善薬のベースライン時の併用有無別（以下，「併用あり」，「併用なし」として示す）の部分集団間及びプラセボ群とレカネマブ 10 mg/kg 隔週群間でいずれも同程度であった（添付資料 5.3.5.1.4 の Table 14.3.1.2.1）。投与中止に至った TEAE の発現率は，各部分集団で同程度であった（併用あり：プラセボ群 2.5%，レカネマブ 10 mg/kg 隔週群 7.3%，併用なし：プラセボ群 3.8%，10 mg/kg 隔週群 6.9%，添付資料 5.3.5.1.4 の Table 14.3.2.3.1）。

301 試験 Core では，TEAE の発現率は「併用あり」，「併用なし」の部分集団間で同程度であり，全体集団の結果と一致していた（添付資料 5.3.5.1.4 の Table 14.3.1.2.1）。

その他，301 試験 Core の TEAE 発現率について，AD 症状改善薬の併用の種類（ドネペジル，ガランタミン，リバスチグミン，メマンチン，併用なし）別，並びに ChE 阻害剤（ドネペジル，ガランタミン，リバスチグミン）の併用有無別の詳細な部分集団解析を SAS の全体集団及び日本人集団を対象に実施した（解析結果は 1.13.2.15 項を参照）。

2.7.4.6.4 薬物相互作用

レカネマブは可溶性 Aβ 凝集体を標的とするモノクローナル抗体であり，サイトカインに対する影響や免疫調節作用を有しないと考えられている。レカネマブは免疫グロブリンの通常の分解経路を介して排泄され，そのクリアランスは低分子薬の併用による影響を受けないと考えられている（2.7.2.3 項）。したがって，レカネマブと併用される薬剤との相互作用は想定されていない。これらの理由から，薬物相互作用の検討を目的とした臨床試験及び非臨床試験は実施しておらず，今後の実施も計画していない。

301 試験及び 201 試験では，ドネペジル，リバスチグミン，ガランタミン及びメマンチン等，AD 症状改善薬の併用が許容された（2.7.4.6.3.2 項参照）。TEAE の発現率及び種類は，AD 症状改善薬の併用有無にかかわらず，レカネマブ群とプラセボ群で同様であった。ARIA-E の発現率に関して，AD 症状改善薬の併用有無による影響は示唆されなかった。

301 試験 Core では，抗血栓薬（抗血小板薬，抗凝固薬及び血栓溶解薬を含む）併用の有無による ARIA-E の発現率に差はなかった。抗血栓薬の「併用あり」の集団における ARIA-E の発現率は，プラセボ群 1.9%（6/311 例），レカネマブ 10 mg/kg 隔週群 11.7%（39/334 例）であった。抗血栓薬の「併用なし」集団における ARIA-E の発現率は，プラセボ群 1.5%（9/586 例），レカネマブ 10 mg/kg 隔週群 13.1%（74/564 例）であった（添付資料 5.3.5.1.4 の Table 14.3.2.6.12）。

脳出血の発現率（non-TEAE を含む）は，レカネマブ 10 mg/kg 隔週投与時に抗凝固薬を併用している被験者（2.4%［2/83 例］）では全体集団（0.7%［6/898 例］）に比してやや高いことが示されたが（表 2.7.4-28，Sabbagh, et al., 2023），AD 以外の集団でも抗凝固薬は単独で脳出血のリスクを増加させるため，脳出血のリスクに対するレカネマブ 10 mg/kg 隔週群の相対的寄与は不明であった。脳アミロイド血管症を併発する AD 集団での脳出血リスクは不明であるが，リスクはより高いことが予測されるため，レカネマブのリスクの増加への寄与に関する判断は困難である。

2.7.4.6.5 薬物乱用

レカネマブは医師の観察下で投与した。レカネマブの薬物乱用及び薬物依存の可能性はこれまでに検討されておらず，また，その可能性は想定されていない。なお，同じ薬剤クラスの類

薬では，薬物乱用の可能性は報告されていない。

乱用の可能性がある TEAE の発現率は，プラセボ群（2.0%［18 例］）と比較してレカネマブ 10 mg/kg 隔週群（0.9%［8 例］）で低かった（添付資料 5.3.5.1.4 の Table 14.3.1.3.6）。全体的に，異常な夢の発現率は低く（プラセボ群 0.7%，レカネマブ 10 mg/kg 隔週群 0.4%），無感情（各群 0.1%），異常感（各群 0.1%），幻覚（プラセボ群 0.6%，レカネマブ 10 mg/kg 隔週群 0.2%），幻聴（プラセボ群 0.3%，レカネマブ 10 mg/kg 隔週群 0%）及び幻視（プラセボ群 0.4%，レカネマブ 10 mg/kg 隔週群 0%）が認められた。

偶発的過量投与が報告された被験者の割合は，プラセボ群（0.3%）とレカネマブ 10 mg/kg 隔週群（0.2%）で同様であった（添付資料 5.3.5.1.4 の Table 14.3.1.3.1）。レカネマブ 10 mg/kg 隔週群において，偶発的過量投与に伴う重篤な TEAE が 1 例（0.1%）に認められ，その重症度は軽度であった（添付資料 5.3.5.1.4 の Table 14.3.2.2.6）。

偶発的過量投与又は投薬過誤が報告された 5 例の叙述は，添付資料 5.3.5.1.4 の 14.3.3 項に示した。

2.7.4.6.6 離脱症状及び反跳現象

レカネマブ投与後の身体的依存に関する報告はない。レカネマブの投与終了後の影響を評価するため，投与中止後も治験を継続した被験者，並びに規定の評価及び来院を完了後フォローアップ評価まで治験を継続した被験者を対象に，投与終了後に発現した有害事象及び重篤な有害事象の発現率について解析を実施した。

301 試験 Core では，（OLE 期に移行しなかった被験者における）投与終了後の有害事象発現率は，プラセボ群 13.3%，レカネマブ 10 mg/kg 隔週群 25.2%であった（添付資料 5.3.5.1.4 の Table 14.3.1.3.7）。フォローアップ期間で調整した投与終了後の有害事象発現頻度（例/人年）はプラセボ群 84.5，レカネマブ 10 mg/kg 隔週群 102.3 であった（添付資料 5.3.5.1.4 の Table 14.3.1.3.8）。投与終了後，OLE 期に移行しなかった被験者のうち，投与中止後にアミロイド関連画像異常-微小出血およびヘモジデリン沈着（ARIA-H 脳微小出血の基本語）が認められた被験者の割合は，プラセボ群 1.6%に対してレカネマブ 10 mg/kg 隔週群では 9.4%であった（添付資料 5.3.5.1.4 の Table 14.3.1.3.7）。これらの事象の多くは，ARIA-E による治験薬の投与中止後，ARIA-E の消失までの安全性フォローアップのための MRI 検査を継続していた被験者で報告された。治験薬投与を中止又は投与を完了し，OLE 期に移行しなかった被験者のうち，プラセボ群及びレカネマブ 10 mg/kg 隔週群ではそれぞれ 1 例の脳出血が認められ，治験薬投与中止に伴う脳出血の反跳現象は認められなかった（添付資料 5.3.5.1.4 の Table 14.3.1.3.7）。

301 試験 Core では，（OLE 期に移行しなかった被験者における）投与終了後の重篤な TEAE の発現率は各投与群で低く（プラセボ群 4.8%［9/188 例］，レカネマブ 10 mg/kg 隔週群 6.0%［14/234 例］，添付資料 5.3.5.1.4 の Table 14.3.2.2.10），201 試験 Core においても同様であった。（OLE 期に移行しなかった被験者における）フォローアップ期間で調整した投与終了後の高度の TEAE の発現頻度（例/人年）は，プラセボ群で 30.4，レカネマブ 10 mg/kg 隔週群で 24.3 であった（添付資料 5.3.5.1.4 の Table 14.3.2.2.11）。

2.7.4.6.7 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

自動車運転及び機械操作に対するレカネマブの影響の検討を目的とした臨床試験は実施していない。301 試験では，失神寸前の状態，失神，傾眠及び低血糖の発現率に 201 試験と同様に，レカネマブ投与による増加はみられなかった（添付資料 5.3.5.1.5 の Table 14.3.1.3.1）。交通事故の発現率は低く，レカネマブとの因果関係は関連なしと判定された（添付資料 5.3.5.1.4 の Table 14.3.1.5.4，添付資料 5.3.5.1.5 の Table 14.3.1.5.4，添付資料 5.3.5.1.1 の Table 14.3.1.5，添付資料 5.3.5.1.3 の Table 14.3.1.5.4）。201 試験においても同様の結果であった。これらの結果から，自動車運転及び機械操作に対するレカネマブの明確な影響はないことが示唆された。

2.7.4.7 薬物有害反応

2.7.4.7.1 全体概要

次の事象をレカネマブの薬物有害反応として定義した：注入に伴う反応，アミロイド関連画像異常-微小出血およびヘモジデリン沈着（ARIA-H 脳微小出血の基本語），アミロイド関連画像異常-浮腫/滲出液貯留，頭痛及び脳表ヘモジデリン沈着症（添付資料 5.3.5.1.4 の Table 14.3.1.3.2.1）。

2.7.4.7.2 薬物有害反応としての有害事象の評価

事象の発現とレカネマブの投与との間に因果関係があると考えられた TEAE を，FDA ガイダンス（FDA, 2006）に基づき，薬物有害反応として定義した。

薬物有害反応の特定には，レカネマブの非盲検安全性データベースを用いた。301 試験 Core は，無作為化例としては最大のデータセット（無作為化例 1795 例，レカネマブ 10 mg/kg 隔週群 898 例）であり，解析した内因性及び外因性要因の大部分について，十分な例数を有することが確認された。201 試験 Core では，治験実施計画書の改訂が EU の規制当局によって規定され，*APOE4* 保因状況が群間不均衡となった。初回の評価では，301 試験 Core の 10 mg/kg 隔週群で 2%以上発現し，かつプラセボ群と比較して発現率が 2%以上高い TEAE と定義した（添付資料 5.3.5.1.4 の Table 14.3.1.3.3）。その後，データを精査した結果，レカネマブ 10 mg/kg 隔週群で発現率が 5%以上かつプラセボ群と比較して発現率が 2%以上高い TEAE がレカネマブの薬物有害反応としてより適切と考え，注入に伴う反応，アミロイド関連画像異常-微小出血およびヘモジデリン沈着（ARIA-H 脳微小出血の基本語），アミロイド関連画像異常-脳浮腫/滲出液貯留，頭痛及び脳表ヘモジデリン沈着症がレカネマブの薬物有害反応として特定された。

