付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
滴下投与部位腫脹	0	1 (1.9)	0	0	0	0	1 (0.2)
倦怠感	4 (1.6)	0	0	0	1 (0.4)	0	1 (0.2)
腫瘤	0	1 (1.9)	0	0	0	0	1 (0.2)
多臓器機能不全症候群	0	0	0	1 (1.1)	0	0	1 (0.2)
非心臓性胸痛	0	0	0	1 (1.1)	4 (1.6)	3 (1.9)	8 (1.3)
末梢性浮腫	8 (3.3)	0	2 (3.9)	3 (3.3)	3 (1.2)	4 (2.5)	12 (2.0)
疼痛	2 (0.8)	0	1 (2.0)	0	2 (0.8)	0	3 (0.5)
末梢腫脹	0	0	0	2 (2.2)	2 (0.8)	0	4 (0.7)
前癌性粘膜病変	1 (0.4)	0	0	0	0	0	0
発熱	5 (2.0)	2 (3.8)	2 (3.9)	4 (4.3)	5 (2.0)	2 (1.2)	15 (2.5)
腫脹	0	0	0	0	0	1 (0.6)	1 (0.2)
体温調節障害	0	0	0	0	0	1 (0.6)	1 (0.2)
口渇	1 (0.4)	0	0	0	0	0	0
潰瘍性出血	0	0	0	1 (1.1)	0	0	1 (0.2)
血管穿刺部位内出血	0	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)

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血管穿刺部位血腫	1 (0.4)	0	0	0	0	0	0
血管穿刺部位出血	0	0	0	1 (1.1)	0	0	1 (0.2)
肝胆道系障害	4 (1.6)	3 (5.8)	0	3 (3.3)	4 (1.6)	2 (1.2)	12 (2.0)
胆管嚢胞	0	1 (1.9)	0	0	0	0	1 (0.2)
胆管炎	1 (0.4)	0	0	0	0	0	0
急性胆管炎	0	0	0	0	0	1 (0.6)	1 (0.2)
胆嚢炎	0	0	0	0	0	1 (0.6)	1 (0.2)
慢性胆嚢炎	0	0	0	0	0	1 (0.6)	1 (0.2)
胆石症	1 (0.4)	0	0	2 (2.2)	2 (0.8)	2 (1.2)	6 (1.0)
肝硬変	1 (0.4)	0	0	0	0	0	0
肝嚢胞	0	0	0	0	1 (0.4)	0	1 (0.2)
肝不全	0	0	0	1 (1.1)	0	0	1 (0.2)
肝病変	1 (0.4)	1 (1.9)	0	0	0	0	1 (0.2)
脂肪肝	0	1 (1.9)	0	0	0	0	1 (0.2)
急性肝炎	0	0	0	1 (1.1)	0	0	1 (0.2)

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高ビリルビン血症	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
免疫系障害	8 (3.3)	0	2 (3.9)	3 (3.3)	1 (0.4)	6 (3.7)	12 (2.0)
節足動物咬傷アレルギー	0	0	0	0	0	1 (0.6)	1 (0.2)
節足動物刺傷アレルギー	1 (0.4)	0	0	0	0	0	0
造影剤反応	1 (0.4)	0	0	0	0	0	0
薬物過敏症	2 (0.8)	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
過敏症	1 (0.4)	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
複合アレルギー	0	0	0	0	0	1 (0.6)	1 (0.2)
季節性アレルギー	3 (1.2)	0	1 (2.0)	2 (2.2)	1 (0.4)	2 (1.2)	6 (1.0)
感染症および寄生虫症	130 (53.1)	22 (42.3)	26 (51.0)	52 (56.5)	110 (43.5)	66 (41.0)	276 (45.3)
急性副鼻腔炎	2 (0.8)	0	0	1 (1.1)	0	0	1 (0.2)
肛門カンジダ症	0	0	0	0	0	1 (0.6)	1 (0.2)
口角口唇炎	0	0	0	0	0	1 (0.6)	1 (0.2)
虫垂炎	1 (0.4)	0	0	0	0	0	0
無症候性細菌尿	0	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)

