付録 2.7.6-8

SOC/PT別の副作用発現率

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 Treatment-related TEAEs	197 (22.0)	401 (44.7)
血液およびリンパ系障害	3 (0.3)	2 (0.2)
貧血	1 (0.1)	0
リンパ球減少症	2 (0.2)	0
好中球減少症	0	1 (0.1)
血小板減少症	0	1 (0.1)
心臓障害	5 (0.6)	4 (0.4)
心房細動	1 (0.1)	0
第一度房室ブロック	0	1 (0.1)
第二度房室ブロック	1 (0.1)	0
徐脈	1 (0.1)	0
左脚ブロック	1 (0.1)	1 (0.1)
動悸	0	1 (0.1)
洞性徐脈	2 (0.2)	1 (0.1)

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).

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.

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
耳および迷路障害	0	1 (0.1)
回転性めまい	0	1 (0.1)
内分泌障害	0	1 (0.1)
自己免疫性甲状腺炎	0	1 (0.1)
眼障害	0	3 (0.3)
眼刺激	0	1 (0.1)
眼窩周囲腫脹	0	1 (0.1)
網膜静脈閉塞	0	1 (0.1)
胃腸障害	3 (0.3)	9 (1.0)
腹部不快感	0	1 (0.1)
大腸炎	0	1 (0.1)
便秘	0	1 (0.1)
下痢	3 (0.3)	1 (0.1)
口内乾燥	0	1 (0.1)

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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.

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
口の感覚鈍麻	0	1 (0.1)
悪心	0	2 (0.2)
嘔吐	0	1 (0.1)
一般・全身障害および投与部位の状態	10 (1.1)	18 (2.0)
無力症	0	1 (0.1)
活力増進	1 (0.1)	0
疲労	3 (0.3)	5 (0.6)
異常感	1 (0.1)	0
冷感	0	1 (0.1)
低体温	0	1 (0.1)
注入部位血管外漏出	3 (0.3)	2 (0.2)
注入部位出血	1 (0.1)	1 (0.1)
注入部位疼痛	0	1 (0.1)
注入部位発疹	0	3 (0.3)

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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).

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.

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
注入部位反応	1 (0.1)	2 (0.2)
倦怠感	0	1 (0.1)
末梢腫脹	0	1 (0.1)
軟部組織の炎症	0	1 (0.1)
肝胆道系障害	1 (0.1)	1 (0.1)
肝機能異常	0	1 (0.1)
高ビリルビン血症	1 (0.1)	0
免疫系障害	6 (0.7)	15 (1.7)
過敏症	6 (0.7)	15 (1.7)
感染症および寄生虫症	1 (0.1)	4 (0.4)
ヘルペス眼感染	0	1 (0.1)
上咽頭炎	0	1 (0.1)
鼻炎	1 (0.1)	0
歯感染	0	1 (0.1)

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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).

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.

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
尿路感染	0	1 (0.1)
傷害、中毒および処置合併症	69 (7.7)	235 (26.2)
偶発的過量投与	1 (0.1)	0
挫傷	1 (0.1)	0
転倒	2 (0.2)	2 (0.2)
注入に伴う反応	64 (7.1)	234 (26.1)
注射に伴う反応	1 (0.1)	0
関節損傷	0	1 (0.1)
皮膚創傷	1 (0.1)	0
臨床検査	8 (0.9)	5 (0.6)
アラニンアミノトランスフェラーゼ増加	2 (0.2)	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.2)	1 (0.1)
血圧上昇	1 (0.1)	0
心電図ＱＴ延長	0	1 (0.1)

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
γ－グルタミルトランスフェラーゼ増加	2 (0.2)	1 (0.1)
グロブリン減少	1 (0.1)	0
ヘマトクリット減少	1 (0.1)	0
肝酵素上昇	1 (0.1)	0
リンパ球数減少	0	1 (0.1)
好中球数減少	2 (0.2)	0
好中球数増加	0	1 (0.1)
赤血球数減少	1 (0.1)	0
体重減少	0	1 (0.1)
白血球数減少	1 (0.1)	0
代謝および栄養障害	1 (0.1)	4 (0.4)
高コレステロール血症	0	2 (0.2)
高血糖	0	1 (0.1)
高脂血症	1 (0.1)	0

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MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
低カルシウム血症	0	1 (0.1)
筋骨格系および結合組織障害	2 (0.2)	5 (0.6)
関節痛	0	1 (0.1)
背部痛	0	1 (0.1)
筋痙縮	0	1 (0.1)
筋肉痛	0	1 (0.1)
変形性関節症	1 (0.1)	0
多発性関節炎	0	1 (0.1)
リウマチ熱	1 (0.1)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (0.1)
再発非ホジキンリンパ腫	0	1 (0.1)
神経系障害	100 (11.1)	199 (22.2)
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	67 (7.5)	122 (13.6)
アミロイド関連画像異常－浮腫／滲出液貯留	15 (1.7)	113 (12.6)

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
平衡障害	1 (0.1)	2 (0.2)
小脳梗塞	1 (0.1)	1 (0.1)
脳出血	0	4 (0.4)
脳梗塞	2 (0.2)	1 (0.1)
認知障害	1 (0.1)	1 (0.1)
浮動性めまい	5 (0.6)	4 (0.4)
認知障害発作	1 (0.1)	0
頭痛	8 (0.9)	16 (1.8)
感覚鈍麻	0	1 (0.1)
ラクナ梗塞	1 (0.1)	1 (0.1)
嗜眠	1 (0.1)	0
記憶障害	0	2 (0.2)
片頭痛	1 (0.1)	0
パーキンソニズム	1 (0.1)	0

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MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
痙攣発作	2 (0.2)	0
くも膜下出血	1 (0.1)	1 (0.1)
脳表ヘモジデリン沈着症	20 (2.2)	47 (5.2)
失神	1 (0.1)	0
緊張性頭痛	0	2 (0.2)
上位運動ニューロンの病変	0	1 (0.1)
精神障害	12 (1.3)	9 (1.0)
異常な夢	3 (0.3)	1 (0.1)
感情不安定	0	1 (0.1)
不安	2 (0.2)	0
錯乱状態	2 (0.2)	2 (0.2)
妄想	1 (0.1)	1 (0.1)
うつ病	3 (0.3)	2 (0.2)
幻視	1 (0.1)	0

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MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
不眠症	2 (0.2)	0
易刺激性	0	1 (0.1)
気分動揺	1 (0.1)	0
悪夢	0	1 (0.1)
睡眠の質低下	0	1 (0.1)
腎および尿路障害	2 (0.2)	3 (0.3)
急性腎障害	0	1 (0.1)
慢性腎臓病	1 (0.1)	0
夜間頻尿	1 (0.1)	0
蛋白尿	0	2 (0.2)
生殖系および乳房障害	0	1 (0.1)
精巣腫瘤	0	1 (0.1)
呼吸器、胸郭および縦隔障害	1 (0.1)	3 (0.3)
咳嗽	0	1 (0.1)

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
呼吸困難	0	1 (0.1)
鼻出血	0	1 (0.1)
鼻漏	1 (0.1)	0
皮膚および皮下組織障害	4 (0.4)	10 (1.1)
脱毛症	1 (0.1)	0
円形脱毛症	0	1 (0.1)
アレルギー性皮膚炎	0	1 (0.1)
紅斑	0	2 (0.2)
類天疱瘡	1 (0.1)	0
そう痒症	1 (0.1)	0
発疹	1 (0.1)	5 (0.6)
紅斑性皮疹	0	1 (0.1)
蕁麻疹	0	1 (0.1)
血管障害	2 (0.2)	4 (0.4)

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

MedDRA Version 25.0.

