付録 2.7.6-5

SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
創傷	1 (0.6)
手首関節骨折	2 (1.1)
臨床検査	26 (14.4)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.6)
血中ビリルビン増加	2 (1.1)
血中コレステロール増加	2 (1.1)
血中乳酸脱水素酵素増加	2 (1.1)
血中カリウム減少	1 (0.6)
血圧上昇	5 (2.8)
尿中結晶陽性	1 (0.6)
心電図異常ＱＲＳ群	1 (0.6)
心電図ＱＴ延長	1 (0.6)
心電図異常Ｔ波	1 (0.6)
心電図異常	1 (0.6)
ヘモグロビン減少	1 (0.6)

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MedDRA Version 25.0.
OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-5

SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
好中球数減少	1 (0.6)
便潜血	1 (0.6)
前立腺特異性抗原増加	2 (1.1)
トロポニン増加	1 (0.6)
尿検査異常	2 (1.1)
体重減少	3 (1.7)
尿中白血球陽性	1 (0.6)
代謝および栄養障害	26 (14.4)
異常体重減少	1 (0.6)
食欲減退	5 (2.8)
脱水	3 (1.7)
痛風	1 (0.6)
高コレステロール血症	2 (1.1)
高血糖	2 (1.1)
高カリウム血症	3 (1.7)

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SOC/PT別の有害事象発現率

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Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
高ナトリウム血症	2 (1.1)
高トリグリセリド血症	1 (0.6)
高尿酸血症	1 (0.6)
血液量増加症	1 (0.6)
低血糖	1 (0.6)
低カリウム血症	3 (1.7)
低ナトリウム血症	1 (0.6)
低リン血症	1 (0.6)
鉄欠乏	1 (0.6)
乳酸アシドーシス	1 (0.6)
２型糖尿病	2 (1.1)
ビタミンD欠乏	1 (0.6)
筋骨格系および結合組織障害	50 (27.8)
関節痛	15 (8.3)
背部痛	13 (7.2)

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SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
滑液包炎	2 (1.1)
椎間関節症候群	1 (0.6)
側腹部痛	1 (0.6)
椎間板変性症	3 (1.7)
椎間板突出	1 (0.6)
関節滲出液	1 (0.6)
関節腫脹	2 (1.1)
筋痙縮	3 (1.7)
筋力低下	2 (1.1)
筋骨格不快感	1 (0.6)
筋骨格硬直	1 (0.6)
筋肉痛	2 (1.1)
頚部痛	3 (1.7)
変形性関節症	2 (1.1)
骨端症	1 (0.6)

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SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
骨粗鬆症	3 (1.7)
四肢痛	6 (3.3)
乾癬性関節症	1 (0.6)
関節リウマチ	1 (0.6)
肩回旋筋腱板症候群	4 (2.2)
側弯症	1 (0.6)
変形性脊椎症	2 (1.1)
脊椎痛	1 (0.6)
脊柱管狭窄症	1 (0.6)
脊椎炎	1 (0.6)
滑膜炎	1 (0.6)
腱炎	1 (0.6)
腱鞘炎	1 (0.6)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	21 (11.7)
結腸腺癌	1 (0.6)

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201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
基底細胞癌	10 (5.6)
眼瞼乳頭腫	1 (0.6)
ボーエン病	1 (0.6)
遠隔転移を伴う乳癌	1 (0.6)
結腸直腸腺腫	1 (0.6)
肺腺癌	1 (0.6)
原発巣不明の悪性新生物	1 (0.6)
メラノサイト性母斑	1 (0.6)
中枢神経系転移	1 (0.6)
神経内分泌癌	1 (0.6)
脂漏性角化症	2 (1.1)
皮膚乳頭腫	1 (0.6)
皮膚有棘細胞癌	5 (2.8)
移行上皮癌	1 (0.6)
神経系障害	84 (46.7)

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Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
後天性てんかん性失語症	1 (0.6)
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	24 (13.3)
アミロイド関連画像異常－浮腫／滲出液貯留	14 (7.8)
失語症	1 (0.6)
平衡障害	1 (0.6)
ベル麻痺	1 (0.6)
脳幹出血	1 (0.6)
頚動脈瘤	1 (0.6)
頚動脈狭窄	1 (0.6)
小脳梗塞	2 (1.1)
脳出血	1 (0.6)
脳梗塞	5 (2.8)
頚髄神経根障害	1 (0.6)
認知障害	1 (0.6)
振動覚低下	1 (0.6)

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Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
アルツハイマー型認知症	2 (1.1)
アルツハイマー型認知症、抑うつを伴う	1 (0.6)
糖尿病性ニューロパチー	1 (0.6)
浮動性めまい	12 (6.7)
体位性めまい	1 (0.6)
脳症	1 (0.6)
てんかん	1 (0.6)
本態性振戦	1 (0.6)
認知障害発作	1 (0.6)
全身性強直性間代性発作	1 (0.6)
頭痛	16 (8.9)
片側感覚鈍麻	1 (0.6)
感覚鈍麻	3 (1.7)
第３脳神経麻痺	1 (0.6)
企図振戦	1 (0.6)

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SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
ラクナ梗塞	1 (0.6)
嗜眠	1 (0.6)
神経圧迫	1 (0.6)
眼振	1 (0.6)
錯感覚	4 (2.2)
患者の逃げ出し	1 (0.6)
ヘルペス後神経痛	1 (0.6)
姿勢時振戦	1 (0.6)
下肢静止不能症候群	1 (0.6)
痙攣発作	1 (0.6)
傾眠	1 (0.6)
硬膜下ヒグローマ	1 (0.6)
脳表ヘモジデリン沈着症	8 (4.4)
失神	4 (2.2)
視床梗塞	1 (0.6)

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SOC/PT別の有害事象発現率

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Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
一過性脳虚血発作	3 (1.7)
振戦	3 (1.7)
声帯麻痺	1 (0.6)
製品の問題	1 (0.6)
医療機器破損	1 (0.6)
精神障害	48 (26.7)
感情不安定	1 (0.6)
攻撃性	2 (1.1)
激越	7 (3.9)
不安	14 (7.8)
行動障害	1 (0.6)
錯乱状態	2 (1.1)
譫妄	3 (1.7)
抑うつ気分	1 (0.6)
うつ病	11 (6.1)

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SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
幻覚	3 (1.7)
幻視	1 (0.6)
不眠症	4 (2.2)
精神状態変化	2 (1.1)
気分変化	1 (0.6)
悪夢	1 (0.6)
パニック発作	1 (0.6)
妄想症	1 (0.6)
処置に対する不安	1 (0.6)
睡眠障害	2 (1.1)
腎および尿路障害	27 (15.0)
急性腎障害	4 (2.2)
膀胱憩室	1 (0.6)
膀胱肉柱形成	1 (0.6)
尿路結石	1 (0.6)

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SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
出血性膀胱炎	1 (0.6)
糖尿	1 (0.6)
血尿	7 (3.9)
水腎症	1 (0.6)
緊張性膀胱	4 (2.2)
腎結石症	3 (1.7)
頻尿	3 (1.7)
蛋白尿	1 (0.6)
腎嚢胞	2 (1.1)
腎機能障害	1 (0.6)
排尿躊躇	1 (0.6)
尿失禁	2 (1.1)
尿閉	1 (0.6)
尿路閉塞	1 (0.6)
尿生殖器出血	1 (0.6)

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付録 2.7.6-5

SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
生殖系および乳房障害	10 (5.6)
良性前立腺肥大症	5 (2.8)
乳房腫瘤	1 (0.6)
卵巣嚢胞	1 (0.6)
骨盤液貯留	1 (0.6)
前立腺腫瘤	1 (0.6)
前立腺炎	1 (0.6)
前立腺腫大	1 (0.6)
呼吸器、胸郭および縦隔障害	36 (20.0)
喘息	4 (2.2)
無気肺	1 (0.6)
カタル	1 (0.6)
慢性閉塞性肺疾患	4 (2.2)
咳嗽	8 (4.4)
発声障害	2 (1.1)

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SOC/PT別の有害事象発現率

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MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
呼吸困難	4 (2.2)
しゃっくり	1 (0.6)
低酸素症	1 (0.6)
間質性肺疾患	1 (0.6)
肺障害	1 (0.6)
鼻閉	6 (3.3)
閉塞性睡眠時無呼吸症候群	1 (0.6)
口腔咽頭痛	3 (1.7)
咽頭紅斑	1 (0.6)
気胸	1 (0.6)
湿性咳嗽	2 (1.1)
肺線維症	1 (0.6)
肺腫瘤	3 (1.7)
鼻漏	2 (1.1)
睡眠時無呼吸症候群	2 (1.1)

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201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
咽喉刺激感	1 (0.6)
上気道咳症候群	1 (0.6)
皮膚および皮下組織障害	26 (14.4)
光線角化症	1 (0.6)
脱毛症	1 (0.6)
褥瘡性潰瘍	1 (0.6)
皮膚嚢腫	1 (0.6)
皮膚炎	3 (1.7)
アトピー性皮膚炎	1 (0.6)
水疱性皮膚炎	1 (0.6)
接触皮膚炎	3 (1.7)
薬疹	1 (0.6)
皮膚乾燥	1 (0.6)
斑状出血	2 (1.1)
湿疹	1 (0.6)

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付録 2.7.6-5

SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
多汗症	1 (0.6)
過角化	1 (0.6)
黒子	1 (0.6)
苔癬様角化症	1 (0.6)
汗疹	1 (0.6)
そう痒症	1 (0.6)
乾癬	1 (0.6)
発疹	4 (2.2)
脂漏性皮膚炎	1 (0.6)
皮膚亀裂	1 (0.6)
皮膚病変	1 (0.6)
皮膚潰瘍	1 (0.6)
蕁麻疹	1 (0.6)
尋常性白斑	1 (0.6)
社会環境	1 (0.6)

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付録 2.7.6-5

SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
死別	1 (0.6)
外科および内科処置	1 (0.6)
歯科インプラント埋込み	1 (0.6)
血管障害	34 (18.9)
大動脈硬化症	1 (0.6)
大動脈拡張	1 (0.6)
動脈硬化症	1 (0.6)
深部静脈血栓症	2 (1.1)
血腫	4 (2.2)
高血圧	14 (7.8)
高血圧クリーゼ	1 (0.6)
低血圧	9 (5.0)
間欠性跛行	1 (0.6)
不安定血圧	1 (0.6)
起立性低血圧	1 (0.6)

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
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.
MedDRA Version 25.0.
OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-5

SOC/PT別の有害事象発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
末梢動脈閉塞性疾患	1 (0.6)
末梢血管障害	1 (0.6)
末梢静脈疾患	1 (0.6)
静脈炎	1 (0.6)

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

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MedDRA Version 25.0.

OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-6

SOC/PT別の副作用発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
Subjects with Any Treatment-related TEAEs	76 (42.2)
心臓障害	1 (0.6)
徐脈	1 (0.6)
眼障害	1 (0.6)
視野欠損	1 (0.6)
胃腸障害	4 (2.2)
腹部不快感	1 (0.6)
顕微鏡的大腸炎	1 (0.6)
悪心	2 (1.1)
嘔吐	1 (0.6)
一般・全身障害および投与部位の状態	9 (5.0)
無力症	2 (1.1)
悪寒	1 (0.6)
疲労	2 (1.1)

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

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Treatment-related TEAEs include TEAEs that were considered by the investigator to be reasonably possibly caused by the study drug or TEAEs with a missing causality.

MedDRA Version 25.0.

OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-6

SOC/PT別の副作用発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
注入部位血管外漏出	2 (1.1)
倦怠感	1 (0.6)
疼痛	1 (0.6)
発熱	3 (1.7)
感染症および寄生虫症	1 (0.6)
慢性副鼻腔炎	1 (0.6)
傷害、中毒および処置合併症	39 (21.7)
偶発的過量投与	1 (0.6)
挫傷	1 (0.6)
転倒	1 (0.6)
注入に伴う反応	36 (20.0)
製品適用過誤	1 (0.6)
臨床検査	2 (1.1)
血中乳酸脱水素酵素増加	2 (1.1)
代謝および栄養障害	2 (1.1)

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

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Treatment-related TEAEs include TEAEs that were considered by the investigator to be reasonably possibly caused by the study drug or TEAEs with a missing causality.

MedDRA Version 25.0.

OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-6

SOC/PT別の副作用発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
食欲減退	2 (1.1)
神経系障害	35 (19.4)
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	22 (12.2)
アミロイド関連画像異常－浮腫／滲出液貯留	14 (7.8)
小脳梗塞	1 (0.6)
脳梗塞	1 (0.6)
浮動性めまい	3 (1.7)
頭痛	3 (1.7)
脳表ヘモジデリン沈着症	6 (3.3)
精神障害	4 (2.2)
錯乱状態	2 (1.1)
妄想症	1 (0.6)
睡眠障害	1 (0.6)
皮膚および皮下組織障害	3 (1.7)
薬疹	1 (0.6)

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

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Treatment-related TEAEs include TEAEs that were considered by the investigator to be reasonably possibly caused by the study drug or TEAEs with a missing causality.

MedDRA Version 25.0.

OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-6

SOC/PT別の副作用発現率

201試験 OLE

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
多汗症	1 (0.6)
発疹	1 (0.6)
血管障害	2 (1.1)
高血圧	1 (0.6)
低血圧	1 (0.6)

Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

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Treatment-related TEAEs include TEAEs that were considered by the investigator to be reasonably possibly caused by the study drug or TEAEs with a missing causality.

MedDRA Version 25.0.

OLE = open-label extension, TEAE = treatment-emergent adverse event.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
Subjects with Any TEAEs	735 (81.9)	798 (88.9)
血液およびリンパ系障害	38 (4.2)	28 (3.1)
貧血	18 (2.0)	7 (0.8)
失血性貧血	1 (0.1)	1 (0.1)
欠乏性貧血	1 (0.1)	0
好酸球増加症	1 (0.1)	0
ヘモグロビン血症	1 (0.1)	0
鉄欠乏性貧血	4 (0.4)	3 (0.3)
白血球減少症	3 (0.3)	1 (0.1)
リンパ節炎	0	1 (0.1)
リンパ節症	1 (0.1)	2 (0.2)
縦隔リンパ節腫脹	1 (0.1)	0
リンパ球減少症	6 (0.7)	1 (0.1)
小球性貧血	1 (0.1)	0

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Subject with two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

Cerebral microhemorrhages include those deemed not ARIA-H by investigator.

MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
単球増加症	0	1 (0.1)
好中球減少症	3 (0.3)	6 (0.7)
正球性貧血	1 (0.1)	2 (0.2)
赤血球増加症	0	2 (0.2)
血小板減少症	3 (0.3)	2 (0.2)
心臓障害	61 (6.8)	85 (9.5)
急性心筋梗塞	0	2 (0.2)
狭心症	3 (0.3)	9 (1.0)
大動脈弁閉鎖不全症	0	1 (0.1)
大動脈弁狭窄	2 (0.2)	0
不整脈	0	3 (0.3)
心房拡大	1 (0.1)	0
心房細動	14 (1.6)	24 (2.7)
心房粗動	0	1 (0.1)
房室ブロック	2 (0.2)	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
完全房室ブロック	1 (0.1)	0
第一度房室ブロック	4 (0.4)	8 (0.9)
第二度房室ブロック	1 (0.1)	0
二束ブロック	0	1 (0.1)
徐脈	5 (0.6)	7 (0.8)
左脚ブロック	3 (0.3)	8 (0.9)
右脚ブロック	2 (0.2)	2 (0.2)
心停止	0	1 (0.1)
うっ血性心不全	0	2 (0.2)
心粗動	1 (0.1)	0
心拡大	0	1 (0.1)
心筋症	1 (0.1)	0
伝導障害	0	1 (0.1)
冠動脈疾患	5 (0.6)	3 (0.3)
冠動脈閉塞	1 (0.1)	0

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
冠動脈狭窄	2 (0.2)	0
変性僧帽弁疾患	1 (0.1)	0
左室不全	1 (0.1)	1 (0.1)
左室肥大	1 (0.1)	0
僧帽弁閉鎖不全症	2 (0.2)	2 (0.2)
心筋梗塞	3 (0.3)	1 (0.1)
心筋虚血	1 (0.1)	0
動悸	4 (0.4)	9 (1.0)
心嚢液貯留	1 (0.1)	0
無症候性心筋梗塞	1 (0.1)	0
洞性徐脈	3 (0.3)	7 (0.8)
洞結節機能不全	1 (0.1)	1 (0.1)
洞性頻脈	1 (0.1)	1 (0.1)
ストレス心筋症	0	1 (0.1)
上室性期外収縮	1 (0.1)	2 (0.2)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
上室性頻脈	1 (0.1)	0
頻脈	3 (0.3)	0
三尖弁閉鎖不全症	1 (0.1)	1 (0.1)
三束ブロック	0	1 (0.1)
心室性期外収縮	3 (0.3)	6 (0.7)
先天性、家族性および遺伝性障害	0	1 (0.1)
動静脈奇形	0	1 (0.1)
耳および迷路障害	24 (2.7)	31 (3.5)
耳垢栓塞	3 (0.3)	2 (0.2)
難聴	2 (0.2)	1 (0.1)
感音性難聴	0	1 (0.1)
片耳難聴	1 (0.1)	1 (0.1)
耳閉	0	1 (0.1)
耳不快感	0	1 (0.1)
耳痛	0	2 (0.2)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
耳垢分泌過多	0	1 (0.1)
聴力低下	1 (0.1)	0
内耳障害	0	1 (0.1)
乳突洞滲出液	0	1 (0.1)
メニエール病	1 (0.1)	1 (0.1)
老人性難聴	1 (0.1)	0
耳鳴	3 (0.3)	2 (0.2)
回転性めまい	7 (0.8)	14 (1.6)
頭位性回転性めまい	6 (0.7)	3 (0.3)
内分泌障害	4 (0.4)	8 (0.9)
自己免疫性甲状腺炎	0	1 (0.1)
副甲状腺機能亢進症	0	1 (0.1)
甲状腺機能亢進症	1 (0.1)	1 (0.1)
甲状腺機能低下症	1 (0.1)	4 (0.4)
甲状腺腫瘤	2 (0.2)	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
眼障害	64 (7.1)	58 (6.5)
調節障害	1 (0.1)	0
閉塞隅角緑内障	1 (0.1)	0
眼瞼炎	1 (0.1)	5 (0.6)
眼瞼痙攣	0	1 (0.1)
片側失明	1 (0.1)	0
白内障	11 (1.2)	15 (1.7)
核性白内障	1 (0.1)	0
霰粒腫	1 (0.1)	0
網脈絡膜症	0	1 (0.1)
結膜出血	5 (0.6)	6 (0.7)
結膜充血	2 (0.2)	2 (0.2)
結膜刺激	1 (0.1)	0
アレルギー性結膜炎	1 (0.1)	1 (0.1)
嚢胞様黄斑浮腫	1 (0.1)	0

