	4 (1.6)	0 (0.0)	22 (5.8)
	腎感染	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	腎盂腎炎	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	単純ヘルペス	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	中耳炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
感染症および寄生虫症	胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	下気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟真菌感染	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)	0 (0.0)	0 (0.0)	0 (0.0)
	感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気管支炎	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)
	限局性感染	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)	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)	0 (0.0)	0 (0.0)
	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	耳感染	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	上気道感染	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	0 (0.0)	2 (2.4)
	腎感染	0 (0.0)	0 (0.0)	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)	0 (0.0)
	帯状疱疹	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	単純ヘルペス	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)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
感染症および寄生虫症	胃腸炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	咽頭炎	3 (0.6)	2 (0.5)	0 (0.0)	0 (0.0)	1 (0.4)	6 (1.3)
	下気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	外陰腟真菌感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	外耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	感染	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	気管支炎	4 (0.9)	1 (0.2)	3 (0.8)	2 (0.7)	0 (0.0)	10 (2.2)
	限局性感染	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	口腔ヘルペス	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	歯感染	0 (0.0)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	3 (0.6)
	歯周炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯肉炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯膿瘍	3 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	耳感染	2 (0.4)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	上気道感染	11 (2.4)	7 (1.7)	4 (1.1)	4 (1.4)	0 (0.0)	24 (5.2)
	腎感染	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	腎盂腎炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	帯状疱疹	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	単純ヘルペス	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	中耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
感染症および寄生虫症	尿路感染	2 (0.5)	3 (0.9)	4 (1.3)	3 (1.2)	0 (0.0)	11 (2.9)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	白癬感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	麦粒腫	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	鼻咽頭炎	25 (6.6)	12 (3.5)	12 (4.0)	13 (5.1)	3 (1.3)	48 (12.7)
	鼻炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	副鼻腔炎	2 (0.5)	1 (0.3)	0 (0.0)	2 (0.8)	0 (0.0)	5 (1.3)
	蜂巣炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	毛巣嚢胞	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	毛包炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	膀胱炎	0 (0.0)	3 (0.9)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
肝胆道系障害	肝炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	急性胆嚢炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	高ビリルビン血症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	胆嚢炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
眼障害	眼瞼痙攣	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	瞬目過多	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
感染症および寄生虫症	尿路感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白癬感染	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	4 (4.7)	3 (3.9)	2 (2.8)	0 (0.0)	0 (0.0)	8 (9.4)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	蜂巣炎	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	毛巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	毛包炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性胆嚢炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胆嚢炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
感染症および寄生虫症	尿路感染	2 (0.4)	3 (0.7)	4 (1.1)	3 (1.1)	0 (0.0)	11 (2.4)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	白癬感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	麦粒腫	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	鼻咽頭炎	29 (6.3)	15 (3.6)	14 (3.8)	13 (4.6)	3 (1.2)	56 (12.1)
	鼻炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	副鼻腔炎	3 (0.6)	1 (0.2)	0 (0.0)	2 (0.7)	0 (0.0)	6 (1.3)
	蜂巣炎	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	毛巣嚢胞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	毛包炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	膀胱炎	0 (0.0)	3 (0.7)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.6)
肝胆道系障害	肝炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	急性胆嚢炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	高ビリルビン血症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	胆嚢炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
眼障害	眼瞼痙攣	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	瞬目過多	0 (0.0)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
眼障害	注視麻痺	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	霧視	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
筋骨格系および結合組織障害	外骨腫	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	滑液嚢腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	関節過伸展	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	関節硬直	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	関節痛	2 (0.5)	2 (0.6)	3 (1.0)	4 (1.6)	0 (0.0)	11 (2.9)
	関節不安定	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	筋萎縮	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	筋緊張	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	筋固縮	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	筋骨格硬直	4 (1.1)	1 (0.3)	4 (1.3)	0 (0.0)	0 (0.0)	8 (2.1)
	筋骨格痛	0 (0.0)	1 (0.3)	2 (0.7)	0 (0.0)	0 (0.0)	3 (0.8)
	筋肉痛	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	筋攣縮	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.5)
	筋痙縮	1 (0.3)	2 (0.6)	0 (0.0)	0 (0.0)	1 (0.4)	4 (1.1)
	頚部痛	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	項部硬直	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	骨壊死	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
眼障害	注視麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	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	外骨腫	0 (0.0)	0 (0.0)	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)	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)	0 (0.0)
	関節硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節不安定	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋萎縮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	0 (0.0)	0 (0.0)	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)	0 (0.0)
	筋骨格硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	筋肉痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	筋攣縮	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)
	頚部痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨壊死	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
眼障害	注視麻痺	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	霧視	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
筋骨格系および結合組織障害	外骨腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	滑液嚢腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	関節過伸展	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	関節硬直	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	関節痛	2 (0.4)	2 (0.5)	3 (0.8)	4 (1.4)	0 (0.0)	11 (2.4)
	関節不安定	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	筋萎縮	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	筋緊張	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	筋固縮	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	筋骨格硬直	4 (0.9)	1 (0.2)	4 (1.1)	0 (0.0)	0 (0.0)	8 (1.7)
	筋骨格痛	1 (0.2)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	4 (0.9)
	筋肉痛	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)
	筋攣縮	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.4)
	筋痙縮	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	1 (0.4)	4 (0.9)
	頚部痛	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	項部硬直	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	骨壊死	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
筋骨格系および結合組織障害	骨端症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	四肢痛	4 (1.1)	2 (0.6)	3 (1.0)	0 (0.0)	0 (0.0)	9 (2.4)
	椎間板障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	椎間板突出	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	背部痛	1 (0.3)	6 (1.7)	3 (1.0)	2 (0.8)	0 (0.0)	12 (3.2)
	腱炎	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	肋骨部痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
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)	1 (0.4)	1 (0.3)
血管障害	起立性低血圧	2 (0.5)	2 (0.6)	1 (0.3)	0 (0.0)	0 (0.0)	5 (1.3)
	血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高血圧	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	潮紅	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	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)
呼吸器、胸郭および縦隔障害	しゃっくり	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	アレルギー性副鼻腔炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	咽喉絞扼感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
	咽頭反射亢進	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
筋骨格系および結合組織障害	骨端症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	椎間板障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板突出	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	2 (2.4)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	3 (3.5)
	腱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼠径部痛	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)
血管障害	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	高血圧	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	潮紅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	本態性高血圧症	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
呼吸器、胸郭および縦隔障害	しゃっくり	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)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	咽喉絞扼感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭反射亢進	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	TOTAL 3-6 MONTHS (N=421) n (%)	TOTAL 6-9 MONTHS (N=370) n (%)	TOTAL 9-12 MONTHS (N=281) n (%)	TOTAL >12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
筋骨格系および結合組織障害	骨端症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢痛	5 (1.1)	2 (0.5)	3 (0.8)	0 (0.0)	0 (0.0)	10 (2.2)
	椎間板障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	椎間板突出	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	背部痛	3 (0.6)	6 (1.4)	4 (1.1)	2 (0.7)	0 (0.0)	15 (3.2)
	腱炎	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	胤径部痛	1 (0.2)	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
血管障害	起立性低血圧	2 (0.4)	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	5 (1.1)
	血腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	高血圧	2 (0.4)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	潮紅	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	本態性高血圧症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
呼吸器、胸郭および縦隔障害	しゃっくり	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	アレルギー性副鼻腔炎	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	咽喉絞扼感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	咽頭反射亢進	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
呼吸器、胸郭および縦隔障害	咳嗽	3 (0.8)	2 (0.6)	1 (0.3)	2 (0.8)	0 (0.0)	7 (1.8)
	胸膜炎	0 (0.0)	0 (0.0)	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)	1 (0.4)	1 (0.3)
	口腔咽頭痛	2 (0.5)	1 (0.3)	2 (0.7)	0 (0.0)	0 (0.0)	5 (1.3)
	上気道の炎症	0 (0.0)	1 (0.3)	0 (0.0)	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)	1 (0.4)	1 (0.3)
	肺障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	鼻乾燥	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	鼻出血	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	鼻閉	2 (0.5)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.8)
	鼻漏	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	慢性閉塞性肺疾患	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	喘息	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	回転性めまい	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.5)
	耳痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	ストレス骨折	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	関節損傷	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	胸部損傷	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
呼吸器、胸郭および縦隔障害	咳嗽	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸膜炎	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	低酸素症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻漏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性閉塞性肺疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	喘息	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
耳および迷路障害	回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳痛	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
傷害、中毒および処置合併症	ストレス骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	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)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		TOTAL					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
呼吸器、胸郭および縦隔障害	咳嗽	3 (0.6)	2 (0.5)	1 (0.3)	2 (0.7)	0 (0.0)	7 (1.5)
	胸膜炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	呼吸困難	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	口腔咽頭痛	2 (0.4)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	5 (1.1)
	上気道の炎症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	低酸素症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	肺障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻乾燥	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻出血	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	鼻閉	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.6)
	鼻漏	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	慢性閉塞性肺疾患	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	喘息	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
耳および迷路障害	回転性めまい	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.4)
	耳痛	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
傷害、中毒および処置合併症	ストレス骨折	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	関節損傷	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	胸部損傷	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
傷害、中毒および処置合併症	挫傷	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	四肢損傷	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)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.5)
	処置による疼痛	0 (0.0)	2 (0.6)	2 (0.7)	2 (0.8)	0 (0.0)	6 (1.6)
	節足動物咬傷	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	足関節部骨折	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	転倒	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	凍瘡	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	肉離れ	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	皮膚擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
	裂傷	1 (0.3)	1 (0.3)	2 (0.7)	0 (0.0)	0 (0.0)	4 (1.1)
	靭帯捻挫	1 (0.3)	0 (0.0)	4 (1.3)	2 (0.8)	2 (0.9)	8 (2.1)
心臓障害	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	急性心筋梗塞	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	動悸	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	頻脈	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.1)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) 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)
	四肢損傷	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	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 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	節足動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	足関節部骨折	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)	0 (0.0)	0 (0.0)	0 (0.0)
	凍瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.2)	0 (0.0)	1 (1.2)
	皮膚擦過傷	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)	0 (0.0)	0 (0.0)	0 (0.0)
	靭帯捻挫	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
心臓障害	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)
	急性心筋梗塞	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)
	心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	動悸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
傷害、中毒および処置合併症	挫傷	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	四肢損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯牙破折	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)
	処置による疼痛	1 (0.2)	2 (0.5)	2 (0.5)	2 (0.7)	0 (0.0)	7 (1.5)
	節足動物咬傷	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	足関節部骨折	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	転倒	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	凍瘡	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	肉離れ	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.7)	0 (0.0)	2 (0.4)
	皮膚擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	裂傷	1 (0.2)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	4 (0.9)
	靭帯捻挫	2 (0.4)	0 (0.0)	4 (1.1)	2 (0.7)	2 (0.8)	9 (1.9)
心臓障害	プリンツメタル狭心症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	急性心筋梗塞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	徐脈	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	動悸	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	頻脈	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
神経系障害	よだれ	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	アカシジア	21 (5.5)	11 (3.2)	7 (2.3)	1 (0.4)	0 (0.0)	38 (10.0)
	ジスキネジア	4 (1.1)	2 (0.6)	0 (0.0)	2 (0.8)	0 (0.0)	6 (1.6)
	ジストニア	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	パーキンソニズム	1 (0.3)	2 (0.6)	1 (0.3)	0 (0.0)	0 (0.0)	4 (1.1)
	運動過多	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	運動緩慢	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.5)
	下肢静止不能症候群	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	過眠症	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	感覚障害	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)	1 (0.3)	1 (0.4)	0 (0.0)	2 (0.5)
	企図振戦	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	傾眠	11 (2.9)	1 (0.3)	2 (0.7)	1 (0.4)	1 (0.4)	15 (4.0)
	構語障害	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	坐骨神経痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	錯感覚	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	自律神経失調	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	失語症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
神経系障害	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	アカシジア	3 (3.5)	4 (5.3)	3 (4.2)	0 (0.0)	0 (0.0)	8 (9.4)
	ジスキネジア	1 (1.2)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	2 (2.4)
	ジストニア	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)	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.2)
	運動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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)
	過眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	感覚鈍麻	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	企図振戦	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)
	構語障害	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)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自律神経失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	失語症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	失神	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
神経系障害	よだれ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	アカシジア	24 (5.2)	15 (3.6)	10 (2.7)	1 (0.4)	0 (0.0)	46 (9.9)
	ジスキネジア	5 (1.1)	2 (0.5)	1 (0.3)	2 (0.7)	0 (0.0)	8 (1.7)
	ジストニア	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	パーキンソニズム	1 (0.2)	2 (0.5)	2 (0.5)	0 (0.0)	0 (0.0)	5 (1.1)
	運動過多	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	運動緩慢	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)
	下肢静止不能症候群	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	過眠症	1 (0.2)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	感覚障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	感覚鈍麻	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.4)	0 (0.0)	2 (0.4)
	企図振戦	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	傾眠	11 (2.4)	1 (0.2)	2 (0.5)	1 (0.4)	1 (0.4)	15 (3.2)
	構語障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	坐骨神経痛	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	錯感覚	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	自律神経失調	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	失語症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	失神	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO											
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n	(%)	3-6 MONTHS (N=345) n	(%)	6-9 MONTHS (N=298) n	(%)	9-12 MONTHS (N=257) n	(%)	>12 MONTHS (N=230) n	(%)	TOTAL (N=379) n	(%)
神経系障害	振戦	14	(3.7)	9	(2.6)	3	(1.0)	2	(0.8)	0	(0.0)	25	(6.6)
	錐体外路障害	3	(0.8)	2	(0.6)	1	(0.3)	1	(0.4)	0	(0.0)	7	(1.8)
	精神的機能障害	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	体位性めまい	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	遅発性ジスキネジア	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	3	(0.8)
	注意力障害	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.4)	0	(0.0)	2	(0.5)
	鎮静	12	(3.2)	3	(0.9)	0	(0.0)	0	(0.0)	2	(0.9)	17	(4.5)
	頭痛	15	(4.0)	5	(1.4)	4	(1.3)	1	(0.4)	0	(0.0)	23	(6.1)
	微細運動機能障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	眉間反射異常	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	浮動性めまい	3	(0.8)	4	(1.2)	2	(0.7)	1	(0.4)	1	(0.4)	9	(2.4)
	副鼻腔炎に伴う頭痛	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	片頭痛	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)	3	(0.8)
	味覚異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)	1	(0.3)
	嗜眠	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
腎および尿路障害	血尿	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	腎結石症	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	蛋白尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.4)	1	(0.3)
	尿意切迫	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
神経系障害	振戦	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	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)	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)	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)
	頭痛	1 (1.2)	3 (3.9)	3 (4.2)	0 (0.0)	0 (0.0)	6 (7.1)
	微細運動機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	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)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	味覚異常	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)
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)	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)
	蛋白尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿意切迫	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 PHASE C 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　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
神経系障害	振戦	14 (3.0)	10 (2.4)	3 (0.8)	2 (0.7)	0 (0.0)	26 (5.6)
	錐体外路障害	3 (0.6)	2 (0.5)	1 (0.3)	1 (0.4)	0 (0.0)	7 (1.5)
	精神的機能障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	体位性めまい	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	遅発性ジスキネジア	1 (0.2)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.6)
	注意力障害	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)
	鎮静	12 (2.6)	3 (0.7)	0 (0.0)	0 (0.0)	2 (0.8)	17 (3.7)
	頭痛	16 (3.4)	8 (1.9)	7 (1.9)	1 (0.4)	0 (0.0)	29 (6.3)
	微細運動機能障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	眉間反射異常	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	浮動性めまい	3 (0.6)	4 (1.0)	2 (0.5)	1 (0.4)	1 (0.4)	9 (1.9)
	副鼻腔炎に伴う頭痛	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	片頭痛	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	3 (0.6)
	味覚異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	嗜眠	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
腎および尿路障害	血尿	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	腎結石症	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	蛋白尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	尿意切迫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
腎および尿路障害	尿管結石症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	尿失禁	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	頻尿	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	夜間頻尿	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
生殖系および乳房障害	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	月経遅延	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)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	性機能不全	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	不規則月経	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	不正子宮出血	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	勃起不全	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	無月経	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	卵巣嚢胞	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	良性前立腺肥大症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
精神障害	うつ病	14 (3.7)	10 (2.9)	3 (1.0)	5 (1.9)	1 (0.4)	26 (6.9)
	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	リビドー減退	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	悪夢	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
腎および尿路障害	尿管結石症	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	尿失禁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	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	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性器発疹	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)
	不規則月経	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	勃起不全	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	無月経	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)	0 (0.0)	0 (0.0)
	良性前立腺肥大症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	うつ病	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)
	リビドー減退	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)	0 (0.0)	0 (0.0)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
腎および尿路障害	尿管結石症	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	尿失禁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	頻尿	0 (0.0)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	夜間頻尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
生殖系および乳房障害	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	月経遅延	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	性器発疹	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	性機能不全	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	不正子宮出血	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	勃起不全	3 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	4 (0.9)
	無月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	卵巣嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	良性前立腺肥大症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
精神障害	うつ病	14 (3.0)	10 (2.4)	3 (0.8)	5 (1.8)	1 (0.4)	26 (5.6)
	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	リビドー減退	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	悪夢	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
精神障害	易刺激性	3 (0.8)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	4 (1.1)
	異常な夢	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	異常行動	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	感情の貧困	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	気分変化	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
	急性ストレス反応	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	軽躁	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.5)
	激越	3 (0.8)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.1)
	故意の自傷行為	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	広場恐怖症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	攻撃性	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	歯ぎしり	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	自殺企図	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	自殺念慮	2 (0.5)	3 (0.9)	2 (0.7)	1 (0.4)	1 (0.4)	7 (1.8)
	自傷行動	1 (0.3)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	衝動行為	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	情動鈍麻	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	神経過敏	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	睡眠障害	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
精神障害	易刺激性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常な夢	1 (1.2)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (2.4)
	異常行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気分変化	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性ストレス反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	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)
	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	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)
	歯ぎしり	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)	0 (0.0)	0 (0.0)
	自殺念慮	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	0 (0.0)	2 (2.4)
	自傷行動	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)	0 (0.0)	0 (0.0)
	衝動行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	情動鈍麻	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)	0 (0.0)	0 (0.0)	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)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	TOTAL 3-6 MONTHS (N=421) n (%)	TOTAL 6-9 MONTHS (N=370) n (%)	TOTAL 9-12 MONTHS (N=281) n (%)	TOTAL >12 MONTHS (N=245) n (%)	TOTAL TOTAL (N=464) n (%)
精神障害	易刺激性	3 (0.6)	0 (0.0)	0 (0.0)	2 (0.7)	0 (0.0)	4 (0.9)
	異常な夢	4 (0.9)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	5 (1.1)
	異常行動	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	感情の貧困	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	気分変化	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
	急性ストレス反応	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	軽躁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.4)
	激越	3 (0.6)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
	故意の自傷行為	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	広場恐怖症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	攻撃性	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	歯ぎしり	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	自殺企図	1 (0.2)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.6)
	自殺念慮	2 (0.4)	4 (1.0)	3 (0.8)	1 (0.4)	1 (0.4)	9 (1.9)
	自傷行動	1 (0.2)	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.6)
	社会逃避行動	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	衝動行為	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	情動鈍麻	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	神経過敏	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	睡眠障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
精神障害	双極１型障害	7 (1.8)	5 (1.4)	7 (2.3)	0 (0.0)	2 (0.9)	18 (4.7)
	双極性障害	1 (0.3)	0 (0.0)	1 (0.3)	1 (0.4)	0 (0.0)	3 (0.8)
	早朝覚醒型不眠症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	大うつ病	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	注意喚起行動	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	不安	19 (5.0)	9 (2.6)	5 (1.7)	7 (2.7)	1 (0.4)	35 (9.2)
	不快気分	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	不眠症	18 (4.7)	14 (4.1)	9 (3.0)	1 (0.4)	3 (1.3)	43 (11.3)
	無感情	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	妄想症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	抑うつ気分	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	抑うつ症状	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)
	落ち着きのなさ	11 (2.9)	4 (1.2)	0 (0.0)	1 (0.4)	0 (0.0)	15 (4.0)
	躁病	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
代謝および栄養障害	２型糖尿病	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.8)	0 (0.0)	3 (0.8)
	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)	0 (0.0)
	高血糖	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) 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)
	双極性障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (1.2)
	早朝覚醒型不眠症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意喚起行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	3 (3.5)	1 (1.3)	1 (1.4)	0 (0.0)	1 (6.7)	3 (3.5)
	不快気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	0 (0.0)	1 (1.3)	1 (1.4)	0 (0.0)	0 (0.0)	2 (2.4)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	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)
	抑うつ症状	0 (0.0)	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)	1 (1.2)
	落ち着きのなさ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	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	２型糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	高血糖	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
精神障害	双極１型障害	7 (1.5)	5 (1.2)	7 (1.9)	0 (0.0)	2 (0.8)	18 (3.9)
	双極性障害	1 (0.2)	0 (0.0)	1 (0.3)	1 (0.4)	1 (0.4)	4 (0.9)
	早朝覚醒型不眠症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	大うつ病	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注意喚起行動	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	不安	22 (4.7)	10 (2.4)	6 (1.6)	7 (2.5)	2 (0.8)	38 (8.2)
	不快気分	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	不眠症	18 (3.9)	15 (3.6)	10 (2.7)	1 (0.4)	3 (1.2)	45 (9.7)
	無感情	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	妄想症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	抑うつ気分	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	抑うつ症状	2 (0.4)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.6)
	落ち着きのなさ	11 (2.4)	4 (1.0)	0 (0.0)	1 (0.4)	0 (0.0)	15 (3.2)
	躁病	2 (0.4)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
代謝および栄養障害	２型糖尿病	1 (0.2)	0 (0.0)	0 (0.0)	2 (0.7)	0 (0.0)	3 (0.6)
	コントロール不良の糖尿病	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	高血糖	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
代謝および栄養障害	高脂血症	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.5)
	食欲減退	3 (0.8)	3 (0.9)	1 (0.3)	0 (0.0)	0 (0.0)	6 (1.6)
	食欲亢進	7 (1.8)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.4)	9 (2.4)
	体液貯留	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	痛風	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	低カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	糖尿病	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
	肥満	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.5)
内分泌障害	甲状腺機能低下症	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.5)
	高プロラクチン血症	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.5)
皮膚および皮下組織障害	ざ瘡様皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	そう痒症	3 (0.8)	0 (0.0)	1 (0.3)	1 (0.4)	0 (0.0)	5 (1.3)
	そう痒性皮疹	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	乾癬	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	光線過敏性反応	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脂漏性皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
代謝および栄養障害	高脂血症	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)	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)
	体液貯留	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痛風	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	低カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	肥満	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
内分泌障害	甲状腺機能低下症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
皮膚および皮下組織障害	ざ瘡様皮膚炎	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)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乾癬	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	光線過敏性反応	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	紅斑	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	脂漏性皮膚炎	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
代謝および栄養障害	高脂血症	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)
	食欲減退	3 (0.6)	3 (0.7)	1 (0.3)	0 (0.0)	0 (0.0)	6 (1.3)
	食欲亢進	7 (1.5)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)	9 (1.9)
	体液貯留	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	痛風	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	低カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	糖尿病	3 (0.6)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
	肥満	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	2 (0.4)
内分泌障害	甲状腺機能低下症	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	2 (0.4)
	高プロラクチン血症	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	2 (0.4)
皮膚および皮下組織障害	ざ瘡様皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	そう痒症	3 (0.6)	0 (0.0)	1 (0.3)	1 (0.4)	0 (0.0)	5 (1.1)
	そう痒性皮疹	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	乾癬	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	光線過敏性反応	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	紅斑	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	脂漏性皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
皮膚および皮下組織障害	湿疹	2 (0.5)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.8)
	寝汗	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	水疱	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	接触性皮膚炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	多汗症	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
	発疹	6 (1.6)	3 (0.9)	0 (0.0)	0 (0.0)	1 (0.4)	9 (2.4)
	斑状丘疹状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	斑状出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	皮膚乾燥	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	嵌入爪	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	蕁麻疹	0 (0.0)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.8)
免疫系障害	季節性アレルギー	1 (0.3)	0 (0.0)	2 (0.7)	0 (0.0)	0 (0.0)	3 (0.8)
	食物アレルギー	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)
	動物アレルギー	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	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)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
皮膚および皮下組織障害	湿疹	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)	0 (0.0)	0 (0.0)	0 (0.0)
	水疱	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)	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)
	発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状丘疹状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	皮膚乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嵌入爪	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蕁麻疹	0 (0.0)	0 (0.0)	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 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	食物アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	動物アレルギー	0 (0.0)	0 (0.0)	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）	基底細胞癌	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL <=3 MONTHS (N=464) n (%)	TOTAL 3-6 MONTHS (N=421) n (%)	TOTAL 6-9 MONTHS (N=370) n (%)	TOTAL 9-12 MONTHS (N=281) n (%)	TOTAL >12 MONTHS (N=245) n (%)	TOTAL TOTAL (N=464) n (%)
皮膚および皮下組織障害	湿疹	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.6)
	寝汗	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	水疱	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	接触性皮膚炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	多汗症	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)
	発疹	6 (1.3)	3 (0.7)	0 (0.0)	0 (0.0)	1 (0.4)	9 (1.9)
	斑状丘疹状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	斑状出血	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	皮膚乾燥	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	嵌入爪	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	蕁麻疹	0 (0.0)	3 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)
免疫系障害	季節性アレルギー	1 (0.2)	1 (0.2)	2 (0.5)	0 (0.0)	0 (0.0)	4 (0.9)
	食物アレルギー	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)
	動物アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	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 (0.3)	0 (0.0)	0 (0.0)	1 (0.2)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) 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）	子宮平滑筋腫	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	脂肪腫	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	乳癌	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	皮膚の新生物	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	扁平上皮癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.3)
	肛門性器疣贅	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
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)	0 (0.0)	2 (0.9)	2 (0.5)
	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)	0 (0.0)	2 (0.9)	2 (0.5)
	グリコヘモグロビン増加	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	ビタミンＤ減少	0 (0.0)	1 (0.3)	0 (0.0)	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)	1 (0.4)	0 (0.0)	1 (0.3)
	肝機能検査値上昇	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	肝酵素上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
	血圧上昇	2 (0.5)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	4 (1.1)
	血圧低下	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) 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）	子宮平滑筋腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脂肪腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乳癌	0 (0.0)	0 (0.0)	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)	0 (0.0)
	扁平上皮癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門性器疣贅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	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)
	ビタミンＤ減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	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)	0 (0.0)	0 (0.0)
	血圧低下	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		TOTAL					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) 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）	子宮平滑筋腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	脂肪腫	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	乳癌	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	皮膚の新生物	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	扁平上皮癌	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	肛門性器疣贅	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
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)	0 (0.0)	2 (0.8)	2 (0.4)
	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)	0 (0.0)	2 (0.8)	2 (0.4)
	グリコヘモグロビン増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	ビタミンＤ減少	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	ヘリコバクター検査陽性	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.2)
	肝機能検査値上昇	1 (0.2)	0 (0.0)	0 (0.0)	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 (0.4)	1 (0.2)
	血圧上昇	2 (0.4)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
	血圧低下	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		DE NOVO					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=379) n (%)	3-6 MONTHS (N=345) n (%)	6-9 MONTHS (N=298) n (%)	9-12 MONTHS (N=257) n (%)	>12 MONTHS (N=230) n (%)	TOTAL (N=379) n (%)
臨床検査	血中クレアチンホスホキナーゼ増加	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.3)	5 (1.3)
	血中コレステロール増加	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	血中トリグリセリド増加	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	血中ブドウ糖増加	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.8)
	血中プロラクチン増加	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	血中尿酸増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
	心雑音	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	心拍数増加	1 (0.3)	1 (0.3)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.8)
	体重減少	3 (0.8)	4 (1.2)	2 (0.7)	1 (0.4)	1 (0.4)	11 (2.9)
	体重増加	20 (5.3)	20 (5.8)	3 (1.0)	2 (0.8)	0 (0.0)	45 (11.9)
	尿中ブドウ糖陽性	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	尿中血陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.3)
	尿中白血球陽性	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.5)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