付録 2.7.6-8

SOC/PT別の副作用発現率

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 (%)
チアノーゼ	0	1 (0.1)
巨細胞性動脈炎	1 (0.1)	0
高血圧	1 (0.1)	1 (0.1)
起立性低血圧	0	2 (0.2)

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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).

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.

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

MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
Subjects with Any TEAEs	1121 (80.6)
血液およびリンパ系障害	38 (2.7)
貧血	10 (0.7)
ビタミンＢ１２欠乏性貧血	1 (0.1)
失血性貧血	1 (0.1)
低色素性貧血	1 (0.1)
鉄欠乏性貧血	4 (0.3)
白血球増加症	1 (0.1)
白血球減少症	2 (0.1)
リンパ節炎	1 (0.1)
リンパ節症	2 (0.1)
リンパ球減少症	2 (0.1)
単球増加症	1 (0.1)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
好中球減少症	6 (0.4)
正球性貧血	2 (0.1)
赤血球増加症	2 (0.1)
血小板減少症	2 (0.1)
血小板増加症	1 (0.1)
心臓障害	104 (7.5)
急性心筋梗塞	5 (0.4)
狭心症	11 (0.8)
大動脈弁閉鎖不全症	2 (0.1)
不整脈	4 (0.3)
心房細動	30 (2.2)
心房粗動	1 (0.1)
心房頻脈	1 (0.1)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
房室ブロック	1 (0.1)
第一度房室ブロック	9 (0.6)
二束ブロック	1 (0.1)
徐脈	9 (0.6)
左脚ブロック	9 (0.6)
右脚ブロック	2 (0.1)
心停止	1 (0.1)
急性心不全	1 (0.1)
うっ血性心不全	2 (0.1)
心拡大	1 (0.1)
伝導障害	1 (0.1)
冠動脈疾患	3 (0.2)
冠動脈狭窄	1 (0.1)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
左室不全	1 (0.1)
僧帽弁閉鎖不全症	2 (0.1)
心筋梗塞	2 (0.1)
動悸	10 (0.7)
洞性徐脈	8 (0.6)
洞結節機能不全	1 (0.1)
洞性頻脈	1 (0.1)
ストレス心筋症	2 (0.1)
上室性期外収縮	4 (0.3)
上室性頻脈	1 (0.1)
三尖弁閉鎖不全症	1 (0.1)
三束ブロック	1 (0.1)
心室性期外収縮	7 (0.5)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
先天性、家族性および遺伝性障害	3 (0.2)
動静脈奇形	1 (0.1)
過長結腸	1 (0.1)
胃腸管動静脈奇形	1 (0.1)
耳および迷路障害	44 (3.2)
耳垢栓塞	2 (0.1)
難聴	1 (0.1)
感音性難聴	1 (0.1)
片耳難聴	1 (0.1)
耳閉	1 (0.1)
耳不快感	1 (0.1)
耳痛	3 (0.2)
耳管機能障害	2 (0.1)

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LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
耳垢分泌過多	1 (0.1)
内耳障害	1 (0.1)
乳突洞滲出液	1 (0.1)
メニエール病	1 (0.1)
耳鳴	5 (0.4)
回転性めまい	21 (1.5)
頭位性回転性めまい	5 (0.4)
内分泌障害	9 (0.6)
自己免疫性甲状腺炎	1 (0.1)
副甲状腺機能亢進症	1 (0.1)
甲状腺機能亢進症	1 (0.1)
甲状腺機能低下症	5 (0.4)
甲状腺腫瘤	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
眼障害	81 (5.8)
眼の異常感	1 (0.1)
加齢黄斑変性	1 (0.1)
一過性黒内障	1 (0.1)
眼瞼炎	6 (0.4)
眼瞼痙攣	1 (0.1)
白内障	21 (1.5)
霰粒腫	1 (0.1)
網脈絡膜症	1 (0.1)
脈絡膜血管新生	1 (0.1)
結膜出血	12 (0.9)
結膜充血	2 (0.1)
アレルギー性結膜炎	1 (0.1)

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LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
糖尿病性眼病変	1 (0.1)
ドライアイ	1 (0.1)
眼瞼湿疹	1 (0.1)
眼脂	1 (0.1)
眼血腫	2 (0.1)
眼出血	1 (0.1)
眼刺激	2 (0.1)
眼痛	1 (0.1)
眼そう痒症	1 (0.1)
眼瞼下垂	2 (0.1)
緑内障	5 (0.4)
水晶体脱臼	1 (0.1)
黄斑変性	1 (0.1)

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LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
眼部不快感	3 (0.2)
眼球瘻	1 (0.1)
眼充血	5 (0.4)
眼窩周囲浮腫	1 (0.1)
眼窩周囲腫脹	1 (0.1)
後嚢部混濁	1 (0.1)
網膜剥離	1 (0.1)
網膜出血	1 (0.1)
網膜静脈閉塞	1 (0.1)
霧視	3 (0.2)
視力低下	1 (0.1)
視野欠損	1 (0.1)
硝子体剥離	1 (0.1)