表 2.7.4-29 レカネマブ 10 mg/kg 隔週群で発現率が 5%以上かつプラセボ群と比較して発現率が 2%以上高い TEAE – 301 試験 Core（SAS）

MedDRA Preferred Term	Placebo (N = 897) n(%)	Lecanemab 10 mg/kg Biweekly (N = 898) n(%)
Subjects with any TEAE	735 (81.9)	798 (88.9)
注入に伴う反応	64 (7.1)	236 (26.3)
アミロイド関連画像異常-微小出血およびヘモジデリン沈着	69 (7.7)	126 (14.0)
アミロイド関連画像異常-浮腫/滲出液貯留	15 (1.7)	113 (12.6)
頭痛	73 (8.1)	100 (11.1)
脳表ヘモジデリン沈着症	22 (2.5)	50 (5.6)

A TEAE is defined as an AE that emerged during treatment or within 30 days following the last dose of study drug, having been absent at pretreatment (Baseline) or reemerged during treatment, having been present at pretreatment (Baseline) but stopped before treatment, or worsened in severity during treatment relative to the pretreatment state, when the AE was continuous. Subject with 2 or more adverse events with the same preferred term is counted only once for that preferred term. Cerebral microhemorrhages include those deemed not ARIA-H by investigator.
TEAEs are ordered by decreasing frequency in 10 mg/kg Biweekly group, then placebo group.
MedDRA Version 25.0.
AE = adverse event, MedDRA = Medical Dictionary for Regulatory Activities, N = number of subjects in treatment group, n = number of subjects at each visit, TEAE = treatment-emergent adverse event.

（添付資料 5.3.5.1.4 の Table 14.3.1.3.2.1 を引用）

2.7.4.8 市販後データ

該当せず。

2.7.4.9 治験結果に対する動物毒性試験データとの関連性の要約

2.7.4.9.1 全体概要

カニクイザルを用いた 4 週間及び 39 週間の反復投与毒性試験では，脾臓の平均絶対重量及び相対重量並びに脾臓の胚中心の増加傾向が認められた。これらの所見は可逆的であり，異種タンパクに対する低レベルの免疫反応，あるいは末梢循環中の可溶性 Aβ 標的に結合したレカネマブの薬理学的活性とそれに続く既知の免疫介在性メカニズムによるクリアランスのいずれかに関連すると考えられる。レカネマブに関連する他の所見はなかったことから，これらの脾臓所見とヒトとの関連性は限定的であると想定される。

2.7.4.9.2 ヒト臨床試験結果に対する動物毒性試験データとの関連性及びまとめ

301 試験及び 201 試験では，臨床検査，心電図及びバイタルサインの結果に臨床的に重要な変化はみられなかった。201 試験 Core では，レカネマブ投与に関連する一過性の好中球数増加及びリンパ球数減少が認められたものの，201 試験及び 301 試験では，これらの減少はその後の投与では認められなかった。白血球の一過性の変化を検討した 201 試験及び 301 試験のデータより，これらの変化は注入に伴う反応及び初回投与時の反応に対する非持続性の反応に関連していることが示唆された。これらの所見は，投与後の血中レカネマブ濃度の上昇に対する一時的な反応であり，臨床的意義や毒性データとの関連性はないと考えられる。

2.7.4.10 結論

本項の要約結果から，レカネマブは早期 AD 患者に対して許容可能な安全性及び忍容性プロファイルを有することが示された。

レカネマブの臨床開発プログラムの強みは，大規模な早期 AD 患者集団で，レカネマブの安全性及び忍容性が厳密に評価されていることである。

301 試験 Core の TEAE の発現率は，プラセボ群（81.9%［735/897 例］）と比較してレカネマブ 10 mg/kg 隔週群（88.9%［798/898 例］）でわずかに高かった。注入に伴う反応，ARIA-E 及び ARIA-H を除いた場合の TEAE の発現率は，プラセボ群（80.2%）とレカネマブ 10 mg/kg 隔週群（83.1%）で同程度であり，早期 AD の患者集団の発現率として一貫していた。

重篤な TEAE の多くは 2 例以下に認められ，301 試験 Core と 201 試験 Core で同様であった。301 試験及び 201 試験の OLE 期において，投与初期に発現した注入に伴う反応及び ARIA-E を除き，レカネマブの長期投与により TEAE の種類及び発現率に変化は認められなかった。ARIA-H は，301 試験及び 201 試験の Core Study 及び OLE 期を通じて発現した。

301 試験 Core 及び 201 試験 Core における ARIA-E 又は ARIA-H と関連のない SMQ の痙攣（すなわち，痙攣発作）に該当する TEAE の発現率は低く，投与群間及び試験間で同程度であった。また，ARIA-E の随伴症状としての痙攣発作の発現は少なかった。

治験期間中（201 試験 OLE 及び 301 試験 OLE のデータカットオフ：2022 年 4 月 15 日）に合計 30 例の被験者が死亡した。周囲に血管原性脳浮腫を伴う脳新生物（ARIA-E としては報告されていない）が原因で死亡し，治験担当医師により治験薬との因果関係が関連あるかもしれないと判定された 201 試験 Core のレカネマブ 2.5 mg/kg 隔週群の 1 例を除き，全ての死亡に至った有害事象は治験薬との因果関係は関連なしと判定された。脳出血による死亡は 301 試験 Core のプラセボ群の 1 例に認められた。その他，301 試験 OLE のデータカットオフ以降に，10 mg/kg 隔週投与例で 2 例に脳出血による死亡が認められたが，この 2 例はそれぞれ tPA 及び抗凝固薬の投与を受けていた。

注入に伴う反応は，概して，重症度が軽度又は中等度であり，初回投与時に発現し，投与中止に至る割合は低く，予防的投薬の有無に依らず再発は少なかった。

ARIA-E は投与初期に発現し，多くは無症候性であり，画像上の重症度にかかわらず自然に消失した。無症候性かつ画像上軽度の ARIA-E は休薬することなく投与を継続することが可能であった。ε4 アレル数の増加は ARIA-E 発現のリスク因子であったが，ARIA-E の臨床経過には影響がなかった。

301 試験 Core 及び 201 試験 Core のレカネマブ 10 mg/kg 隔週群で認められた ARIA-E の大部分は，画像上軽度又は中等度であり，*APOE4* 遺伝子型（ε4 アレル数）にかかわらず，多くが投与開始後 3 ヵ月以内，大部分が投与開始後 6 ヵ月以内に発現し，大部分は発現から 4 ヵ月以内に画像上で消失した。症候性 ARIA-E の発現率は両試験とも低く，レカネマブ 10 mg/kg 隔週群で症候性 ARIA-E が認められた被験者の割合は約 3%であった。

ARIA-H 単独は，治験期間中に散発的に発現し，ほとんどが無症候性であり，治験薬の処置は不要であった。ε4 アレル数の増加は ARIA-H 発現のリスク因子であったが，ARIA-H 単独の臨床経過には影響がなかった。

レカネマブ 10 mg/kg を隔週投与したときの安全性プロファイルは，早期 AD 患者に対する治

療薬としてのレカネマブの使用を支持するものである。

2.7.4.11 付録

付録 2.7.4-1　死亡に至った TEAE 一覧
付録 2.7.4-2　重篤な TEAE 一覧

付録2.7.4-1　死亡に至ったTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	90	M	W	456	死亡	462	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	82	F	W	1	急性呼吸不全	4	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	79	M	W	33	心筋梗塞	36		Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	75	F	W	532	骨転移	546	62	Moderate	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	72	M	W	355	頭蓋内出血	1	402	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	86	F	W	393	COVID－19	404	13	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	85	M	W	71	膵癌	71	249	Moderate	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	85	F	W	421	死亡	434	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	79	M	W	237	脳血管発作	263	20	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	70	M	W	220	心筋梗塞	230	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	88	F	W	330	呼吸不全	351	55	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	77	M	W	519	髄膜転移	534	30	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	76	M	W	380	COVID－19	375	28	Severe	Not related	DRUG WITHDRAWN	FATAL

Age is age at Informed Consent; M = Male, F = Female; W = White, B = Black or African American, J = Japanese, C = Chinese, K = South Korean, I = Asian Indian, OA = Other Asian, N = American Indian or Alaska Native, O = Other.
PT = preferred term, TEAE = treatment-emergent adverse event.
MedDRA Version 25.0

付録2.7.4-1　死亡に至ったTEAE一覧（301試験OLE）
LEC10-BW-Treated Period

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	79	F	W	1	心筋梗塞	11	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	69	M	W	98	COVID－19肺炎	103	27	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	85	F	W	421	死亡	434	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	79	M	W	237	脳血管発作	263	20	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	70	M	W	220	心筋梗塞	230	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	88	F	W	330	呼吸不全	351	55	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	77	M	W	519	髄膜転移	534	30	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	76	M	W	380	COVID－19	375	28	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	81	M	J	667	急性心不全	777	1	Severe	Not related	DRUG WITHDRAWN	FATAL

Age is age at Informed Consent of Core Study for subjects assigned to lecanemab in Core Study, and of OLE Phase for those assigned to placebo in Core Study; M = Male, F = Female; W = White, B = Black or African American, J = Japanese, C = Chinese, K = South Korean, I = Asian Indian, OA = Other Asian, N = American Indian or Alaska Native, P = Native Hawaiian or other Pacific Islander, O = Other; TEAE = treatment-emergent adverse event.
LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.
Duration of treatment = date of last dose of study drug - date of first dose of study drug + 1.
MedDRA Version 25.0