CT-8.2.4.5
Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		ROLLOVER					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=85) n (%)	3-6 MONTHS (N=76) n (%)	6-9 MONTHS (N=72) n (%)	9-12 MONTHS (N=24) n (%)	>12 MONTHS (N=15) n (%)	TOTAL (N=85) n (%)
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)
	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)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	血中プロラクチン増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中尿酸増加	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	心拍数増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	体重増加	1 (1.2)	4 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	5 (5.9)
	尿中ブドウ糖陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中白血球陽性	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 PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

表 2.7.4.7-62　　初回発現時期別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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CT-8.2.4.5

Incidence of Treatment-emergent Adverse Events in Phase C by System Organ Class and MedDRA Preferred Term
Started within Certain Time Period after First Injection in Phase C
(Phase C Safety Sample)

		TOTAL					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=3 MONTHS (N=464) n (%)	3-6 MONTHS (N=421) n (%)	6-9 MONTHS (N=370) n (%)	9-12 MONTHS (N=281) n (%)	>12 MONTHS (N=245) n (%)	TOTAL (N=464) n (%)
臨床検査	血中クレアチンホスホキナーゼ増加	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.2)	5 (1.1)
	血中コレステロール増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血中トリグリセリド増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血中ブドウ糖増加	2 (0.4)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	3 (0.6)
	血中プロラクチン増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血中尿酸増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	心雑音	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	心拍数増加	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	3 (0.6)
	体重減少	4 (0.9)	4 (1.0)	2 (0.5)	1 (0.4)	1 (0.4)	12 (2.6)
	体重増加	21 (4.5)	24 (5.7)	3 (0.8)	2 (0.7)	0 (0.0)	50 (10.8)
	尿中ブドウ糖陽性	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	尿中血陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.2)
	尿中白血球陽性	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)

NOTE: ALL ADVERSE EVENTS STARTED AFTER FIRST INJECTION IN PHASE C 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: ADAE22A.LIS, RUN: [redacted]20[redacted] 15:42; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J¥ADAE22.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　CT-8.2.4.5　FINAL

＜資料番号 5.3.5.2-01：CT-8.2.4.5＞

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	DE NOVO (N=379) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	DAYS NOT RECOV. n (%)
感染症および寄生虫症	気管支炎	5 (1.3)	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	蜂巣炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	膀胱炎	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳感染	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	毛包炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せつ	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	1 (0.3)	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	9 (2.4)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	歯肉炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	帯状疱疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感染	1 (0.3)	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	6 (1.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	腎感染	1 (0.3)	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	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下気道感染	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	32 (8.4)	7 (1.8)	4 (1.1)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	4 (1.1)
	外耳炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	0 (0.0)	0 (0.0)	1 (0.3)	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 OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	歯周炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	咽頭炎	3	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	レンサ球菌性咽頭炎	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	毛巣嚢胞	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肺炎	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	マイコプラズマ性肺炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎盂腎炎	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	副鼻腔炎	3	(0.8)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮下組織膿瘍	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯膿瘍	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道感染	16	(4.2)	5	(1.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿路感染	7	(1.8)	4	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ウイルス性上気道感染	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯感染	1	(0.3)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	白癬感染	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ダニ皮膚炎	0	(0.0)	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰膣真菌感染	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口腔ヘルペス	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ノロウイルス性胃腸炎	1	(0.3)	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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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）	基底細胞癌	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	乳癌	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂肪腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	皮膚の新生物	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	扁平上皮癌	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	子宮平滑筋腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	肛門性器疣贅	0	(0.0)	1	(0.3)	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	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
免疫系障害	動物アレルギー	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食物アレルギー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	季節性アレルギー	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
内分泌障害	高プロラクチン血症	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	甲状腺機能低下症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
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)	1	(0.3)	0	(0.0)	3	(0.8)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	体液貯留	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	耐糖能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.3)
	高血糖	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	低カリウム血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	食欲亢進	1	(0.3)	2	(0.5)	1	(0.3)	0	(0.0)	3	(0.8)	5	(1.3)	0	(0.0)	4	(1.1)
	肥満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	食欲減退	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	1	(0.3)
	高脂血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	過小食	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	3	(0.8)
精神障害	異常な夢	0	(0.0)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	急性ストレス反応	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	攻撃性	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	激越	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(1.8)
	広場恐怖症	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	9	(2.4)	3	(0.8)	2	(0.5)	5	(1.3)	5	(1.3)	1	(0.3)	0	(0.0)	18	(4.7)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	注意喚起行動	1	(0.3)	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	2	(0.5)	3	(0.8)	5	(1.3)	2	(0.5)	1	(0.3)	2	(0.5)	0	(0.0)	3	(0.8)
	情動鈍麻	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	抑うつ気分	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	うつ病	4	(1.1)	8	(2.1)	5	(1.3)	3	(0.8)	1	(0.3)	2	(0.5)	0	(0.0)	3	(0.8)
	不快気分	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	感情の貧困	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	軽躁	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.3)
	不眠症	8	(2.1)	7	(1.8)	6	(1.6)	3	(0.8)	0	(0.0)	4	(1.1)	0	(0.0)	21	(5.5)
	故意の自傷行為	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	易刺激性	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	1	(0.3)
	躁病	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	気分変化	1	(0.3)	1	(0.3)	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)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪夢	0	(0.0)	2	(0.5)	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)	1	(0.3)
	妄想症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)

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表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	落ち着きのなさ	4	(1.1)	2	(0.5)	1	(0.3)	2	(0.5)	2	(0.5)	0	(0.0)	1	(0.3)	11	(2.9)
	睡眠障害	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	社会逃避行動	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺念慮	6	(1.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺企図	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	抑うつ症状	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	双極性障害	1	(0.3)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	1	(0.3)
	異常行動	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自傷行動	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	早朝覚醒型不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
神経系障害	アカシジア	1	(0.3)	4	(1.1)	8	(2.1)	9	(2.4)	4	(1.1)	7	(1.8)	2	(0.5)	25	(6.6)
	失語症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	自律神経失調	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	運動緩慢	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注意力障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
	浮動性めまい	4	(1.1)	1	(0.3)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	2	(0.5)
	体位性めまい	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.1)
	よだれ	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	構語障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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.