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LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
硝子体浮遊物	4 (0.3)
胃腸障害	258 (18.5)
腹部癒着	1 (0.1)
腹部不快感	5 (0.4)
腹部膨満	2 (0.1)
腹部ヘルニア	1 (0.1)
腹痛	17 (1.2)
下腹部痛	3 (0.2)
上腹部痛	13 (0.9)
肛門びらん	1 (0.1)
肛門出血	1 (0.1)
肛門失禁	3 (0.2)
アフタ性潰瘍	2 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
口唇炎	1 (0.1)
慢性胃炎	1 (0.1)
大腸炎	2 (0.1)
顕微鏡的大腸炎	1 (0.1)
潰瘍性大腸炎	2 (0.1)
便秘	26 (1.9)
齲歯	14 (1.0)
下痢	56 (4.0)
憩室	4 (0.3)
腸憩室	4 (0.3)
口内乾燥	4 (0.3)
十二指腸潰瘍	1 (0.1)
十二指腸炎	3 (0.2)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
消化不良	13 (0.9)
嚥下障害	1 (0.1)
心窩部不快感	1 (0.1)
おくび	1 (0.1)
変色便	1 (0.1)
鼓腸	1 (0.1)
食中毒	1 (0.1)
排便回数増加	2 (0.1)
機能性胃腸障害	1 (0.1)
胃ポリープ	1 (0.1)
胃炎	7 (0.5)
びらん性胃炎	1 (0.1)
胃腸管血管異形成	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
胃腸出血	1 (0.1)
消化器痛	1 (0.1)
胃食道逆流性疾患	19 (1.4)
歯肉水疱	1 (0.1)
歯肉痛	1 (0.1)
舌炎	1 (0.1)
血便排泄	4 (0.3)
痔出血	2 (0.1)
痔核	11 (0.8)
裂孔ヘルニア	2 (0.1)
口の感覚鈍麻	1 (0.1)
イレウス	1 (0.1)
鼠径ヘルニア	13 (0.9)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
腸管ポリープ	2 (0.1)
過敏性腸症候群	4 (0.3)
大腸ポリープ	9 (0.6)
口腔白斑症	1 (0.1)
口唇腫脹	1 (0.1)
腰ヘルニア	1 (0.1)
機械的イレウス	1 (0.1)
口腔内潰瘍形成	1 (0.1)
悪心	39 (2.8)
口腔障害	2 (0.1)
口腔そう痒症	1 (0.1)
膵炎	1 (0.1)
消化性潰瘍	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
歯周の炎症	1 (0.1)
直腸出血	2 (0.1)
直腸ポリープ	1 (0.1)
逆流性胃炎	1 (0.1)
レッチング	1 (0.1)
流涎過多	1 (0.1)
スピゲリウスヘルニア	1 (0.1)
口内炎	2 (0.1)
亜イレウス	1 (0.1)
歯の障害	2 (0.1)
歯の吸収症	1 (0.1)
歯痛	9 (0.6)
臍ヘルニア	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
腸の軸捻転	1 (0.1)
嘔吐	39 (2.8)
一般・全身障害および投与部位の状態	215 (15.5)
適用部位紅斑	1 (0.1)
適用部位過敏反応	1 (0.1)
適用部位損傷	1 (0.1)
無力症	8 (0.6)
胸部不快感	3 (0.2)
胸痛	7 (0.5)
悪寒	16 (1.2)
死亡	1 (0.1)
不快感	3 (0.2)
疲労	47 (3.4)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
異常感	3 (0.2)
冷感	7 (0.5)
熱感	1 (0.1)
歩行障害	6 (0.4)
高体温症	1 (0.1)
低体温	1 (0.1)
炎症	2 (0.1)
インフルエンザ様疾患	4 (0.3)
注入部位紅斑	1 (0.1)
注入部位血管外漏出	17 (1.2)
注入部位血腫	2 (0.1)
注入部位出血	1 (0.1)
注入部位炎症	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
注入部位疼痛	2 (0.1)
注入部位発疹	3 (0.2)
注入部位反応	3 (0.2)
注入部位腫脹	2 (0.1)
注射部位不快感	2 (0.1)
注射部位漏出	1 (0.1)
注射部位出血	1 (0.1)
注射部位結節	1 (0.1)
注射部位疼痛	10 (0.7)
注射部位発疹	1 (0.1)
倦怠感	7 (0.5)
非心臓性胸痛	12 (0.9)
浮腫	2 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
末梢性浮腫	16 (1.2)
疼痛	5 (0.4)
末梢腫脹	14 (1.0)
穿刺部位疼痛	3 (0.2)
発熱	34 (2.4)
軟部組織の炎症	1 (0.1)
恥骨上痛	1 (0.1)
腫脹	1 (0.1)
全身性炎症反応症候群	2 (0.1)
ワクチン接種部位疼痛	14 (1.0)
ワクチン接種部位反応	1 (0.1)
血管穿刺部位紅斑	1 (0.1)
血管穿刺部位反応	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
肝胆道系障害	17 (1.2)
胆管結石	1 (0.1)
胆管炎	1 (0.1)
胆嚢炎	2 (0.1)
急性胆嚢炎	2 (0.1)
胆石症	2 (0.1)
薬物性肝障害	1 (0.1)
肝動脈瘤	1 (0.1)
肝嚢胞	2 (0.1)
肝機能異常	1 (0.1)
肝腫瘤	2 (0.1)
脂肪肝	2 (0.1)
高ビリルビン血症	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
高トランスアミナーゼ血症	1 (0.1)
免疫系障害	40 (2.9)
節足動物咬傷アレルギー	2 (0.1)
造影剤アレルギー	1 (0.1)
薬物過敏症	3 (0.2)
食物アレルギー	1 (0.1)
過敏症	20 (1.4)
免疫反応	2 (0.1)
乳アレルギー	1 (0.1)
季節性アレルギー	10 (0.7)
感染症および寄生虫症	437 (31.4)
ダニ皮膚炎	1 (0.1)
急性副鼻腔炎	3 (0.2)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
無症候性ＣＯＶＩＤ－１９	15 (1.1)
無症候性細菌尿	2 (0.1)
異型肺炎	2 (0.1)
細菌感染	1 (0.1)
細菌性膣症	1 (0.1)
体部白癬	1 (0.1)
ボレリア感染	1 (0.1)
乳房膿瘍	1 (0.1)
乳房蜂巣炎	1 (0.1)
気管支炎	14 (1.0)
ＣＯＶＩＤ－１９	115 (8.3)
ＣＯＶＩＤ－１９肺炎	5 (0.4)