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
複視	2 (0.2)	0
ドライアイ	5 (0.6)	1 (0.1)
眼瞼湿疹	0	1 (0.1)
眼瞼内反	1 (0.1)	0
眼脂	0	1 (0.1)
眼血腫	1 (0.1)	2 (0.2)
眼出血	1 (0.1)	1 (0.1)
眼刺激	0	2 (0.2)
眼痛	2 (0.2)	1 (0.1)
眼そう痒症	2 (0.2)	0
眼瞼嚢胞	1 (0.1)	0
眼瞼下垂	1 (0.1)	1 (0.1)
眼の異物感	2 (0.2)	0
緑内障	5 (0.6)	3 (0.3)
虹彩毛様体炎	1 (0.1)	0

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
角膜炎	1 (0.1)	0
流涙増加	2 (0.2)	0
黄斑変性	1 (0.1)	1 (0.1)
黄斑浮腫	1 (0.1)	0
黄斑症	1 (0.1)	0
眼部不快感	1 (0.1)	3 (0.3)
眼充血	1 (0.1)	2 (0.2)
眼窩周囲浮腫	1 (0.1)	1 (0.1)
眼窩周囲腫脹	0	1 (0.1)
光視症	1 (0.1)	0
後嚢部混濁	1 (0.1)	0
翼状片	1 (0.1)	0
網膜剥離	0	1 (0.1)
網膜出血	0	1 (0.1)
網膜静脈閉塞	0	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
強膜出血	1 (0.1)	0
潰瘍性角膜炎	1 (0.1)	0
霧視	3 (0.3)	3 (0.3)
視力低下	1 (0.1)	1 (0.1)
視野欠損	0	1 (0.1)
視力障害	1 (0.1)	0
硝子体剥離	0	1 (0.1)
硝子体浮遊物	4 (0.4)	4 (0.4)
胃腸障害	190 (21.2)	196 (21.8)
腹部癒着	0	1 (0.1)
腹部不快感	4 (0.4)	2 (0.2)
腹部膨満	4 (0.4)	2 (0.2)
腹部ヘルニア	1 (0.1)	1 (0.1)
腹痛	15 (1.7)	14 (1.6)
下腹部痛	4 (0.4)	3 (0.3)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
上腹部痛	6 (0.7)	11 (1.2)
急性腹症	1 (0.1)	0
肛門出血	1 (0.1)	0
肛門失禁	2 (0.2)	3 (0.3)
肛門ポリープ	1 (0.1)	0
口角口唇炎	1 (0.1)	0
アフタ性潰瘍	1 (0.1)	2 (0.2)
バレット食道	1 (0.1)	0
便習慣変化	1 (0.1)	0
口唇炎	0	1 (0.1)
慢性胃炎	3 (0.3)	1 (0.1)
大腸炎	1 (0.1)	2 (0.2)
潰瘍性大腸炎	1 (0.1)	0
便秘	22 (2.5)	19 (2.1)
齲歯	8 (0.9)	9 (1.0)

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MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

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Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
下痢	58 (6.5)	48 (5.3)
憩室	1 (0.1)	4 (0.4)
腸憩室	2 (0.2)	3 (0.3)
口内乾燥	2 (0.2)	4 (0.4)
十二指腸潰瘍	0	1 (0.1)
十二指腸炎	0	2 (0.2)
消化不良	7 (0.8)	10 (1.1)
嚥下障害	6 (0.7)	1 (0.1)
糞塊	1 (0.1)	0
変色便	0	1 (0.1)
軟便	1 (0.1)	0
鼓腸	1 (0.1)	1 (0.1)
食中毒	2 (0.2)	1 (0.1)
排便回数増加	1 (0.1)	2 (0.2)
機能性胃腸障害	1 (0.1)	1 (0.1)

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胃ポリープ	2 (0.2)	1 (0.1)
胃黄色腫	1 (0.1)	0
胃炎	1 (0.1)	6 (0.7)
びらん性胃炎	1 (0.1)	1 (0.1)
胃腸管血管異形成	1 (0.1)	0
胃腸障害	1 (0.1)	0
消化管運動障害	1 (0.1)	0
消化器痛	0	1 (0.1)
胃食道逆流性疾患	7 (0.8)	15 (1.7)
歯肉出血	1 (0.1)	0
歯肉水疱	0	1 (0.1)
歯肉不快感	1 (0.1)	0
歯肉痛	1 (0.1)	1 (0.1)
吐血	1 (0.1)	0
血便排泄	2 (0.2)	2 (0.2)

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痔出血	0	2 (0.2)
痔核	9 (1.0)	7 (0.8)
裂孔ヘルニア	2 (0.2)	2 (0.2)
歯の知覚過敏	1 (0.1)	0
口の感覚鈍麻	0	1 (0.1)
イレウス	1 (0.1)	1 (0.1)
炎症性腸疾患	1 (0.1)	0
鼠径ヘルニア	6 (0.7)	11 (1.2)
腸閉塞	1 (0.1)	0
腸管ポリープ	0	2 (0.2)
過敏性腸症候群	1 (0.1)	4 (0.4)
大腸穿孔	1 (0.1)	0
大腸ポリープ	11 (1.2)	7 (0.8)
口腔白斑症	0	1 (0.1)
口唇腫脹	0	1 (0.1)

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Safety Analysis Set

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弛緩歯	2 (0.2)	0
機械的イレウス	0	1 (0.1)
口腔内潰瘍形成	1 (0.1)	1 (0.1)
悪心	25 (2.8)	31 (3.5)
食道狭窄	1 (0.1)	0
食道炎	1 (0.1)	0
口腔障害	0	2 (0.2)
口腔知覚不全	1 (0.1)	0
歯周病	1 (0.1)	0
歯周の炎症	0	1 (0.1)
咽頭食道憩室	1 (0.1)	0
直腸出血	3 (0.3)	2 (0.2)
直腸ポリープ	0	1 (0.1)
流涎過多	1 (0.1)	1 (0.1)
小腸閉塞	2 (0.2)	0

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スピゲリウスヘルニア	0	1 (0.1)
脂肪便	1 (0.1)	0
口内炎	0	2 (0.2)
亜イレウス	0	1 (0.1)
歯の障害	1 (0.1)	1 (0.1)
埋伏歯	1 (0.1)	0
歯の脱落	1 (0.1)	0
歯の吸収症	0	1 (0.1)
歯痛	8 (0.9)	7 (0.8)
臍ヘルニア	0	1 (0.1)
腸の軸捻転	0	1 (0.1)
嘔吐	22 (2.5)	29 (3.2)
一般・全身障害および投与部位の状態	122 (13.6)	171 (19.0)
投与部位内出血	1 (0.1)	0
投与部位紅斑	1 (0.1)	0

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投与部位漏出	1 (0.1)	0
適用部位紅斑	0	1 (0.1)
適用部位過敏反応	0	1 (0.1)
適用部位損傷	0	1 (0.1)
適用部位腫脹	1 (0.1)	0
無力症	7 (0.8)	6 (0.7)
カテーテル留置部位疼痛	1 (0.1)	0
胸部不快感	5 (0.6)	1 (0.1)
胸痛	4 (0.4)	5 (0.6)
悪寒	4 (0.4)	11 (1.2)
医療機器関連合併症	1 (0.1)	0
死亡	1 (0.1)	1 (0.1)
不快感	1 (0.1)	2 (0.2)
活力増進	1 (0.1)	0
疲労	24 (2.7)	37 (4.1)

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異常感	1 (0.1)	1 (0.1)
冷感	0	6 (0.7)
熱感	1 (0.1)	1 (0.1)
歩行障害	3 (0.3)	5 (0.6)
高体温症	0	1 (0.1)
低体温	1 (0.1)	1 (0.1)
炎症	0	1 (0.1)
インフルエンザ様疾患	0	2 (0.2)
注入部位内出血	2 (0.2)	0
注入部位紅斑	0	1 (0.1)
注入部位血管外漏出	8 (0.9)	14 (1.6)
注入部位血腫	0	2 (0.2)
注入部位出血	1 (0.1)	1 (0.1)
注入部位炎症	1 (0.1)	1 (0.1)
注入部位刺激感	1 (0.1)	0

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注入部位疼痛	4 (0.4)	2 (0.2)
注入部位発疹	0	3 (0.3)
注入部位反応	2 (0.2)	2 (0.2)
注入部位腫脹	0	1 (0.1)
注射部位内出血	3 (0.3)	0
注射部位不快感	0	1 (0.1)
注射部位出血	0	1 (0.1)
注射部位結節	0	1 (0.1)
注射部位疼痛	7 (0.8)	8 (0.9)
注射部位発疹	0	1 (0.1)
注射部位反応	2 (0.2)	0
倦怠感	6 (0.7)	6 (0.7)
非心臓性胸痛	4 (0.4)	9 (1.0)
浮腫	0	1 (0.1)
末梢性浮腫	6 (0.7)	12 (1.3)

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疼痛	3 (0.3)	4 (0.4)
骨盤腔内腫瘤	1 (0.1)	0
末梢腫脹	7 (0.8)	9 (1.0)
前癌状態	1 (0.1)	0
穿刺部位出血	1 (0.1)	0
穿刺部位疼痛	0	3 (0.3)
発熱	18 (2.0)	24 (2.7)
軟部組織の炎症	0	1 (0.1)
恥骨上痛	1 (0.1)	1 (0.1)
全身性炎症反応症候群	1 (0.1)	2 (0.2)
口渇	1 (0.1)	0
ワクチン接種部位不快感	1 (0.1)	0
ワクチン接種部位紅斑	1 (0.1)	0
ワクチン接種部位疼痛	12 (1.3)	11 (1.2)
ワクチン接種部位反応	0	1 (0.1)