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菌血症	0	0	0	1 (1.1)	0	0	1 (0.2)
乳房蜂巣炎	1 (0.4)	0	0	0	0	0	0
気管支炎	15 (6.1)	0	0	2 (2.2)	9 (3.6)	4 (2.5)	15 (2.5)
細菌性気管支炎	1 (0.4)	0	0	0	0	0	0
カンジダ感染	0	0	0	0	1 (0.4)	0	1 (0.2)
蜂巣炎	3 (1.2)	0	0	1 (1.1)	3 (1.2)	2 (1.2)	6 (1.0)
慢性副鼻腔炎	0	0	0	0	2 (0.8)	0	2 (0.3)
クロストリジウム性敗血症	1 (0.4)	0	0	0	0	0	0
クロストリジウム・ディフィシレ大腸炎	1 (0.4)	0	0	0	0	0	0
クロストリジウム・ディフィシレ感染	0	0	0	0	1 (0.4)	0	1 (0.2)
結膜炎	1 (0.4)	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)
膀胱炎	1 (0.4)	1 (1.9)	1 (2.0)	0	1 (0.4)	1 (0.6)	4 (0.7)
皮膚糸状菌症	0	0	0	0	1 (0.4)	0	1 (0.2)
憩室炎	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
赤痢	1 (0.4)	0	0	0	0	0	0

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耳感染	4 (1.6)	1 (1.9)	1 (2.0)	1 (1.1)	1 (0.4)	0	4 (0.7)
感染性小腸結腸炎	1 (0.4)	0	0	0	0	0	0
眼感染	1 (0.4)	0	0	1 (1.1)	0	0	1 (0.2)
毛包炎	0	0	0	3 (3.3)	0	0	3 (0.5)
真菌感染	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
皮膚真菌感染	1 (0.4)	0	0	2 (2.2)	1 (0.4)	0	3 (0.5)
真菌尿	2 (0.8)	0	0	1 (1.1)	3 (1.2)	2 (1.2)	6 (1.0)
せつ	1 (0.4)	0	0	0	0	0	0
胃腸炎	5 (2.0)	1 (1.9)	0	0	5 (2.0)	1 (0.6)	7 (1.1)
ウイルス性胃腸炎	1 (0.4)	2 (3.8)	2 (3.9)	0	3 (1.2)	1 (0.6)	8 (1.3)
ウイルス性消化管感染	1 (0.4)	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
歯肉炎	0	0	0	2 (2.2)	0	2 (1.2)	4 (0.7)
ヘリコバクター感染	2 (0.8)	0	0	0	0	0	0
帯状疱疹	1 (0.4)	1 (1.9)	2 (3.9)	2 (2.2)	3 (1.2)	3 (1.9)	11 (1.8)
麦粒腫	2 (0.8)	0	0	0	0	0	0

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感染性嚢腫	0	0	1 (2.0)	0	0	0	1 (0.2)
インフルエンザ	2 (0.8)	0	1 (2.0)	5 (5.4)	7 (2.8)	3 (1.9)	16 (2.6)
腎感染	0	0	0	1 (1.1)	0	0	1 (0.2)
喉頭炎	0	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
限局性感染	1 (0.4)	1 (1.9)	1 (2.0)	0	0	0	2 (0.3)
肺膿瘍	0	1 (1.9)	0	0	0	0	1 (0.2)
ライム病	1 (0.4)	0	0	0	0	0	0
爪感染	0	0	0	0	1 (0.4)	0	1 (0.2)
上咽頭炎	28 (11.4)	3 (5.8)	7 (13.7)	9 (9.8)	19 (7.5)	13 (8.1)	51 (8.4)
爪真菌症	0	0	0	1 (1.1)	1 (0.4)	1 (0.6)	3 (0.5)
口腔カンジダ症	1 (0.4)	0	0	1 (1.1)	2 (0.8)	0	3 (0.5)
口腔ヘルペス	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
中耳炎	3 (1.2)	0	0	1 (1.1)	0	0	1 (0.2)
爪囲炎	0	0	0	0	1 (0.4)	0	1 (0.2)
耳下腺炎	1 (0.4)	0	0	0	0	0	0