蜂巣炎	12 (0.9)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
慢性副鼻腔炎	1 (0.1)
結膜炎	8 (0.6)
膀胱炎	10 (0.7)
皮膚糸状菌症	1 (0.1)
爪の皮膚糸状菌症	2 (0.1)
憩室炎	5 (0.4)
耳感染	3 (0.2)
エンテロバクター性菌血症	1 (0.1)
精巣上体炎	1 (0.1)
遊走性紅斑	1 (0.1)
大腸菌性尿路感染	1 (0.1)
外耳蜂巣炎	1 (0.1)
真菌性足感染	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
皮膚真菌感染	2 (0.1)
胃腸炎	9 (0.6)
ウイルス性胃腸炎	4 (0.3)
ウイルス性消化管感染	1 (0.1)
歯肉膿瘍	1 (0.1)
歯肉炎	7 (0.5)
肝嚢胞感染	1 (0.1)
ヘルペス性皮膚炎	1 (0.1)
ヘルペス眼感染	2 (0.1)
単純ヘルペス	1 (0.1)
ヘルペスウイルス感染	1 (0.1)
帯状疱疹	11 (0.8)
皮膚播種性帯状疱疹	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
麦粒腫	8 (0.6)
膿痂疹	1 (0.1)
咬傷感染	1 (0.1)
感染性脊椎炎	1 (0.1)
インフルエンザ	5 (0.4)
腎感染	1 (0.1)
喉頭炎	1 (0.1)
限局性感染	1 (0.1)
下気道感染	3 (0.2)
ライム病	1 (0.1)
リンパ管炎	1 (0.1)
乳様突起炎	2 (0.1)
爪感染	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
上咽頭炎	48 (3.5)
爪真菌症	4 (0.3)
口腔カンジダ症	2 (0.1)
口腔ヘルペス	4 (0.3)
外耳炎	1 (0.1)
中耳炎	2 (0.1)
爪囲炎	2 (0.1)
耳下腺炎	1 (0.1)
歯周炎	2 (0.1)
咽頭炎	7 (0.5)
肺炎	8 (0.6)
急性ＣＯＶＩＤ－１９後症候群	1 (0.1)
術後膿瘍	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
術後創感染	1 (0.1)
膿尿	3 (0.2)
ＲＳウイルス感染	1 (0.1)
気道感染	1 (0.1)
鼻炎	9 (0.6)
敗血症	2 (0.1)
副鼻腔炎	16 (1.2)
細菌性副鼻腔炎	1 (0.1)
皮膚細菌感染	1 (0.1)
皮膚カンジダ	1 (0.1)
皮膚感染	1 (0.1)
皮下組織膿瘍	1 (0.1)
ＣＯＶＩＤ－１９の疑い	3 (0.2)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
白癬感染	1 (0.1)
足部白癬	4 (0.3)
扁桃炎	1 (0.1)
歯膿瘍	9 (0.6)
歯感染	10 (0.7)
上気道感染	30 (2.2)
尿路感染	103 (7.4)
腟感染	2 (0.1)
移植血管感染	1 (0.1)
前庭神経炎	1 (0.1)
ウイルス感染	5 (0.4)
外陰腟真菌感染	2 (0.1)
外陰腟炎	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
創傷感染	1 (0.1)
傷害、中毒および処置合併症	517 (37.2)
腹部損傷	1 (0.1)
偶発的過量投与	2 (0.1)
動物咬傷	2 (0.1)
足関節部骨折	3 (0.2)
節足動物咬傷	3 (0.2)
節足動物刺傷	1 (0.1)
骨挫傷	3 (0.2)
脳挫傷	1 (0.1)
第１度熱傷	1 (0.1)
子宮頚部損傷	1 (0.1)
化学性腹膜炎	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
凍瘡	1 (0.1)
鎖骨骨折	1 (0.1)
低温損傷	1 (0.1)
低温による損傷	1 (0.1)
脳振盪	1 (0.1)
挫傷	51 (3.7)
冠動脈再狭窄	1 (0.1)
頭蓋脳損傷	1 (0.1)
上顎炎	1 (0.1)
経口曝露	1 (0.1)
眼挫傷	1 (0.1)
眼外傷	1 (0.1)
顔面損傷	2 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
顔面骨骨折	2 (0.1)
転倒	118 (8.5)
大腿骨頚部骨折	3 (0.2)
大腿骨骨折	1 (0.1)
腓骨骨折	1 (0.1)
足骨折	3 (0.2)
前腕骨折	1 (0.1)
眼内異物	1 (0.1)
手骨折	3 (0.2)
頭部損傷	2 (0.1)
熱中症	1 (0.1)
股関節部骨折	3 (0.2)
上腕骨骨折	6 (0.4)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
瘢痕ヘルニア	2 (0.1)
誤用量投与	1 (0.1)
注入に伴う反応	334 (24.0)
関節脱臼	2 (0.1)
関節損傷	6 (0.4)
靱帯捻挫	11 (0.8)
四肢損傷	11 (0.8)
口唇損傷	1 (0.1)
半月板損傷	4 (0.3)
口腔内損傷	1 (0.1)
肉離れ	12 (0.9)
鼻部損傷	1 (0.1)
眼処置合併症	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
膝蓋骨骨折	3 (0.2)
骨盤骨折	1 (0.1)
眼窩周囲出血	2 (0.1)
腰椎穿刺後症候群	2 (0.1)
処置後合併症	2 (0.1)
処置後発熱	1 (0.1)
処置後出血	2 (0.1)
外傷後疼痛	1 (0.1)
術後創合併症	1 (0.1)
処置による疼痛	3 (0.2)
橈骨骨折	7 (0.5)
肋骨骨折	5 (0.4)
交通事故	3 (0.2)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
瘢痕	1 (0.1)
皮膚擦過傷	21 (1.5)
皮膚損傷	1 (0.1)
皮膚裂傷	30 (2.2)
皮膚創傷	1 (0.1)
軟部組織損傷	1 (0.1)
脊柱損傷	1 (0.1)
脊椎圧迫骨折	3 (0.2)
刺創	1 (0.1)
胸骨骨折	1 (0.1)
ストレス骨折	1 (0.1)
皮下血腫	2 (0.1)
硬膜下血腫	9 (0.6)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
腱損傷	2 (0.1)
熱傷	3 (0.2)
胸椎骨折	3 (0.2)
歯牙破折	9 (0.6)
歯牙損傷	1 (0.1)
外傷性腰椎穿刺	1 (0.1)
尺骨骨折	1 (0.1)
上肢骨折	2 (0.1)
ワクチン接種合併症	7 (0.5)
創傷	4 (0.3)
創離開	1 (0.1)
手首関節骨折	5 (0.4)
臨床検査	139 (10.0)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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.