付録2.7.4-1　死亡に至ったTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	76	M	W	71	肉腫（医師記載語：左腋窩の悪性腫瘍－肉腫）	89	50	Severe	Not related	NOT APPLICABLE	FATAL
						肉腫（医師記載語：脊椎の悪性腫瘍－肉腫）	89	50	Severe	Not related	NOT APPLICABLE	FATAL
Placebo	[redacted]	74	M	W	70	急性呼吸不全	84	1	Severe	Not related	DRUG WITHDRAWN	FATAL
2.5 mg/kg bi-Weekly	[redacted]	81	F	W	464	脳新生物	449	151	Severe	Possibly related	DRUG WITHDRAWN	FATAL
2.5 mg/kg bi-Weekly	[redacted]	75	F	W	378	心停止	395	1	Severe	Not related	DRUG WITHDRAWN	FATAL
5 mg/kg bi-Weekly	[redacted]	79	F	W	421	肝不全	421	6	Severe	Not related	DRUG WITHDRAWN	FATAL
						急性腎障害	422	5	Severe	Not related	DRUG WITHDRAWN	FATAL
						菌血症	425	2	Severe	Not related	NOT APPLICABLE	FATAL
						凝血異常	425	2	Severe	Not related	NOT APPLICABLE	FATAL
						白血球減少症	425	2	Severe	Not related	NOT APPLICABLE	FATAL
						代謝性脳症	425	2	Severe	Not related	DRUG WITHDRAWN	FATAL
						多臓器機能不全症候群	425	2	Severe	Not related	NOT APPLICABLE	FATAL
10 mg/kg Monthly	[redacted]	78	M	W	201	脊髄損傷	212	10	Severe	Not related	DRUG WITHDRAWN	FATAL

Age is age at Informed Consent; M = Male, F = Female; W = White, B = Black or African American, J = Japanese, C = Chinese, OA = Other Asian, P = Native Hawaiian or other Pacific Islander, N = American Indian or Alaska Native, O = Other.
PT = preferred term, TEAE = treatment-emergent adverse event.
MedDRA Version 24.0

付録2.7.4-1　死亡に至ったTEAE一覧（201試験OLE）

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	79	M	W	837	中枢神経系転移	859	21	Severe	Not related	NOT APPLICABLE	FATAL
5 mg/kg bi-Weekly	[redacted]	80	F	W	488	頚椎骨折	495	11	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg Monthly	[redacted]	76	M	W	966	原発巣不明の悪性新生物	974	11	Severe	Not related	DRUG WITHDRAWN	FATAL
						神経内分泌癌	982	3	Severe	Not related	DRUG WITHDRAWN	FATAL

Age is age at Informed Consent for OLE Phase; M = Male, F = Female; W = White, B = Black or African American, C = Chinese, J = Japanese, OA = Other Asian, N = American Indian or Alaska Native, P = Native Hawaiian or other Pacific Islander, O = Other.
OLE = open-label extension, PT = preferred term, TEAE = treatment-emergent adverse event.
MedDRA Version 25.0

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	72	M	B	352	錯乱状態	100	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	F	W	538	心房細動	109	3	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	77	M	W	535	脱水	226	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	M	W	240	無力症	144	4	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						無力症	147	1	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	81	M	W	534	肺炎	284	19	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	90	M	W	456	死亡	462	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	78	M	W	527	硬膜下血腫	339	159	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	74	F	W	533	急性呼吸不全	7	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	78	F	W	533	股関節部骨折	5	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	76	F	W	541	失神寸前の状態	521	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	72	F	W	538	心房細動	491	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	86	M	W	539	低血圧	206	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	82	F	W	1	急性呼吸不全	4	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	68	F	W	505	肺塞栓症	514	4	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	73	F	W	540	乳管内増殖性病変	313	38	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	59	F	W	537	腎結石症	169	62	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	M	W	539	脳血管発作	84	86	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
						悪性黒色腫	457	113	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	77	M	W	527	前立腺癌	275	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	74	F	W	535	脊椎すべり症	148	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
Placebo	[redacted]	72	F	W	192	腸閉塞	174	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	F	W	533	貧血	316	13	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	76	M	W	477	うつ病	28	7	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						自殺念慮	28	7	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	83	M	W	532	血圧上昇	468	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						視床梗塞	541	75	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	66	M	W	532	転倒	15	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						運動失調	19	5	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	73	F	W	533	感染性胆嚢炎	183	193	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	77	M	W	505	結腸腺癌	98	187	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肺の悪性新生物	125	104	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						大動脈弁狭窄	315	83	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						骨髄異形成症候群	517	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	82	F	W	351	高血圧	371	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						高血圧性脳症	371	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						ラクナ梗塞	371	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						精神状態変化	371	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	F	W	531	直腸出血	315	6	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	66	M	W	530	膀胱出口部閉塞	464	147	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	M	W	533	COVID-19	4	11	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肺炎	8	9	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	M	W	533	上室性頻脈	159	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	71	M	W	533	心房細動	109	14	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	M	W	541	SARS-CoV-2検査陽性	16	14	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						頭部損傷	188	3	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						身体的暴行	188	3	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	57	M	W	533	顔面骨骨折	60	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	M	W	533	非小細胞肺癌	66	15	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	71	M	W	534	急性呼吸不全	116	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	89	M	W	529	股関節部骨折	12	2	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	72	M	W	533	皮膚有棘細胞癌	100	55	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	76	M	W	442	骨壊死	206	218	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	M	W	33	心筋梗塞	36	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	55	F	W	218	腹痛	93	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	68	F	W	526	失神	100	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	70	M	W	239	認知障害発作	36	1	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	85	M	W	532	前立腺癌	114	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	75	F	W	532	骨転移	546	62	Moderate	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	73	F	W	531	背部痛	368	4	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						背部痛	436	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	69	F	W	539	血栓性脳卒中	168	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	78	F	W	539	上肢骨折	527	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	70	F	W	541	足関節部骨折	205	158	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	64	F	W	484	変形性関節症	114	186	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	72	M	W	355	頭蓋内出血	1	402	Severe	Not related	DRUG WITHDRAWN	FATAL
						錯乱状態	361	42	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	68	F	W	538	脱水	308	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肺炎	308	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	72	F	W	533	急性腹症	450	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						菌血症	450	12	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						大腸穿孔	450	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						骨盤膿瘍	450	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						腹膜炎	450	12	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	84	F	W	211	一過性脳虚血発作	224	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	73	M	W	141	硬膜下血腫	118	-	Severe	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	86	F	W	393	COVID-19	404	13	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	73	M	W	519	肺塞栓症	523	27	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	87	M	W	335	小腸閉塞	365	-	Moderate	Not related	NOT APPLICABLE	RECOVERING/RESOLVING
Placebo	[redacted]	85	M	W	71	膵癌	71	249	Moderate	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	63	M	W	532	足関節部骨折	78	106	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	76	M	W	338	小腸閉塞	345	12	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	F	W	527	大腿骨頚部骨折	233	23	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						薬物過敏症	474	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	M	W	533	前立腺癌	178	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	60	M	W	536	錯乱状態	607	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						嘔吐	607	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	73	M	W	530	冠動脈狭窄	524	106	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	67	M	W	537	変形性関節症	237	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	78	M	W	533	硬膜下血腫	335	52	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	66	F	W	538	骨粗鬆症性骨折	230	15	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	64	F	W	534	便秘	350	15	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	75	M	W	183	結腸腺癌	105	-	Mild	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	74	M	W	29	心筋梗塞	42	31	Severe	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED
Placebo	[redacted]	73	M	W	533	虚血性脳卒中	479	2	Mild	Not related	NOT APPLICABLE	RECOVERED/RESOLVED

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	66	M	W	394	深部静脈血栓症	399	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						肺塞栓症	399	-	Severe	Not related	DRUG WITHDRAWN	RECOVERING/RESOLVING
						膵新生物	402	-	Severe	Not related	DOSE NOT CHANGED	UNKNOWN
Placebo	[redacted]	79	F	N	533	喉頭扁平上皮癌	472	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	72	F	W	533	憩室炎	376	116	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
Placebo	[redacted]	82	M	-	536	単径ヘルニア	2	380	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						シュードモナス性肺炎	305	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	67	F	-	533	メニエール病	220	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	60	M	-	533	巨細胞性動脈炎	480	10	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	71	M	W	537	皮膚嚢腫	77	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						単径ヘルニア	144	12	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	72	M	W	145	譫妄	47	26	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						尿路感染	152	52	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	64	F	W	528	乳管内増殖性病変	39	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	75	M	J	421	洞結節機能不全	394	24	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						リードの位置ずれ	430	12	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	68	F	J	247	損傷	253	-	Severe	Not related	DRUG WITHDRAWN	RECOVERING/RESOLVING
Placebo	[redacted]	75	M	J	190	挫傷	216	130	Mild	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	70	F	J	526	足関節部骨折	275	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	76	F	J	457	脊椎圧迫骨折	463	-	Severe	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
						脊椎圧迫骨折	542	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	64	M	J	528	膀胱結石	138	31	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						膀胱癌	154	15	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						膀胱結石	260	588	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	86	F	J	534	変形性関節症	187	29	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						水腎症	485	98	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						脳梗塞	491	79	Severe	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	70	F	J	533	白内障	160	94	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	71	M	J	526	脊椎圧迫骨折	387	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	57	M	K	536	胃腺腫	31	60	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	70	M	K	533	椎間板突出	177	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	80	M	K	537	肝機能検査値上昇	364	149	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
Placebo	[redacted]	75	F	K	533	脊椎圧迫骨折	43	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING

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Placebo	[redacted]	66	F	K	534	腰部脊柱管狭窄症	370	12	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						変形性脊椎症	370	12	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						脊椎すべり症	370	12	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	66	M	K	534	滑膜炎	404	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	68	M	K	533	一過性脳虚血発作	183	7	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						骨髄生検	302	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	56	F	K	527	筋損傷	81	50	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						腱損傷	81	50	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	59	F	K	534	大腸ポリープ	447	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	78	F	K	141	レヴィ小体型認知症	127	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	71	F	W	169	くも膜下出血	175	35	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	M	W	540	腎出血	393	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						COVID-19肺炎	452	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	534	大腿骨頸部骨折	113	23	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	M	W	539	蜂巣炎	148	36	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	F	W	48	脳出血	48	5	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	W	355	洞結節機能不全	358	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	62	F	W	533	憩室炎	63	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	M	W	440	冠動脈疾患	344	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	57	M	W	540	脱水	475	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性心筋梗塞	476	19	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						エンテロバクター性菌血症	476	14	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						代謝性脳症	476	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						横紋筋融解症	476	4	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	F	W	534	偶発的過量投与	1	1	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	M	W	541	冠動脈疾患	330	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						一過性脳虚血発作	437	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	85	F	W	421	死亡	434	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	62	M	B	539	臍ヘルニア	56	296	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						前立腺腫大	134	218	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						腎結石症	329	23	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED

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10 mg/kg bi-Weekly	[redacted]	83	M	W	539	第一度房室ブロック	353	51	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						心電図QT延長	353	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						左室不全	353	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						洞性徐脈	353	51	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	F	W	534	注入に伴う反応	408	1	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	M	W	237	腹痛	251	8	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						脳血管発作	263	20	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	89	M	W	497	急性呼吸不全	220	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性呼吸不全	509	7	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性呼吸不全	535	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	79	M	W	536	下痢	415	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	W	527	非心臓性胸痛	245	17	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	F	W	537	注入に伴う反応	1	5	Severe	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						狭心症	263	12	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	F	W	529	大腿骨頚部骨折	511	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	F	W	527	一過性脳虚血発作	283	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	534	椎間板突出	51	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	W	1	心房細動	4	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	355	硬膜下血腫	359	3	Severe	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	57	M	W	528	憩室炎	543	9	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	526	転倒	271	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						上腕骨骨折	271	165	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						肋骨骨折	271	107	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	M	W	511	脳血管発作	519	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	81	M	W	421	転倒	423	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						再発非ホジキンリンパ腫	423	-	Severe	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						胸椎骨折	423	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	71	F	W	337	卵巣癌	339	-	Moderate	Not related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						肺塞栓症	339	-	Mild	Not related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	M	W	541	扁平上皮癌	463	17	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	M	W	526	非心臓性胸痛	393	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	1	注入に伴う反応	1	2	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED

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10 mg/kg bi-Weekly	[redacted]	72	M	W	540	COVID−19	372	14	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						低酸素症	380	28	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	W	546	狭心症	98	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						労作性呼吸困難	98	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						心房細動	141	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	F	W	519	注入に伴う反応	346	6	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	F	W	533	股関節部骨折	449	101	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	W	32	アミロイド関連画像異常－微小出血およびヘモジデリン沈着	39	-	Moderate	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						アミロイド関連画像異常－浮腫／滲出液貯留	39	43	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	295	遠隔転移を伴う前立腺癌	282	-	Mild	Not related	DRUG WITHDRAWN	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	77	F	W	519	うっ血性心不全	208	9	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						直腸癌	523	50	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
						肺水腫	568	5	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	M	W	220	心筋梗塞	230	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	88	F	W	330	心房細動	347	59	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						肺水腫	347	59	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						心停止	351	1	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE
						肺炎	351	55	Severe	Not related	NOT APPLICABLE	RECOVERING/RESOLVING
						呼吸不全	351	55	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	81	M	B	537	COVID−19肺炎	56	29	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	M	B	539	勃起不全	207	429	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	69	M	W	435	狭心症	321	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						脳出血	441	-	Severe	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	M	W	535	処置後発熱	129	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	82	F	W	549	脱水	446	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	P	1	注入に伴う反応	1	3	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	M	W	533	急性心筋梗塞	33	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	M	W	533	故意の自傷行為	127	1	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						硬膜下血腫	127	60	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性腎障害	141	6	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						肺炎	141	6	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性腎障害	159	5	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						尿路閉塞	159	4	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED

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10 mg/kg bi-Weekly	[redacted]	77	F	W	506	尿路感染	239	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	W	519	髄膜転移	534	30	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	72	M	W	168	重症筋無力症	176	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	M	W	43	アミロイド関連画像異常－浮腫／滲出液貯留	44	90	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	F	W	532	狭心症	501	6	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	W	421	憩室炎	213	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						痙攣発作	213	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						失神	213	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	W	526	失神	116	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						一過性脳虚血発作	116	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	F	W	526	疲労	91	44	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	378	ラクナ梗塞	249	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						小細胞肺癌	345	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						低ナトリウム血症	378	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	65	M	W	525	心房細動	267	22	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	M	W	531	股関節部骨折	138	63	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	540	失神	63	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	F	W	531	非心臓性胸痛	544	3	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	M	W	534	アミロイド関連画像異常－微小出血およびヘモジデリン沈着	535	-	Mild	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						アミロイド関連画像異常－浮腫／滲出液貯留	535	-	Mild	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	F	W	542	変形性関節症	66	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	F	W	240	手首関節骨折	247	-	Severe	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	M	W	529	心房細動	363	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	80	F	W	50	アミロイド関連画像異常－浮腫／滲出液貯留	72	85	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						尿閉	74	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	15	アミロイド関連画像異常－浮腫／滲出液貯留	8	193	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	F	W	408	乳癌	433	-	Moderate	Not related	DRUG WITHDRAWN	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	80	M	W	533	ウイルス感染	2	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	1	注入に伴う反応	1	2	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	W	161	表在性静脈血栓症	172	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	86	M	W	526	便秘	440	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						低ナトリウム血症	443	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	73	F	W	1	注入に伴う反応	1	2	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						RSウイルス感染	3	83	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						転倒	5	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	M	W	1	注入に伴う反応	1	1	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	W	1	注入に伴う反応	1	1	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	W	1	過敏症	1	2	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						敗血症	1	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	61	M	W	505	急性呼吸不全	248	13	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	F	W	533	鉄欠乏性貧血	143	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	83	F	W	534	唾液腺の良性新生物	250	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	61	F	W	533	鼠径ヘルニア	544	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	F	W	519	三叉神経痛	281	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	W	380	COVID-19	375	28	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	67	F	W	183	形質細胞腫	193	-	Mild	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	F	W	533	浸潤性乳管癌	204	63	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						乳房の上皮内癌	238	50	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	M	W	29	アミロイド関連画像異常－浮腫／滲出液貯留	35	195	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	64	M	W	541	足関節部骨折	165	180	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	F	W	535	憩室炎	276	15	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	W	506	下痢	450	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
						体重減少	450	-	Mild	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	83	M	W	44	肺炎	55	10	Moderate	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
						呼吸不全	55	10	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	74	M	-	442	急性腎障害	442	-	Moderate	Related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	O	537	股関節部骨折	181	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						化学性腹膜炎	195	18	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性胆嚢炎	195	18	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	64	M	O	530	前立腺癌	9	91	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	O	533	卵巣良性腫瘍	72	209	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	F	O	148	アミロイド関連画像異常－浮腫／滲出液貯留	156	58	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						急性肺水腫	159	4	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						胸椎骨折	163	67	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	63	F	W	528	アルツハイマー型認知症	466	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						失見当識	466	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	52	M	W	535	片側運動失調	131	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						良性副甲状腺腫瘍	283	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	W	533	うつ病	322	52	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	F	W	533	瘢痕ヘルニア	16	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	51	F	W	532	失神	248	46	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	531	腸の軸捻転	107	28	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						イレウス	111	24	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						亜イレウス	168	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						機械的イレウス	201	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						失神	338	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						亜イレウス	363	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						失神	363	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						腹部癒着	471	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	F	W	336	感覚鈍麻	207	-	Moderate	Related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						口の感覚鈍麻	207	-	Moderate	Related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	F	W	532	心電図異常	545	7	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						低カリウム血症	547	5	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	J	537	変形性関節症	81	38	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	83	F	J	1	注入に伴う反応	2	9	Mild	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						胆管炎	4	12	Mild	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						失神	4	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	J	435	脳出血	439	-	Moderate	Related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	F	J	315	上肢骨折	189	149	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	M	J	533	鼠径ヘルニア	428	31	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	J	525	狭心症	211	22	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						鼠径ヘルニア	539	27	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	61	M	J	533	蜂巣炎	63	78	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	J	533	狭心症	493	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	90	M	J	531	硬膜下血腫	44	91	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						硬膜下血腫	66	70	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						意識変容状態	171	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED

付録2.7.4-2　重篤なTEAE一覧（301試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	81	M	J	533	挫傷	16	29	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						創傷	16	29	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	J	533	末梢動脈瘤	239	14	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	J	533	膀胱癌	308	59	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						膀胱癌	378	44	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	59	F	K	85	膝蓋骨骨折	90	10	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	72	F	K	533	脂肪腫	67	163	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	64	F	K	513	くも膜下出血	310	12	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	F	K	534	医療機器位置異常	208	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	K	534	胆嚢炎	8	26	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肝嚢胞感染	8	26	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肝嚢胞	166	291	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	55	F	K	533	注入に伴う反応	1	1	Mild	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	60	F	K	267	前腕骨折	38	200	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	W	534	胃食道逆流性疾患	19	6	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						非心臓性胸痛	19	6	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						上腹部痛	41	48	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						悪心	41	48	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	81	M	W	547	心房細動	177	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						心房細動	249	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	W	526	浸潤性乳管癌	299	125	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	68	M	W	85	運動ニューロン疾患	57	-	Mild	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED

Age is age at Informed Consent; M = Male, F = Female; W = White, B = Black or African American, J = Japanese, C = Chinese, K = South Korean, I = Asian Indian, OA = Other Asian, N = American Indian or Alaska Native, O = Other.
PT = preferred term, TEAE = treatment-emergent adverse event.
MedDRA Version 25.0