FILE: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	味覚異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	ジスキネジア	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	2	(0.5)
	ジストニア	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	錐体外路障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.1)	0	(0.0)	7	(1.8)
	頭痛	18	(4.7)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	運動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	過眠症	1	(0.3)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	企図振戦	0	(0.0)	1	(0.3)	1	(0.3)	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	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)
	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)	0	(0.0)
	片頭痛	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	パーキンソニズム	0	(0.0)	0	(0.0)	2	(0.5)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	坐骨神経痛	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	鎮静	4	(1.1)	2	(0.5)	2	(0.5)	1	(0.3)	1	(0.3)	3	(0.8)	0	(0.0)	4	(1.1)
	感覚障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	副鼻腔炎に伴う頭痛	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	6	(1.6)	3	(0.8)	2	(0.5)	1	(0.3)	3	(0.8)	0	(0.0)	0	(0.0)	5	(1.3)
	失神	1	(0.3)	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)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	振戦	4	(1.1)	2	(0.5)	5	(1.3)	2	(0.5)	0	(0.0)	3	(0.8)	0	(0.0)	11	(2.9)
	眉間反射異常	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	下肢静止不能症候群	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.8)
	微細運動機能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
眼障害	眼瞼痙攣	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	糖尿病性白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	霧視	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注視麻痺	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	瞬目過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
耳および迷路障害	耳痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	回転性めまい	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
心臓障害	急性心筋梗塞	1	(0.3)	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)	1	(0.3)
	心停止	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.3)
	動悸	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	プリンツメタル狭心症	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頻脈	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)
	潮紅	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	起立性低血圧	3	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
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)
	慢性閉塞性肺疾患	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咳嗽	6	(1.6)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽喉乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	0	(0.0)	1	(0.3)
	鼻出血	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	しゃっくり	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	低酸素症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	肺障害	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻閉	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	鼻乾燥	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸膜炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻漏	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽喉絞扼感	1	(0.3)	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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5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
呼吸器、胸郭および縦隔障害	アレルギー性副鼻腔炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道の炎症	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口腔咽頭痛	5	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)
胃腸障害	腹部不快感	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腹部膨満	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腹痛	1	(0.3)	1	(0.3)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	上腹部痛	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)
	慢性胃炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	4	(1.1)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	3	(0.8)
	齲歯	2	(0.5)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	下痢	15	(4.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	口内乾燥	1	(0.3)	0	(0.0)	2	(0.5)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	2	(0.5)
	消化不良	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	嚥下障害	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腸炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胃炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	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)	0	(0.0)	1	(0.3)
	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)

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.

FILE: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	痔核	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.3)
	悪心	11	(2.9)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	歯周病	1	(0.3)	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)	1	(0.3)	3	(0.8)	0	(0.0)	2	(0.5)	6	(1.6)	0	(0.0)	2	(0.5)
	歯の知覚過敏	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
	歯の脱落	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯痛	7	(1.8)	1	(0.3)	5	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	嘔吐	9	(2.4)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心窩部不快感	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)
肝胆道系障害	胆嚢炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	急性胆嚢炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	水疱	0	(0.0)	1	(0.3)	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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
皮膚および皮下組織障害	皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	ざ瘡様皮膚炎	1	(0.3)	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	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	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)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	斑状出血	0	(0.0)	1	(0.3)	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)	1	(0.3)	1	(0.3)	1	(0.3)	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)
	多汗症	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)
	嵌入爪	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	光線過敏性反応	1	(0.3)	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	4	(1.1)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	乾癬	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	4	(1.1)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)
	斑状皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	斑状丘疹状皮疹	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	そう痒性皮疹	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂漏性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	蕁麻疹	1	(0.3)	0	(0.0)	1	(0.3)	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	関節痛	2	(0.5)	3	(0.8)	3	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	2	(0.5)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	背部痛	6	(1.6)	1	(0.3)	2	(0.5)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	外骨腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	鼡径部痛	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋固縮	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋痙縮	1	(0.3)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	筋攣縮	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	頚部痛	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨端症	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨壊死	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢痛	3	(0.8)	3	(0.8)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	滑液嚢腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	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)
	腱炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)
	筋緊張	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	椎間板突出	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	筋骨格硬直	3	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	3	(0.8)

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	項部硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	椎間板障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	関節過伸展	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	関節不安定	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
腎および尿路障害	血尿	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿意切迫	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎結石症	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	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)	1	(0.3)
	頻尿	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	蛋白尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	尿失禁	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿管結石症	0	(0.0)	0	(0.0)	1	(0.3)	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	無月経	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	良性前立腺肥大症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	性器発疹	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経遅延	1	(0.3)	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)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	不正子宮出血	1	(0.3)	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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FILE: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
生殖系および乳房障害	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)	1	(0.3)
	性機能不全	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰腟乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	勃起不全	0	(0.0)	0	(0.0)	3	(0.8)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
先天性、家族性および遺伝性障害	多発性脂腺嚢腫	1	(0.3)	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	無菌膿瘍	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	無力症	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	胸部不快感	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸痛	4	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	嚢胞	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疲労	3	(0.8)	2	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	3	(0.8)	1	(0.3)	5	(1.3)
	異常感	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歩行障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	インフルエンザ様疾患	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注射部位内出血	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位紅斑	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位硬結	1	(0.3)	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 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	注射部位腫瘤	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位疼痛	32	(8.4)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	倦怠感	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	末梢性浮腫	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	発熱	5	(1.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口渇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注射部位腫脹	3	(0.8)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	小結節	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	非心臓性胸痛	0	(0.0)	1	(0.3)	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	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	0	(0.0)	1	(0.3)	1	(0.3)
	血中クレアチンホスホキナーゼ増加	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	血中ブドウ糖増加	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	血圧低下	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
臨床検査	血圧上昇	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	血中プロラクチン減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	血中プロラクチン増加	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中トリグリセリド増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	血中尿酸増加	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	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)	0	(0.0)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)
	尿中ブドウ糖陽性	0	(0.0)	1	(0.3)	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)	1	(0.3)
	尿中血陽性	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心拍数増加	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	体重減少	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	9	(2.4)
	体重増加	0	(0.0)	0	(0.0)	2	(0.5)	5	(1.3)	2	(0.5)	11	(2.9)	2	(0.5)	34	(9.0)
	尿中白血球陽性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
	起立血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	肝酵素上昇	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	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)	0	(0.0)	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)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)

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(Phase C Safety Sample)

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傷害、中毒および処置合併症	足関節部骨折	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	節足動物咬傷	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	凍瘡	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	転倒	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	裂傷	3	(0.8)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	靭帯捻挫	1	(0.3)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.1)
	ストレス骨折	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肉離れ	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節損傷	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)
	胸部損傷	1	(0.3)	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	処置による疼痛	3	(0.8)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	皮膚擦過傷	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
TOTAL1)		32	(8.4)	19	(5.0)	32	(8.4)	15	(4.0)	10	(2.6)	28	(7.4)	9	(2.4)	178	(47.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	気管支炎	2	(2.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	蜂巣炎	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	膀胱炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	耳感染	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	毛包炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	せつ	1	(1.2)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯肉炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	単純ヘルペス	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	帯状疱疹	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	インフルエンザ	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	下気道感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻咽頭炎	6	(7.1)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	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)
	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)

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表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	歯周炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽頭炎	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)
	毛巣嚢胞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	マイコプラズマ性肺炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎盂腎炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	副鼻腔炎	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮下組織膿瘍	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯膿瘍	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道感染	1	(1.2)	1	(1.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	白癬感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ダニ皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰膣真菌感染	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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）	基底細胞癌	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	乳癌	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂肪腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮膚の新生物	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	扁平上皮癌	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	子宮平滑筋腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肛門性器疣贅	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)
免疫系障害	動物アレルギー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食物アレルギー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	季節性アレルギー	0	(0.0)	0	(0.0)	1	(1.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	甲状腺機能低下症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	1	(1.2)

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代謝および栄養障害	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)	0	(0.0)	0	(0.0)	1	(1.2)
	体液貯留	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	耐糖能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	痛風	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	低カリウム血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食欲亢進	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肥満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	過小食	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)
精神障害	異常な夢	0	(0.0)	1	(1.2)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	急性ストレス反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	激越	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	広場恐怖症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	1	(1.2)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	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)

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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¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)		15-28DAYS n (%)		29-56DAYS n (%)		57-84DAYS n (%)		85-112DAYS n (%)		113-336DAYS n (%)		337<= DAYS n (%)		NOT RECOV. n (%)	
精神障害	注意喚起行動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	情動鈍麻	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	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)
	不快気分	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	感情の貧困	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	衝動行為	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)
	不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)
	故意の自傷行為	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	躁病	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	気分変化	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	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)
	妄想症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	落ち着きのなさ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	自殺念慮	1	(1.2)	0	(0.0)	1	(1.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	抑うつ症状	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	双極性障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	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)
	異常行動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自傷行動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	早朝覚醒型不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
神経系障害	アカシジア	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	5	(5.9)
	失語症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自律神経失調	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	注意力障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	浮動性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	体位性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	よだれ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)

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(Phase C Safety Sample)

		ROLLOVER (N=85)													
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神経系障害	味覚異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(1.2)
	ジストニア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	錐体外路障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頭痛	3	(3.5)	1	(1.2)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	運動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	企図振戦	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	精神的機能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	パーキンソニズム	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	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)
	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)
	感覚障害	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	副鼻腔炎に伴う頭痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)

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(Phase C Safety Sample)

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神経系障害	振戦	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	眉間反射異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	微細運動機能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
眼障害	眼瞼痙攣	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	糖尿病性白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	注視麻痺	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	瞬目過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
耳および迷路障害	耳痛	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	回転性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	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)
	心停止	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心筋梗塞	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	動悸	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)	0	(0.0)
	頻脈	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	1	(1.2)
	潮紅	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血腫	0	(0.0)	1	(1.2)	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)	0	(0.0)	1	(1.2)
	起立性低血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	1	(1.2)
	慢性閉塞性肺疾患	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	咽喉乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	呼吸困難	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	しゃっくり	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	低酸素症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肺障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻閉	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)
	胸膜炎	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻漏	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽喉絞扼感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
呼吸器、胸郭および縦隔障害	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)	1	(1.2)
	上気道の炎症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	咽頭反射亢進	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
胃腸障害	腹部不快感	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	腹痛	1	(1.2)	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)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	慢性胃炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	便秘	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	齲歯	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	下痢	2	(2.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	嚥下障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	胃炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	消化器痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血便排泄	1	(1.2)	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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(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	痔核	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	過敏性腸症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪心	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯周病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	流涎過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	口内炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯の脱落	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)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	嘔吐	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心窩部不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口の錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
肝胆道系障害	胆嚢炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	急性胆嚢炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	0	(0.0)	0	(0.0)
	水疱	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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		ROLLOVER (N=85)													
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皮膚および皮下組織障害	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)
	ざ瘡様皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	接触性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	斑状出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	紅斑	1	(1.2)	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)
	嵌入爪	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	光線過敏性反応	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	乾癬	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	斑状皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	斑状丘疹状皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	そう痒性皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂漏性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	蕁麻疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	0	(0.0)	0	(0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	背部痛	2	(2.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
	外骨腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼡径部痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋固縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	筋骨格痛	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	1	(1.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨端症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨壊死	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢痛	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	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)	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)	1	(1.2)	0	(0.0)	0	(0.0)
	腱炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	筋緊張	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	椎間板突出	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)	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 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	項部硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	椎間板障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節過伸展	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節不安定	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	0	(0.0)	0	(0.0)
	尿意切迫	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)
	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)
	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)
	蛋白尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿失禁	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿管結石症	1	(1.2)	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	無月経	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	良性前立腺肥大症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	性器発疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経遅延	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	不正子宮出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
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生殖系および乳房障害	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)
	性機能不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰腟乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	勃起不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	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	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	無菌膿瘍	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	胸部不快感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	疲労	1	(1.2)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(1.2)
	異常感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歩行障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	インフルエンザ様疾患	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位紅斑	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位硬結	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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(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	注射部位腫瘤	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発熱	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口渇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	小結節	0	(0.0)	0	(0.0)	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)	1	(1.2)	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	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)
	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)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血圧低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
臨床検査	血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中プロラクチン減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中プロラクチン増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中トリグリセリド増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中尿酸増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心雑音	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿中ブドウ糖陽性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	尿中血陽性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心拍数増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	1	(1.2)
	体重増加	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(5.9)
	尿中白血球陽性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	起立血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝酵素上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)	0	(0.0)	0	(0.0)
	肝機能検査値上昇	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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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
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)	0 (0.0)	0 (0.0)
	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)
	凍瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靭帯捻挫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
	ストレス骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	0 (0.0)	0 (0.0)	1 (1.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢損傷	0 (0.0)	0 (0.0)	1 (1.2)	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)
	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)
	処置による疼痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		9 (10.6)	9 (10.6)	5 (5.9)	1 (1.2)	0 (0.0)	5 (5.9)	0 (0.0)	22 (25.9)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
感染症および寄生虫症	気管支炎	7 (1.5)	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	蜂巣炎	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	膀胱炎	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳感染	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	毛包炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せつ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	1 (0.2)	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	9 (1.9)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	歯肉炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	帯状疱疹	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感染	1 (0.2)	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	6 (1.3)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	腎感染	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下気道感染	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	38 (8.2)	8 (1.7)	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	5 (1.1)
	外耳炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
感染症および寄生虫症	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	咽頭炎	3 (0.6)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	毛巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	マイコプラズマ性肺炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎盂腎炎	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	3 (0.6)	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮下組織膿瘍	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	2 (0.4)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	17 (3.7)	6 (1.3)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	7 (1.5)	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	1 (0.2)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白癬感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	0 (0.0)	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰膣真菌感染	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ノロウイルス性胃腸炎	1 (0.2)	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 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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）	基底細胞癌	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	乳癌	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂肪腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	皮膚の新生物	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	扁平上皮癌	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	子宮平滑筋腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	肛門性器疣贅	0	(0.0)	1	(0.2)	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	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
免疫系障害	動物アレルギー	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	食物アレルギー	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	季節性アレルギー	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	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)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	2	(0.4)
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)	1	(0.2)	0	(0.0)	4	(0.9)