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
アラニンアミノトランスフェラーゼ増加	7 (0.5)
アスパラギン酸アミノトランスフェラーゼ増加	6 (0.4)
尿中ビリルビン陽性	1 (0.1)
血中アルブミン減少	1 (0.1)
血中アルカリホスファターゼ増加	2 (0.1)
血中ビリルビン増加	1 (0.1)
血中カルシウム減少	2 (0.1)
血中カルシウム増加	1 (0.1)
血中クロール減少	1 (0.1)
血中コレステロール増加	9 (0.6)
血中クレアチニン増加	3 (0.2)
血中ブドウ糖増加	4 (0.3)
血中インスリン増加	1 (0.1)

TEAE = treatment-emergent adverse event.

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
血中リン減少	2 (0.1)
血中カリウム減少	1 (0.1)
血圧低下	2 (0.1)
血圧上昇	9 (0.6)
血中ナトリウム減少	3 (0.2)
血中テストステロン減少	1 (0.1)
血中トリグリセリド増加	6 (0.4)
血中尿素増加	2 (0.1)
血中尿酸	1 (0.1)
血中尿酸異常	1 (0.1)
血中尿酸増加	4 (0.3)
体温上昇	1 (0.1)
骨密度減少	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
骨スキャン正常	1 (0.1)
糖鎖抗原１９－９増加	1 (0.1)
心雑音	1 (0.1)
クロストリジウム検査陽性	1 (0.1)
脳ＭＲＩ拡散強調画像異常	1 (0.1)
心電図ＰＲ延長	2 (0.1)
心電図ＱＴ延長	6 (0.4)
心電図ＳＴ部分下降	1 (0.1)
心電図異常Ｔ波	1 (0.1)
心電図Ｔ波振幅減少	1 (0.1)
心電図Ｔ波逆転	4 (0.3)
心電図異常	1 (0.1)
好酸球数増加	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
γ－グルタミルトランスフェラーゼ増加	7 (0.5)
グロブリン減少	1 (0.1)
グリコヘモグロビン増加	1 (0.1)
ヘマトクリット増加	1 (0.1)
ヘモグロビン減少	2 (0.1)
ヘモグロビン増加	1 (0.1)
心拍数不整	1 (0.1)
ヘリコバクター検査陽性	2 (0.1)
肝酵素上昇	3 (0.2)
A型インフルエンザウイルス検査陽性	1 (0.1)
国際標準比増加	1 (0.1)
眼圧上昇	2 (0.1)
脂質異常	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
肝機能検査異常	1 (0.1)
肝機能検査値上昇	2 (0.1)
低比重リポ蛋白増加	1 (0.1)
リンパ球数減少	3 (0.2)
神経学的検査異常	1 (0.1)
好中球数増加	2 (0.1)
便潜血陽性	2 (0.1)
プロカルシトニン増加	1 (0.1)
前立腺特異性抗原増加	3 (0.2)
総蛋白減少	1 (0.1)
尿蛋白	1 (0.1)
尿中蛋白陽性	1 (0.1)
尿中赤血球陽性	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
ＳＡＲＳ－ＣｏＶ－２検査陽性	21 (1.5)
トランスアミナーゼ上昇	1 (0.1)
尿円柱	1 (0.1)
ビタミンD減少	2 (0.1)
体重減少	13 (0.9)
体重増加	1 (0.1)
代謝および栄養障害	106 (7.6)
異常体重減少	2 (0.1)
食欲減退	19 (1.4)
脱水	8 (0.6)
糖尿病	4 (0.3)
コントロール不良の糖尿病	1 (0.1)
脂質異常症	3 (0.2)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
電解質失調	1 (0.1)
葉酸欠乏	3 (0.2)
耐糖能障害	1 (0.1)
痛風	5 (0.4)
高カルシウム血症	1 (0.1)
高コレステロール血症	10 (0.7)
高フェリチン血症	1 (0.1)
高血糖	7 (0.5)
高カリウム血症	5 (0.4)
高リパーゼ血症	1 (0.1)
高脂血症	5 (0.4)
高ナトリウム血症	1 (0.1)
高トリグリセリド血症	5 (0.4)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
高尿酸血症	2 (0.1)
低カルシウム血症	2 (0.1)
低血糖	4 (0.3)
低カリウム血症	5 (0.4)
低マグネシウム血症	1 (0.1)
低ナトリウム血症	8 (0.6)
低リン血症	1 (0.1)
鉄欠乏	1 (0.1)
２型糖尿病	3 (0.2)
ビタミンＢ１２欠乏	1 (0.1)
ビタミンＤ欠乏	7 (0.5)
亜鉛欠乏	1 (0.1)
筋骨格系および結合組織障害	279 (20.1)

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付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
関節痛	78 (5.6)
関節炎	9 (0.6)
背部痛	76 (5.5)
骨嚢腫	1 (0.1)
骨痛	1 (0.1)
滑液包炎	4 (0.3)
肋軟骨炎	2 (0.1)
クラウンド・デンス症候群	1 (0.1)
変性骨疾患	1 (0.1)
デュプイトラン拘縮	1 (0.1)
外骨腫	1 (0.1)
側腹部痛	2 (0.1)
足変形	2 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
大転子疼痛症候群	1 (0.1)
単径部痛	2 (0.1)
出血性関節症	1 (0.1)
筋肉内血腫	1 (0.1)
椎間板変性症	2 (0.1)
椎間板障害	1 (0.1)
椎間板突出	1 (0.1)
関節腫脹	5 (0.4)
四肢不快感	2 (0.1)
腰部脊柱管狭窄症	3 (0.2)
筋痙縮	16 (1.2)
筋攣縮	1 (0.1)
筋力低下	3 (0.2)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
筋骨格系胸痛	7 (0.5)
筋骨格不快感	1 (0.1)
筋骨格痛	3 (0.2)
筋骨格硬直	3 (0.2)
筋肉痛	16 (1.2)
頚部痛	18 (1.3)
変形性関節症	23 (1.7)
骨減少症	1 (0.1)
骨粗鬆症	6 (0.4)
四肢痛	44 (3.2)
顎痛	2 (0.1)
関節周囲炎	2 (0.1)
足底腱膜線維腫症	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
足底筋膜炎	4 (0.3)
多発性関節炎	2 (0.1)
多発性筋炎	1 (0.1)
姿勢異常	1 (0.1)
横紋筋融解症	1 (0.1)
関節リウマチ	1 (0.1)
肩回旋筋腱板症候群	6 (0.4)
変形性脊椎症	2 (0.1)
脊椎痛	1 (0.1)
脊椎炎	2 (0.1)
脊椎すべり症	1 (0.1)
滑液嚢腫	1 (0.1)
顎関節症候群	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
腱障害	1 (0.1)
腱炎	1 (0.1)
腱鞘炎	2 (0.1)
斜頸	1 (0.1)
弾発指	2 (0.1)
椎間孔狭窄	3 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	96 (6.9)
アクロコルドン	1 (0.1)
結腸腺癌	1 (0.1)
副腎腺腫	1 (0.1)
副腎新生物	1 (0.1)
基底細胞癌	20 (1.4)
胃の良性新生物	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
卵巣良性腫瘍	1 (0.1)
唾液腺の良性新生物	1 (0.1)
膀胱癌	2 (0.1)
ボーエン病	1 (0.1)
乳癌	2 (0.1)
乳房の上皮内癌	1 (0.1)
結腸直腸腺腫	3 (0.2)
皮膚リンパ腫	1 (0.1)
異形成母斑	1 (0.1)
外耳の悪性新生物	2 (0.1)
消化管粘膜下腫瘍	1 (0.1)
皮膚血管腫	1 (0.1)
乳管内増殖性病変	2 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
浸潤性乳管癌	2 (0.1)
ケラトアカントーマ	1 (0.1)
大腸の良性新生物	1 (0.1)
喉頭癌	1 (0.1)
喉頭扁平上皮癌	1 (0.1)
口唇新生物	1 (0.1)
脂肪腫	4 (0.3)
悪性黒色腫	1 (0.1)
メラノサイト性母斑	2 (0.1)
肝転移	1 (0.1)
髄膜転移	1 (0.1)
皮膚の新生物	1 (0.1)
再発非ホジキンリンパ腫	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
膨大細胞腫	1 (0.1)
卵巣癌	1 (0.1)
リンパ腫性乳頭状嚢胞腺腫	1 (0.1)
良性副甲状腺腫瘍	1 (0.1)
下垂体の良性腫瘍	1 (0.1)
形質細胞腫	1 (0.1)
前立腺癌	3 (0.2)
遠隔転移を伴う前立腺癌	1 (0.1)
直腸癌	1 (0.1)
腎細胞癌	1 (0.1)
脂漏性角化症	8 (0.6)
皮膚癌	1 (0.1)
皮膚乳頭腫	4 (0.3)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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).