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血管穿刺部位紅斑	0	1 (0.1)
血管穿刺部位血腫	1 (0.1)	0
血管穿刺部位疼痛	1 (0.1)	0
血管穿刺部位反応	0	1 (0.1)
乾燥症	2 (0.2)	0
肝胆道系障害	6 (0.7)	13 (1.4)
胆管結石	1 (0.1)	1 (0.1)
胆管炎	0	1 (0.1)
胆嚢炎	0	2 (0.2)
急性胆嚢炎	0	2 (0.2)
胆石症	3 (0.3)	0
薬物性肝障害	0	1 (0.1)
肝動脈瘤	0	1 (0.1)
肝嚢胞	0	1 (0.1)
肝機能異常	0	1 (0.1)

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肝腫瘤	0	1 (0.1)
脂肪肝	0	2 (0.2)
高ビリルビン血症	1 (0.1)	1 (0.1)
高トランスアミナーゼ血症	0	1 (0.1)
胆汁うっ滞性黄疸	1 (0.1)	0
非アルコール性脂肪性肝炎	1 (0.1)	0
免疫系障害	22 (2.5)	29 (3.2)
動物アレルギー	1 (0.1)	0
節足動物咬傷アレルギー	0	2 (0.2)
節足動物刺傷アレルギー	1 (0.1)	0
化学物質アレルギー	1 (0.1)	0
アナフィラキシー反応	1 (0.1)	0
造影剤アレルギー	1 (0.1)	1 (0.1)
薬物過敏症	1 (0.1)	2 (0.2)
食物アレルギー	1 (0.1)	1 (0.1)

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過敏症	8 (0.9)	15 (1.7)
免疫反応	0	1 (0.1)
乳アレルギー	0	1 (0.1)
ダニアレルギー	1 (0.1)	0
季節性アレルギー	8 (0.9)	6 (0.7)
感染症および寄生虫症	280 (31.2)	326 (36.3)
急性副鼻腔炎	2 (0.2)	1 (0.1)
肛門膿瘍	1 (0.1)	0
無症候性ＣＯＶＩＤ－１９	5 (0.6)	8 (0.9)
無症候性細菌尿	2 (0.2)	2 (0.2)
非定型マイコバクテリア肺炎	1 (0.1)	0
異型肺炎	0	1 (0.1)
菌血症	1 (0.1)	0
細菌感染	0	1 (0.1)
細菌性前立腺炎	1 (0.1)	0

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細菌性膣症	0	1 (0.1)
細菌尿	1 (0.1)	0
体部白癬	1 (0.1)	1 (0.1)
ボレリア感染	0	1 (0.1)
乳房膿瘍	0	1 (0.1)
乳房蜂巣炎	0	1 (0.1)
気管支炎	4 (0.4)	12 (1.3)
ＣＯＶＩＤ－１９	60 (6.7)	64 (7.1)
ＣＯＶＩＤ－１９肺炎	1 (0.1)	3 (0.3)
蜂巣炎	7 (0.8)	11 (1.2)
感染性胆嚢炎	1 (0.1)	0
慢性副鼻腔炎	1 (0.1)	1 (0.1)
結膜炎	4 (0.4)	7 (0.8)
細菌性結膜炎	1 (0.1)	0
膀胱炎	3 (0.3)	9 (1.0)

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爪の皮膚糸状菌症	0	2 (0.2)
医療機器関連感染	1 (0.1)	0
憩室炎	5 (0.6)	5 (0.6)
耳感染	4 (0.4)	1 (0.1)
エンテロバクター性菌血症	0	1 (0.1)
遊走性紅斑	2 (0.2)	1 (0.1)
大腸菌性尿路感染	1 (0.1)	0
外耳蜂巣炎	0	1 (0.1)
眼感染	2 (0.2)	0
眼瞼感染	1 (0.1)	0
毛包炎	2 (0.2)	0
真菌性足感染	0	1 (0.1)
真菌感染	1 (0.1)	0
皮膚真菌感染	0	2 (0.2)
せつ	3 (0.3)	0

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MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
胃腸炎	5 (0.6)	9 (1.0)
ウイルス性胃腸炎	2 (0.2)	2 (0.2)
消化管感染	1 (0.1)	0
ウイルス性消化管感染	1 (0.1)	1 (0.1)
歯肉膿瘍	0	1 (0.1)
歯肉炎	3 (0.3)	6 (0.7)
ヘリコバクター性胃炎	1 (0.1)	0
肝嚢胞感染	0	1 (0.1)
ヘルペス性皮膚炎	0	1 (0.1)
ヘルペス眼感染	0	2 (0.2)
単純ヘルペス	0	1 (0.1)
ヘルペスウイルス感染	0	1 (0.1)
帯状疱疹	6 (0.7)	8 (0.9)
皮膚播種性帯状疱疹	0	1 (0.1)
麦粒腫	8 (0.9)	8 (0.9)

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咬傷感染	1 (0.1)	1 (0.1)
インフルエンザ	1 (0.1)	5 (0.6)
喉頭炎	0	1 (0.1)
咽喉頭炎	1 (0.1)	0
限局性感染	1 (0.1)	1 (0.1)
下気道感染	0	2 (0.2)
ライム病	1 (0.1)	1 (0.1)
リンパ管炎	0	1 (0.1)
乳様突起炎	1 (0.1)	1 (0.1)
爪感染	0	1 (0.1)
鼻膿瘍	1 (0.1)	0
上咽頭炎	35 (3.9)	36 (4.0)
爪真菌症	4 (0.4)	3 (0.3)
卵巣炎	1 (0.1)	0
眼帯状疱疹	1 (0.1)	0

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口腔カンジダ症	1 (0.1)	1 (0.1)
口腔ヘルペス	2 (0.2)	2 (0.2)
外耳炎	1 (0.1)	1 (0.1)
中耳炎	1 (0.1)	2 (0.2)
急性中耳炎	1 (0.1)	0
寄生虫性胃腸炎	1 (0.1)	0
爪囲炎	1 (0.1)	2 (0.2)
耳下腺炎	1 (0.1)	0
骨盤膿瘍	1 (0.1)	0
ヘリコバクター性消化性潰瘍	1 (0.1)	0
歯周炎	0	1 (0.1)
直腸周囲膿瘍	1 (0.1)	0
腹膜炎	1 (0.1)	0
咽頭炎	2 (0.2)	6 (0.7)
レンサ球菌性咽頭炎	1 (0.1)	0

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肺炎	7 (0.8)	4 (0.4)
シュードモナス性肺炎	1 (0.1)	0
ブドウ球菌性肺炎	1 (0.1)	0
処置後感染	2 (0.2)	0
急性ＣＯＶＩＤ－１９後症候群	2 (0.2)	0
術後膿瘍	0	1 (0.1)
術後創感染	1 (0.1)	1 (0.1)
歯髄炎	1 (0.1)	0
腎盂腎炎	1 (0.1)	0
膿尿	2 (0.2)	2 (0.2)
ＲＳウイルス感染	0	1 (0.1)
気道感染	1 (0.1)	0
鼻炎	11 (1.2)	7 (0.8)
根管感染	1 (0.1)	0
敗血症	0	1 (0.1)

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副鼻腔炎	12 (1.3)	10 (1.1)
細菌性副鼻腔炎	1 (0.1)	1 (0.1)
皮膚細菌感染	0	1 (0.1)
皮膚カンジダ	0	1 (0.1)
皮膚感染	0	1 (0.1)
皮下組織膿瘍	3 (0.3)	1 (0.1)
ＣＯＶＩＤ－１９の疑い	0	2 (0.2)
股部白癬	2 (0.2)	0
白癬感染	0	1 (0.1)
足部白癬	3 (0.3)	4 (0.4)
扁桃炎	1 (0.1)	1 (0.1)
歯膿瘍	5 (0.6)	9 (1.0)
歯感染	12 (1.3)	7 (0.8)
気管気管支炎	1 (0.1)	0
上気道感染	19 (2.1)	25 (2.8)

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尿路感染	82 (9.1)	78 (8.7)
細菌性尿路感染	1 (0.1)	0
膣感染	1 (0.1)	2 (0.2)
水痘帯状疱疹ウイルス感染	1 (0.1)	0
前庭神経炎	0	1 (0.1)
ウイルス感染	0	5 (0.6)
外陰部膿瘍	1 (0.1)	0
外陰部膣カンジダ症	1 (0.1)	0
外陰膣真菌感染	0	2 (0.2)
創傷感染	1 (0.1)	1 (0.1)
傷害、中毒および処置合併症	254 (28.3)	371 (41.3)
腹部損傷	0	1 (0.1)
事故	1 (0.1)	0
偶発的製品曝露	1 (0.1)	0
偶発的過量投与	3 (0.3)	2 (0.2)

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動物咬傷	7 (0.8)	1 (0.1)
足関節部骨折	4 (0.4)	2 (0.2)
節足動物咬傷	10 (1.1)	2 (0.2)
節足動物刺傷	1 (0.1)	1 (0.1)
骨挫傷	1 (0.1)	3 (0.3)
脳挫傷	0	1 (0.1)
第２度熱傷	1 (0.1)	0
化学性腹膜炎	0	1 (0.1)
凍瘡	0	1 (0.1)
低温損傷	0	1 (0.1)
低温による損傷	0	1 (0.1)
脳振盪	2 (0.2)	1 (0.1)
挫傷	39 (4.3)	38 (4.2)
冠動脈再狭窄	1 (0.1)	0
歯科修復不成功	1 (0.1)	0