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FILE: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	体液貯留	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	耐糖能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	痛風	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	高血糖	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	低カリウム血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	食欲亢進	1	(0.2)	2	(0.4)	1	(0.2)	0	(0.0)	3	(0.6)	5	(1.1)	0	(0.0)	4	(0.9)
	肥満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)
	食欲減退	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.2)	1	(0.2)
	高脂血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	過小食	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	3	(0.6)
精神障害	異常な夢	0	(0.0)	3	(0.6)	0	(0.0)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	急性ストレス反応	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	攻撃性	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	激越	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	7	(1.5)
	広場恐怖症	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	10	(2.2)	4	(0.9)	2	(0.4)	5	(1.1)	5	(1.1)	1	(0.2)	0	(0.0)	19	(4.1)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
精神障害	注意喚起行動	1 (0.2)	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	2 (0.4)	3 (0.6)	5 (1.1)	2 (0.4)	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	情動鈍麻	0 (0.0)	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	抑うつ気分	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	4 (0.9)	8 (1.7)	5 (1.1)	3 (0.6)	1 (0.2)	2 (0.4)	0 (0.0)	3 (0.6)
	不快気分	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	衝動行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	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)	1 (0.2)
	不眠症	8 (1.7)	7 (1.5)	6 (1.3)	3 (0.6)	0 (0.0)	4 (0.9)	0 (0.0)	23 (5.0)
	故意の自傷行為	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	リビドー減退	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	1 (0.2)
	躁病	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	気分変化	1 (0.2)	1 (0.2)	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)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	0 (0.0)	2 (0.4)	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)	1 (0.2)
	妄想症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	落ち着きのなさ	4	(0.9)	2	(0.4)	1	(0.2)	2	(0.4)	2	(0.4)	0	(0.0)	1	(0.2)	11	(2.4)
	睡眠障害	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	社会逃避行動	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺念慮	7	(1.5)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自殺企図	3	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	抑うつ症状	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	双極性障害	1	(0.2)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.2)
	異常行動	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	自傷行動	3	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	早朝覚醒型不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
神経系障害	アカシジア	1	(0.2)	4	(0.9)	10	(2.2)	9	(1.9)	4	(0.9)	8	(1.7)	2	(0.4)	30	(6.5)
	失語症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	自律神経失調	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	運動緩慢	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注意力障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)
	浮動性めまい	4	(0.9)	1	(0.2)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	2	(0.4)
	体位性めまい	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.9)
	よだれ	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	構語障害	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
神経系障害	味覚異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	ジスキネジア	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	3 (0.6)
	ジストニア	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	2 (0.4)
	錐体外路障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)	0 (0.0)	7 (1.5)
	頭痛	21 (4.5)	2 (0.4)	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	3 (0.6)
	運動過多	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	過眠症	1 (0.2)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	企図振戦	0 (0.0)	1 (0.2)	1 (0.2)	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 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)
	精神的機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	片頭痛	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	0 (0.0)	0 (0.0)	2 (0.4)	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	坐骨神経痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	鎮静	4 (0.9)	2 (0.4)	2 (0.4)	1 (0.2)	1 (0.2)	3 (0.6)	0 (0.0)	4 (0.9)
	感覚障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	6 (1.3)	3 (0.6)	2 (0.4)	1 (0.2)	3 (0.6)	0 (0.0)	0 (0.0)	5 (1.1)
	失神	1 (0.2)	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)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	2 (0.4)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
神経系障害	振戦	4 (0.9)	3 (0.6)	5 (1.1)	2 (0.4)	0 (0.0)	3 (0.6)	0 (0.0)	11 (2.4)
	眉間反射異常	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.6)
	微細運動機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注視麻痺	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	耳痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	回転性めまい	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
心臓障害	急性心筋梗塞	1 (0.2)	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)	1 (0.2)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	動悸	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	プリンツメタル狭心症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
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)	1	(0.2)
	潮紅	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血腫	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	3	(0.6)
	起立性低血圧	3	(0.6)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.2)
	慢性閉塞性肺疾患	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咳嗽	6	(1.3)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽喉乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	0	(0.0)	1	(0.2)
	鼻出血	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	しゃっくり	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	低酸素症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	肺障害	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻閉	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	鼻乾燥	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸膜炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻漏	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	咽喉絞扼感	1	(0.2)	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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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
呼吸器、胸郭および縦隔障害	アレルギー性副鼻腔炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	上気道の炎症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔咽頭痛	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭反射亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
胃腸障害	腹部不快感	2 (0.4)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹部膨満	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	2 (0.4)	1 (0.2)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	上腹部痛	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	便秘	4 (0.9)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	3 (0.6)
	齲歯	2 (0.4)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	下痢	17 (3.7)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	口内乾燥	1 (0.2)	0 (0.0)	2 (0.4)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)
	消化不良	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	嚥下障害	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腸炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	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)	1 (0.2)
	消化器痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血便排泄	1 (0.2)	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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(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	痔核	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	過敏性腸症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	悪心	11	(2.4)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	歯周病	1	(0.2)	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)	1	(0.2)	3	(0.6)	0	(0.0)	2	(0.4)	6	(1.3)	0	(0.0)	2	(0.4)
	歯の知覚過敏	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌障害	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)
	歯の脱落	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歯痛	7	(1.5)	2	(0.4)	5	(1.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	嘔吐	10	(2.2)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	心窩部不快感	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)
肝胆道系障害	胆嚢炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	急性胆嚢炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	水疱	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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.

FILE: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
皮膚および皮下組織障害	皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	ざ瘡様皮膚炎	1	(0.2)	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	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	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)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	斑状出血	0	(0.0)	1	(0.2)	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)	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)
	紅斑	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	多汗症	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)
	嵌入爪	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	光線過敏性反応	1	(0.2)	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	4	(0.9)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	乾癬	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	発疹	4	(0.9)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	斑状皮疹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	斑状丘疹状皮疹	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	そう痒性皮疹	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	脂漏性皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	蕁麻疹	1	(0.2)	0	(0.0)	1	(0.2)	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	関節痛	2	(0.4)	3	(0.6)	3	(0.6)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	2	(0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	背部痛	8	(1.7)	1	(0.2)	2	(0.4)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	2	(0.4)
	外骨腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	鼡径部痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋固縮	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋痙縮	1	(0.2)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	筋攣縮	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	3	(0.6)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	3	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	頚部痛	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨端症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	骨壊死	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢痛	4	(0.9)	3	(0.6)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	滑液嚢腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	顎関節症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	腱炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)
	筋緊張	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	椎間板突出	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	筋骨格硬直	3	(0.6)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	3	(0.6)

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表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
筋骨格系および結合組織障害	項部硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	椎間板障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	関節過伸展	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	関節不安定	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿意切迫	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腎結石症	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	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)	1	(0.2)
	頻尿	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	蛋白尿	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	尿失禁	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿管結石症	1	(0.2)	0	(0.0)	1	(0.2)	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	無月経	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	良性前立腺肥大症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	性器発疹	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経遅延	1	(0.2)	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)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	不正子宮出血	1	(0.2)	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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		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
生殖系および乳房障害	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)	1	(0.2)
	性機能不全	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰腟乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	勃起不全	0	(0.0)	0	(0.0)	3	(0.6)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
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)	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	無菌膿瘍	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	無力症	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
	胸部不快感	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸痛	4	(0.9)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	嚢胞	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	疲労	4	(0.9)	3	(0.6)	2	(0.4)	0	(0.0)	0	(0.0)	4	(0.9)	1	(0.2)	6	(1.3)
	異常感	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歩行障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	インフルエンザ様疾患	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注射部位内出血	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位紅斑	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位硬結	1	(0.2)	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 OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
一般・全身障害および投与部位の状態	注射部位腫瘤	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	32 (6.9)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	末梢性浮腫	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	発熱	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位腫脹	3 (0.6)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	小結節	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	非心臓性胸痛	0 (0.0)	2 (0.4)	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	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	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)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	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)	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	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	血中ブドウ糖増加	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	血圧低下	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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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-5-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
臨床検査	血圧上昇	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	2 (0.4)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血中プロラクチン増加	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	血中尿酸増加	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	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)	0 (0.0)	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)
	尿中ブドウ糖陽性	0 (0.0)	1 (0.2)	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)	1 (0.2)
	尿中血陽性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.4)
	体重減少	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	10 (2.2)
	体重増加	0 (0.0)	0 (0.0)	3 (0.6)	5 (1.1)	2 (0.4)	11 (2.4)	2 (0.4)	39 (8.4)
	尿中白血球陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
	起立血圧上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	肝酵素上昇	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	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)	0 (0.0)	0 (0.0)	1 (0.2)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-5-252　FINAL

表 2.7.4.7-63　　持続期間別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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5.3.5.3-5-252

Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C

(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
傷害、中毒および処置合併症	足関節部骨折	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	節足動物咬傷	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	凍瘡	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	転倒	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	裂傷	3	(0.6)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	靭帯捻挫	1	(0.2)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.1)
	ストレス骨折	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肉離れ	1	(0.2)	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	関節損傷	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	四肢損傷	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	胸部損傷	1	(0.2)	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	処置による疼痛	4	(0.9)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	皮膚擦過傷	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
TOTAL1)		41	(8.8)	28	(6.0)	37	(8.0)	16	(3.4)	10	(2.2)	33	(7.1)	9	(1.9)	200	(43.1)

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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　　5.3.5.3-5-252　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-5-252 より作成＞

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C

(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
感染症および寄生虫症	気管支炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	ウイルス性胃腸炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	鼻咽頭炎	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	上気道感染	1	(0.3)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	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）	脂肪腫	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
免疫系障害	季節性アレルギー	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
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)	0	(0.0)	2	(0.5)
	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)	0	(0.0)	0	(0.0)	0	(0.0)
	耐糖能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	高血糖	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	食欲亢進	1	(0.3)	2	(0.5)	1	(0.3)	0	(0.0)	3	(0.8)	5	(1.3)	0	(0.0)	4	(1.1)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
代謝および栄養障害	肥満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	食欲減退	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)
	過小食	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)
精神障害	異常な夢	0	(0.0)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	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)	0	(0.0)	6	(1.6)
	広場恐怖症	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	4	(1.1)	3	(0.8)	1	(0.3)	3	(0.8)	2	(0.5)	1	(0.3)	0	(0.0)	9	(2.4)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	双極１型障害	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	2	(0.5)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	抑うつ気分	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	うつ病	3	(0.8)	5	(1.3)	2	(0.5)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	感情の貧困	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	軽躁	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	衝動行為	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.3)
	不眠症	3	(0.8)	4	(1.1)	3	(0.8)	1	(0.3)	0	(0.0)	2	(0.5)	0	(0.0)	16	(4.2)
	故意の自傷行為	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	易刺激性	0	(0.0)	1	(0.3)	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.

FILE: ADAE24BC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)
	躁病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	神経過敏	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	悪夢	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	妄想症	1	(0.3)	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	2	(0.5)	2	(0.5)	1	(0.3)	2	(0.5)	2	(0.5)	0	(0.0)	1	(0.3)	11	(2.9)
	睡眠障害	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	自殺念慮	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	抑うつ症状	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	1	(0.3)
	異常行動	1	(0.3)	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	1	(0.3)	4	(1.1)	8	(2.1)	9	(2.4)	4	(1.1)	7	(1.8)	2	(0.5)	25	(6.6)
	運動緩慢	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注意力障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
	浮動性めまい	2	(0.5)	0	(0.0)	2	(0.5)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
	体位性めまい	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.1)
	よだれ	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	構語障害	0	(0.0)	1	(0.3)	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)	1	(0.3)	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	2	(0.5)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	ジストニア	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	錐体外路障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(1.1)	0	(0.0)	7	(1.8)
	頭痛	7	(1.8)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	運動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	過眠症	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	企図振戦	0	(0.0)	0	(0.0)	1	(0.3)	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	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	1	(0.3)
	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)	0	(0.0)
	片頭痛	1	(0.3)	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)	2	(0.5)	1	(0.3)	0	(0.0)	1	(0.3)	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)	1	(0.3)
	鎮静	4	(1.1)	2	(0.5)	2	(0.5)	1	(0.3)	1	(0.3)	3	(0.8)	0	(0.0)	3	(0.8)
	感覚障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	5	(1.3)	2	(0.5)	2	(0.5)	1	(0.3)	3	(0.8)	0	(0.0)	0	(0.0)	4	(1.1)
	遅発性ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)
	振戦	4	(1.1)	2	(0.5)	4	(1.1)	2	(0.5)	0	(0.0)	3	(0.8)	0	(0.0)	9	(2.4)
	眉間反射異常	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	下肢静止不能症候群	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.8)
眼障害	眼瞼痙攣	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	糖尿病性白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
眼障害	霧視	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注視麻痺	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	瞬目過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)
耳および迷路障害	回転性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
心臓障害	動悸	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頻脈	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
血管障害	高血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	起立性低血圧	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
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)	0	(0.0)	1	(0.3)	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)	0	(0.0)	1	(0.3)
	鼻出血	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	しゃっくり	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻乾燥	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腹痛	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)	0	(0.0)	2	(0.5)

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5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	下痢	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内乾燥	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	2	(0.5)
	消化不良	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	嚥下障害	0	(0.0)	0	(0.0)	1	(0.3)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	悪心	4	(1.1)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	流涎過多	0	(0.0)	1	(0.3)	3	(0.8)	0	(0.0)	2	(0.5)	6	(1.6)	0	(0.0)	1	(0.3)
	歯の知覚過敏	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌障害	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)
	嘔吐	1	(0.3)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)
肝胆道系障害	肝炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	ざ瘡様皮膚炎	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.3)
	多汗症	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)	0	(0.0)	0	(0.0)
	寝汗	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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FILE: ADAE24BC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
皮膚および皮下組織障害	発疹	2	(0.5)	2	(0.5)	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	関節痛	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋固縮	0	(0.0)	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	筋攣縮	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)
	四肢痛	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.3)	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)
	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)	1	(0.3)
	筋緊張	1	(0.3)	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	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	項部硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
腎および尿路障害	血尿	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿失禁	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
生殖系および乳房障害	無月経	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
生殖系および乳房障害	月経障害	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経遅延	1	(0.3)	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)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
	不正子宮出血	1	(0.3)	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)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰腟乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	勃起不全	0	(0.0)	0	(0.0)	3	(0.8)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	無力症	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	疲労	3	(0.8)	2	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	2	(0.5)	1	(0.3)	5	(1.3)
	異常感	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歩行障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注射部位内出血	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位紅斑	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位硬結	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫瘤	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位疼痛	31	(8.2)	1	(0.3)	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)	1	(0.3)
	末梢性浮腫	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C

(Phase C Safety Sample)

		DE NOVO (N=379)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	発熱	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口渇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	注射部位腫脹	3	(0.8)	1	(0.3)	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)	1	(0.3)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	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)	1	(0.3)	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)	0	(0.0)	0	(0.0)	1	(0.3)
	血中クレアチンホスホキナーゼ増加	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	血中ブドウ糖増加	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	血圧低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)
	血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	血中プロラクチン減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	1	(0.3)
	尿中血陽性	1	(0.3)	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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Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
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		DE NOVO (N=379)													
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臨床検査	心拍数増加	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.5)
	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)	4	(1.1)
	体重増加	0	(0.0)	0	(0.0)	2	(0.5)	3	(0.8)	2	(0.5)	11	(2.9)	2	(0.5)	29	(7.7)
	起立血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
	肝酵素上昇	0	(0.0)	0	(0.0)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.3)
傷害、中毒および処置合併症	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)	1	(0.3)
TOTAL1)		15	(4.0)	12	(3.2)	21	(5.5)	12	(3.2)	9	(2.4)	31	(8.2)	8	(2.1)	129	(34.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	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)
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)	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)	0	(0.0)	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)	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)	0	(0.0)	1	(1.2)
	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)	0	(0.0)	0	(0.0)	1	(1.2)
	耐糖能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	食欲亢進	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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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　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
代謝および栄養障害	肥満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	過小食	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)
精神障害	異常な夢	0	(0.0)	1	(1.2)	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)	0	(0.0)	0	(0.0)
	広場恐怖症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)
	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)
	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)
	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)
	感情の貧困	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	衝動行為	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)
	不眠症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)
	故意の自傷行為	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)

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5.3.5.3-7-252

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(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
精神障害	リビドー減退	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	躁病	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	妄想症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	落ち着きのなさ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	自殺念慮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	抑うつ症状	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)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	異常行動	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
神経系障害	アカシジア	0	(0.0)	0	(0.0)	2	(2.4)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	5	(5.9)
	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)
	注意力障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	浮動性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	体位性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	よだれ	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)

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5.3.5.3-7-252

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(Phase C Safety Sample)

		ROLLOVER (N=85)													
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神経系障害	ジストニア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	錐体外路障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頭痛	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	運動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	企図振戦	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	精神的機能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	パーキンソニズム	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	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)
	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)
	感覚障害	0	(0.0)	1	(1.2)	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)	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)
	振戦	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	眉間反射異常	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
眼障害	眼瞼痙攣	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	糖尿病性白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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眼障害	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)
	注視麻痺	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	瞬目過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
耳および迷路障害	回転性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
心臓障害	動悸	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頻脈	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
血管障害	高血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	起立性低血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	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)	0	(0.0)	0	(0.0)
	鼻出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	しゃっくり	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)
	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)
	便秘	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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	下痢	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	嚥下障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	悪心	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	舌障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	嘔吐	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口の錯感覚	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
肝胆道系障害	肝炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	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)
	ざ瘡様皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	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)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C

(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. 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)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋固縮	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)
	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)
	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)
	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)
	顎関節症候群	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	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)
	筋緊張	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	項部硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	0	(0.0)	0	(0.0)
	尿失禁	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
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)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
生殖系および乳房障害	月経障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	月経遅延	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	不正子宮出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	性機能不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	外陰腟乾燥	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	勃起不全	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	疲労	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	1	(1.2)
	異常感	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	歩行障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位内出血	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位紅斑	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位硬結	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫瘤	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位疼痛	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	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)

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(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	発熱	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口渇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	注射部位腫脹	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
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)	0	(0.0)	0	(0.0)	0	(0.0)	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)
	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)	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)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血圧低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中プロラクチン減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	血中トリグリセリド増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿中血陽性	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
臨床検査	心拍数増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)
	体重増加	0	(0.0)	0	(0.0)	1	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(5.9)
	起立血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝酵素上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
傷害、中毒および処置合併症	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)
TOTAL1)		2	(2.4)	3	(3.5)	2	(2.4)	1	(1.2)	0	(0.0)	5	(5.9)	0	(0.0)	13	(15.3)