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
小細胞肺癌	1 (0.1)
脊髄脂肪腫	1 (0.1)
扁平上皮癌	3 (0.2)
皮膚有棘細胞癌	13 (0.9)
神経系障害	528 (38.0)
意識変容状態	1 (0.1)
健忘	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	178 (12.8)
アミロイド関連画像異常－浮腫／滲出液貯留	166 (11.9)
無嗅覚	1 (0.1)
失語症	2 (0.1)
失行症	1 (0.1)
運動失調	2 (0.1)

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付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
平衡障害	8 (0.6)
脳損傷	1 (0.1)
頚動脈硬化症	2 (0.1)
頚動脈狭窄	2 (0.1)
手根管症候群	4 (0.3)
中枢痛症候群	1 (0.1)
小脳梗塞	4 (0.3)
脳出血	6 (0.4)
脳梗塞	7 (0.5)
虚血性脳小血管疾患	1 (0.1)
脳血管発作	2 (0.1)
頚髄神経根障害	1 (0.1)
頚原性頭痛	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
認知障害	8 (0.6)
振動覚低下	2 (0.1)
認知症	2 (0.1)
アルツハイマー型認知症	13 (0.9)
アルツハイマー型認知症、妄想を伴う	1 (0.1)
糖尿病性ニューロパチー	3 (0.2)
浮動性めまい	65 (4.7)
体位性めまい	2 (0.1)
転倒発作	1 (0.1)
異常感覚	1 (0.1)
反復拮抗運動不全	2 (0.1)
ジスキネジア	2 (0.1)
電気ショック様感覚	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
本態性振戦	1 (0.1)
頭部不快感	2 (0.1)
頭部動揺	1 (0.1)
頭痛	131 (9.4)
片側運動失調	1 (0.1)
片側感覚鈍麻	1 (0.1)
不全片麻痺	1 (0.1)
過眠症	1 (0.1)
高血圧性脳症	1 (0.1)
筋緊張亢進	1 (0.1)
感覚鈍麻	8 (0.6)
反射減弱	1 (0.1)
第３脳神経麻痺	1 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
企図振戦	1 (0.1)
肋間神経痛	1 (0.1)
虚血性脳卒中	2 (0.1)
ラクナ梗塞	8 (0.6)
嗜眠	4 (0.3)
意識消失	1 (0.1)
腰髄神経根障害	3 (0.2)
記憶障害	4 (0.3)
代謝性脳症	1 (0.1)
片頭痛	3 (0.2)
運動ニューロン疾患	1 (0.1)
運動障害	1 (0.1)
不随意性筋収縮	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
重症筋無力症	1 (0.1)
ミオクローヌス	2 (0.1)
神経痛	2 (0.1)
神経学的無視症候群	1 (0.1)
末梢性ニューロパチー	1 (0.1)
起立時振戦	1 (0.1)
錯感覚	10 (0.7)
パーキンソン病	2 (0.1)
パーキンソニズム	3 (0.2)
部分発作	2 (0.1)
患者の逃げ出し	2 (0.1)
末梢性感覚ニューロパチー	1 (0.1)
多発ニューロパチー	2 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
ヘルペス後神経痛	2 (0.1)
失神寸前の状態	14 (1.0)
神経根障害	1 (0.1)
反射異常	1 (0.1)
安静時振戦	1 (0.1)
下肢静止不能症候群	2 (0.1)
坐骨神経痛	9 (0.6)
痙攣発作	3 (0.2)
副鼻腔炎に伴う頭痛	3 (0.2)
傾眠	2 (0.1)
会話障害	1 (0.1)
くも膜下出血	2 (0.1)
脳表ヘモジデリン沈着症	67 (4.8)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
失神	22 (1.6)
味覚障害	1 (0.1)
緊張性頭痛	8 (0.6)
視床出血	1 (0.1)
一過性全健忘	1 (0.1)
一過性脳虚血発作	4 (0.3)
振戦	14 (1.0)
三叉神経痛	2 (0.1)
上位運動ニューロンの病変	1 (0.1)
白質病変	2 (0.1)
製品の問題	3 (0.2)
医療機器位置異常	1 (0.1)
医療機器のゆるみ	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
医療機器機能不良	1 (0.1)
精神障害	190 (13.7)
異常な夢	4 (0.3)
睡眠関連異常事象	1 (0.1)
感情不安定	5 (0.4)
感情障害	1 (0.1)
攻撃性	2 (0.1)
激越	12 (0.9)
不安	59 (4.2)
無感情	1 (0.1)
行動障害	2 (0.1)
身体疾患による行動障害	1 (0.1)
閉所恐怖症	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
錯乱状態	18 (1.3)
譫妄	3 (0.2)
妄想	4 (0.3)
抑うつ気分	6 (0.4)
うつ病	32 (2.3)
抑うつ症状	8 (0.6)
失見当識	2 (0.1)
幻覚	3 (0.2)
幻視	1 (0.1)
混合性幻覚	1 (0.1)
性欲過剰	1 (0.1)
初期不眠症	2 (0.1)
不眠症	31 (2.2)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
故意の自傷行為	1 (0.1)
易刺激性	7 (0.5)
リビドー亢進	1 (0.1)
大うつ病	2 (0.1)
精神状態変化	4 (0.3)
混合性不安抑うつ障害	4 (0.3)
神経過敏	1 (0.1)
神経症	2 (0.1)
悪夢	4 (0.3)
パニック発作	5 (0.4)
持続性抑うつ障害	1 (0.1)
睡眠の質低下	1 (0.1)
処置に対する不安	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
精神病性障害	1 (0.1)
落ち着きのなさ	3 (0.2)
睡眠障害	6 (0.4)
睡眠時驚愕	1 (0.1)
自殺念慮	1 (0.1)
腎および尿路障害	92 (6.6)
急性腎障害	9 (0.6)
膀胱痙縮	1 (0.1)
慢性腎臓病	2 (0.1)
排尿困難	11 (0.8)
糖尿	1 (0.1)
血尿	24 (1.7)
緊張性膀胱	4 (0.3)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
白血球尿	3 (0.2)
下部尿路症状	1 (0.1)
尿意切迫	3 (0.2)
腎結石症	11 (0.8)
頻尿	8 (0.6)
蛋白尿	4 (0.3)
腎仙痛	1 (0.1)
腎嚢胞	5 (0.4)
腎不全	2 (0.1)
腎出血	1 (0.1)
腎機能障害	2 (0.1)
尿管結石症	1 (0.1)
尿道分泌物	1 (0.1)