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上顎炎	2 (0.2)	1 (0.1)
硬膜外血腫	1 (0.1)	0
眼挫傷	1 (0.1)	0
眼外傷	1 (0.1)	1 (0.1)
顔面損傷	2 (0.2)	1 (0.1)
顔面骨骨折	4 (0.4)	2 (0.2)
転倒	86 (9.6)	93 (10.4)
大腿骨頚部骨折	1 (0.1)	2 (0.2)
腓骨骨折	0	1 (0.1)
足骨折	3 (0.3)	1 (0.1)
前腕骨折	1 (0.1)	1 (0.1)
手骨折	1 (0.1)	2 (0.2)
頭部損傷	17 (1.9)	2 (0.2)
熱中症	0	1 (0.1)
股関節部骨折	3 (0.3)	3 (0.3)

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上腕骨骨折	1 (0.1)	5 (0.6)
瘢痕ヘルニア	0	2 (0.2)
誤用量投与	1 (0.1)	1 (0.1)
注入に伴う反応	64 (7.1)	236 (26.3)
注射に伴う反応	1 (0.1)	0
損傷	1 (0.1)	0
顎の骨折	1 (0.1)	0
関節脱臼	2 (0.2)	1 (0.1)
関節損傷	9 (1.0)	6 (0.7)
靱帯損傷	1 (0.1)	0
靱帯捻挫	8 (0.9)	9 (1.0)
四肢損傷	5 (0.6)	8 (0.9)
口唇損傷	1 (0.1)	1 (0.1)
半月板損傷	0	1 (0.1)
口腔内損傷	1 (0.1)	1 (0.1)

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筋損傷	1 (0.1)	0
筋断裂	1 (0.1)	0
肉離れ	6 (0.7)	10 (1.1)
爪損傷	1 (0.1)	0
鼻部損傷	0	1 (0.1)
頚部損傷	1 (0.1)	0
眼処置合併症	0	1 (0.1)
口腔挫傷	1 (0.1)	0
膝蓋骨骨折	1 (0.1)	1 (0.1)
骨盤骨折	1 (0.1)	0
眼窩周囲出血	1 (0.1)	2 (0.2)
腰椎穿刺後症候群	5 (0.6)	2 (0.2)
処置後合併症	1 (0.1)	2 (0.2)
処置後挫傷	1 (0.1)	0
処置後発熱	0	1 (0.1)

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処置後出血	0	1 (0.1)
処置後腫脹	1 (0.1)	0
外傷後頚部症候群	1 (0.1)	0
外傷後疼痛	0	1 (0.1)
術後創合併症	0	1 (0.1)
処置による頭痛	1 (0.1)	0
処置による疼痛	2 (0.2)	3 (0.3)
橈骨骨折	1 (0.1)	6 (0.7)
肋骨骨折	3 (0.3)	5 (0.6)
交通事故	4 (0.4)	2 (0.2)
瘢痕	0	1 (0.1)
引っかき傷	3 (0.3)	0
皮膚擦過傷	12 (1.3)	15 (1.7)
皮膚損傷	1 (0.1)	0
皮膚裂傷	22 (2.5)	23 (2.6)

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皮膚創傷	1 (0.1)	1 (0.1)
軟部組織損傷	2 (0.2)	1 (0.1)
脊柱損傷	2 (0.2)	1 (0.1)
脊椎圧迫骨折	4 (0.4)	2 (0.2)
胸骨骨折	0	1 (0.1)
ストレス骨折	1 (0.1)	1 (0.1)
皮下血腫	1 (0.1)	1 (0.1)
硬膜下血腫	4 (0.4)	7 (0.8)
硬膜下出血	1 (0.1)	0
腱損傷	1 (0.1)	2 (0.2)
熱傷	3 (0.3)	2 (0.2)
胸椎骨折	1 (0.1)	2 (0.2)
舌損傷	1 (0.1)	0
歯の完全脱臼	1 (0.1)	0
歯牙破折	4 (0.4)	6 (0.7)

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歯牙損傷	0	1 (0.1)
外傷性血腫	2 (0.2)	0
外傷性腰椎穿刺	0	1 (0.1)
尺骨骨折	2 (0.2)	0
上肢骨折	3 (0.3)	1 (0.1)
ワクチン接種合併症	7 (0.8)	6 (0.7)
血管確保合併症	1 (0.1)	0
創傷	2 (0.2)	3 (0.3)
創合併症	1 (0.1)	0
手首関節骨折	4 (0.4)	4 (0.4)
臨床検査	91 (10.1)	104 (11.6)
アラニンアミノトランスフェラーゼ増加	2 (0.2)	7 (0.8)
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.2)	6 (0.7)
骨髄生検	1 (0.1)	0
前立腺生検	1 (0.1)	0

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血中アルブミン減少	0	1 (0.1)
血中アルカリホスファターゼ増加	1 (0.1)	1 (0.1)
血中ビリルビン増加	0	1 (0.1)
血中カルシウム減少	0	2 (0.2)
血中カルシウム増加	0	1 (0.1)
血中クロール減少	0	1 (0.1)
血中コレステロール増加	6 (0.7)	5 (0.6)
血中コリンエステラーゼ減少	1 (0.1)	0
血中クレアチニン増加	1 (0.1)	2 (0.2)
血中ブドウ糖減少	2 (0.2)	0
血中ブドウ糖増加	5 (0.6)	4 (0.4)
血中インスリン増加	0	1 (0.1)
血中リン減少	0	2 (0.2)
血中カリウム減少	0	1 (0.1)
血中カリウム増加	1 (0.1)	0

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MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
血圧低下	0	2 (0.2)
血圧上昇	7 (0.8)	8 (0.9)
収縮期血圧異常	1 (0.1)	0
収縮期血圧上昇	1 (0.1)	0
血中ナトリウム減少	0	1 (0.1)
血中テストステロン減少	0	1 (0.1)
血中トリグリセリド増加	5 (0.6)	4 (0.4)
血中尿素増加	0	1 (0.1)
血中尿酸	0	1 (0.1)
血中尿酸増加	2 (0.2)	3 (0.3)
尿中血陽性	2 (0.2)	0
体温上昇	0	1 (0.1)
骨密度減少	0	1 (0.1)
骨スキャン正常	0	1 (0.1)
心機能検査異常	1 (0.1)	0

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心雑音	2 (0.2)	1 (0.1)
心臓負荷試験異常	1 (0.1)	0
脳ＭＲＩ拡散強調画像異常	0	1 (0.1)
心筋梗塞の心電図所見	1 (0.1)	0
心筋虚血の心電図所見	1 (0.1)	0
駆出率減少	1 (0.1)	0
心電図ＰＲ延長	0	2 (0.2)
心電図ＱＴ延長	0	6 (0.7)
心電図ＳＴ部分下降	1 (0.1)	1 (0.1)
心電図ＳＴ部分上昇	1 (0.1)	0
心電図異常Ｔ波	0	1 (0.1)
心電図Ｔ波振幅減少	1 (0.1)	1 (0.1)
心電図Ｔ波逆転	4 (0.4)	3 (0.3)
心電図異常	0	1 (0.1)
好酸球数増加	0	1 (0.1)

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γ－グルタミルトランスフェラーゼ増加	7 (0.8)	5 (0.6)
グロブリン減少	1 (0.1)	1 (0.1)
尿中ブドウ糖陽性	2 (0.2)	0
グリコヘモグロビン増加	1 (0.1)	1 (0.1)
ヘマトクリット減少	2 (0.2)	0
ヘマトクリット増加	0	1 (0.1)
ヘモグロビン減少	4 (0.4)	1 (0.1)
ヘモグロビン増加	0	1 (0.1)
心拍数減少	1 (0.1)	0
心拍数不整	1 (0.1)	0
ヘリコバクター検査陽性	1 (0.1)	1 (0.1)
肝酵素上昇	2 (0.2)	2 (0.2)
A型インフルエンザウイルス検査陽性	0	1 (0.1)
眼圧上昇	0	2 (0.2)
肝機能検査異常	0	1 (0.1)

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肝機能検査値上昇	2 (0.2)	2 (0.2)
低比重リポ蛋白増加	0	1 (0.1)
リンパ球数減少	3 (0.3)	2 (0.2)
神経学的検査異常	0	1 (0.1)
好中球数減少	2 (0.2)	0
好中球数増加	2 (0.2)	2 (0.2)
便潜血	2 (0.2)	0
便潜血陽性	0	2 (0.2)
前立腺特異性抗原増加	0	1 (0.1)
総蛋白減少	1 (0.1)	1 (0.1)
尿蛋白	0	1 (0.1)
尿中蛋白陽性	0	1 (0.1)
赤血球数減少	2 (0.2)	0
尿中赤血球陽性	1 (0.1)	1 (0.1)
ＳＡＲＳ－ＣｏＶ－２検査陽性	9 (1.0)	13 (1.4)

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感覚レベル異常	1 (0.1)	0
トランスアミナーゼ上昇	1 (0.1)	0
トロポニン増加	1 (0.1)	0
尿円柱	0	1 (0.1)
振動検査異常	1 (0.1)	0
ビタミンＢ１２減少	1 (0.1)	0
ビタミンD減少	0	2 (0.2)
体重減少	12 (1.3)	9 (1.0)
体重増加	1 (0.1)	0
白血球数減少	1 (0.1)	0
尿中白血球陽性	1 (0.1)	0
代謝および栄養障害	78 (8.7)	81 (9.0)
異常体重減少	0	1 (0.1)
悪液質	1 (0.1)	0
食欲減退	12 (1.3)	12 (1.3)