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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 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=464) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
感染症および寄生虫症	気管支炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	ウイルス性胃腸炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	鼻咽頭炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	1 (0.2)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	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）	脂肪腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)	1 (0.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
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)	0 (0.0)	3 (0.6)
	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)	0 (0.0)	0 (0.0)	1 (0.2)
	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	高血糖	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	食欲亢進	1 (0.2)	2 (0.4)	1 (0.2)	0 (0.0)	3 (0.6)	5 (1.1)	0 (0.0)	4 (0.9)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
代謝および栄養障害	肥満	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)
	食欲減退	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)
	過小食	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)
精神障害	異常な夢	0	(0.0)	3	(0.6)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	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)	0	(0.0)	6	(1.3)
	広場恐怖症	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	不安	4	(0.9)	4	(0.9)	1	(0.2)	3	(0.6)	2	(0.4)	1	(0.2)	0	(0.0)	9	(1.9)
	無感情	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	双極１型障害	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	2	(0.4)
	歯ぎしり	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)
	抑うつ気分	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	うつ病	3	(0.6)	5	(1.1)	2	(0.4)	2	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.4)
	感情の貧困	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	軽躁	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	衝動行為	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	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)	1	(0.2)
	不眠症	3	(0.6)	4	(0.9)	3	(0.6)	1	(0.2)	0	(0.0)	2	(0.4)	0	(0.0)	18	(3.9)
	故意の自傷行為	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	易刺激性	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	TOTAL (N=464) <=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	DAYS NOT RECOV. n (%)
精神障害	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	神経過敏	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	1 (0.2)	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	2 (0.4)	2 (0.4)	1 (0.2)	2 (0.4)	2 (0.4)	0 (0.0)	1 (0.2)	11 (2.4)
	睡眠障害	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)
	自殺念慮	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	0 (0.0)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	1 (0.2)
	異常行動	1 (0.2)	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	1 (0.2)	4 (0.9)	10 (2.2)	9 (1.9)	4 (0.9)	8 (1.7)	2 (0.4)	30 (6.5)
	運動緩慢	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注意力障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)
	浮動性めまい	2 (0.4)	0 (0.0)	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.2)
	体位性めまい	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	4 (0.9)
	よだれ	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	0 (0.0)	1 (0.2)	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)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	1 (0.2)	0 (0.0)	2 (0.4)

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表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
神経系障害	ジストニア	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.4)
	錐体外路障害	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.9)	0	(0.0)	7	(1.5)
	頭痛	7	(1.5)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	運動過多	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	過眠症	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	企図振戦	0	(0.0)	0	(0.0)	1	(0.2)	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	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	1	(0.2)
	精神的機能障害	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	片頭痛	1	(0.2)	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)	2	(0.4)	2	(0.4)	0	(0.0)	1	(0.2)	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)	1	(0.2)
	鎮静	4	(0.9)	2	(0.4)	2	(0.4)	1	(0.2)	1	(0.2)	3	(0.6)	0	(0.0)	3	(0.6)
	感覚障害	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	傾眠	5	(1.1)	2	(0.4)	2	(0.4)	1	(0.2)	3	(0.6)	0	(0.0)	0	(0.0)	4	(0.9)
	遅発性ジスキネジア	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.4)
	振戦	4	(0.9)	3	(0.6)	4	(0.9)	2	(0.4)	0	(0.0)	3	(0.6)	0	(0.0)	9	(1.9)
	眉間反射異常	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	下肢静止不能症候群	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.6)
眼障害	眼瞼痙攣	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	糖尿病性白内障	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
眼障害	霧視	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注視麻痺	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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	回転性めまい	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
心臓障害	動悸	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	頻脈	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)
血管障害	高血圧	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	起立性低血圧	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
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)	0	(0.0)	1	(0.2)	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)	0	(0.0)	1	(0.2)
	鼻出血	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	しゃっくり	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	鼻乾燥	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	腹痛	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	便秘	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.4)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
胃腸障害	下痢	2	(0.4)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口内乾燥	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	2	(0.4)
	消化不良	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	嚥下障害	0	(0.0)	0	(0.0)	1	(0.2)	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)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	悪心	4	(0.9)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	流涎過多	0	(0.0)	1	(0.2)	3	(0.6)	0	(0.0)	2	(0.4)	6	(1.3)	0	(0.0)	1	(0.2)
	歯の知覚過敏	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	舌障害	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)
	嘔吐	1	(0.2)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	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)	0	(0.0)
肝胆道系障害	肝炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	高ビリルビン血症	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	皮膚炎	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	ざ瘡様皮膚炎	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	1	(0.2)
	多汗症	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	0	(0.0)
	寝汗	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
皮膚および皮下組織障害	発疹	2	(0.4)	2	(0.4)	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	関節痛	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	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)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	筋萎縮	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋固縮	0	(0.0)	1	(0.2)	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)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	筋攣縮	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)
	筋骨格痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	筋肉痛	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)
	四肢痛	1	(0.2)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)	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)	1	(0.2)
	筋緊張	1	(0.2)	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	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)
	項部硬直	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	尿失禁	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
生殖系および乳房障害	無月経	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n (%)	15-28DAYS n (%)	29-56DAYS n (%)	57-84DAYS n (%)	85-112DAYS n (%)	113-336DAYS n (%)	337<= DAYS n (%)	NOT RECOV. n (%)
生殖系および乳房障害	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.2)	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)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	勃起不全	0 (0.0)	0 (0.0)	3 (0.6)	1 (0.2)	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	無菌膿瘍	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	疲労	4 (0.9)	2 (0.4)	2 (0.4)	0 (0.0)	0 (0.0)	3 (0.6)	1 (0.2)	6 (1.3)
	異常感	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	注射部位内出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	31 (6.7)	1 (0.2)	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)	1 (0.2)
	末梢性浮腫	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
一般・全身障害および投与部位の状態	発熱	2	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	口渇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	注射部位腫脹	3	(0.6)	1	(0.2)	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)	1	(0.2)	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	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	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)	1	(0.2)	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)	0	(0.0)	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)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血中ブドウ糖増加	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血圧低下	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血中プロラクチン減少	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	血中トリグリセリド増加	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	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)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.2)
	尿中血陽性	1	(0.2)	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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SUBJECTS ARE COUNTED ONCE PER TERM FOR OTHER THAN RECOVERED/LONGEST DURATION 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: ADAE24BC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

表 2.7.4.7-64　　持続期間別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

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5.3.5.3-7-252

Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Duration in Phase C

(Phase C Safety Sample)

		TOTAL (N=464)													
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	<=14DAYS n	(%)	15-28DAYS n	(%)	29-56DAYS n	(%)	57-84DAYS n	(%)	85-112DAYS n	(%)	113-336DAYS n	(%)	337<= DAYS n	(%)	NOT RECOV. n	(%)
臨床検査	心拍数増加	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)
	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)	4	(0.9)
	体重増加	0	(0.0)	0	(0.0)	3	(0.6)	3	(0.6)	2	(0.4)	11	(2.4)	2	(0.4)	34	(7.3)
	起立血圧上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
	肝酵素上昇	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
	肝機能検査値上昇	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)
傷害、中毒および処置合併症	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)	1	(0.2)
TOTAL1)		17	(3.7)	15	(3.2)	23	(5.0)	13	(2.8)	9	(1.9)	36	(7.8)	8	(1.7)	142	(30.6)

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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¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-7-252　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-7-252 より作成＞

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	気管支炎	8 (2.1)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	膀胱炎	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳感染	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	毛包炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せつ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	10 (2.6)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	単純ヘルペス	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	帯状疱疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	6 (1.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	腎感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	限局性感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下気道感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	44 (11.6)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	外耳炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯周炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	4 (1.1)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	毛巣嚢胞	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	マイコプラズマ性肺炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎盂腎炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮下組織膿瘍	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	22 (5.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	11 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白癬感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	外陰膣真菌感染	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔ヘルペス	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ノロウイルス性胃腸炎	1 (0.3)	0 (0.0)	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）	基底細胞癌	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乳癌	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脂肪腫	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚の新生物	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	扁平上皮癌	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮平滑筋腫	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門性器疣贅	1 (0.3)	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	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	動物アレルギー	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食物アレルギー	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	季節性アレルギー	2 (0.5)	0 (0.0)	1 (0.3)	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
内分泌障害	高プロラクチン血症	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	甲状腺機能低下症	0 (0.0)	0 (0.0)	2 (0.5)	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)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体液貯留	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	耐糖能障害	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痛風	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	高血糖	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	低カリウム血症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	12 (3.2)	1 (0.3)	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)
	肥満	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	6 (1.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	1 (0.3)	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)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	異常な夢	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性ストレス反応	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	攻撃性	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	1 (0.3)	4 (1.1)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	25 (6.6)	3 (0.8)	14 (3.7)	0 (0.0)	1 (0.3)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	注意喚起行動	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	15 (4.0)	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	情動鈍麻	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	23 (6.1)	0 (0.0)	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)
	不快気分	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	28 (7.4)	3 (0.8)	17 (4.5)	0 (0.0)	1 (0.3)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	故意の自傷行為	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	3 (0.8)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気分変化	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パニック発作	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	12 (3.2)	0 (0.0)	9 (2.4)	0 (0.0)	2 (0.5)	0 (0.0)
	睡眠障害	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	社会逃避行動	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺企図	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自傷行動	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	早朝覚醒型不眠症	0 (0.0)	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	35 (9.2)	7 (1.8)	16 (4.2)	1 (0.3)	1 (0.3)	0 (0.0)
	失語症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	自律神経失調	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動緩慢	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	8 (2.1)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	1 (0.3)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	味覚異常	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	4 (1.1)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	5 (1.3)	2 (0.5)	4 (1.1)	0 (0.0)	1 (0.3)	0 (0.0)
	頭痛	21 (5.5)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	運動過多	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
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神経系障害	企図振戦	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錯感覚	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	13 (3.4)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	15 (4.0)	0 (0.0)	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
	失神	1 (0.3)	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 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	16 (4.2)	3 (0.8)	8 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	微細運動機能障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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(Phase C Safety Sample)

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眼障害	糖尿病性白内障	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	回転性めまい	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	急性心筋梗塞	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	徐脈	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
	心筋梗塞	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	動悸	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	プリンツメタル狭心症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	2 (0.5)	1 (0.3)	1 (0.3)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	潮紅	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
血管障害	高血圧	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	起立性低血圧	4 (1.1)	0 (0.0)	1 (0.3)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性閉塞性肺疾患	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咳嗽	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉乾燥	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	呼吸困難	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻出血	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	低酸素症	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻閉	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸膜炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻漏	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉絞扼感	1 (0.3)	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	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道の炎症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
呼吸器、胸郭および縦隔障害	口腔咽頭痛	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭反射亢進	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部不快感	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹部膨満	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	4 (1.1)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	上腹部痛	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性胃炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	7 (1.8)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	4 (1.1)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	17 (4.5)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	6 (1.6)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腸炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃炎	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	消化器痛	0 (0.0)	0 (0.0)	1 (0.3)	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)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	痔核	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	過敏性腸症候群	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	14 (3.7)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯周病	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	12 (3.2)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の脱落	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	13 (3.4)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	11 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心窩部不快感	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	胆嚢炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	急性胆嚢炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
皮膚および皮下組織障害	嚢胞性ざ瘡	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	水疱	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ざ瘡様皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	接触性皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状出血	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	湿疹	3 (0.8)	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)
	多汗症	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嵌入爪	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	寝汗	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	光線過敏性反応	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒症	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乾癬	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	8 (2.1)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状皮疹	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状丘疹状皮疹	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒性皮疹	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
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皮膚および皮下組織障害	脂漏性皮膚炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	蕁麻疹	3 (0.8)	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	関節痛	9 (2.4)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	11 (2.9)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	外骨腫	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼠径部痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節硬直	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋萎縮	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋固縮	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	筋攣縮	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頚部痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨端症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨壊死	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	8 (2.1)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	滑液嚢腫	0 (0.0)	0 (0.0)	1 (0.3)	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	顎関節症候群	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腱炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板突出	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	5 (1.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節過伸展	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節不安定	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	血尿	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿意切迫	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎結石症	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蛋白尿	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿管結石症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
生殖系および乳房障害	無月経	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	良性前立腺肥大症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	性器発疹	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟乾燥	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	4 (1.1)	0 (0.0)	1 (0.3)	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 (0.3)	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	無菌膿瘍	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	胸部不快感	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸痛	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚢胞	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	11 (2.9)	1 (0.3)	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)
	異常感	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ様疾患	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	34 (9.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	5 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	小結節	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	非心臓性胸痛	1 (0.3)	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	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	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	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中コレステロール増加	1 (0.3)	1 (0.3)	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	3 (0.8)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	2 (0.5)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン増加	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中尿酸増加	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心雑音	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
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臨床検査	γ－グルタミルトランスフェラーゼ増加	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中ブドウ糖陽性	1 (0.3)	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)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	3 (0.8)	2 (0.5)	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	22 (5.8)	5 (1.3)	29 (7.7)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中白血球陽性	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立血圧上昇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	1 (0.3)	0 (0.0)	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)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘリコバクター検査陽性	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	足関節部骨折	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	節足動物咬傷	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	凍瘡	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	転倒	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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傷害、中毒および処置合併症	裂傷	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靱帯捻挫	4 (1.1)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	ストレス骨折	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	挫傷	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	1 (0.3)	0 (0.0)	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)	0 (0.0)
	胸部損傷	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	5 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚擦過傷	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		145 (38.3)	28 (7.4)	141 (37.2)	1 (0.3)	7 (1.8)	1 (0.3)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	気管支炎	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	膀胱炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳感染	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	毛包炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せつ	1 (1.2)	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)	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)	0 (0.0)	0 (0.0)
	歯肉炎	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	帯状疱疹	1 (1.2)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	感染	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	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎感染	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)
	下気道感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	7 (8.2)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	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)
	歯周炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	1 (1.2)	0 (0.0)	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)	0 (0.0)
	毛巣嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	マイコプラズマ性肺炎	0 (0.0)	0 (0.0)	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)	0 (0.0)
	鼻炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮下組織膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	2 (2.4)	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)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白癬感染	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	外陰膣真菌感染	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)	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)	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）	基底細胞癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乳癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脂肪腫	0 (0.0)	0 (0.0)	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)	0 (0.0)
	扁平上皮癌	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮平滑筋腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門性器疣贅	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)
免疫系障害	動物アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食物アレルギー	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	季節性アレルギー	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)
	甲状腺機能低下症	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	糖尿病	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	体液貯留	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痛風	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)	0 (0.0)	0 (0.0)	0 (0.0)
	低カリウム血症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肥満	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)	0 (0.0)	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)
	過小食	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)

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5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	異常な夢	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性ストレス反応	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)
	広場恐怖症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	2 (2.4)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意喚起行動	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)	0 (0.0)	0 (0.0)	0 (0.0)
	情動鈍麻	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)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不快気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	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	0 (0.0)	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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(Phase C Safety Sample)

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精神障害	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気分変化	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)	0 (0.0)	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)
	パニック発作	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	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)	0 (0.0)	0 (0.0)	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)
	社会逃避行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	2 (2.4)	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)	0 (0.0)	0 (0.0)
	抑うつ症状	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自傷行動	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	早朝覚醒型不眠症	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	3 (3.5)	3 (3.5)	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
	失語症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自律神経失調	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	注意力障害	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)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	味覚異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	1 (1.2)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	5 (5.9)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	運動過多	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)	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)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	企図振戦	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)
	精神的機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	錯感覚	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	1 (1.2)	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)
	感覚障害	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	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	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)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	微細運動機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
眼障害	糖尿病性白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	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	耳痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	回転性めまい	0 (0.0)	0 (0.0)	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)	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)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心筋梗塞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	動悸	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	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)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	潮紅	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
血管障害	高血圧	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	起立性低血圧	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)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性閉塞性肺疾患	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)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉乾燥	0 (0.0)	0 (0.0)	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)
	鼻出血	0 (0.0)	0 (0.0)	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)	0 (0.0)
	低酸素症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻閉	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸膜炎	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻漏	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉絞扼感	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)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道の炎症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)
	咽頭反射亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部不快感	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上腹部痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性胃炎	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	胃炎	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)	0 (0.0)	0 (0.0)
	消化器痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血便排泄	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	痔核	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過敏性腸症候群	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)	0 (0.0)	0 (0.0)
	歯周病	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)	0 (0.0)	0 (0.0)	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)
	口内炎	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	歯の脱落	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心窩部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	胆嚢炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性胆嚢炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	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 WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)	0 (0.0)
	水疱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	ざ瘡様皮膚炎	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)	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)	0 (0.0)
	斑状出血	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	1 (1.2)	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)
	嵌入爪	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)	0 (0.0)	0 (0.0)	0 (0.0)
	光線過敏性反応	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)	0 (0.0)	0 (0.0)	0 (0.0)
	乾癬	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)	0 (0.0)	0 (0.0)
	斑状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状丘疹状皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒性皮疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
皮膚および皮下組織障害	脂漏性皮膚炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蕁麻疹	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	関節痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	2 (2.4)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	外骨腫	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胤径部痛	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	筋萎縮	0 (0.0)	0 (0.0)	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)	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	1 (1.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	骨端症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨壊死	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	1 (1.2)	0 (0.0)	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)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	顎関節症候群	1 (1.2)	0 (0.0)	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)	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)
	筋緊張	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板突出	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板障害	0 (0.0)	0 (0.0)	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)	0 (0.0)
	関節不安定	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	血尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿意切迫	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)
	夜間頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蛋白尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿管結石症	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)	0 (0.0)
	良性前立腺肥大症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性器発疹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	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)
	不正子宮出血	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)	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)
	外陰腟乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	1 (1.2)	0 (0.0)	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	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	無菌膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
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(Phase C Safety Sample)