付録2.7.4-2　重篤なTEAE一覧（301試験OLE）
LEC10-BW-Treated Period

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	83	F	W	374	肺炎	125	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	F	W	1	心筋梗塞	11	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	81	F	W	57	脳出血	58	86	Mild	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
Placebo	[redacted]	83	M	W	1	注入に伴う反応	1	1	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
Placebo	[redacted]	69	M	W	98	COVID－19肺炎	103	27	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	59	F	W	1	注入に伴う反応	1	2	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
Placebo	[redacted]	77	F	W	338	うつ病	1	62	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						激越	13	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	74	M	W	330	尿路感染	186	15	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	77	M	W	302	不全片麻痺	289	16	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	83	F	W	170	脳梗塞	197	-	Mild	Not related	DOSE NOT CHANGED	UNKNOWN
Placebo	[redacted]	68	M	B	213	心房細動	28	9	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性心筋梗塞	31	5	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	75	M	W	210	結腸直腸腺腫	205	20	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	74	M	W	50	低ナトリウム血症	23	5	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	65	M	W	134	尿路感染	58	9	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	73	M	W	199	糖尿病性眼病変	204	78	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	69	F	W	88	消化性潰瘍	69	4	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE
						硬膜下血腫	92	14	Mild	Related	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
						硬膜下血腫	106	-	Severe	Related	DRUG INTERRUPTED	RECOVERING/RESOLVING
Placebo	[redacted]	83	F	W	137	脳表ヘモジデリン沈着症	85	-	Mild	Related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						アミロイド関連画像異常－微小出血およびヘモジデリン沈着	113	-	Mild	Related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	81	F	B	22	アミロイド関連画像異常－浮腫／滲出液貯留	32	-	Severe	Related	DRUG WITHDRAWN	RECOVERING/RESOLVING
						アミロイド関連画像異常－微小出血およびヘモジデリン沈着	50	-	Severe	Related	DRUG WITHDRAWN	RECOVERING/RESOLVING
Placebo	[redacted]	60	M	W	12	注入に伴う反応	1	4	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	79	M	W	154	注入に伴う反応	1	1	Severe	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	64	M	W	295	下気道感染	14	10	Severe	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						過敏症	15	4	Severe	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	84	F	W	281	注入に伴う反応	1	9	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	70	F	W	1	注入に伴う反応	1	1	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
Placebo	[redacted]	63	M	W	166	喉頭扁平上皮癌	170	-	Mild	Not related	NOT APPLICABLE	NOT RECOVERED/NOT RESOLVED
Placebo	[redacted]	65	F	W	294	尿路感染	252	9	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	69	F	W	278	アミロイド関連画像異常－浮腫／滲出液貯留	57	34	Mild	Related	DRUG INTERRUPTED	RECOVERED/RESOLVED
Placebo	[redacted]	71	F	J	330	大腿骨頸部骨折	86	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING

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LEC10-BW-Treated Period

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	81	M	J	275	白内障	143	-	Mild	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	65	M	J	272	膀胱癌	244	119	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	56	F	J	1	注入に伴う反応	1	13	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
Placebo	[redacted]	71	F	J	260	腹部不快感	169	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						視床出血	276	-	Severe	Related	DRUG WITHDRAWN	RECOVERING/RESOLVING
Placebo	[redacted]	85	M	J	218	単径ヘルニア	39	82	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
Placebo	[redacted]	58	F	K	57	尺骨骨折	62	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
Placebo	[redacted]	80	F	K	15	アミロイド関連画像異常－浮腫／滲出液貯留	27	-	Severe	Related	DRUG WITHDRAWN	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	80	M	W	1032	腎出血	393	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						COVID－19肺炎	452	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	920	大腿骨頸部骨折	113	23	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	82	M	W	723	肺炎	741	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						尿路感染	745	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	69	M	W	654	蜂巣炎	148	36	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	F	W	48	脳出血	48	5	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	W	355	洞結節機能不全	358	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	62	F	W	534	憩室炎	63	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	M	W	440	冠動脈疾患	344	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	57	M	W	673	脱水	475	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性心筋梗塞	476	19	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						エンテロバクター性菌血症	476	14	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						代謝性脳症	476	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						横紋筋融解症	476	4	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	F	W	955	偶発的過量投与	1	1	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						大腿骨骨折	747	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	W	835	肺炎	579	22	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	M	W	541	冠動脈疾患	330	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						一過性脳虚血発作	437	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	85	F	W	421	死亡	434	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	62	M	B	715	臍ヘルニア	56	296	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						前立腺腫大	134	218	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						腎結石症	329	23	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED

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投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	83	M	W	681	第一度房室ブロック	353	51	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						心電図QT延長	353	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						左室不全	353	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						洞性徐脈	353	51	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	F	W	534	注入に伴う反応	408	1	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	M	W	237	腹痛	251	8	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						脳血管発作	263	20	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	89	M	W	771	急性呼吸不全	220	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性呼吸不全	509	7	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性呼吸不全	535	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	70	M	W	875	COVID－19肺炎	735	7	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	M	W	819	胃腸出血	770	47	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	M	W	817	下痢	415	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	W	646	非心臓性胸痛	245	17	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	F	W	538	注入に伴う反応	1	5	Severe	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						狭心症	263	12	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						注入に伴う反応	559	7	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	F	W	798	大腿骨頸部骨折	511	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						嘔吐	752	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						痙攣発作	826	1	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	F	W	662	一過性脳虚血発作	283	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	828	椎間板突出	51	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	W	1	心房細動	4	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	355	硬膜下血腫	359	3	Severe	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	57	M	W	528	憩室炎	543	9	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	526	転倒	271	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						上腕骨骨折	271	165	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						肋骨骨折	271	107	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	M	W	511	脳血管発作	519	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	70	M	W	688	胆石症	703	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	421	転倒	423	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						再発非ホジキンリンパ腫	423	-	Severe	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						胸椎骨折	423	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING

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10 mg/kg bi-Weekly	[redacted]	71	F	W	337	卵巣癌	339	-	Moderate	Not related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						肺塞栓症	339	-	Mild	Not related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	M	W	780	扁平上皮癌	463	17	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	M	W	723	非心臓性胸痛	393	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	W	1	注入に伴う反応	1	2	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	M	W	835	COVID－19	372	14	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						低酸素症	380	28	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	W	573	狭心症	98	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						労作性呼吸困難	98	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						心房細動	141	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	F	W	519	注入に伴う反応	346	6	Moderate	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	F	W	533	股関節部骨折	449	101	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	80	F	W	32	アミロイド関連画像異常－微小出血およびヘモジデリン沈着	39	-	Moderate	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						アミロイド関連画像異常－浮腫／滲出液貯留	39	43	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	M	W	641	急性心筋梗塞	559	13	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	295	遠隔転移を伴う前立腺癌	282	-	Mild	Not related	DRUG WITHDRAWN	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	77	F	W	660	うっ血性心不全	208	9	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						直腸癌	523	50	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED WITH SEQUELAE
						肺水腫	568	5	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	M	W	727	腎細胞癌	708	18	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	70	M	W	220	心筋梗塞	230	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	88	F	W	330	心房細動	347	59	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						肺水腫	347	59	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						心停止	351	1	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE
						肺炎	351	55	Severe	Not related	NOT APPLICABLE	RECOVERING/RESOLVING
						呼吸不全	351	55	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	81	M	B	650	COVID－19肺炎	56	29	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						結腸腺癌	614	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	73	M	B	611	勃起不全	207	429	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	69	M	W	435	狭心症	321	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						脳出血	441	-	Severe	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	M	W	535	処置後発熱	129	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	82	F	W	734	脱水	446	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	P	1	注入に伴う反応	1	3	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED

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10 mg/kg bi-Weekly	[redacted]	70	M	W	855	急性心筋梗塞	33	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	M	W	856	故意の自傷行為	127	1	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						硬膜下血腫	127	60	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性腎障害	141	6	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						肺炎	141	6	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						急性腎障害	159	5	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						尿路閉塞	159	4	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	786	高血圧性脳症	611	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						精神状態変化	611	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	F	W	506	尿路感染	239	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	W	519	髄膜転移	534	30	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	72	M	W	168	重症筋無力症	176	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	M	W	43	アミロイド関連画像異常－浮腫／滲出液貯留	44	90	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	F	W	724	狭心症	501	6	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	W	421	憩室炎	213	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						痙攣発作	213	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						失神	213	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	W	672	失神	116	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						一過性脳虚血発作	116	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	F	W	574	疲労	91	44	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	378	ラクナ梗塞	249	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						小細胞肺癌	345	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						低ナトリウム血症	378	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	65	M	W	525	心房細動	267	22	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	M	W	656	股関節部骨折	138	63	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	W	667	失神	63	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	F	W	586	非心臓性胸痛	544	3	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	M	W	534	アミロイド関連画像異常－微小出血およびヘモジデリン沈着	535	-	Mild	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						アミロイド関連画像異常－浮腫／滲出液貯留	535	-	Mild	Related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	69	F	W	571	変形性関節症	66	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	F	W	240	手首関節骨折	247	-	Severe	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	M	W	529	心房細動	363	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	80	F	W	50	アミロイド関連画像異常－浮腫／滲出液貯留	72	85	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						尿閉	74	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

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10 mg/kg bi-Weekly	[redacted]	78	M	W	15	アミロイド関連画像異常－浮腫／滲出液貯留	8	193	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	75	F	W	408	乳癌	433	-	Moderate	Not related	DRUG WITHDRAWN	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	80	M	W	533	ウイルス感染	2	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	1	注入に伴う反応	1	2	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	W	161	表在性静脈血栓症	172	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	86	M	W	526	便秘	440	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						低ナトリウム血症	443	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	73	F	W	1	注入に伴う反応	1	2	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						RSウイルス感染	3	83	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						転倒	5	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	M	W	1	注入に伴う反応	1	1	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	W	1	注入に伴う反応	1	1	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	W	1	過敏症	1	2	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						敗血症	1	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	61	M	W	505	急性呼吸不全	248	13	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	F	W	546	眼球瘻	578	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	F	W	554	鉄欠乏性貧血	143	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	83	F	W	549	唾液腺の良性新生物	250	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	61	F	W	546	単径ヘルニア	544	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	F	W	519	三叉神経痛	281	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	W	380	COVID－19	375	28	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	74	M	W	562	アミロイド関連画像異常－浮腫／滲出液貯留	589	101	Moderate	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	F	W	183	形質細胞腫	193	-	Mild	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	F	W	533	浸潤性乳管癌	204	63	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						乳房の上皮内癌	238	50	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	M	W	29	アミロイド関連画像異常－浮腫／滲出液貯留	35	195	Severe	Related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	64	M	W	833	足関節部骨折	165	180	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	60	F	W	815	転倒	783	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	F	W	535	憩室炎	276	15	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	79	F	W	506	下痢	450	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
						体重減少	450	-	Mild	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
10 mg/kg bi-Weekly	[redacted]	83	M	W	44	肺炎	55	10	Moderate	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED WITH SEQUELAE
						呼吸不全	55	10	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	74	M	-	442	急性腎障害	442	-	Moderate	Related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED