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歯周炎	0	0	0	0	0	1 (0.6)	1 (0.2)
咽頭炎	0	0	1 (2.0)	1 (1.1)	2 (0.8)	0	4 (0.7)
肺炎	1 (0.4)	0	0	4 (4.3)	3 (1.2)	2 (1.2)	9 (1.5)
マイコプラズマ性肺炎	0	0	0	1 (1.1)	0	0	1 (0.2)
処置後蜂巣炎	0	0	1 (2.0)	0	0	0	1 (0.2)
処置後感染	0	0	0	0	1 (0.4)	0	1 (0.2)
術後創感染	4 (1.6)	0	0	0	0	0	0
歯髄炎	1 (0.4)	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
腎盂腎炎	1 (0.4)	0	0	0	0	0	0
膿尿	1 (0.4)	0	0	0	0	0	0
膿疱性皮疹	0	0	0	0	1 (0.4)	0	1 (0.2)
気道感染	2 (0.8)	0	0	0	0	0	0
ウイルス性気道感染	0	0	0	0	1 (0.4)	0	1 (0.2)
鼻炎	1 (0.4)	1 (1.9)	0	0	3 (1.2)	1 (0.6)	5 (0.8)
敗血症	0	0	0	0	0	1 (0.6)	1 (0.2)

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副鼻腔炎	8 (3.3)	1 (1.9)	5 (9.8)	1 (1.1)	9 (3.6)	7 (4.3)	23 (3.8)
皮膚カンジダ	0	0	0	0	1 (0.4)	0	1 (0.2)
レンサ球菌性敗血症	0	0	0	0	0	1 (0.6)	1 (0.2)
皮下組織膿瘍	2 (0.8)	0	0	0	0	0	0
股部白癬	0	0	0	0	0	1 (0.6)	1 (0.2)
足部白癬	0	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
扁桃炎	0	0	0	1 (1.1)	0	0	1 (0.2)
歯膿瘍	8 (3.3)	0	2 (3.9)	1 (1.1)	1 (0.4)	3 (1.9)	7 (1.1)
歯感染	5 (2.0)	0	1 (2.0)	0	4 (1.6)	1 (0.6)	6 (1.0)
白癬性肉芽腫	0	0	0	0	1 (0.4)	0	1 (0.2)
上気道感染	41 (16.7)	7 (13.5)	7 (13.7)	10 (10.9)	23 (9.1)	19 (11.8)	66 (10.8)
尿路感染	33 (13.5)	5 (9.6)	5 (9.8)	17 (18.5)	25 (9.9)	17 (10.6)	69 (11.3)
尿路性敗血症	1 (0.4)	0	0	0	0	0	0
腟感染	2 (0.8)	0	0	1 (1.1)	0	0	1 (0.2)
水痘帯状疱疹ウイルス感染	0	0	0	1 (1.1)	0	0	1 (0.2)

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ウイルス感染	1 (0.4)	0	0	0	5 (2.0)	1 (0.6)	6 (1.0)
ウイルス性咽頭炎	0	0	0	0	0	1 (0.6)	1 (0.2)
ウイルス性上気道感染	3 (1.2)	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
外陰部腟カンジダ症	0	0	0	1 (1.1)	0	0	1 (0.2)
外陰腟真菌感染	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
外陰腟炎	0	1 (1.9)	0	0	0	0	1 (0.2)
創傷感染	1 (0.4)	0	0	1 (1.1)	0	0	1 (0.2)
傷害、中毒および処置合併症	77 (31.4)	14 (26.9)	21 (41.2)	38 (41.3)	113 (44.7)	67 (41.6)	253 (41.5)
アルコール中毒	1 (0.4)	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
麻酔による神経系合併症	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
動物咬傷	2 (0.8)	0	0	0	3 (1.2)	0	3 (0.5)
動物による引っかき傷	1 (0.4)	0	0	0	0	0	0
足関節部骨折	0	1 (1.9)	0	0	4 (1.6)	0	5 (0.8)
節足動物咬傷	1 (0.4)	2 (3.8)	2 (3.9)	1 (1.1)	1 (0.4)	2 (1.2)	8 (1.3)
節足動物刺傷	2 (0.8)	0	1 (2.0)	2 (2.2)	1 (0.4)	1 (0.6)	5 (0.8)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
背部損傷	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
骨挫傷	0	0	0	0	0	1 (0.6)	1 (0.2)
第２度熱傷	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
胸部損傷	0	0	0	0	0	1 (0.6)	1 (0.2)
脳振盪	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
挫傷	7 (2.9)	2 (3.8)	5 (9.8)	6 (6.5)	11 (4.3)	7 (4.3)	31 (5.1)
角膜擦過傷	0	0	0	1 (1.1)	0	0	1 (0.2)
頭蓋脳損傷	0	0	1 (2.0)	0	0	0	1 (0.2)
耳擦過傷	1 (0.4)	0	0	0	0	0	0
耳部損傷	1 (0.4)	0	0	0	0	0	0
眼瞼損傷	1 (0.4)	0	1 (2.0)	0	0	0	1 (0.2)
顔面損傷	1 (0.4)	0	1 (2.0)	0	0	0	1 (0.2)
顔面骨骨折	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
転倒	32 (13.1)	3 (5.8)	6 (11.8)	13 (14.1)	22 (8.7)	17 (10.6)	61 (10.0)
大腿骨頚部骨折	0	0	0	0	1 (0.4)	0	1 (0.2)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