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一般・全身障害および投与部位の状態	胸部不快感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚢胞	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	3 (3.5)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ様疾患	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	小結節	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	非心臓性胸痛	1 (1.2)	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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)	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)	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)	0 (0.0)	0 (0.0)
	血圧低下	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)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中尿酸増加	0 (0.0)	0 (0.0)	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)	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　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中ブドウ糖陽性	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)
	尿中血陽性	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	体重減少	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	1 (1.2)	1 (1.2)	4 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中白血球陽性	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	肝酵素上昇	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	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)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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)
	節足動物咬傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	凍瘡	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)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
傷害、中毒および処置合併症	裂傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靱帯捻挫	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ストレス骨折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	1 (1.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢損傷	1 (1.2)	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 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚擦過傷	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		29 (34.1)	5 (5.9)	16 (18.8)	1 (1.2)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	気管支炎	10 (2.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蜂巣炎	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	膀胱炎	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	耳感染	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	毛包炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	せつ	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃腸炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	10 (2.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯肉炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	単純ヘルペス	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	帯状疱疹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	麦粒腫	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ	7 (1.5)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	腎感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	限局性感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	51 (11.0)	1 (0.2)	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	外耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	中耳炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯周炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭炎	5 (1.1)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	レンサ球菌性咽頭炎	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	毛巣嚢胞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	マイコプラズマ性肺炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎盂腎炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎	6 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮下組織膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯膿瘍	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	24 (5.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	11 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性上気道感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯感染	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	白癬感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ダニ皮膚炎	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	外陰膣真菌感染	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口腔ヘルペス	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ノロウイルス性胃腸炎	1 (0.2)	0 (0.0)	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）	基底細胞癌	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乳癌	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脂肪腫	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚の新生物	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	扁平上皮癌	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	子宮平滑筋腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肛門性器疣贅	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	動物アレルギー	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食物アレルギー	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	季節性アレルギー	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
内分泌障害	高プロラクチン血症	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	甲状腺機能低下症	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
代謝および栄養障害	糖尿病	1 (0.2)	0 (0.0)	3 (0.6)	1 (0.2)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	体液貯留	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	耐糖能障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	痛風	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	高血糖	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	低カリウム血症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	12 (2.6)	1 (0.2)	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)
	肥満	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	6 (1.3)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	高脂血症	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	1 (0.2)	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)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	異常な夢	6 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	急性ストレス反応	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	攻撃性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	1 (0.2)	4 (0.9)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	27 (5.8)	3 (0.6)	15 (3.2)	0 (0.0)	1 (0.2)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	注意喚起行動	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	15 (3.2)	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	情動鈍麻	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.2)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	23 (5.0)	0 (0.0)	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)
	不快気分	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	初期不眠症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	28 (6.0)	5 (1.1)	17 (3.7)	0 (0.0)	1 (0.2)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	故意の自傷行為	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	3 (0.6)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	気分変化	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パニック発作	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	12 (2.6)	0 (0.0)	9 (1.9)	0 (0.0)	2 (0.4)	0 (0.0)
	睡眠障害	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	社会逃避行動	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	9 (1.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺企図	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自傷行動	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

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(Phase C Safety Sample)

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精神障害	早朝覚醒型不眠症	0 (0.0)	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	38 (8.2)	10 (2.2)	18 (3.9)	1 (0.2)	1 (0.2)	0 (0.0)
	失語症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	自律神経失調	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動緩慢	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注意力障害	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	8 (1.7)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	1 (0.2)	1 (0.2)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	味覚異常	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	5 (1.1)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	2 (0.4)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	5 (1.1)	2 (0.4)	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)
	頭痛	26 (5.6)	1 (0.2)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	運動過多	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚鈍麻	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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神経系障害	企図振戦	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	2 (0.4)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	坐骨神経痛	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	13 (2.8)	0 (0.0)	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	副鼻腔炎に伴う頭痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	傾眠	15 (3.2)	0 (0.0)	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)
	失神	1 (0.2)	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 (0.2)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	17 (3.7)	3 (0.6)	8 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.2)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	微細運動機能障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	4 (0.9)	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
眼障害	糖尿病性白内障	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	耳痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	回転性めまい	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	急性心筋梗塞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	徐脈	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	心停止	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)
	心筋梗塞	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	動悸	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	プリンツメタル狭心症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	2 (0.4)	1 (0.2)	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	潮紅	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
血管障害	高血圧	1 (0.2)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	起立性低血圧	4 (0.9)	0 (0.0)	1 (0.2)	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)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性閉塞性肺疾患	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咳嗽	7 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉乾燥	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	呼吸困難	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻出血	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	低酸素症	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肺障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻閉	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸膜炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻漏	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽喉絞扼感	1 (0.2)	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	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道の炎症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
呼吸器、胸郭および縦隔障害	口腔咽頭痛	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	咽頭反射亢進	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部不快感	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹部膨満	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	5 (1.1)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	上腹部痛	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	慢性胃炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	7 (1.5)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	齲歯	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	19 (4.1)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	6 (1.3)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腸炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胃炎	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	胃食道逆流性疾患	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	消化器痛	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血便排泄	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	痔核	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	過敏性腸症候群	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	14 (3.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯周病	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	12 (2.6)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の脱落	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯痛	14 (3.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	嘔吐	12 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心窩部不快感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	胆嚢炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	急性胆嚢炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

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皮膚および皮下組織障害	嚢胞性ざ瘡	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	水疱	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ざ瘡様皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	接触性皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	湿疹	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	紅斑	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嵌入爪	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	寝汗	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	光線過敏性反応	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒症	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	乾癬	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	8 (1.7)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状皮疹	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	斑状丘疹状皮疹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	そう痒性皮疹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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(Phase C Safety Sample)

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皮膚および皮下組織障害	脂漏性皮膚炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	蕁麻疹	3 (0.6)	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	関節痛	9 (1.9)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	背部痛	13 (2.8)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	外骨腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胤径部痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節硬直	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋萎縮	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋固縮	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	筋攣縮	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頚部痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨端症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	骨壊死	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	9 (1.9)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	滑液嚢腫	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	顎関節症候群	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腱炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板突出	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	5 (1.1)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	椎間板障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節過伸展	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節不安定	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	血尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿意切迫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腎結石症	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	夜間頻尿	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻尿	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	蛋白尿	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿管結石症	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
生殖系および乳房障害	無月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	良性前立腺肥大症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	性器発疹	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	卵巣嚢胞	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	外陰腟乾燥	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	5 (1.1)	0 (0.0)	1 (0.2)	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 (0.2)	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	無菌膿瘍	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	胸部不快感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸痛	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚢胞	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	14 (3.0)	1 (0.2)	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)
	異常感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	インフルエンザ様疾患	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	34 (7.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疼痛	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-9-252　FINAL

表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-9-252
Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	小結節	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	非心臓性胸痛	2 (0.4)	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	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	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	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中コレステロール増加	1 (0.2)	1 (0.2)	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	3 (0.6)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	2 (0.4)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	2 (0.4)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中尿酸増加	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心雑音	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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(Phase C Safety Sample)

TOTAL (N=464)

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臨床検査	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)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中ブドウ糖陽性	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	1 (0.2)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	体重減少	3 (0.6)	2 (0.4)	8 (1.7)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	23 (5.0)	6 (1.3)	33 (7.1)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中白血球陽性	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立血圧上昇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	1 (0.2)	0 (0.0)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	ヘリコバクター検査陽性	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	足関節部骨折	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	節足動物咬傷	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	凍瘡	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	転倒	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-65　転帰別有害事象［長期投与試験の IM デポ剤維持治療期（Phase C）］

OPC14597　　60 OF 60

PROTOCOL 31-08-252

5.3.5.3-9-252

Incidence of Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome in Phase C

(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
傷害、中毒および処置合併症	裂傷	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	靱帯捻挫	4 (0.9)	1 (0.2)	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
	ストレス骨折	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肉離れ	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	挫傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢損傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	胸部損傷	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歯牙破折	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	処置による疼痛	6 (1.3)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚擦過傷	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		174 (37.5)	33 (7.1)	157 (33.8)	2 (0.4)	7 (1.5)	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 WORST OUTCOME 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: ADAE24CA.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-9-252　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-9-252 より作成＞

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	気管支炎	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	1 (0.3)	0 (0.0)	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）	脂肪腫	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	季節性アレルギー	1 (0.3)	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)	1 (0.3)	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)	2 (0.5)	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)	0 (0.0)
	耐糖能障害	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
代謝および栄養障害	高血糖	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	12 (3.2)	1 (0.3)	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)
	肥満	0 (0.0)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	1 (0.3)	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)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	異常な夢	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	0 (0.0)	3 (0.8)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	14 (3.7)	2 (0.5)	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	3 (0.8)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	13 (3.4)	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)
	感情の貧困	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	初期不眠症	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	13 (3.4)	2 (0.5)	13 (3.4)	0 (0.0)	1 (0.3)	0 (0.0)
	故意の自傷行為	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	10 (2.6)	0 (0.0)	9 (2.4)	0 (0.0)	2 (0.5)	0 (0.0)
	睡眠障害	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	1 (0.3)	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	35 (9.2)	7 (1.8)	16 (4.2)	1 (0.3)	1 (0.3)	0 (0.0)
	運動緩慢	2 (0.5)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	注意力障害	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	5 (1.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	1 (0.3)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	4 (1.1)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	5 (1.3)	2 (0.5)	4 (1.1)	0 (0.0)	1 (0.3)	0 (0.0)
	頭痛	8 (2.1)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動過多	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	企図振戦	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	4 (1.1)	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)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	13 (3.4)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	傾眠	13 (3.4)	0 (0.0)	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	1 (0.3)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	15 (4.0)	2 (0.5)	7 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.3)	0 (0.0)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性白内障	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	回転性めまい	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	動悸	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	2 (0.5)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	高血圧	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立性低血圧	2 (0.5)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
呼吸器、胸郭および縦隔障害	咽喉乾燥	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	呼吸困難	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻出血	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部膨満	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	3 (0.8)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	3 (0.8)	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	1 (0.3)	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)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	5 (1.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	12 (3.2)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	嘔吐	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	肝炎	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	1 (0.3)	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	嚢胞性ざ瘡	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ざ瘡様皮膚炎	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	寝汗	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	4 (1.1)	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	関節痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節硬直	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋萎縮	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋固縮	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME OF MULTIPLE OCCURRENCES OF A SPECIFIC MEDDRA PREFERRED TERM.
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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	筋攣縮	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	3 (0.8)	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)
	開口障害	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	2 (0.5)	0 (0.0)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	血尿	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	1 (0.3)	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	無月経	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
生殖系および乳房障害	外陰膣乾燥	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	4 (1.1)	0 (0.0)	1 (0.3)	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	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	10 (2.6)	1 (0.3)	3 (0.8)	0 (0.0)	1 (0.3)	0 (0.0)
	異常感	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	32 (8.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	4 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
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一般・全身障害および投与部位の状態	非心臓性胸痛	1 (0.3)	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	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	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	1 (0.3)	0 (0.0)	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)	1 (0.3)	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 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	1 (0.3)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	1 (0.3)	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	1 (0.3)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	1 (0.3)	2 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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5.3.5.3-11-252
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in Phase C
(Phase C Safety Sample)

		DE NOVO (N=379)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	体重減少	0 (0.0)	1 (0.3)	3 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	20 (5.3)	5 (1.3)	24 (6.3)	0 (0.0)	0 (0.0)	0 (0.0)
	起立血圧上昇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	歯牙破折	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		108 (28.5)	22 (5.8)	100 (26.4)	1 (0.3)	6 (1.6)	0 (0.0)

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Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL 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)	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)	0 (0.0)	0 (0.0)
	鼻咽頭炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	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)	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）	脂肪腫	0 (0.0)	0 (0.0)	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)	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)	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)	1 (1.2)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	0 (0.0)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	耐糖能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)
	食欲亢進	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肥満	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)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	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	異常な夢	1 (1.2)	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)
	広場恐怖症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	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)
	抑うつ気分	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	感情の貧困	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	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	0 (0.0)	2 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	故意の自傷行為	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	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)	0 (0.0)	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)
	妄想症	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)	0 (0.0)	0 (0.0)	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)
	自殺念慮	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	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)	0 (0.0)
	大うつ病	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	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	3 (3.5)	3 (3.5)	2 (2.4)	0 (0.0)	0 (0.0)	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)

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神経系障害	注意力障害	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)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	ジスキネジア	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頭痛	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動過多	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)	0 (0.0)	0 (0.0)	0 (0.0)
	企図振戦	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)
	精神的機能障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	パーキンソニズム	1 (1.2)	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)
	感覚障害	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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神経系障害	傾眠	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)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
眼障害	眼瞼痙攣	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性白内障	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	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	回転性めまい	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	動悸	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	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)	0 (0.0)	0 (0.0)
	起立性低血圧	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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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)	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)
	鼻出血	0 (0.0)	0 (0.0)	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)	0 (0.0)
	鼻乾燥	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	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)	0 (0.0)	0 (0.0)
	悪心	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)	0 (0.0)	0 (0.0)	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)
	舌障害	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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
胃腸障害	嘔吐	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	肝炎	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	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	嚢胞性ざ瘡	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	ざ瘡様皮膚炎	0 (0.0)	0 (0.0)	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)	0 (0.0)
	多汗症	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)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	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	関節痛	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)
	筋萎縮	0 (0.0)	0 (0.0)	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)	0 (0.0)
	筋痙縮	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 WORST OUTCOME 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　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
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)
	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	顎関節症候群	1 (1.2)	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)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	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)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	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	血尿	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	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	無月経	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	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)
	不正子宮出血	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)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
生殖系および乳房障害	外陰膣乾燥	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	1 (1.2)	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	無菌膿瘍	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	2 (2.4)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
	異常感	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	1 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	非心臓性胸痛	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	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	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)
	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)	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)	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)	0 (0.0)	0 (0.0)
	血圧低下	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)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)	0 (0.0)	0 (0.0)
	尿中血陽性	0 (0.0)	0 (0.0)	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)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		ROLLOVER (N=85)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	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	1 (1.2)	1 (1.2)	4 (4.7)	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)	0 (0.0)	0 (0.0)
	肝酵素上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	歯牙破折	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		13 (15.3)	5 (5.9)	7 (8.2)	1 (1.2)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
感染症および寄生虫症	気管支炎	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ウイルス性胃腸炎	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻咽頭炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	上気道感染	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿路感染	1 (0.2)	0 (0.0)	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）	脂肪腫	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
免疫系障害	季節性アレルギー	1 (0.2)	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)	1 (0.2)	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)	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)
	コントロール不良の糖尿病	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	耐糖能障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

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Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

TOTAL (N=464)

SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
代謝および栄養障害	高血糖	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲亢進	12 (2.6)	1 (0.2)	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)
	肥満	0 (0.0)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	食欲減退	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	過小食	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
精神障害	異常な夢	5 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	激越	0 (0.0)	3 (0.6)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	広場恐怖症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不安	15 (3.2)	2 (0.4)	7 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	無感情	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	双極１型障害	3 (0.6)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	歯ぎしり	1 (0.2)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ気分	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	うつ病	13 (2.8)	0 (0.0)	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)
	感情の貧困	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	軽躁	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	衝動行為	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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SUBJECTS ARE COUNTED ONCE PER TERM FOR WORST OUTCOME 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¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
精神障害	初期不眠症	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	不眠症	13 (2.8)	4 (0.9)	13 (2.8)	0 (0.0)	1 (0.2)	0 (0.0)
	故意の自傷行為	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	易刺激性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	リビドー減退	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	神経過敏	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	悪夢	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	妄想症	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	落ち着きのなさ	10 (2.2)	0 (0.0)	9 (1.9)	0 (0.0)	2 (0.4)	0 (0.0)
	睡眠障害	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	自殺念慮	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	抑うつ症状	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	双極性障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	大うつ病	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	異常行動	1 (0.2)	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	38 (8.2)	10 (2.2)	18 (3.9)	1 (0.2)	1 (0.2)	0 (0.0)
	運動緩慢	2 (0.4)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	注意力障害	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	浮動性めまい	5 (1.1)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	体位性めまい	1 (0.2)	1 (0.2)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	よだれ	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	構語障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ジスキネジア	5 (1.1)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	ジストニア	2 (0.4)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	錐体外路障害	5 (1.1)	2 (0.4)	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)
	頭痛	9 (1.9)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	運動過多	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	過眠症	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	企図振戦	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嗜眠	3 (0.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	精神的機能障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	片頭痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	パーキンソニズム	5 (1.1)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	鎮静	13 (2.8)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	感覚障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
神経系障害	傾眠	13 (2.8)	0 (0.0)	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
	遅発性ジスキネジア	1 (0.2)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	振戦	16 (3.4)	2 (0.4)	7 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
	眉間反射異常	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	下肢静止不能症候群	1 (0.2)	0 (0.0)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
眼障害	眼瞼痙攣	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	糖尿病性白内障	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	霧視	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	注視麻痺	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	瞬目過多	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
耳および迷路障害	回転性めまい	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	動悸	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	頻脈	2 (0.4)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
血管障害	高血圧	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立性低血圧	2 (0.4)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