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脱水	9 (1.0)	8 (0.9)
糖尿病	0	2 (0.2)
コントロール不良の糖尿病	2 (0.2)	1 (0.1)
脂質異常症	2 (0.2)	3 (0.3)
電解質失調	0	1 (0.1)
体液貯留	1 (0.1)	0
葉酸欠乏	0	3 (0.3)
食物不耐性	1 (0.1)	0
耐糖能障害	2 (0.2)	1 (0.1)
痛風	3 (0.3)	4 (0.4)
高カルシウム血症	1 (0.1)	1 (0.1)
高コレステロール血症	8 (0.9)	6 (0.7)
高フェリチン血症	0	1 (0.1)
高血糖	7 (0.8)	5 (0.6)
高ホモシステイン血症	1 (0.1)	0

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高カリウム血症	7 (0.8)	5 (0.6)
高脂血症	8 (0.9)	3 (0.3)
高ナトリウム血症	0	1 (0.1)
高トリグリセリド血症	3 (0.3)	3 (0.3)
高尿酸血症	2 (0.2)	2 (0.2)
低カルシウム血症	0	2 (0.2)
低血糖	1 (0.1)	3 (0.3)
低カリウム血症	1 (0.1)	5 (0.6)
低マグネシウム血症	1 (0.1)	1 (0.1)
低ナトリウム血症	2 (0.2)	5 (0.6)
低リン血症	4 (0.4)	1 (0.1)
血液量減少症	1 (0.1)	0
空腹時血中ブドウ糖不良	2 (0.2)	0
鉄欠乏	0	1 (0.1)
２型糖尿病	5 (0.6)	3 (0.3)

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ビタミンＢ１２欠乏	3 (0.3)	1 (0.1)
ビタミンD欠乏	5 (0.6)	7 (0.8)
筋骨格系および結合組織障害	215 (24.0)	217 (24.2)
関節痛	62 (6.9)	53 (5.9)
関節炎	3 (0.3)	8 (0.9)
背部痛	52 (5.8)	60 (6.7)
骨嚢腫	0	1 (0.1)
骨痛	1 (0.1)	1 (0.1)
滑液包障害	1 (0.1)	0
滑液包炎	3 (0.3)	4 (0.4)
肋軟骨炎	0	1 (0.1)
クラウンド・デンス症候群	0	1 (0.1)
変性骨疾患	0	1 (0.1)
デュプイトラン拘縮	1 (0.1)	1 (0.1)
外骨腫	4 (0.4)	0

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顎骨の外骨腫	1 (0.1)	0
線維筋痛	1 (0.1)	0
側腹部痛	1 (0.1)	2 (0.2)
大転子疼痛症候群	2 (0.2)	0
尿径部痛	0	2 (0.2)
出血性関節症	2 (0.2)	1 (0.1)
筋肉内血腫	0	1 (0.1)
尿径部腫瘤	1 (0.1)	0
椎間板変性症	1 (0.1)	2 (0.2)
椎間板障害	0	1 (0.1)
椎間板突出	3 (0.3)	1 (0.1)
関節滲出液	1 (0.1)	0
関節腫脹	4 (0.4)	4 (0.4)
四肢不快感	0	2 (0.2)
四肢腫瘤	1 (0.1)	0

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腰部脊柱管狭窄症	3 (0.3)	2 (0.2)
筋不快感	1 (0.1)	0
筋痙縮	15 (1.7)	13 (1.4)
筋攣縮	0	1 (0.1)
筋力低下	0	2 (0.2)
筋骨格系胸痛	7 (0.8)	7 (0.8)
筋骨格不快感	1 (0.1)	1 (0.1)
筋骨格痛	2 (0.2)	3 (0.3)
筋骨格硬直	3 (0.3)	2 (0.2)
筋肉痛	14 (1.6)	14 (1.6)
頚部痛	12 (1.3)	16 (1.8)
項部硬直	1 (0.1)	0
変形性関節症	14 (1.6)	18 (2.0)
骨軟骨炎	1 (0.1)	0
骨壊死	1 (0.1)	0

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骨減少症	1 (0.1)	0
骨粗鬆症	4 (0.4)	4 (0.4)
骨粗鬆症性骨折	1 (0.1)	0
四肢痛	34 (3.8)	32 (3.6)
顎痛	0	1 (0.1)
関節周囲炎	3 (0.3)	2 (0.2)
足底筋膜炎	1 (0.1)	2 (0.2)
多発性関節炎	0	2 (0.2)
リウマチ性多発筋痛	1 (0.1)	0
姿勢異常	0	1 (0.1)
横紋筋融解症	0	1 (0.1)
リウマチ性障害	1 (0.1)	0
リウマチ熱	1 (0.1)	0
関節リウマチ	0	1 (0.1)
肩回旋筋腱板症候群	7 (0.8)	6 (0.7)

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仙骨痛	2 (0.2)	0
軟部組織腫脹	3 (0.3)	0
変形性脊椎症	6 (0.7)	2 (0.2)
脊椎痛	0	1 (0.1)
脊椎炎	1 (0.1)	2 (0.2)
脊椎すべり症	2 (0.2)	1 (0.1)
滑液嚢腫	4 (0.4)	1 (0.1)
滑膜炎	1 (0.1)	0
顎関節症候群	0	1 (0.1)
腱障害	3 (0.3)	0
腱痛	1 (0.1)	0
腱炎	3 (0.3)	1 (0.1)
腱鞘炎	0	2 (0.2)
狭窄性腱鞘炎	1 (0.1)	0
斜頸	0	1 (0.1)

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弾発指	4 (0.4)	2 (0.2)
椎間孔狭窄	0	3 (0.3)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	56 (6.2)	77 (8.6)
アクロコルドン	0	1 (0.1)
結腸腺癌	2 (0.2)	0
副腎腺腫	0	1 (0.1)
副腎新生物	0	1 (0.1)
基底細胞癌	10 (1.1)	15 (1.7)
胃の良性新生物	0	1 (0.1)
皮膚良性新生物	2 (0.2)	0
甲状腺の良性新生物	1 (0.1)	0
卵巣良性腫瘍	0	1 (0.1)
唾液腺の良性新生物	0	1 (0.1)
膀胱癌	1 (0.1)	1 (0.1)
ボーエン病	2 (0.2)	1 (0.1)

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乳癌	0	2 (0.2)
乳房の上皮内癌	0	1 (0.1)
乳房新生物	1 (0.1)	0
結腸直腸腺腫	2 (0.2)	2 (0.2)
類腱腫	1 (0.1)	0
異形成母斑	1 (0.1)	1 (0.1)
外耳の悪性新生物	1 (0.1)	2 (0.2)
乳腺線維腺腫	1 (0.1)	0
胃腺腫	1 (0.1)	0
消化管粘膜下腫瘍	0	1 (0.1)
皮膚血管腫	1 (0.1)	1 (0.1)
膵管内乳頭粘液性腫瘍	1 (0.1)	0
乳管内増殖性病変	2 (0.2)	1 (0.1)
浸潤性乳管癌	0	2 (0.2)
ケラトアカントーマ	1 (0.1)	1 (0.1)

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MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
大腸の良性新生物	0	1 (0.1)
喉頭扁平上皮癌	1 (0.1)	0
口唇新生物	0	1 (0.1)
脂肪腫	0	4 (0.4)
肺腺癌	1 (0.1)	0
肺の悪性新生物	1 (0.1)	0
悪性黒色腫	1 (0.1)	1 (0.1)
表皮内悪性黒色腫	1 (0.1)	0
メラノサイト性母斑	3 (0.3)	2 (0.2)
骨転移	1 (0.1)	0
肝転移	0	1 (0.1)
肺転移	1 (0.1)	0
髄膜転移	0	1 (0.1)
骨髄異形成症候群	1 (0.1)	0
再発非ホジキンリンパ腫	0	1 (0.1)

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非小細胞肺癌	1 (0.1)	0
卵巣癌	0	1 (0.1)
膵癌	2 (0.2)	0
膵新生物	1 (0.1)	0
リンパ腫性乳頭状嚢胞腺腫	0	1 (0.1)
良性副甲状腺腫瘍	0	1 (0.1)
下垂体の良性腫瘍	0	1 (0.1)
形質細胞腫	0	1 (0.1)
前立腺癌	9 (1.0)	3 (0.3)
遠隔転移を伴う前立腺癌	0	1 (0.1)
直腸癌	0	1 (0.1)
脂漏性角化症	4 (0.4)	4 (0.4)
皮膚癌	1 (0.1)	1 (0.1)
皮膚乳頭腫	0	3 (0.3)
小細胞肺癌	0	1 (0.1)

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脊髄脂肪腫	0	1 (0.1)
扁平上皮癌	3 (0.3)	3 (0.3)
皮膚有棘細胞癌	6 (0.7)	10 (1.1)
神経系障害	291 (32.4)	391 (43.5)
動作時振戦	2 (0.2)	0
味覚消失	1 (0.1)	0
意識変容状態	0	1 (0.1)
健忘	1 (0.1)	1 (0.1)
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)
無嗅覚	0	1 (0.1)
失語症	0	2 (0.2)
運動失調	2 (0.2)	1 (0.1)
前兆	1 (0.1)	0
平衡障害	1 (0.1)	7 (0.8)

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脳損傷	0	1 (0.1)
頚動脈硬化症	0	1 (0.1)
頚動脈狭窄	1 (0.1)	1 (0.1)
手根管症候群	2 (0.2)	2 (0.2)
中枢痛症候群	0	1 (0.1)
小脳梗塞	4 (0.4)	4 (0.4)
脳出血	0	5 (0.6)
脳梗塞	4 (0.4)	5 (0.6)
虚血性脳小血管疾患	0	1 (0.1)
脳血管発作	2 (0.2)	2 (0.2)
頚髄神経根障害	1 (0.1)	0
頚腕症候群	1 (0.1)	0
頚原性頭痛	0	1 (0.1)
概日リズム睡眠障害	1 (0.1)	0
認知障害	10 (1.1)	6 (0.7)