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大腿骨骨折	1 (0.4)	0	0	0	0	0	0
腓骨骨折	0	0	0	0	0	1 (0.6)	1 (0.2)
足骨折	4 (1.6)	0	0	2 (2.2)	1 (0.4)	2 (1.2)	5 (0.8)
眼内異物	0	0	0	0	0	1 (0.6)	1 (0.2)
手骨折	3 (1.2)	0	0	2 (2.2)	1 (0.4)	0	3 (0.5)
股関節部骨折	2 (0.8)	0	0	0	0	0	0
上腕骨骨折	1 (0.4)	0	0	0	2 (0.8)	0	2 (0.3)
前房出血	0	0	0	0	1 (0.4)	0	1 (0.2)
切開部位痛	0	0	0	0	2 (0.8)	0	2 (0.3)
誤用量投与	0	0	0	0	1 (0.4)	0	1 (0.2)
注入に伴う反応	8 (3.3)	3 (5.8)	4 (7.8)	11 (12.0)	59 (23.3)	32 (19.9)	109 (17.9)
顎の骨折	2 (0.8)	0	0	0	0	0	0
関節損傷	2 (0.8)	0	0	1 (1.1)	2 (0.8)	1 (0.6)	4 (0.7)
裂傷	8 (3.3)	0	2 (3.9)	4 (4.3)	7 (2.8)	6 (3.7)	19 (3.1)
靱帯断裂	0	0	0	0	0	1 (0.6)	1 (0.2)

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SOC/PT別の有害事象発現率

201試験 Core

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靱帯捻挫	3 (1.2)	1 (1.9)	2 (3.9)	2 (2.2)	5 (2.0)	2 (1.2)	12 (2.0)
四肢損傷	3 (1.2)	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
口唇損傷	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
腰椎骨折	2 (0.8)	0	0	0	0	0	0
多発性外傷	0	0	1 (2.0)	0	0	0	1 (0.2)
筋断裂	0	0	1 (2.0)	1 (1.1)	2 (0.8)	0	4 (0.7)
肉離れ	0	0	2 (3.9)	0	2 (0.8)	2 (1.2)	6 (1.0)
筋骨格系損傷	0	0	0	0	0	1 (0.6)	1 (0.2)
爪裂離	1 (0.4)	0	0	0	0	0	0
膝蓋骨骨折	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
骨盤骨折	3 (1.2)	0	0	0	1 (0.4)	0	1 (0.2)
眼窩周囲血腫	1 (0.4)	0	0	0	0	0	0
眼窩周囲出血	0	0	0	1 (1.1)	0	0	1 (0.2)
処置後合併症	0	0	0	1 (1.1)	0	0	1 (0.2)
処置後便秘	0	0	0	0	1 (0.4)	0	1 (0.2)

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SOC/PT別の有害事象発現率

201試験 Core

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処置後血腫	0	0	0	0	1 (0.4)	0	1 (0.2)
処置後出血	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
処置後腫脹	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
処置に対する不安	0	0	0	1 (1.1)	0	0	1 (0.2)
処置による疼痛	4 (1.6)	3 (5.8)	2 (3.9)	2 (2.2)	4 (1.6)	4 (2.5)	15 (2.5)
橈骨骨折	1 (0.4)	0	0	2 (2.2)	0	1 (0.6)	3 (0.5)
フューム吸引性呼吸障害	1 (0.4)	0	0	0	0	0	0
肋骨骨折	5 (2.0)	0	1 (2.0)	0	3 (1.2)	2 (1.2)	6 (1.0)
交通事故	0	0	0	2 (2.2)	1 (0.4)	1 (0.6)	4 (0.7)
漿液腫	1 (0.4)	0	0	0	0	0	0
皮膚擦過傷	8 (3.3)	0	1 (2.0)	1 (1.1)	13 (5.1)	4 (2.5)	19 (3.1)
脊椎圧迫骨折	1 (0.4)	0	0	0	0	0	0
脊髄損傷	0	0	0	0	1 (0.4)	0	1 (0.2)
脾破裂	0	0	0	0	0	1 (0.6)	1 (0.2)
胸骨骨折	1 (0.4)	0	0	0	0	0	0