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表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
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(Phase C Safety Sample)

		TOTAL (N=464)					
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呼吸器、胸郭および縦隔障害	咽喉乾燥	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	呼吸困難	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	しゃっくり	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	鼻乾燥	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
胃腸障害	腹部膨満	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	腹痛	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	便秘	3 (0.6)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	下痢	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口内乾燥	3 (0.6)	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	消化不良	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	嚥下障害	1 (0.2)	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)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	悪心	5 (1.1)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	流涎過多	12 (2.6)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	歯の知覚過敏	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	舌障害	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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胃腸障害	嘔吐	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口の錯感覚	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
肝胆道系障害	肝炎	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	高ビリルビン血症	1 (0.2)	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	嚢胞性ざ瘡	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	ざ瘡様皮膚炎	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	皮膚乾燥	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	多汗症	4 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	寝汗	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発疹	4 (0.9)	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	関節痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	関節硬直	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋萎縮	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋固縮	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋痙縮	1 (0.2)	0 (0.0)	1 (0.2)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
筋骨格系および結合組織障害	筋攣縮	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格痛	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋肉痛	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	四肢痛	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	顎関節症候群	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	開口障害	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋緊張	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	筋骨格硬直	2 (0.4)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
	項部硬直	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
腎および尿路障害	血尿	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿失禁	1 (0.2)	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	無月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経障害	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	月経遅延	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不規則月経	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	不正子宮出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	性機能不全	1 (0.2)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
生殖系および乳房障害	外陰膣乾燥	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	勃起不全	5 (1.1)	0 (0.0)	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	無力症	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	疲労	12 (2.6)	1 (0.2)	4 (0.9)	0 (0.0)	1 (0.2)	0 (0.0)
	異常感	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	歩行障害	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位内出血	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位紅斑	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位硬結	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫瘤	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位疼痛	32 (6.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	倦怠感	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	末梢性浮腫	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	発熱	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	口渇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	注射部位腫脹	4 (0.9)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
一般・全身障害および投与部位の状態	非心臓性胸痛	1 (0.2)	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	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	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	1 (0.2)	0 (0.0)	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)	1 (0.2)	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 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血中ブドウ糖増加	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧低下	1 (0.2)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血圧上昇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	血中プロラクチン減少	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
	血中トリグリセリド増加	0 (0.0)	1 (0.2)	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	1 (0.2)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	尿中血陽性	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心拍数増加	1 (0.2)	2 (0.4)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

表 2.7.4.7-66　　転帰別副作用［長期投与試験の IM デポ剤維持治療期（Phase C）］

5.3.5.3-11-252
Incidence of Potentially Drug-related Treatment-emergent Adverse Events by System Organ Class and MedDRA Preferred Term by Outcome
in Phase C
(Phase C Safety Sample)

		TOTAL (N=464)					
SYSTEM ORGAN CLASS	ADVERSE EVENT (MedDRA PREFERRED TERM)	RECOVERED/ RESOLVED n (%)	RECOVERING/ RESOLVING n (%)	NOT RECOVERED/ NOT RESOLVED n (%)	RECOVERED/ RESOLVED WITH SEQUELAE n (%)	UNKNOWN n (%)	FATAL n (%)
臨床検査	体重減少	0 (0.0)	1 (0.2)	3 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
	体重増加	21 (4.5)	6 (1.3)	28 (6.0)	0 (0.0)	0 (0.0)	0 (0.0)
	起立血圧上昇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝酵素上昇	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	肝機能検査値上昇	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
傷害、中毒および処置合併症	歯牙破折	0 (0.0)	0 (0.0)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
TOTAL1)		121 (26.1)	27 (5.8)	107 (23.1)	2 (0.4)	6 (1.3)	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 WORST OUTCOME 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: ADAE24CC.LIS, RUN: [redacted]20[redacted] 14:30; ANALYSIS DATASET CREATED: [redacted]20[redacted] 14:28
PROGRAM: C:¥OPC14597¥P3108252¥PROGRAM.DEV¥J2¥ADAE24.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　　5.3.5.3-11-252　FINAL

＜資料番号 5.3.5.3-01：5.3.5.3-11-252 より作成＞

表 2.7.4.7-67　器官別大分類別重篤な有害事象（死亡例を含む）［二重盲検試験の二重盲検期（Phase D）］

CT-8.5.1
Incidence of Serious Treatment-emergent Adverse Events 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	(%)
感染症および寄生虫症	0	(0.0)	1	(0.8)	1	(0.4)
精神障害	7	(5.3)	21	(15.8)	28	(10.6)
神経系障害	3	(2.3)	0	(0.0)	3	(1.1)
心臓障害	2	(1.5)	0	(0.0)	2	(0.8)
呼吸器、胸郭および縦隔障害	1	(0.8)	0	(0.0)	1	(0.4)
胃腸障害	1	(0.8)	1	(0.8)	2	(0.8)
生殖系および乳房障害	0	(0.0)	1	(0.8)	1	(0.4)
傷害、中毒および処置合併症	0	(0.0)	1	(0.8)	1	(0.4)
TOTAL1)	10	(7.6)	25	(18.8)	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 (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] 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-8.5.1　FINAL

＜資料番号 5.3.5.1-01：CT-8.5.1 より作成＞

表 2.7.4.7-68　重症度別重篤な有害事象（死亡例を含む）［二重盲検試験の二重盲検期（Phase D）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events 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 (%)
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)	1 (0.8)	0 (0.0)	1 (0.8)
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)	1 (0.8)	1 (0.8)
	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)
	双極１型障害	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)	0 (0.0)	2 (1.5)	1 (0.8)	3 (2.3)
	軽躁	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	躁病	0 (0.0)	1 (0.8)	1 (0.8)	2 (1.5)	0 (0.0)	5 (3.8)	5 (3.8)	10 (7.5)
	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)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	3 (2.3)	3 (2.3)
	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)	0 (0.0)	1 (0.8)	1 (0.8)	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)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	脳損傷	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
心臓障害	心房細動	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	心肺停止	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	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)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	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)

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] 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-8.5.3　FINAL

表 2.7.4.7-68　重症度別重篤な有害事象（死亡例を含む）［二重盲検試験の二重盲検期（Phase D）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events 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 (%)
感染症および寄生虫症	肺炎	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
精神障害	感情障害	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	攻撃性	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	双極１型障害	0 (0.0)	3 (1.1)	2 (0.8)	5 (1.9)
	軽躁	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	躁病	0 (0.0)	6 (2.3)	6 (2.3)	12 (4.5)
	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)	1 (0.4)	3 (1.1)	4 (1.5)
	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)	0 (0.0)	1 (0.4)	1 (0.4)
	一過性脳虚血発作	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	脳損傷	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
心臓障害	心房細動	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
	心肺停止	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
呼吸器、胸郭および縦隔障害	喘息	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	呼吸不全	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 (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2ADC.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-8.5.3　FINAL

表 2.7.4.7-68　重症度別重篤な有害事象（死亡例を含む）［二重盲検試験の二重盲検期（Phase D）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events 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 (%)
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)	1 (0.8)	1 (0.8)
	痔出血	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
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)	0 (0.0)	1 (0.8)	0 (0.0)	1 (0.8)
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)	0 (0.0)	1 (0.8)	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 (VERSION 19.0) PREFERRED TERM.

FILE: ADAE2ADC.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-8.5.3　FINAL

表 2.7.4.7-68　重症度別重篤な有害事象（死亡例を含む）［二重盲検試験の二重盲検期（Phase D）］

CT-8.5.3
Incidence of Serious Treatment-emergent Adverse Events 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 (%)
胃腸障害	潰瘍性大腸炎	0 (0.0)	0 (0.0)	1 (0.4)	1 (0.4)
	痔出血	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.4)
生殖系および乳房障害	骨盤癒着症	0 (0.0)	1 (0.4)	0 (0.0)	1 (0.4)
傷害、中毒および処置合併症	橈骨骨折	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: ADAE2ADC.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-8.5.3　FINAL

＜資料番号 5.3.5.1-01：CT-8.5.3 より作成＞

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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.	アカシジア*/AKATHESIA	神経系障害	20[redacted]-09-16	同年*-09-18	12	SEVERE
		[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]	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
		[redacted]	4[redacted]/M/OTHER	躁病*/MANIA	精神障害	20[redacted]-01-04	同年*-01-08	19	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]	1[redacted]/M/BLACK	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	20[redacted]-11-20 12:00	同年*-11-26 11:00	-23	SEVERE
		[redacted]	6[redacted]/M/CAUC.	双極１型障害*/EXACERBATION OF BIPOLAR MANIA	精神障害	20[redacted]-07-05 18:00	同年*-07-21 16:16	10	MODERATE
		[redacted]	3[redacted]/F/CAUC.	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-08-06	同年*-08-19	21	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: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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.	アカシジア*/AKATHESIA	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	大うつ病*/SEVERE DEPRESSION WITH PSYCHOSIS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/OTHER	躁病*/MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	双極性障害*/BIPOLAR AFFECTIVE DISORDER AGGRAVATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	1[redacted]/M/BLACK	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	双極１型障害*/EXACERBATION OF BIPOLAR MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	2[redacted]/M/BLACK	激越*/AGITATION	精神障害	20[redacted]-03-18 17:15	同年*-03-26 10:50	28	SEVERE
				躁病*/RELAPSE OF MANIC MOOD EPISODE	精神障害	20[redacted]-04-09 10:00	同年*-04-15 10:00	50	SEVERE
				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]	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
		[redacted]	4[redacted]/M/CAUC.	喘息*/ASTHMA, ACUTE EXACERBATION	呼吸器、胸郭および縦隔障害	20[redacted]-04-14	同年*-04-17	20	SEVERE
				喘息*/ASTHMA ATTACK	呼吸器、胸郭および縦隔障害	20[redacted]-05-05 05:00	ONGOING	41	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: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	2[redacted]/M/BLACK	激越*/AGITATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				躁病*/RELAPSE OF MANIC MOOD EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				躁病*/MANIA AGGRAVATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	脳血管発作*/SMALL STROKE	神経系障害	MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				双極１型障害*/BIPOLAR AFFECTIVE DISORDER TYPE I, DEPRESSED EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	喘息*/ASTHMA, ACUTE EXACERBATION	呼吸器、胸郭および縦隔障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				喘息*/ASTHMA ATTACK	呼吸器、胸郭および縦隔障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERING/ RESOLVING

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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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.	狭心症*/CARDIAC CHEST PAIN	心臓障害	20[redacted]-05-01	同年*-05-03	20	SEVERE
		[redacted]	3[redacted]/M/AM.IND.	幻聴*/INCREASED AUDITORY HALLUCINATIONS	精神障害	20[redacted]-04-13	同年*-04-15	-5	SEVERE
		[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
		[redacted]	6[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR MANIA	精神障害	20[redacted]-02-24	同年*-02-28	28	MODERATE
		[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]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-03-24 08:00	同年*-03-28 14:00	36	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

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: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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.	狭心症*/CARDIAC CHEST PAIN	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/AM.IND.	幻聴*/INCREASED AUDITORY HALLUCINATIONS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	NOT APPLICABLE	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	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]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	20[redacted]-06-19 15:00	同年*-06-27 11:00	23	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]	2[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-07-19 14:48	同年*-07-31 13:00	37	MODERATE
		[redacted]	5[redacted]/F/CAUC.	躁病*/MANIA DUE TO NONCOMPLIANCE	精神障害	20[redacted]-06-17	同年*-07-01	-22	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: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	2[redacted]/M/OTHER	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/BLACK	躁病*/MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	躁病*/MANIA DUE TO NONCOMPLIANCE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	NOT APPLICABLE	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.
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PROGRAM: C:¥OPC14597¥P3108250¥PROGRAM.DEV¥SAFETY_J¥ADAE1.SAS
OPDC, NEW DRUG APPLICATION, IND # 114,284　OPC14597　CT-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/ASIAN	双極１型障害*/BIPOLAR I DISORDER DEPRESSED WITH PSYCHOTIC FEATURES	精神障害	20[redacted]-09-06 09:00	同年*-10-22	22	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]	4[redacted]/F/ASIAN	抑うつ気分*/DEPRESSIVE MOOD	精神障害	20[redacted]-04-17	同年*-05-22	15	MILD
		[redacted]	2[redacted]/M/ASIAN	アカシジア*/AKATHISIA	神経系障害	20[redacted]-02-07 16:00	同年*-04-17 12:00	43	MODERATE
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME WORSENING	神経系障害	20[redacted]-02-07 16:00	同年*-04-17 12:00	43	MODERATE
				抑うつ気分*/DEPRESSIVE MOOD	精神障害	20[redacted]-02-07 16:00	同年*-04-17 12:00	43	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: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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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 A	ARIP 5-15MG	[redacted]	5[redacted]/F/ASIAN	双極１型障害*/BIPOLAR I DISORDER DEPRESSED WITH PSYCHOTIC FEATURES	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	アカシジア*/AGGRAVATION OF AKATHISIA	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/ASIAN	抑うつ気分*/DEPRESSIVE MOOD	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE INCREASED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/ASIAN	アカシジア*/AKATHISIA	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED RESOLVED/ WITH SEQUELAE
				錐体外路障害*/EXTRAPYRAMIDAL SYNDROME WORSENING	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED RESOLVED/ WITH SEQUELAE
				抑うつ気分*/DEPRESSIVE MOOD	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED RESOLVED/ WITH SEQUELAE

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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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]	4[redacted]/F/ASIAN	躁病*/INCREASED MANIC EPISODE	精神障害	20[redacted]-05-12	同年*-08-07	-28	MODERATE
		[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]	3[redacted]/F/CAUC.	食中毒*/FOOD POISONING	胃腸障害	20[redacted]-11-12	同年*-11-16	15	SEVERE
		[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]	3[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIA	精神障害	20[redacted]-04-03 10:00	同年*-04-07 15:00	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]	4[redacted]/M/CAUC.	心筋梗塞*/MYOCARDIAL INFARCTION	心臓障害	20[redacted]-03-04	同年*-03-04 05:45	15	SEVERE
		[redacted]	3[redacted]/M/CAUC.	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	20[redacted]-05-29	同年*-06-02	48	SEVERE

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2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	4[redacted]/F/ASIAN	躁病*/INCREASED MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/ASIAN	躁病*/MANIC EPISODE AGGRAVATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE B	ARIP 10-30MG	[redacted]	3[redacted]/F/CAUC.	食中毒*/FOOD POISONING	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	躁病*/MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	心筋梗塞*/MYOCARDIAL INFARCTION	心臓障害	DEATH	NOT LIKELY	DOSE NOT CHANGED	FATAL
		[redacted]	3[redacted]/M/CAUC.	双極性障害*/EXACERBATION OF BIPOLAR DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 10-30MG	[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]	3[redacted]/F/CAUC.	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-12-09	同年*-12-15	20	MODERATE
		[redacted]	2[redacted]/F/CAUC.	躁病*/WORSENING OF MANIA REQUIRING HOSPITALIZATION	精神障害	20[redacted]-02-11	同年*-02-20	6	MODERATE
				うつ病*/WORSENING OF DEPRESSION	精神障害	20[redacted]-03-18	同年*-03-25	41	MODERATE
		[redacted]	4[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	20[redacted]-04-28	同年*-04-30	57	MODERATE
		[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]	4[redacted]/F/CAUC.	躁病*/EXACERBATION OF MANIC SYMPTOMS	精神障害	20[redacted]-05-21 10:00	同年*-06-05 10:00	30	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

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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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 B	ARIP 10-30MG	[redacted]	4[redacted]/F/BLACK	抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	抑うつ症状*/WORSENING OF DEPRESSIVE SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	躁病*/WORSENING OF MANIA REQUIRING HOSPITALIZATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE INCREASED	RECOVERED/ RESOLVED
				うつ病*/WORSENING OF DEPRESSION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE INCREASED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIC SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	躁病*/EXACERBATION OF MANIC SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	躁病*/WORSENING OF MANIC SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 10-30MG	[redacted]	4[redacted]/F/CAUC.	うつ病*/DEPRESSED EPISODE	精神障害	20[redacted]-11-09	同年*-11-12	34	MODERATE
				自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-11-09	同年*-11-12	34	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]	2[redacted]/F/CAUC.	胆汁うっ滞*/INTRAHEPATIC CHOLESTASIS	肝胆道系障害	20[redacted]-10-02	翌年*-01-06	176	MILD
		[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.
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: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 10-30MG	[redacted]	4[redacted]/F/CAUC.	うつ病*/DEPRESSED EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	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	LIFE-THREATENING CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	胆汁うっ滞*/INTRAHEPATIC CHOLESTASIS	肝胆道系障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	不眠症*/WORSENING OF INSOMNIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/BLACK	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 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]	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.
3)TRIAL DAY = AE ONSET DATE - DATE OF FIRST DOSE IN THE CORRESPONDING PHASE + 1.