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協調運動異常	1 (0.1)	0
振動覚低下	0	1 (0.1)
認知症	4 (0.4)	2 (0.2)
アルツハイマー型認知症	11 (1.2)	10 (1.1)
アルツハイマー型認知症、譫妄を伴う	1 (0.1)	0
アルツハイマー型認知症、妄想を伴う	0	1 (0.1)
レヴィ小体型認知症	3 (0.3)	0
糖尿病性ニューロパチー	0	2 (0.2)
注意力障害	1 (0.1)	0
浮動性めまい	46 (5.1)	49 (5.5)
体位性めまい	2 (0.2)	1 (0.1)
転倒発作	0	1 (0.1)
異常感覚	1 (0.1)	1 (0.1)
反復拮抗運動不全	0	2 (0.2)
味覚不全	2 (0.2)	0

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ジスキネジア	0	2 (0.2)
電気ショック様感覚	1 (0.1)	0
本態性振戦	0	1 (0.1)
認知障害発作	2 (0.2)	0
頭蓋内出血	1 (0.1)	0
頭部不快感	1 (0.1)	2 (0.2)
頭部動揺	0	1 (0.1)
頭痛	73 (8.1)	100 (11.1)
片側運動失調	0	1 (0.1)
片側感覚鈍麻	0	1 (0.1)
過眠症	2 (0.2)	1 (0.1)
高血圧性脳症	1 (0.1)	0
筋緊張亢進	0	1 (0.1)
感覚鈍麻	9 (1.0)	6 (0.7)
運動低下	1 (0.1)	0

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反射減弱	1 (0.1)	1 (0.1)
第３脳神経麻痺	0	1 (0.1)
第４脳神経不全麻痺	1 (0.1)	0
企図振戦	2 (0.2)	1 (0.1)
肋間神経痛	0	1 (0.1)
虚血性脳梗塞	1 (0.1)	0
虚血性脳卒中	1 (0.1)	2 (0.2)
ラクナ梗塞	5 (0.6)	5 (0.6)
嗜眠	2 (0.2)	3 (0.3)
意識消失	0	1 (0.1)
腰髄神経根障害	1 (0.1)	2 (0.2)
記憶障害	2 (0.2)	3 (0.3)
代謝性脳症	0	1 (0.1)
片頭痛	3 (0.3)	2 (0.2)
運動ニューロン疾患	0	1 (0.1)

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運動障害	0	1 (0.1)
筋痙直	1 (0.1)	0
重症筋無力症	0	1 (0.1)
筋無力症候群	1 (0.1)	0
ミオクローヌス	1 (0.1)	1 (0.1)
神経圧迫	2 (0.2)	0
神経痛	2 (0.2)	1 (0.1)
神経学的無視症候群	1 (0.1)	0
末梢性ニューロパチー	1 (0.1)	1 (0.1)
起立時振戦	0	1 (0.1)
錯感覚	8 (0.9)	8 (0.9)
パーキンソン病	0	1 (0.1)
パーキンソニズム	2 (0.2)	2 (0.2)
部分発作	0	1 (0.1)
患者の逃げ出し	1 (0.1)	1 (0.1)

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末梢性感覚ニューロパチー	0	1 (0.1)
多発ニューロパチー	1 (0.1)	2 (0.2)
ヘルペス後神経痛	0	1 (0.1)
失神寸前の状態	11 (1.2)	9 (1.0)
精神運動亢進	2 (0.2)	0
神経根障害	1 (0.1)	1 (0.1)
反射異常	1 (0.1)	1 (0.1)
安静時振戦	1 (0.1)	1 (0.1)
下肢静止不能症候群	1 (0.1)	2 (0.2)
坐骨神経ニューロパチー	1 (0.1)	0
坐骨神経痛	10 (1.1)	8 (0.9)
痙攣発作	2 (0.2)	2 (0.2)
感覚障害	2 (0.2)	0
副鼻腔炎に伴う頭痛	0	1 (0.1)
傾眠	3 (0.3)	2 (0.2)

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会話障害	1 (0.1)	1 (0.1)
くも膜下出血	1 (0.1)	2 (0.2)
硬膜下滲出液	1 (0.1)	0
脳表ヘモジデリン沈着症	22 (2.5)	50 (5.6)
失神	12 (1.3)	18 (2.0)
味覚障害	0	1 (0.1)
緊張性頭痛	3 (0.3)	7 (0.8)
視床梗塞	1 (0.1)	0
血栓性脳卒中	1 (0.1)	0
咬舌	1 (0.1)	0
一過性脳虚血発作	2 (0.2)	4 (0.4)
振戦	8 (0.9)	12 (1.3)
三叉神経痛	0	2 (0.2)
刺激無反応	1 (0.1)	0
上位運動ニューロンの病変	0	1 (0.1)

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白質病変	1 (0.1)	2 (0.2)
製品の問題	4 (0.4)	2 (0.2)
医療機器破損	1 (0.1)	0
医療機器位置異常	0	1 (0.1)
医療機器機能不良	0	1 (0.1)
リードの位置ずれ	1 (0.1)	0
製品リーク	1 (0.1)	0
人工心臓弁不具合	1 (0.1)	0
精神障害	157 (17.5)	142 (15.8)
異常な夢	6 (0.7)	4 (0.4)
睡眠関連異常事象	0	1 (0.1)
抑うつ気分を伴う適応障害	2 (0.2)	0
感情不安定	1 (0.1)	3 (0.3)
感情障害	1 (0.1)	1 (0.1)
攻撃性	2 (0.2)	2 (0.2)

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激越	10 (1.1)	8 (0.9)
怒り	1 (0.1)	0
不安	38 (4.2)	45 (5.0)
不安障害	3 (0.3)	0
無感情	1 (0.1)	1 (0.1)
行動障害	1 (0.1)	0
身体疾患による行動障害	0	1 (0.1)
閉所恐怖症	1 (0.1)	1 (0.1)
錯乱状態	14 (1.6)	14 (1.6)
汚言症	1 (0.1)	0
譫妄	3 (0.3)	2 (0.2)
妄想	7 (0.8)	2 (0.2)
替え玉妄想	1 (0.1)	0
抑うつ気分	5 (0.6)	6 (0.7)
うつ病	38 (4.2)	23 (2.6)

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抑うつ症状	4 (0.4)	6 (0.7)
失見当識	2 (0.2)	1 (0.1)
幻覚	5 (0.6)	2 (0.2)
幻聴	3 (0.3)	0
幻視	4 (0.4)	0
混合性幻覚	0	1 (0.1)
性欲過剰	1 (0.1)	1 (0.1)
初期不眠症	0	1 (0.1)
不眠症	21 (2.3)	24 (2.7)
故意の自傷行為	0	1 (0.1)
易刺激性	6 (0.7)	7 (0.8)
リビドー減退	1 (0.1)	0
大うつ病	4 (0.4)	1 (0.1)
精神状態変化	1 (0.1)	1 (0.1)
混合性不安抑うつ障害	2 (0.2)	4 (0.4)

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気分動揺	1 (0.1)	0
神経過敏	0	1 (0.1)
神経精神症状	1 (0.1)	0
神経症	0	1 (0.1)
悪夢	2 (0.2)	4 (0.4)
パニック発作	2 (0.2)	4 (0.4)
妄想症	2 (0.2)	0
睡眠の質低下	0	1 (0.1)
処置に対する不安	0	1 (0.1)
精神運動制止遅滞	1 (0.1)	0
精神病性障害	0	1 (0.1)
レム睡眠行動障害	1 (0.1)	0
落ち着きのなさ	1 (0.1)	1 (0.1)
季節性感情障害	1 (0.1)	0
不適切な性的行動	1 (0.1)	0

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MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
睡眠障害	4 (0.4)	6 (0.7)
睡眠時驚愕	1 (0.1)	1 (0.1)
自殺念慮	4 (0.4)	1 (0.1)
腎および尿路障害	56 (6.2)	68 (7.6)
急性腎障害	2 (0.2)	7 (0.8)
膀胱出口部閉塞	1 (0.1)	0
膀胱結石	1 (0.1)	0
尿路結石	1 (0.1)	0
着色尿	1 (0.1)	0
慢性腎臓病	1 (0.1)	0
排尿困難	8 (0.9)	10 (1.1)
糖尿	0	1 (0.1)
血尿	7 (0.8)	21 (2.3)
水腎症	2 (0.2)	0
緊張性膀胱	2 (0.2)	2 (0.2)

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白血球尿	1 (0.1)	2 (0.2)
下部尿路症状	0	1 (0.1)
尿意切迫	2 (0.2)	1 (0.1)
腎結石症	5 (0.6)	8 (0.9)
夜間頻尿	2 (0.2)	0
頻尿	5 (0.6)	5 (0.6)
蛋白尿	2 (0.2)	4 (0.4)
腎仙痛	1 (0.1)	1 (0.1)
腎嚢胞	2 (0.2)	3 (0.3)
腎不全	3 (0.3)	2 (0.2)
腎出血	0	1 (0.1)
腎機能障害	0	1 (0.1)
尿管結石症	0	1 (0.1)
尿道分泌物	0	1 (0.1)
尿道狭窄	1 (0.1)	0

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膀胱ポリープ	1 (0.1)	0
排尿躊躇	0	1 (0.1)
尿失禁	7 (0.8)	6 (0.7)
尿閉	2 (0.2)	3 (0.3)
尿路閉塞	0	1 (0.1)
生殖系および乳房障害	20 (2.2)	17 (1.9)
萎縮性外陰腟炎	1 (0.1)	0
良性前立腺肥大症	4 (0.4)	3 (0.3)
乳房嚢胞	0	1 (0.1)
乳房腫瘤	2 (0.2)	2 (0.2)
乳房圧痛	0	2 (0.2)
子宮内膜増殖症	0	1 (0.1)
勃起不全	1 (0.1)	2 (0.2)
線維嚢胞性乳腺疾患	1 (0.1)	0
女性化乳房	0	1 (0.1)