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皮下血腫	1 (0.4)	0	0	0	0	0	0
硬膜下血腫	2 (0.8)	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)
硬膜下出血	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
サンバーン	1 (0.4)	0	0	0	0	0	0
腱断裂	0	0	0	0	0	1 (0.6)	1 (0.2)
熱傷	1 (0.4)	0	0	0	0	0	0
胸椎骨折	1 (0.4)	0	0	0	0	0	0
歯牙破折	0	1 (1.9)	0	0	2 (0.8)	3 (1.9)	6 (1.0)
外傷性血腫	0	1 (1.9)	0	1 (1.1)	0	0	2 (0.3)
上肢骨折	0	1 (1.9)	0	0	1 (0.4)	1 (0.6)	3 (0.5)
創傷	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
創離開	0	0	0	1 (1.1)	0	0	1 (0.2)
手首関節骨折	0	0	0	2 (2.2)	2 (0.8)	0	4 (0.7)
臨床検査	25 (10.2)	6 (11.5)	7 (13.7)	13 (14.1)	30 (11.9)	19 (11.8)	75 (12.3)

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アラニンアミノトランスフェラーゼ増加	0	0	0	0	1 (0.4)	0	1 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	1 (1.1)	0	0	1 (0.2)
細菌検査陽性	3 (1.2)	0	0	0	0	1 (0.6)	1 (0.2)
血中ビリルビン増加	1 (0.4)	0	1 (2.0)	0	0	0	1 (0.2)
血中コレステロール増加	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
血中クレアチニン異常	0	0	0	1 (1.1)	0	0	1 (0.2)
血中クレアチニン増加	0	0	0	0	1 (0.4)	0	1 (0.2)
血中葉酸減少	0	0	0	1 (1.1)	0	0	1 (0.2)
血中ブドウ糖増加	0	0	0	0	0	1 (0.6)	1 (0.2)
血中鉄減少	0	0	0	0	1 (0.4)	0	1 (0.2)
血中カリウム減少	0	0	0	0	1 (0.4)	0	1 (0.2)
血中カリウム増加	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
血圧異常	0	0	0	1 (1.1)	0	0	1 (0.2)

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血圧低下	0	0	0	2 (2.2)	0	0	2 (0.3)
拡張期血圧上昇	0	0	0	1 (1.1)	0	0	1 (0.2)
血圧上昇	0	0	0	1 (1.1)	3 (1.2)	0	4 (0.7)
血中ナトリウム減少	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
血中甲状腺刺激ホルモン異常	0	0	1 (2.0)	0	0	0	1 (0.2)
血中トリグリセリド増加	0	2 (3.8)	0	1 (1.1)	0	1 (0.6)	4 (0.7)
血中尿素増加	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
血中尿酸増加	1 (0.4)	0	0	0	0	0	0
尿中血陽性	0	0	0	0	1 (0.4)	0	1 (0.2)
体温上昇	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
心雑音	1 (0.4)	1 (1.9)	0	0	2 (0.8)	0	3 (0.5)
結腸内視鏡検査正常	0	0	0	0	1 (0.4)	0	1 (0.2)
尿中結晶陽性	0	0	1 (2.0)	0	0	0	1 (0.2)
心筋虚血の心電図所見	1 (0.4)	0	0	1 (1.1)	0	0	1 (0.2)
心電図ＱＴ延長	2 (0.8)	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)