FILE: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 10-30MG	[redacted]	2[redacted]/M/CAUC.	躁病*/WORSENING OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/BLACK	躁病*/WORSENING OF MANIA	精神障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	うつ病*/DEPRESSIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	うつ病*/RECURRENCE OF MOOD EPISODE DEPRESIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	大うつ病*/MAJOR DEPRESSIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	躁病*/MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/BLACK	双極１型障害*/EXACERBATION OF BIPOLAR I DISORDER	精神障害	20[redacted]-08-03	同年*-08-07	19	SEVERE
		[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]	5[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-05-12	同年*-05-15	12	MILD
				頭部損傷*/HEAD INJURY, NOT INTENTIONAL	傷害、中毒および処置合併症	20[redacted]-05-12	同年*-05-12	12	MILD
		[redacted]	4[redacted]/M/CAUC.	心房細動*/ACUTE ATRIAL FIBRILLATION	心臓障害	20[redacted]-03-31 10:42	同年*-04-01	201	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.
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: ADAE1D.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-9.2　FINAL

＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/BLACK	双極１型障害*/EXACERBATION OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	血栓症*/BLOOD CLOT RIGHT CALF	血管障害	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				頭部損傷*/HEAD INJURY, NOT INTENTIONAL	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	心房細動*/ACUTE ATRIAL FIBRILLATION	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	うつ病*/RECURRENCE OF MOOD EPISODE DEPRESSIVE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	自殺企図*/SUICIDE ATTEMPT	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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
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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/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]/F/CAUC.	うつ病*/INCREASED DEPRESSION WITH HOPELESSNESS	精神障害	20[redacted]-05-08	同年*-06-05	36	SEVERE
		[redacted]	4[redacted]/M/CAUC.	うつ病*/INCREASED DEPRESSION	精神障害	20[redacted]-12-08	同年*-12-21	96	MODERATE
		[redacted]	4[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	20[redacted]-05-09	同年*-05-16	101	MODERATE
		[redacted]	2[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	20[redacted]-04-24	同年*-04-30	15	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.	自殺念慮*/SUICIDAL IDEATION	精神障害	20[redacted]-02-11	同年*-02-13	47	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: ADAE1D.LIS, RUN: [redacted]20[redacted] 10:38; ANALYSIS DATASET CREATED: [redacted]20[redacted] 13:53
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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]/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）	MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
		[redacted]	4[redacted]/F/CAUC.	うつ病*/INCREASED DEPRESSION WITH HOPELESSNESS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	うつ病*/INCREASED DEPRESSION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	うつ病*/WORSENING OF DEPRESSION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	躁病*/RECURRENCE OF MANIC MOOD EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/CAUC.	自殺念慮*/SUICIDAL IDEATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	4[redacted]/F/BLACK	喘息*/ASTHMA EXACERBATION LIKELY SECONDARY TO VIRAL ETIOLOGY	呼吸器、胸郭および縦隔障害	20[redacted]-02-17	同年*-02-19	57	MODERATE
		[redacted]	5[redacted]/M/CAUC.	横紋筋融解症*/RHABDOMYOLYSIS	筋骨格系および結合組織障害	20[redacted]-09-10	同年*-09-14	58	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]	5[redacted]/F/CAUC.	腹痛*/ACUTE ABDOMINAL PAIN, UNKNOWN ORIGIN	胃腸障害	20[redacted]-04-28	同年*-05-06	148	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]	3[redacted]/F/CAUC.	外陰部膿瘍*/VULVAR ABCESS	感染症および寄生虫症	20[redacted]-05-23 11:00	同年*-06-13 06:54	22	SEVERE
		[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

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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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 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/BLACK	喘息*/ASTHMA EXACERBATION LIKELY SECONDARY TO VIRAL ETIOLOGY	呼吸器、胸郭および縦隔障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	横紋筋融解症*/RHABDOMYOLYSIS	筋骨格系および結合組織障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	躁病*/EXACERBATION OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	腹痛*/ACUTE ABDOMINAL PAIN, UNKNOWN ORIGIN	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/WORSENING OF BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/CAUC.	外陰部膿瘍*/VULVAR ABCESS	感染症および寄生虫症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED RESOLVED/ WITH SEQUELAE
		[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	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]	4[redacted]/F/CAUC.	急性腎障害*/ACUTE RENAL FAILURE	腎および尿路障害	20[redacted]-01-28	同年*-02-05	204	SEVERE
				腎尿細管壊死*/ACUTE TUBULAR NECROSIS	腎および尿路障害	20[redacted]-01-28	同年*-02-05	204	SEVERE
				腎盂腎炎*/RIGHT PYELONEPHRITIS	感染症および寄生虫症	20[redacted]-01-28	同年*-02-17	204	SEVERE
				敗血症*/SEPSIS	感染症および寄生虫症	20[redacted]-01-28	同年*-02-05	204	SEVERE
				腎結石症*/RENAL CALYCEAL STONE RIGHT KIDNEY	腎および尿路障害	20[redacted]-02-04	ONGOING	211	MILD
		[redacted]	5[redacted]/M/BLACK	神経根障害*/RADICULOPATHY	神経系障害	20[redacted]-05-05 08:00	同年*-05-07 15:00	104	SEVERE
		[redacted]	4[redacted]/M/CAUC.	急性心筋梗塞*/ACUTE MYOCARDIAL INFARCTION	心臓障害	20[redacted]-06-23	同年*-06-25	64	MODERATE
		[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

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: ADAE1D.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-9.2　FINAL

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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/CAUC.	急性腎障害*/ACUTE RENAL FAILURE	腎および尿路障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				腎尿細管壊死*/ACUTE TUBULAR NECROSIS	腎および尿路障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				腎盂腎炎*/RIGHT PYELONEPHRITIS	感染症および寄生虫症	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				敗血症*/SEPSIS	感染症および寄生虫症	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				腎結石症*/RENAL CALYCEAL STONE RIGHT KIDNEY	腎および尿路障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	UNKNOWN
		[redacted]	5[redacted]/M/BLACK	神経根障害*/RADICULOPATHY	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	急性心筋梗塞*/ACUTE MYOCARDIAL INFARCTION	心臓障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/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.	不安*/ANXIETY	精神障害	20[redacted]-04-30	同年*-07-01	27	SEVERE
		[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]	5[redacted]/F/ASIAN	振戦*/WHOLE BODY TREMOR	神経系障害	20[redacted]-03-04 08:00	同年*-05-01 09:00	104	MODERATE
		[redacted]	4[redacted]/M/ASIAN	うつ病*/DEPRESSIVE STATE	精神障害	20[redacted]-01-05 09:48	同年*-03-18 12:38	112	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

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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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/CAUC.	躁病*/EXACERBATION OF MANIA WITH HOSPITALISATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/CAUC.	不安*/ANXIETY	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	躁病*/MENTAL CONDITION MANIC EXACERBATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	躁病*/RELAPSE OF MANIA	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 1 DISORDER, MANIC WITH PSYCHOTIC FEATURES	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/ASIAN	振戦*/WHOLE BODY TREMOR	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/ASIAN	うつ病*/DEPRESSIVE STATE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/M/ASIAN	躁病*/MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	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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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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]/F/ASIAN	抑うつ症状*/DEPRESSIVE SYMPTOM AGGRAVATED	精神障害	20[redacted]-08-01 10:00	同年*-10-25 10:10	45	SEVERE
		[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	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	痔出血*/HEMORRHAGE OF INTERNAL HEMORRHOID	胃腸障害	20[redacted]-02-17 12:59	同年*-02-18 18:19	167	MILD
				喘息*/ASTHMA ATTACK	呼吸器、胸郭および縦隔障害	20[redacted]-05-18	同年*-05-18	257	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.
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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 C	ARIP IMD 400/300MG	[redacted]	5[redacted]/F/ASIAN	抑うつ症状*/DEPRESSIVE SYMPTOM AGGRAVATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/ASIAN	うつ病*/INCREASED DEPRESSIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
PHASE D	ARIP IMD	[redacted]	2[redacted]/F/BLACK	自殺企図*/SUICIDE ATTEMPT	精神障害	LIFE-THREATENING CONDITION, HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	痔出血*/HEMORRHAGE OF INTERNAL HEMORRHOID	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				喘息*/ASTHMA ATTACK	呼吸器、胸郭および縦隔障害	LIFE-THREATENING CONDITION, HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	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.
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FILE: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 D	ARIP IMD	[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
				心肺停止*/CARDIO PULMONARY ARREST	心臓障害	20[redacted]-05-19	同年*-05-19	258	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: ADAE1D.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-9.2　FINAL

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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 D ARIP IMD		[redacted]	4[redacted]/M/BLACK	呼吸不全*/RESPIRATORY FAILURE	呼吸器、胸郭および縦隔障害	DEATH, LIFE-THREATENING CONDITION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY, HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DRUG WITHDRAWN	FATAL
				心肺停止*/CARDIO PULMONARY ARREST	心臓障害	LIFE-THREATENING CONDITION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY, HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DOSE NOT CHANGED	RECOVERED RESOLVED/ WITH SEQUELAE

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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 D ARIP IMD		[redacted]	4[redacted]/M/BLACK	脳損傷*/ANOXIC BRAIN INJURY	神経系障害	20[redacted]-05-19	同年*-07-15 01:31	258	SEVERE
		[redacted]	6[redacted]/F/CAUC.	一過性脳虚血発作*/TRANSIENT ISCHEMIC ATTACK	神経系障害	20[redacted]-01-18	同年*-01-21	35	SEVERE
				躁病*/RELAPSE OF MANIC SYMPTOMS	精神障害	20[redacted]-02-24	同年*-03-02	72	SEVERE
		[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
		[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

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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 D ARIP IMD		[redacted]	4[redacted]/M/BLACK	脳損傷*/ANOXIC BRAIN INJURY	神経系障害	DEATH, LIFE-THREATENING CONDITION, PERSISTENT OR SIGNIFICANT DISABILITY/INCAPACITY, HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DOSE NOT CHANGED	FATAL
		[redacted]	6[redacted]/F/CAUC.	一過性脳虚血発作*/TRANSIENT ISCHEMIC ATTACK	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
				躁病*/RELAPSE OF MANIC SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/F/CAUC.	アカシジア*/ACUTE AKATHISIA	神経系障害	HOSPITALIZATION - INITIAL OR PROLONGED	DEFINITE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE BIPOLAR I DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 D	ARIP IMD	[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]	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
				軽躁*/HYPOMANIC EPISODE	精神障害	20[redacted]-09-24 13:00	翌年*-06-19 12:00	205	MODERATE
		[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
	PLACEBO	[redacted]	5[redacted]/M/BLACK	躁病*/MANIC EPISODE	精神障害	20[redacted]-05-19	同年*-05-21	76	SEVERE
		[redacted]	6[redacted]/M/CAUC.	橈骨骨折*/RIGHT WRIST DISTAL RADIUS INTRAARTICULAR FRACTURE	傷害、中毒および処置合併症	20[redacted]-01-19	同年*-01-22	229	MODERATE
		[redacted]	4[redacted]/F/CAUC.	肺炎*/PNEUMONIA	感染症および寄生虫症	20[redacted]-12-23 13:00	翌年*-01-03 12:30	365	MODERATE

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表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 D	ARIP IMD	[redacted]	6[redacted]/M/CAUC.	双極性障害*/BYPOLAR I DISEASE, DEPRESIVE EPISODE	精神障害	MEDICALLY SIGNIFICANT CONDITION	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	双極１型障害*/MANIC EPISODE, BIPOLAR DISORDER	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/ASIAN	感情不安定*/EMOTIONAL INSTABILITY	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
				軽躁*/HYPOMANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
	PLACEBO	[redacted]	5[redacted]/M/BLACK	躁病*/MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	橈骨骨折*/RIGHT WRIST DISTAL RADIUS INTRAARTICULAR FRACTURE	傷害、中毒および処置合併症	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	肺炎*/PNEUMONIA	感染症および寄生虫症	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 BEFORE THE MEDDRA TERM INDICATE IT IS COUNTED IN THE SUBSETS OF TREATMENT-EMERGENT ADVERSE EVENTS.
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CT-9.2
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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 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]	3[redacted]/F/BLACK	骨盤癒着症*/PELVIC ADHESIONS	生殖系および乳房障害	20[redacted]-07-30	同年*-08-13	30	MODERATE
		[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]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOM	精神障害	20[redacted]-11-16	同年*-11-18	55	SEVERE
		[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]	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]	5[redacted]/M/CAUC.	潰瘍性大腸炎*/EXACERBATION OF ULCERATIVE COLITIS SYMPTOMS	胃腸障害	20[redacted]-04-14 12:00	同年*-04-17 12:30	230	SEVERE
		[redacted]	1[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIA	精神障害	20[redacted]-05-22	同年*-05-29	46	MODERATE

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PHASE D	PLACEBO	[redacted]	5[redacted]/F/CAUC.	感情障害*/RECURRENCE OF MOOD EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/BLACK	骨盤癒着症*/PELVIC ADHESIONS	生殖系および乳房障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/BLACK	双極性障害*/WORSENING OF BIPOLAR ILLNESS REQUIRING HOSPITALIZATION	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/M/BLACK	双極性障害*/WORSENING OF BIPOLAR SYMPTOM	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	NOT LIKELY	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/OTHER	躁病*/RECURRENCE OF MOOD EPISODE, MANIC	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/F/CAUC.	自殺企図*/INTERRUPTED SUICIDE ATTEMPT	精神障害	LIFE-THREATENING CONDITION	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/CAUC.	潰瘍性大腸炎*/EXACERBATION OF ULCERATIVE COLITIS SYMPTOMS	胃腸障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	1[redacted]/M/CAUC.	躁病*/EXACERBATION OF MANIA	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	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 D	PLACEBO	[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]	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]	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]	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

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
2)ADVERSE EVENTS CODED IN MEDDRA (VERSION 19.0).
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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 D	PLACEBO	[redacted]	4[redacted]/F/BLACK	躁病*/MANIC MOOD EVENT	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/F/CAUC.	攻撃性*/AGRESSIVE BEHAVIOUR	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	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	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/SEVERE MAJOR DEPRESSIVE EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/CAUC.	大うつ病*/SEVER MAJOR DEPRESIVE EPISOD	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	6[redacted]/M/CAUC.	躁病*/MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	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	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	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: ADAE1D.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-9.2　FINAL

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 D	PLACEBO	[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
		[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	躁病*/MANIC EPISODE	精神障害	20[redacted]-11-25 16:00	翌年*-03-26 09:00	282	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

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＊新薬承認情報提供時に置き換え

表 2.7.4.7-69　重篤な有害事象一覧表［二重盲検試験の IM デポ剤安定期（Phase C），二重盲検期（Phase D）］

CT-9.2
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 D	PLACEBO	[redacted]	2[redacted]/F/CAUC.	双極１型障害*/BYPOLAR DISORDER,MIXED EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED, MEDICALLY SIGNIFICANT CONDITION	NOT LIKELY	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	5[redacted]/M/ASIAN	双極性障害*/WORSENING OF BIPOLAR SYMPTOMS	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/ASIAN	躁病*/RECURRENCE OF MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	PROBABLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	2[redacted]/M/ASIAN	躁病*/RECURRENCE OF MANIC STATE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
		[redacted]	4[redacted]/F/ASIAN	躁病*/MANIC EPISODE	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	UNRELATED	DOSE NOT CHANGED	RECOVERED/ RESOLVED
		[redacted]	3[redacted]/F/ASIAN	躁病*/MANIC EPISODE AGGRAVATED	精神障害	HOSPITALIZATION - INITIAL OR PROLONGED	POSSIBLE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

1)SUBJECT ID = CENTER NUMBER + SUBJECT SCREENING NUMBER.
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＜資料番号 5.3.5.1-01：CT-9.2 より作成＞