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付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
排尿躊躇	1 (0.1)
尿失禁	11 (0.8)
尿閉	3 (0.2)
尿路閉塞	1 (0.1)
生殖系および乳房障害	25 (1.8)
後天性包茎	1 (0.1)
萎縮性外陰腟炎	1 (0.1)
良性前立腺肥大症	4 (0.3)
乳房嚢胞	1 (0.1)
乳房腫瘤	2 (0.1)
乳房圧痛	2 (0.1)
子宮内膜増殖症	1 (0.1)
勃起不全	2 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
性器出血	1 (0.1)
女性化乳房	1 (0.1)
閉経期症状	1 (0.1)
骨盤痛	1 (0.1)
閉経後出血	1 (0.1)
持続勃起症	1 (0.1)
前立腺嚢胞	1 (0.1)
前立腺炎	2 (0.1)
前立腺腫大	3 (0.2)
陰部そう痒症	1 (0.1)
精巣腫瘤	1 (0.1)
外陰腟不快感	2 (0.1)
呼吸器、胸郭および縦隔障害	118 (8.5)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
急性肺水腫	1 (0.1)
急性呼吸不全	2 (0.1)
アレルギー性咳嗽	1 (0.1)
喘息	3 (0.2)
気管支痙攣	1 (0.1)
慢性閉塞性肺疾患	9 (0.6)
咳嗽	30 (2.2)
呼吸困難	8 (0.6)
労作性呼吸困難	5 (0.4)
肺気腫	2 (0.1)
鼻出血	9 (0.6)
しゃっくり	2 (0.1)
低酸素症	1 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
気管支分泌増加	1 (0.1)
鼻閉	13 (0.9)
鼻乾燥	1 (0.1)
鼻閉塞	1 (0.1)
閉塞性睡眠時無呼吸症候群	2 (0.1)
口腔咽頭痛	11 (0.8)
副鼻腔嚢胞	1 (0.1)
副鼻腔不快感	1 (0.1)
咽頭潰瘍	1 (0.1)
胸水	1 (0.1)
気胸	1 (0.1)
湿性咳嗽	4 (0.3)
肺塞栓症	1 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
肺腫瘤	2 (0.1)
肺水腫	2 (0.1)
ラ音	1 (0.1)
呼吸不全	2 (0.1)
気道うっ血	2 (0.1)
アレルギー性鼻炎	2 (0.1)
鼻漏	16 (1.2)
副鼻腔うっ血	3 (0.2)
睡眠時無呼吸症候群	3 (0.2)
くしゃみ	1 (0.1)
上気道咳症候群	2 (0.1)
血管運動性鼻炎	1 (0.1)
喘鳴	2 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
皮膚および皮下組織障害	154 (11.1)
ざ瘡	1 (0.1)
光線性弾性線維症	1 (0.1)
光線角化症	11 (0.8)
脱毛症	10 (0.7)
円形脱毛症	1 (0.1)
血管浮腫	1 (0.1)
冷汗	1 (0.1)
褥瘡性潰瘍	1 (0.1)
皮膚嚢腫	1 (0.1)
皮膚炎	3 (0.2)
アレルギー性皮膚炎	2 (0.1)
アトピー性皮膚炎	1 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
接触皮膚炎	12 (0.9)
皮膚乾燥	2 (0.1)
斑状出血	9 (0.6)
湿疹	8 (0.6)
皮脂欠乏性湿疹	2 (0.1)
紅斑	11 (0.8)
皮下出血	3 (0.2)
手皮膚炎	1 (0.1)
過角化	3 (0.2)
陥入爪	1 (0.1)
黒子	2 (0.1)
苔癬様角化症	1 (0.1)
爪成長異常	1 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
神経皮膚炎	1 (0.1)
寝汗	5 (0.4)
天疱瘡	1 (0.1)
陰茎潰瘍形成	1 (0.1)
光線過敏性反応	1 (0.1)
前癌性皮膚病変	2 (0.1)
痒疹	1 (0.1)
そう痒症	13 (0.9)
乾癬	1 (0.1)
紫斑	1 (0.1)
発疹	35 (2.5)
紅斑性皮疹	1 (0.1)
斑状丘疹状皮疹	1 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
丘疹性皮疹	1 (0.1)
そう痒性皮疹	2 (0.1)
酒さ	2 (0.1)
痂皮	1 (0.1)
瘢痕痛	1 (0.1)
脂漏性皮膚炎	3 (0.2)
皮膚亀裂	1 (0.1)
皮膚刺激	2 (0.1)
皮膚病変	11 (0.8)
皮膚腫瘤	1 (0.1)
皮膚臭異常	1 (0.1)
皮膚反応	1 (0.1)
皮膚潰瘍	2 (0.1)

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
うっ滞性皮膚炎	3 (0.2)
蕁麻疹	6 (0.4)
蕁麻疹様血管炎	1 (0.1)
乾皮症	1 (0.1)
社会環境	2 (0.1)
日常活動における個人の自立の喪失	1 (0.1)
閉経	1 (0.1)
血管障害	115 (8.3)
大動脈瘤	1 (0.1)
大動脈拡張	1 (0.1)
動脈硬化症	1 (0.1)
コントロール不良の血圧	2 (0.1)
腕頭静脈血栓症	1 (0.1)

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付録 2.7.6-9

SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
チアノーゼ	1 (0.1)
深部静脈血栓症	7 (0.5)
拡張期低血圧	1 (0.1)
血腫	9 (0.6)
ほてり	3 (0.2)
高血圧	55 (4.0)
高血圧切迫症	1 (0.1)
低血圧	15 (1.1)
起立性高血圧	1 (0.1)
起立性低血圧	10 (0.7)
末梢動脈閉塞性疾患	1 (0.1)
末梢動脈瘤	1 (0.1)
末梢血管塞栓症	1 (0.1)

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MedDRA Version 25.0.