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心電図異常T波	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
心電図異常	0	0	0	0	1 (0.4)	0	1 (0.2)
糸球体濾過率減少	0	0	0	0	1 (0.4)	0	1 (0.2)
尿中ブドウ糖陽性	0	0	0	0	0	1 (0.6)	1 (0.2)
ヘモグロビン減少	1 (0.4)	0	0	1 (1.1)	2 (0.8)	0	3 (0.5)
心拍数不整	0	0	0	1 (1.1)	0	0	1 (0.2)
ヘリコバクター検査陽性	0	0	0	0	0	1 (0.6)	1 (0.2)
眼圧上昇	2 (0.8)	0	0	0	2 (0.8)	0	2 (0.3)
肝機能検査値上昇	1 (0.4)	0	1 (2.0)	0	2 (0.8)	0	3 (0.5)
リンパ球数減少	0	0	1 (2.0)	0	0	2 (1.2)	3 (0.5)
好中球数減少	1 (0.4)	0	0	1 (1.1)	0	0	1 (0.2)
好中球数増加	0	0	0	0	0	2 (1.2)	2 (0.3)
脳核磁気共鳴画像異常	0	0	0	0	0	1 (0.6)	1 (0.2)
便潜血陽性	0	0	1 (2.0)	0	0	0	1 (0.2)
血小板数減少	0	1 (1.9)	0	0	0	0	1 (0.2)

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201試験 Core

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前立腺特異性抗原増加	0	0	0	0	2 (0.8)	0	2 (0.3)
赤血球数減少	1 (0.4)	0	0	0	0	0	0
トランスアミナーゼ上昇	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
尿中白血球エステラーゼ陽性	0	0	0	0	1 (0.4)	0	1 (0.2)
ビタミンＢ１２減少	1 (0.4)	0	0	0	0	0	0
体重減少	4 (1.6)	1 (1.9)	0	2 (2.2)	6 (2.4)	5 (3.1)	14 (2.3)
体重増加	1 (0.4)	1 (1.9)	1 (2.0)	0	2 (0.8)	0	4 (0.7)
尿中白血球陽性	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
代謝および栄養障害	24 (9.8)	5 (9.6)	5 (9.8)	12 (13.0)	19 (7.5)	17 (10.6)	58 (9.5)
アシドーシス	0	0	1 (2.0)	0	0	0	1 (0.2)
食欲障害	0	0	0	0	0	1 (0.6)	1 (0.2)
食欲減退	3 (1.2)	0	0	2 (2.2)	4 (1.6)	0	6 (1.0)
脱水	6 (2.4)	0	0	2 (2.2)	1 (0.4)	3 (1.9)	6 (1.0)
糖尿病	0	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)
コントロール不良の糖尿病	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)

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MedDRA Version 20.1.
MedDRA = Medical Dictionary for Regulatory Activities, TEAE = treatment-emergent adverse event.

付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
脂質異常症	0	0	0	1 (1.1)	0	0	1 (0.2)
電解質失調	0	0	1 (2.0)	0	0	0	1 (0.2)
葉酸欠乏	1 (0.4)	0	0	0	0	0	0
痛風	1 (0.4)	2 (3.8)	1 (2.0)	1 (1.1)	1 (0.4)	2 (1.2)	7 (1.1)
高コレステロール血症	2 (0.8)	0	1 (2.0)	0	0	0	1 (0.2)
高血糖	1 (0.4)	0	0	0	0	2 (1.2)	2 (0.3)
高カリウム血症	2 (0.8)	0	0	0	2 (0.8)	1 (0.6)	3 (0.5)
高脂血症	1 (0.4)	0	1 (2.0)	0	1 (0.4)	1 (0.6)	3 (0.5)
高ナトリウム血症	0	0	1 (2.0)	0	3 (1.2)	0	4 (0.7)
高トリグリセリド血症	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
高尿酸血症	0	0	0	2 (2.2)	0	0	2 (0.3)
低クロール血症	1 (0.4)	0	0	0	0	0	0
低血糖	0	0	0	1 (1.1)	1 (0.4)	2 (1.2)	4 (0.7)
低カリウム血症	3 (1.2)	0	0	3 (3.3)	2 (0.8)	1 (0.6)	6 (1.0)
低ナトリウム血症	2 (0.8)	0	0	1 (1.1)	1 (0.4)	1 (0.6)	3 (0.5)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Total (N = 609) n (%)
栄養障害	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
代謝性アシドーシス	2 (0.8)	0	0	0	0	0	0
ビタミンＢ１２欠乏	0	1 (1.9)	0	0	1 (0.4)	1 (0.6)	3 (0.5)
ビタミンＤ欠乏	1 (0.4)	1 (1.9)	0	0	3 (1.2)	1 (0.6)	5 (0.8)
筋骨格系および結合組織障害	74 (30.2)	11 (21.2)	17 (33.3)	24 (26.1)	69 (27.3)	36 (22.4)	157 (25.8)
関節痛	17 (6.9)	0	4 (7.8)	6 (6.5)	12 (4.7)	7 (4.3)	29 (4.8)
関節炎	2 (0.8)	1 (1.9)	0	1 (1.1)	1 (0.4)	2 (1.2)	5 (0.8)
関節障害	0	0	1 (2.0)	0	0	0	1 (0.2)
背部痛	24 (9.8)	4 (7.7)	6 (11.8)	4 (4.3)	20 (7.9)	11 (6.8)	45 (7.4)
骨痛	0	0	0	0	1 (0.4)	0	1 (0.2)
滑液貯留	1 (0.4)	0	0	0	0	0	0
滑液包炎	2 (0.8)	2 (3.8)	1 (2.0)	0	2 (0.8)	2 (1.2)	7 (1.1)
頚部脊柱管狭窄症	0	0	0	0	0	1 (0.6)	1 (0.2)
椎間関節症候群	2 (0.8)	0	0	0	0	0	0
線維筋痛	0	0	0	0	2 (0.8)	1 (0.6)	3 (0.5)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