付録2.7.4-2　重篤なTEAE一覧（301試験OLE）
LEC10-BW-Treated Period

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	76	M	O	537	股関節部骨折	181	-	Severe	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						化学性腹膜炎	195	18	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性胆嚢炎	195	18	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	64	M	O	530	前立腺癌	9	91	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	O	647	卵巣良性腫瘍	72	209	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	68	F	O	148	アミロイド関連画像異常－浮腫／滲出液貯留	156	58	Severe	Related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						急性肺水腫	159	4	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						胸椎骨折	163	67	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	63	F	W	528	アルツハイマー型認知症	466	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						失見当識	466	-	Moderate	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	52	M	W	535	片側運動失調	131	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						良性副甲状腺腫瘍	283	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	73	F	W	590	うつ病	322	52	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	F	W	548	瘢痕ヘルニア	16	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	51	F	W	532	失神	248	46	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	74	M	W	531	腸の軸捻転	107	28	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						イレウス	111	24	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						亜イレウス	168	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						機械的イレウス	201	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						失神	338	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						亜イレウス	363	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						失神	363	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						腹部癒着	471	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	66	F	W	336	感覚鈍麻	207	-	Moderate	Related	DOSE NOT CHANGED	RECOVERING/RESOLVING
						口の感覚鈍麻	207	-	Moderate	Related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	F	W	532	心電図異常	545	7	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
						低カリウム血症	547	5	Severe	Not related	NOT APPLICABLE	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	J	613	変形性関節症	81	38	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	J	569	白内障	562	92	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						白内障	562	106	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	83	F	J	1	注入に伴う反応	2	9	Mild	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						胆管炎	4	12	Mild	Not related	DRUG WITHDRAWN	RECOVERED/RESOLVED
						失神	4	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	70	M	J	849	腰部脊柱管狭窄症	810	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING/RESOLVING

付録2.7.4-2　重篤なTEAE一覧（301試験OLE）
LEC10-BW-Treated Period

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	79	F	J	435	脳出血	439	-	Moderate	Related	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	67	F	J	315	上肢骨折	189	149	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	M	J	870	単径ヘルニア	428	31	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	J	554	狭心症	211	22	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						単径ヘルニア	539	27	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	61	M	J	716	蜂巣炎	63	78	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	76	M	J	533	狭心症	493	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
10 mg/kg bi-Weekly	[redacted]	90	M	J	539	硬膜下血腫	44	91	Severe	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						硬膜下血腫	66	70	Mild	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						意識変容状態	171	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	81	M	J	667	挫傷	16	29	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						創傷	16	29	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						急性心不全	777	1	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg bi-Weekly	[redacted]	80	F	J	813	末梢動脈瘤	239	14	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						末梢血管塞栓症	615	15	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						冠動脈狭窄	669	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						移植血管感染	826	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
						感染性脊椎炎	853	107	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
						日常活動における個人の自立の喪失	853	-	Moderate	Not related	DRUG INTERRUPTED	RECOVERING/RESOLVING
						橈骨骨折	857	103	Moderate	Not related	DRUG INTERRUPTED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	78	M	J	745	膀胱癌	308	59	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						膀胱癌	378	44	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	59	F	K	85	膝蓋骨骨折	90	10	Moderate	Not related	NOT APPLICABLE	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	72	F	K	533	脂肪腫	67	163	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	64	F	K	513	くも膜下出血	310	12	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	71	F	K	534	医療機器位置異常	208	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	77	M	K	644	胆嚢炎	8	26	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肝嚢胞感染	8	26	Severe	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						肝嚢胞	166	291	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	55	F	K	724	注入に伴う反応	1	1	Mild	Related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	60	F	K	267	前腕骨折	38	200	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED

付録2.7.4-2　重篤なTEAE一覧（301試験OLE）
LEC10-BW-Treated Period

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	72	F	W	534	胃食道逆流性疾患	19	6	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						非心臓性胸痛	19	6	Mild	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						上腹部痛	41	48	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						悪心	41	48	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	81	M	W	547	心房細動	177	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
						心房細動	249	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED
10 mg/kg bi-Weekly	[redacted]	72	F	W	526	浸潤性乳管癌	299	125	Moderate	Not related	DOSE NOT CHANGED	RECOVERED/RESOLVED WITH SEQUELAE
10 mg/kg bi-Weekly	[redacted]	68	M	W	85	運動ニューロン疾患	57	-	Mild	Not related	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED

Age is age at Informed Consent of Core Study for subjects assigned to lecanemab in Core Study, and of OLE Phase for those assigned to placebo in Core Study; M = Male, F = Female; W = White, B = Black or African American, J = Japanese, C = Chinese, K = South Korean, I = Asian Indian, OA = Other Asian, N = American Indian or Alaska Native, P = Native Hawaiian or other Pacific Islander, Other; TEAE = treatment-emergent adverse event.
LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.
Duration of treatment = date of last dose of study drug - date of first dose of study drug + 1.
MedDRA Version 25.0

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	83	F	W	189	顔面骨骨折	118	43	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						転倒	118	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						顎の骨折	118	43	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	77	F	W	537	股関節部骨折	440	15	Severe	Not related	DRUG INTERRUPTED	RECOVERED
						肋骨骨折	440	65	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
Placebo	[redacted]	64	F	W	533	浮動性めまい	17	26	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
						硬膜下血腫	17	28	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
Placebo	[redacted]	59	M	W	535	腎結石症	220	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	62	F	B	540	一過性脳虚血発作	300	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						変形性関節症	310	88	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	85	M	W	428	悪性黒色腫	448	7	Moderate	Not related	DRUG WITHDRAWN	RECOVERED
Placebo	[redacted]	76	M	W	533	不安定狭心症	327	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						転倒	478	56	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	68	M	W	532	失神	242	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	62	F	W	533	大腸炎	96	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	72	F	W	71	洞性徐脈	96	2	Moderate	Possibly related	NOT APPLICABLE	RECOVERED
						失神	96	2	Moderate	Possibly related	NOT APPLICABLE	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	73	M	W	533	失神	213	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						洞結節機能不全	402	－	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED
Placebo	[redacted]	80	F	W	533	骨盤骨折	4	69	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	85	F	W	535	脳血管発作	377	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	63	M	W	351	嘔吐	120	10	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						アルコール中毒	353	4	Moderate	Not related	DRUG WITHDRAWN	RECOVERED
Placebo	[redacted]	87	F	W	65	尿路感染	6	4	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
						クロストリジウム・ディフィシレ大腸炎	75	－	Moderate	Not related	DRUG INTERRUPTED	RECOVERING
Placebo	[redacted]	74	F	W	539	狭心症	532	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	78	F	W	529	嚢胞	203	13	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	70	F	W	540	回転性めまい	261	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	88	M	W	528	憩室炎	433	8	Severe	Not related	DRUG INTERRUPTED	RECOVERED
Placebo	[redacted]	70	F	W	141	尿路性敗血症	145	4	Severe	Not related	DRUG INTERRUPTED	RECOVERED
						発熱	149	5	Severe	Not related	DRUG INTERRUPTED	RECOVERED
Placebo	[redacted]	77	F	B	531	頭痛	251	38	Moderate	Possibly related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	75	F	W	281	浸潤性乳管癌	181	46	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						肝細胞癌	265	－	Moderate	Not related	DRUG WITHDRAWN	UNKNOWN