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SOC/PT別の有害事象発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
末梢静脈疾患	2 (0.1)
静脈炎	2 (0.1)
静脈穿刺不良	4 (0.3)
表在性静脈血栓症	2 (0.1)
血栓症	1 (0.1)
静脈瘤	4 (0.3)
静脈破裂	1 (0.1)
四肢静脈血栓症	1 (0.1)

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MedDRA Version 25.0.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
Subjects with Any Treatment-related TEAEs	575 (41.3)
血液およびリンパ系障害	3 (0.2)
白血球減少症	1 (0.1)
好中球減少症	1 (0.1)
血小板減少症	1 (0.1)
心臓障害	5 (0.4)
第一度房室ブロック	1 (0.1)
左脚ブロック	1 (0.1)
動悸	1 (0.1)
洞性徐脈	1 (0.1)
上室性期外収縮	1 (0.1)
耳および迷路障害	2 (0.1)

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

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.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
回転性めまい	2 (0.1)
内分泌障害	1 (0.1)
自己免疫性甲状腺炎	1 (0.1)
眼障害	3 (0.2)
結膜出血	1 (0.1)
眼刺激	1 (0.1)
眼窩周囲腫脹	1 (0.1)
網膜静脈閉塞	1 (0.1)
胃腸障害	12 (0.9)
腹部不快感	1 (0.1)
大腸炎	1 (0.1)
便秘	1 (0.1)
下痢	2 (0.1)

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

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.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
口内乾燥	1 (0.1)
消化不良	1 (0.1)
口の感覚鈍麻	1 (0.1)
悪心	3 (0.2)
レッチング	1 (0.1)
嘔吐	2 (0.1)
一般・全身障害および投与部位の状態	26 (1.9)
無力症	1 (0.1)
疲労	7 (0.5)
異常感	1 (0.1)
冷感	1 (0.1)
低体温	1 (0.1)
注入部位血管外漏出	3 (0.2)

TEAE = treatment-emergent adverse event.

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

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.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
注入部位出血	1 (0.1)
注入部位疼痛	1 (0.1)
注入部位発疹	3 (0.2)
注入部位反応	3 (0.2)
注入部位腫脹	1 (0.1)
倦怠感	1 (0.1)
末梢性浮腫	1 (0.1)
疼痛	1 (0.1)
末梢腫脹	1 (0.1)
発熱	2 (0.1)
軟部組織の炎症	1 (0.1)
肝胆道系障害	1 (0.1)
肝機能異常	1 (0.1)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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

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.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
免疫系障害	20 (1.4)
過敏症	20 (1.4)
感染症および寄生虫症	6 (0.4)
ＣＯＶＩＤ－１９	1 (0.1)
ヘルペス眼感染	1 (0.1)
下気道感染	1 (0.1)
上咽頭炎	1 (0.1)
歯感染	1 (0.1)
尿路感染	1 (0.1)
傷害、中毒および処置合併症	334 (24.0)
転倒	2 (0.1)
注入に伴う反応	332 (23.9)
関節損傷	1 (0.1)

TEAE = treatment-emergent adverse event.

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MedDRA Version 25.0.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
硬膜下血腫	1 (0.1)
臨床検査	7 (0.5)
アラニンアミノトランスフェラーゼ増加	2 (0.1)
アスパラギン酸アミノトランスフェラーゼ増加	1 (0.1)
心電図ＱＴ延長	1 (0.1)
γ－グルタミルトランスフェラーゼ増加	2 (0.1)
リンパ球数減少	1 (0.1)
好中球数増加	1 (0.1)
体重減少	2 (0.1)
代謝および栄養障害	8 (0.6)
食欲減退	2 (0.1)
高コレステロール血症	2 (0.1)
高血糖	1 (0.1)

TEAE = treatment-emergent adverse event.

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SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
高トリグリセリド血症	1 (0.1)
低カルシウム血症	1 (0.1)
低血糖	1 (0.1)
筋骨格系および結合組織障害	5 (0.4)
関節痛	1 (0.1)
背部痛	1 (0.1)
筋痙縮	1 (0.1)
筋肉痛	1 (0.1)
多発性関節炎	1 (0.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (0.1)
再発非ホジキンリンパ腫	1 (0.1)
脂漏性角化症	1 (0.1)
神経系障害	283 (20.3)

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SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
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	172 (12.4)
アミロイド関連画像異常－浮腫／滲出液貯留	166 (11.9)
平衡障害	3 (0.2)
小脳梗塞	1 (0.1)
脳出血	5 (0.4)
脳梗塞	1 (0.1)
認知障害	1 (0.1)
浮動性めまい	5 (0.4)
頭痛	19 (1.4)
感覚鈍麻	1 (0.1)
ラクナ梗塞	4 (0.3)
記憶障害	2 (0.1)
不随意性筋収縮	1 (0.1)

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SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
くも膜下出血	1 (0.1)
脳表ヘモジデリン沈着症	62 (4.5)
緊張性頭痛	2 (0.1)
視床出血	1 (0.1)
上位運動ニューロンの病変	1 (0.1)
精神障害	14 (1.0)
異常な夢	1 (0.1)
感情不安定	1 (0.1)
不安	1 (0.1)
錯乱状態	3 (0.2)
妄想	1 (0.1)
うつ病	4 (0.3)
幻覚	1 (0.1)

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SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
易刺激性	1 (0.1)
悪夢	1 (0.1)
睡眠の質低下	1 (0.1)
腎および尿路障害	3 (0.2)
急性腎障害	1 (0.1)
蛋白尿	2 (0.1)
生殖系および乳房障害	1 (0.1)
精巣腫瘤	1 (0.1)
呼吸器、胸郭および縦隔障害	3 (0.2)
咳嗽	1 (0.1)
呼吸困難	1 (0.1)
鼻出血	1 (0.1)
皮膚および皮下組織障害	13 (0.9)

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SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
円形脱毛症	1 (0.1)
アレルギー性皮膚炎	1 (0.1)
紅斑	3 (0.2)
光線過敏性反応	1 (0.1)
発疹	5 (0.4)
紅斑性皮疹	1 (0.1)
皮膚臭異常	1 (0.1)
蕁麻疹	1 (0.1)
血管障害	8 (0.6)
チアノーゼ	1 (0.1)
高血圧	3 (0.2)
起立性高血圧	1 (0.1)

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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.

付録 2.7.6-10

SOC/PT別の副作用発現率

LEC10-BW-Treated Period

301試験 OLE

Safety Analysis Set

MedDRA System Organ Class_J Preferred Term_J	Lecanemab 10 mg/kg Biweekly (N = 1391) n (%)
起立性低血圧	2 (0.1)
四肢静脈血栓症	1 (0.1)

TEAE = treatment-emergent adverse event.

LEC10-BW-Treated Period includes Core Study and OLE Phase in which subjects received lecanemab 10 mg/kg Biweekly.

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.

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