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月経中間期出血	1 (0.1)	0
骨盤痛	1 (0.1)	1 (0.1)
閉経後出血	1 (0.1)	0
前立腺嚢胞	0	1 (0.1)
前立腺炎	1 (0.1)	1 (0.1)
前立腺腫大	0	3 (0.3)
陰部そう痒症	0	1 (0.1)
陰嚢皮膚炎	1 (0.1)	0
陰嚢紅斑	1 (0.1)	0
精液瘤	1 (0.1)	0
精巣腫瘤	0	1 (0.1)
精巣痛	1 (0.1)	0
精巣腫脹	2 (0.2)	0
腟分泌物	1 (0.1)	0
外陰腟不快感	0	1 (0.1)

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外陰膣乾燥	2 (0.2)	0
呼吸器、胸郭および縦隔障害	85 (9.5)	88 (9.8)
急性肺水腫	0	1 (0.1)
急性呼吸不全	3 (0.3)	2 (0.2)
アレルギー性咳嗽	0	1 (0.1)
失声症	1 (0.1)	0
誤嚥	1 (0.1)	0
喘息	6 (0.7)	1 (0.1)
気管支拡張症	2 (0.2)	0
気管支痙攣	1 (0.1)	1 (0.1)
カタル	1 (0.1)	0
慢性閉塞性肺疾患	2 (0.2)	6 (0.7)
咳嗽	17 (1.9)	20 (2.2)
発声障害	2 (0.2)	0
呼吸困難	9 (1.0)	7 (0.8)

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労作性呼吸困難	5 (0.6)	4 (0.4)
肺気腫	1 (0.1)	1 (0.1)
鼻出血	9 (1.0)	4 (0.4)
喀血	1 (0.1)	0
しゃっくり	0	1 (0.1)
過敏性肺臓炎	1 (0.1)	0
過換気	1 (0.1)	0
低酸素症	0	1 (0.1)
気管支分泌増加	0	1 (0.1)
間質性肺疾患	2 (0.2)	0
鼻閉	5 (0.6)	9 (1.0)
鼻部不快感	1 (0.1)	0
鼻乾燥	0	1 (0.1)
鼻粘膜毛細血管拡張症	1 (0.1)	0
鼻閉塞	0	1 (0.1)

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鼻中隔障害	1 (0.1)	0
閉塞性睡眠時無呼吸症候群	1 (0.1)	2 (0.2)
口腔咽頭不快感	2 (0.2)	0
口腔咽頭痛	6 (0.7)	9 (1.0)
副鼻腔嚢胞	0	1 (0.1)
副鼻腔不快感	0	1 (0.1)
咽頭潰瘍	0	1 (0.1)
胸水	1 (0.1)	0
胸膜炎	1 (0.1)	0
胸膜痛	3 (0.3)	0
気胸	0	1 (0.1)
湿性咳嗽	2 (0.2)	4 (0.4)
肺塞栓症	3 (0.3)	1 (0.1)
肺高血圧症	2 (0.2)	0
肺腫瘤	3 (0.3)	2 (0.2)

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肺水腫	1 (0.1)	2 (0.2)
ラ音	0	1 (0.1)
呼吸不全	0	2 (0.2)
気道うっ血	0	2 (0.2)
アレルギー性鼻炎	1 (0.1)	1 (0.1)
鼻漏	9 (1.0)	9 (1.0)
副鼻腔うっ血	3 (0.3)	3 (0.3)
副鼻腔痛	2 (0.2)	0
睡眠時無呼吸症候群	1 (0.1)	3 (0.3)
くしゃみ	2 (0.2)	1 (0.1)
咳払い	1 (0.1)	0
上気道咳症候群	2 (0.2)	1 (0.1)
血管運動性鼻炎	0	1 (0.1)
声帯ポリープ	1 (0.1)	0
喘鳴	0	2 (0.2)

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皮膚および皮下組織障害	104 (11.6)	121 (13.5)
ざ瘡	0	1 (0.1)
光線性弾性線維症	0	1 (0.1)
光線角化症	11 (1.2)	8 (0.9)
脱毛症	4 (0.4)	7 (0.8)
円形脱毛症	0	1 (0.1)
冷汗	1 (0.1)	1 (0.1)
皮膚嚢腫	4 (0.4)	1 (0.1)
皮膚炎	4 (0.4)	2 (0.2)
アレルギー性皮膚炎	2 (0.2)	1 (0.1)
アトピー性皮膚炎	1 (0.1)	1 (0.1)
接触皮膚炎	10 (1.1)	12 (1.3)
糖尿病性足病変	1 (0.1)	0
皮膚乾燥	1 (0.1)	2 (0.2)
斑状出血	6 (0.7)	8 (0.9)

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湿疹	9 (1.0)	5 (0.6)
皮脂欠乏性湿疹	1 (0.1)	2 (0.2)
紅斑	1 (0.1)	6 (0.7)
皮下出血	1 (0.1)	3 (0.3)
手皮膚炎	1 (0.1)	1 (0.1)
多汗症	2 (0.2)	0
過角化	2 (0.2)	2 (0.2)
陥入爪	1 (0.1)	0
黒子	1 (0.1)	1 (0.1)
苔癬様角化症	0	1 (0.1)
粘液様嚢胞	1 (0.1)	0
神経皮膚炎	0	1 (0.1)
寝汗	0	5 (0.6)
爪甲剥離症	1 (0.1)	0
皮膚疼痛	2 (0.2)	0

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類天疱瘡	1 (0.1)	0
天疱瘡	0	1 (0.1)
陰茎潰瘍形成	0	1 (0.1)
点状出血	1 (0.1)	0
光線性皮膚症	1 (0.1)	0
色素沈着障害	2 (0.2)	0
前癌性皮膚病変	1 (0.1)	2 (0.2)
痒疹	0	1 (0.1)
そう痒症	9 (1.0)	11 (1.2)
乾癬	0	1 (0.1)
発疹	17 (1.9)	29 (3.2)
紅斑性皮疹	0	1 (0.1)
斑状皮疹	2 (0.2)	0
斑状丘疹状皮疹	2 (0.2)	0
丘疹性皮疹	2 (0.2)	0

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そう痒性皮疹	0	2 (0.2)
酒さ	1 (0.1)	2 (0.2)
痂皮	1 (0.1)	1 (0.1)
瘢痕痛	0	1 (0.1)
脂漏性皮膚炎	0	2 (0.2)
皮膚剥脱	3 (0.3)	0
皮膚亀裂	0	1 (0.1)
皮膚刺激	2 (0.2)	2 (0.2)
皮膚病変	7 (0.8)	6 (0.7)
皮膚腫瘤	0	1 (0.1)
皮膚反応	0	1 (0.1)
皮膚腫脹	1 (0.1)	0
皮膚潰瘍	3 (0.3)	1 (0.1)
うっ滞性皮膚炎	0	2 (0.2)
蕁麻疹	3 (0.3)	5 (0.6)

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蕁麻疹様血管炎	0	1 (0.1)
乾皮症	0	1 (0.1)
社会環境	1 (0.1)	1 (0.1)
閉経	0	1 (0.1)
身体的暴行	1 (0.1)	0
血管障害	85 (9.5)	91 (10.1)
大動脈瘤	0	1 (0.1)
大動脈拡張	0	1 (0.1)
大動脈狭窄	2 (0.2)	0
動脈硬化症	0	1 (0.1)
コントロール不良の血圧	0	2 (0.2)
腕頭静脈血栓症	0	1 (0.1)
チアノーゼ	0	1 (0.1)
深部静脈血栓症	4 (0.4)	6 (0.7)
拡張期低血圧	0	1 (0.1)

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本態性高血圧症	1 (0.1)	0
潮紅	1 (0.1)	0
巨細胞性動脈炎	1 (0.1)	0
血腫	11 (1.2)	8 (0.9)
ほてり	5 (0.6)	3 (0.3)
高血圧	43 (4.8)	41 (4.6)
高血圧クリーゼ	1 (0.1)	0
高血圧切迫症	0	1 (0.1)
低血圧	8 (0.9)	11 (1.2)
起立性低血圧	2 (0.2)	7 (0.8)
末梢動脈閉塞性疾患	1 (0.1)	1 (0.1)
末梢動脈瘤	0	1 (0.1)
末梢動脈閉塞	1 (0.1)	0
末梢冷感	1 (0.1)	0
末梢血管障害	2 (0.2)	0

TEAE = treatment-emergent adverse event.

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 two or more adverse events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).

Cerebral microhemorrhages include those deemed not ARIA-H by investigator.

MedDRA Version 25.0.

付録 2.7.6-7

SOC/PT別の有害事象発現率

301試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term J	Placebo (N = 897) n (%)	Lecanemab 10 mg/kg Biweekly (N = 898) n (%)
末梢静脈疾患	0	1 (0.1)
静脈炎	1 (0.1)	1 (0.1)
表在性静脈炎	1 (0.1)	0
静脈穿刺不良	0	4 (0.4)
鎖骨下動脈血栓症	1 (0.1)	0
帽状腱膜下血腫	1 (0.1)	0
表在性静脈血栓症	0	2 (0.2)
血栓症	0	1 (0.1)
静脈瘤	4 (0.4)	4 (0.4)
血管痛	1 (0.1)	0
静脈破裂	0	1 (0.1)
四肢静脈血栓症	1 (0.1)	0

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