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	76	M	W	71	肉腫（医師記載語：左腋窩の悪性腫瘍－肉腫）	89	50	Severe	Not related	NOT APPLICABLE	FATAL
						肉腫（医師記載語：脊椎の悪性腫瘍－肉腫）	89	50	Severe	Not related	NOT APPLICABLE	FATAL
Placebo	[redacted]	68	F	W	539	膣脱	53	194	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	81	F	W	450	大脳動脈血栓症	460	85	Severe	Not related	DRUG WITHDRAWN	RECOVERED WITH SEQUELAE
Placebo	[redacted]	56	M	W	85	塞栓性脳卒中	96	6	Moderate	Possibly related	DRUG WITHDRAWN	RECOVERED
Placebo	[redacted]	89	M	W	172	転倒	135	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	79	M	W	533	変形性関節症	231	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	68	F	W	534	虫垂炎	304	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	74	M	W	70	譫妄	78	7	Severe	Not related	NOT APPLICABLE	UNKNOWN
						急性呼吸不全	84	1	Severe	Not related	DRUG WITHDRAWN	FATAL
Placebo	[redacted]	80	M	W	281	クロストリジウム性敗血症	283	17	Severe	Not related	NOT APPLICABLE	RECOVERED
Placebo	[redacted]	64	F	W	539	変形性関節症	73	413	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	77	M	W	45	胸骨骨折	34	72	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	86	F	W	538	背部痛	134	82	Severe	Not related	DRUG INTERRUPTED	RECOVERED
Placebo	[redacted]	77	F	W	527	転倒	248	3	Mild	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	64	M	W	435	単径ヘルニア	227	3	Mild	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	80	M	W	421	処置後出血	430	90	Moderate	Not related	NOT APPLICABLE	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	71	F	W	530	乳管内増殖性病変	516	138	Severe	Not related	DRUG WITHDRAWN	RECOVERED
Placebo	[redacted]	70	F	W	531	胸椎骨折	341	179	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	53	M	W	221	精神病性障害	224	－	Moderate	Possibly related	DRUG WITHDRAWN	RECOVERING
Placebo	[redacted]	76	M	W	533	上腕骨骨折	59	70	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
Placebo	[redacted]	86	F	J	534	大腿骨骨折	545	72	Moderate	Not related	NOT APPLICABLE	RECOVERED
2.5 mg/kg bi-Weekly	[redacted]	77	M	W	424	心筋梗塞	432	4	Moderate	Not related	NOT APPLICABLE	RECOVERED WITH SEQUELAE
2.5 mg/kg bi-Weekly	[redacted]	81	M	W	151	卒中の出血性変化	162	25	Severe	Possibly related	DRUG WITHDRAWN	RECOVERED
2.5 mg/kg bi-Weekly	[redacted]	86	F	W	435	心房細動	447	2	Severe	Not related	DRUG WITHDRAWN	RECOVERED
2.5 mg/kg bi-Weekly	[redacted]	81	F	W	464	脳新生物	449	151	Severe	Possibly related	DRUG WITHDRAWN	FATAL
2.5 mg/kg bi-Weekly	[redacted]	71	M	W	529	肺腫瘤	57	174	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
2.5 mg/kg bi-Weekly	[redacted]	75	F	W	378	心停止	395	1	Severe	Not related	DRUG WITHDRAWN	FATAL
2.5 mg/kg bi-Weekly	[redacted]	75	M	W	533	鼠径ヘルニア	495	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
2.5 mg/kg bi-Weekly	[redacted]	77	F	W	526	ストレス心筋症	536	8	Severe	Possibly related	DRUG WITHDRAWN	RECOVERED
5 mg/kg Monthly	[redacted]	72	F	W	396	頭蓋脳損傷	270	2	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
5 mg/kg Monthly	[redacted]	84	M	W	450	一過性脳虚血発作	96	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						一過性脳虚血発作	358	3	Mild	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg Monthly	[redacted]	68	F	W	335	一過性脳虚血発作	344	15	Moderate	Not related	NOT APPLICABLE	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
5 mg/kg Monthly	[redacted]	66	M	W	533	単径ヘルニア	89	45	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						尿閉	121	6	Mild	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	64	F	W	64	幻覚	71	－	Moderate	Not related	DRUG WITHDRAWN	RECOVERING
5 mg/kg bi-Weekly	[redacted]	84	M	W	534	医療機器破損	154	11	Severe	Not related	DRUG INTERRUPTED	RECOVERED
						創離開	170	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	75	F	W	540	潰瘍性出血	91	9	Severe	Not related	DRUG INTERRUPTED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	73	M	W	533	精神状態変化	262	3	Moderate	Possibly related	DOSE NOT CHANGED	RECOVERED
						認知障害発作	547	－	Severe	Possibly related	NOT APPLICABLE	NOT RECOVERED
5 mg/kg bi-Weekly	[redacted]	72	M	W	184	脳血管発作	203	1	Moderate	Possibly related	NOT APPLICABLE	RECOVERED
5 mg/kg bi-Weekly	[redacted]	78	M	W	15	肺炎	15	36	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	79	F	W	421	肝不全	421	6	Severe	Not related	DRUG WITHDRAWN	FATAL
						急性肝炎	421	6	Severe	Not related	DOSE NOT CHANGED	NOT RECOVERED
						急性腎障害	422	5	Severe	Not related	DRUG WITHDRAWN	FATAL
						リンパ腫	423	4	Severe	Not related	NOT APPLICABLE	NOT RECOVERED
						菌血症	425	2	Severe	Not related	NOT APPLICABLE	FATAL
						凝血異常	425	2	Severe	Not related	NOT APPLICABLE	FATAL
						白血球減少症	425	2	Severe	Not related	NOT APPLICABLE	FATAL

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
5 mg/kg bi-Weekly	[redacted]	79	F	W	421	代謝性脳症	425	2	Severe	Not related	DRUG WITHDRAWN	FATAL
						多臓器機能不全症候群	425	2	Severe	Not related	NOT APPLICABLE	FATAL
5 mg/kg bi-Weekly	[redacted]	81	F	W	508	血中クレアチニン異常	19	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						関節痛	101	23	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	73	F	W	533	うっ血性心不全	537	108	Severe	Not related	NOT APPLICABLE	RECOVERED WITH SEQUELAE
						末梢腫脹	537	6	Severe	Not related	NOT APPLICABLE	RECOVERED
5 mg/kg bi-Weekly	[redacted]	85	F	W	491	虚血性脳卒中	501	－	Severe	Not related	NOT APPLICABLE	RECOVERING
5 mg/kg bi-Weekly	[redacted]	59	M	W	538	失神	118	1	Severe	Not related	DRUG INTERRUPTED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	66	F	W	533	冠動脈狭窄	364	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	72	M	W	518	攻撃性	209	10	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						激越	209	10	Severe	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	67	F	W	533	自殺念慮	261	37	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	68	M	J	532	腸炎	262	8	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	72	F	J	535	意識変容状態	306	20	Mild	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	78	M	W	533	クロストリジウム・ディフィシレ感染	246	50	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						失神寸前の状態	246	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	77	F	W	444	膵腺管癌	449	－	Severe	Not related	DRUG WITHDRAWN	NOT RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg Monthly	[redacted]	88	M	W	308	失神	316	3	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg Monthly	[redacted]	85	M	W	540	胃腸出血	378	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	77	M	W	43	徐脈	55	4	Mild	Not related	NOT APPLICABLE	RECOVERED
10 mg/kg Monthly	[redacted]	75	F	W	532	慢性閉塞性肺疾患	269	4	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	77	M	W	534	非心臓性胸痛	35	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	71	F	W	29	一過性脳虚血発作	29	3	Severe	Possibly related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	73	F	W	533	浸潤性乳管癌	204	30	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	77	M	W	533	頚髄神経根障害	177	3	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	81	M	W	533	腸管腫瘤	535	30	Moderate	Not related	NOT APPLICABLE	RECOVERED
10 mg/kg Monthly	[redacted]	66	M	W	100	冠動脈疾患	30	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	78	M	W	541	上気道感染	179	7	Mild	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	71	M	W	532	転倒	281	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						上腕骨骨折	281	17	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						膝蓋骨骨折	281	17	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	71	M	W	533	前立腺癌	6	—	Mild	Not related	DRUG INTERRUPTED	NOT RECOVERED
10 mg/kg Monthly	[redacted]	76	F	W	296	幻覚	301	179	Severe	Not related	DRUG WITHDRAWN	RECOVERED
10 mg/kg Monthly	[redacted]	71	M	W	392	肺塞栓症	398	5	Severe	Not related	DRUG INTERRUPTED	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg Monthly	[redacted]	69	F	W	394	上部消化管出血	293	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	82	M	W	435	うっ血性心不全	448	4	Moderate	Not related	DRUG WITHDRAWN	RECOVERED
						心筋梗塞	448	5	Moderate	Not related	NOT APPLICABLE	RECOVERED
10 mg/kg Monthly	[redacted]	77	M	W	531	大腿骨頚部骨折	329	3	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg Monthly	[redacted]	82	M	W	534	椎間板突出	264	68	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	79	M	W	78	アミロイド関連画像異常－浮腫／滲出液貯留	81	90	Moderate	Probably related	DRUG WITHDRAWN	RECOVERED
10 mg/kg Monthly	[redacted]	78	M	W	534	足関節部骨折	123	69	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg Monthly	[redacted]	76	M	W	74	正常圧水頭症	65	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						急性呼吸不全	87	10	Severe	Not related	NOT APPLICABLE	RECOVERED
						高ナトリウム血症	87	1	Mild	Not related	NOT APPLICABLE	RECOVERED
						痙攣発作	87	10	Severe	Not related	DRUG WITHDRAWN	RECOVERED WITH SEQUELAE
10 mg/kg Monthly	[redacted]	73	M	W	534	良性前立腺肥大症	424	－	Moderate	Not related	DOSE NOT CHANGED	RECOVERING
10 mg/kg Monthly	[redacted]	58	M	W	527	非心臓性胸痛	309	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	86	M	W	526	インフルエンザ	492	7	Mild	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg Monthly	[redacted]	64	M	W	536	網膜剥離	532	－	Moderate	Not related	DOSE NOT CHANGED	RECOVERING
10 mg/kg Monthly	[redacted]	78	M	W	201	脊髄損傷	212	10	Severe	Not related	DRUG WITHDRAWN	FATAL

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted][a]	56	F	W	28	アミロイド関連画像異常－浮腫／滲出液貯留	34	176	Severe	Probably related	DRUG WITHDRAWN	RECOVERED
						脳微小出血	34	－	Severe	Probably related	NOT APPLICABLE	NOT RECOVERED
10 mg/kg bi-Weekly	[redacted]	69	F	W	540	関節炎	105	4	Mild	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	77	F	W	540	慢性閉塞性肺疾患	94	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	72	M	W	43	心房細動	57	3	Moderate	Not related	DRUG WITHDRAWN	RECOVERED
10 mg/kg bi-Weekly	[redacted]	83	M	W	533	蜂巣炎	553	16	Moderate	Not related	NOT APPLICABLE	RECOVERED
						レンサ球菌性敗血症	553	16	Moderate	Not related	NOT APPLICABLE	RECOVERED
10 mg/kg bi-Weekly	[redacted]	87	M	W	176	食道食物嵌入	128	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	86	F	W	538	非心臓性胸痛	211	2	Mild	Not related	DRUG INTERRUPTED	RECOVERED
						関節痛	443	13	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						肋骨骨折	443	22	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						脾破裂	443	22	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	72	F	W	491	下痢	501	4	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	74	F	W	540	腸閉塞	449	10	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	87	M	W	531	急性胆管炎	277	10	Severe	Not related	DRUG INTERRUPTED	RECOVERED
						慢性胆嚢炎	277	10	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						敗血症	277	10	Severe	Not related	DRUG INTERRUPTED	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験Core）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	69	M	W	69	アミロイド関連画像異常－浮腫／滲出液貯留	80	71	Severe	Probably related	DRUG WITHDRAWN	RECOVERED
						失語症	80	1	Severe	Probably related	NOT APPLICABLE	RECOVERED
						一過性脳虚血発作	80	3	Severe	Probably related	NOT APPLICABLE	RECOVERED
10 mg/kg bi-Weekly	[redacted]	77	F	W	533	失神	360	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	69	F	W	534	関節痛	387	188	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	84	F	W	533	尿路感染	365	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	60	F	B	283	呼吸困難	270	3	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	73	F	W	34	顔面骨骨折	39	26	Severe	Not related	DRUG INTERRUPTED	RECOVERED
						上肢骨折	39	26	Severe	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	57	M	W	156	胸痛	3	2	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	70	M	W	115	移行上皮癌	8	1	Mild	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	72	M	W	72	アミロイド関連画像異常－浮腫／滲出液貯留	73	－	Severe	Probably related	DRUG WITHDRAWN	UNKNOWN
						脳微小出血	78	－	Moderate	Probably related	NOT APPLICABLE	NOT RECOVERED
10 mg/kg bi-Weekly	[redacted]	86	M	W	99	完全房室ブロック	108	1	Severe	Not related	DRUG WITHDRAWN	RECOVERED
10 mg/kg bi-Weekly	[redacted]	78	M	W	15	注入に伴う反応	15	4	Moderate	Probably related	DRUG WITHDRAWN	RECOVERED

Age is age at Informed Consent; M = Male, F = Female; W = White, B = Black or African American, J = Japanese, C = Chinese, OA = Other Asian, P = Native Hawaiian or other Pacific Islander, N = American Indian or Alaska Native, O = Other.
PT = preferred term, TEAE = Treatment-emergent adverse event.
MedDRA Version 24.0
a: In addition to these 2 serious TEAEs, another 1 serious TEAE (subdural haemorrhage) was newly reported in the CSR Version 2.0 updated on 09 Dec 2022.

付録2.7.4-2　重篤なTEAE一覧（201試験OLE）

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	74	F	W	855	頚椎骨折	155	75	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						転倒	155	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						脊髄損傷	155	75	Severe	Not related	DRUG INTERRUPTED	RECOVERED
						汎血球減少症	863	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED
Placebo	[redacted]	79	M	W	1107	狭心症	11	2	Mild	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	84	F	W	1148	胸部不快感	16	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	55	M	W	15	硬膜下出血	23	2	Moderate	Not related	DRUG WITHDRAWN	RECOVERED
Placebo	[redacted]	80	M	W	981	脊柱管狭窄症	43	48	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	79	F	W	883	尿路性敗血症	860	9	Severe	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	82	F	W	939	転倒	757	370	Mild	Not related	DOSE NOT CHANGED	RECOVERED
Placebo	[redacted]	79	M	W	837	中枢神経系転移	859	21	Severe	Not related	NOT APPLICABLE	FATAL
Placebo	[redacted]	70	M	W	436	脳梗塞	390	5	Moderate	Not related	DRUG INTERRUPTED	RECOVERED WITH SEQUELAE
						視床梗塞	390	5	Moderate	Not related	DRUG INTERRUPTED	RECOVERED WITH SEQUELAE
Placebo	[redacted]	72	F	W	827	脳出血	34	-	Moderate	Not related	DRUG INTERRUPTED	NOT RECOVERED
Placebo	[redacted]	72	M	W	1	注入に伴う反応	1	13	Severe	Related	DRUG WITHDRAWN	RECOVERED
Placebo	[redacted]	79	F	J	1093	尿路結石	1057	45	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
2.5 mg/kg bi-Weekly	[redacted]	52	M	W	1163	頭蓋顔面骨折	642	69	Severe	Not related	DRUG INTERRUPTED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	76	M	W	981	頚椎骨折	900	48	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						転倒	900	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg bi-Weekly	[redacted]	80	F	W	488	頚椎骨折	495	11	Severe	Not related	DRUG WITHDRAWN	FATAL
5 mg/kg bi-Weekly	[redacted]	82	F	B	995	硬膜下血腫	897	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED
						硬膜下ヒグローマ	897	-	Mild	Not related	DOSE NOT CHANGED	NOT RECOVERED
						転倒	1008	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED WITH SEQUELAE
5 mg/kg bi-Weekly	[redacted]	75	M	W	492	肺腺癌	478	-	Moderate	Not related	DRUG INTERRUPTED	UNKNOWN
10 mg/kg bi-Weekly	[redacted]	86	M	W	1159	胸痛	144	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	87	F	W	1065	痙攣発作	498	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg bi-Weekly	[redacted]	66	F	W	890	気胸	416	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING
						肋骨骨折	416	-	Moderate	Not related	DOSE NOT CHANGED	RECOVERING
10 mg/kg bi-Weekly	[redacted]	80	M	W	727	移行上皮癌	735	-	Moderate	Not related	DRUG INTERRUPTED	UNKNOWN
10 mg/kg bi-Weekly	[redacted]	74	F	W	958	後天性てんかん性失語症	106	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験OLE）

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg bi-Weekly	[redacted]	62	M	J	1123	肋骨骨折	473	162	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						外傷性腎損傷	473	55	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
5 mg/kg Monthly	[redacted]	80	F	W	210	アミロイド関連画像異常－浮腫／滲出液貯留	181	368	Mild	Related	DOSE NOT CHANGED	RECOVERED
						脳表ヘモジデリン沈着症	181	368	Mild	Related	DOSE NOT CHANGED	RECOVERED
5 mg/kg Monthly	[redacted]	75	F	W	466	股関節部骨折	476	-	Severe	Not related	DOSE NOT CHANGED	NOT RECOVERED
5 mg/kg Monthly	[redacted]	72	M	W	778	胃腸炎	369	7	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						急性腎障害	371	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	81	F	W	1080	精神状態変化	599	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	82	M	W	1122	血尿	27	2	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
						良性前立腺肥大症	48	1	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						処置後低血圧	48	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	78	M	W	823	胸部不快感	272	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						精神状態変化	629	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						心房細動	630	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	85	F	W	428	失神	97	35	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						肺炎	441	42	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						急性腎障害	453	5	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	81	F	W	914	股関節部骨折	634	139	Severe	Not related	DOSE NOT CHANGED	RECOVERED WITH SEQUELAE
						敗血症	914	13	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	83	M	W	902	一過性脳虚血発作	817	4	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						急性腎障害	832	8	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	77	F	W	407	遠隔転移を伴う乳癌	421	-	Moderate	Not related	DRUG WITHDRAWN	NOT RECOVERED
10 mg/kg Monthly	[redacted]	80	M	W	1163	冠動脈疾患	334	6	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	76	F	W	1	無力症	2	13	Moderate	Related	DOSE NOT CHANGED	RECOVERED WITH SEQUELAE
						悪心	2	3	Moderate	Related	DOSE NOT CHANGED	RECOVERED
						嘔吐	2	3	Moderate	Related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	58	F	W	897	全身性強直性間代性発作	804	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	71	M	W	1164	一過性脳虚血発作	294	4	Moderate	Not related	DRUG INTERRUPTED	RECOVERED
						脱水	820	3	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						回転性めまい	863	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED

付録2.7.4-2　重篤なTEAE一覧（201試験OLE）

投与群（Core Study）	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
10 mg/kg Monthly	[redacted]	78	M	W	1164	大動脈弁狭窄	287	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	76	M	W	966	原発巣不明の悪性新生物	974	11	Severe	Not related	DRUG WITHDRAWN	FATAL
						肺炎	974	11	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						腹水	980	5	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
						神経内分泌癌	982	3	Severe	Not related	DRUG WITHDRAWN	FATAL
10 mg/kg Monthly	[redacted]	78	M	W	998	心筋梗塞	199	1	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	72	F	W	967	結腸腺癌	69	59	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						小腸閉塞	657	2	Severe	Not related	DRUG INTERRUPTED	RECOVERED
10 mg/kg Monthly	[redacted]	64	M	W	344	便秘	252	2	Severe	Not related	DOSE NOT CHANGED	RECOVERED
						尿路感染	260	6	Severe	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	78	M	J	365	肩回旋筋腱板症候群	50	-	Mild	Not related	DOSE NOT CHANGED	RECOVERING
10 mg/kg Monthly	[redacted]	60	M	J	505	誤嚥性肺炎	508	7	Moderate	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	70	M	J	1106	心房細動	106	4	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						一過性脳虚血発作	106	4	Mild	Not related	DOSE NOT CHANGED	RECOVERED
						心房細動	279	3	Mild	Not related	DOSE NOT CHANGED	RECOVERED
10 mg/kg Monthly	[redacted]	72	M	K	972	関節損傷	379	97	Mild	Not related	DOSE NOT CHANGED	RECOVERED

Age is age at Informed Consent for OLE Phase; M = Male, F = Female; W = White, B = Black or African American, C = Chinese, J = Japanese, OA = Other Asian, N = American Indian or Alaska Native, P = Native Hawaiian or other Pacific Islander, O = Other.
OLE = open-label extension, PT = preferred term, TEAE = treatment-emergent adverse event.
MedDRA Version 25.0

付録2.7.4-2　重篤なTEAE一覧（101試験）

投与群	被験者識別コード	年齢	性別	人種	投与期間（日）	有害事象（TEAE）MedDRA（PT）	発現日（Day）	持続期間（日）	重症度	治験薬との因果関係	治験薬の処置	転帰
Placebo	[redacted]	66	M	W	1	薬疹	88	31	Severe	Not related	Not Applicable	Recovered
SAD BAN2401 1 mg/kg	[redacted]	81	M	W	1	脳出血	21	31	Mild	Possibly related	Not Applicable	Recovered
SAD BAN2401 3 mg/kg	[redacted]	67	F	B	1	脳腫瘤	29	－	Mild	Not related	Not Applicable	Not recovered
						血管原性脳浮腫	29	－	Mild	Not related	Not Applicable	Not recovered
SAD BAN2401 15 mg/kg	[redacted]	87	F	W	1	急性冠動脈症候群	2	191	Mild	Not related	Not Applicable	Recovered
						非心臓性胸痛	40	1	Moderate	Not related	Not Applicable	Recovered

Age is age at Informed Consent; M = Male, F = Female; W = White, B = Black or African American, A = Asian, P = Native Hawaiian or other Pacific Islander, N = American Indian or Alaska Native, O = Other.
PT = preferred term, SAD = single ascending dose, TEAE = treatment-emergent adverse event.
MedDRA Version 15.0