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側腹部痛	2 (0.8)	0	0	0	2 (0.8)	2 (1.2)	4 (0.7)
足変形	2 (0.8)	0	0	1 (1.1)	0	0	1 (0.2)
骨折痛	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
肌径部痛	0	0	1 (2.0)	0	0	0	1 (0.2)
椎間板変性症	2 (0.8)	0	0	0	0	0	0
椎間板突出	0	0	0	0	2 (0.8)	0	2 (0.3)
関節滲出液	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
関節ロック	0	0	0	0	1 (0.4)	0	1 (0.2)
関節腫脹	1 (0.4)	0	1 (2.0)	1 (1.1)	0	0	2 (0.3)
脊柱後弯症	1 (0.4)	0	0	0	0	0	0
四肢不快感	0	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
腰部脊柱管狭窄症	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
運動性低下	1 (0.4)	0	0	0	0	0	0
筋萎縮	1 (0.4)	0	0	0	0	0	0
筋拘縮	2 (0.8)	0	0	0	0	0	0

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201試験 Core

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筋痙縮	5 (2.0)	1 (1.9)	6 (11.8)	0	5 (2.0)	3 (1.9)	15 (2.5)
筋緊張	0	0	1 (2.0)	0	0	0	1 (0.2)
筋攣縮	1 (0.4)	1 (1.9)	0	1 (1.1)	0	0	2 (0.3)
筋力低下	4 (1.6)	0	0	1 (1.1)	2 (0.8)	1 (0.6)	4 (0.7)
筋骨格系胸痛	4 (1.6)	0	1 (2.0)	0	1 (0.4)	2 (1.2)	4 (0.7)
筋骨格痛	4 (1.6)	0	0	3 (3.3)	4 (1.6)	1 (0.6)	8 (1.3)
筋骨格硬直	0	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
筋肉痛	1 (0.4)	0	0	0	5 (2.0)	3 (1.9)	8 (1.3)
頚部腫瘤	0	0	0	0	0	1 (0.6)	1 (0.2)
頚部痛	3 (1.2)	0	2 (3.9)	3 (3.3)	3 (1.2)	1 (0.6)	9 (1.5)
変形性関節症	7 (2.9)	0	1 (2.0)	1 (1.1)	4 (1.6)	2 (1.2)	8 (1.3)
骨減少症	1 (0.4)	0	0	0	0	0	0
骨粗鬆症	4 (1.6)	0	0	0	1 (0.4)	0	1 (0.2)
四肢痛	10 (4.1)	1 (1.9)	2 (3.9)	7 (7.6)	8 (3.2)	3 (1.9)	21 (3.4)
顎痛	0	0	0	1 (1.1)	2 (0.8)	1 (0.6)	4 (0.7)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

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関節周囲炎	0	0	0	0	1 (0.4)	0	1 (0.2)
足底筋膜炎	0	0	0	0	0	1 (0.6)	1 (0.2)
リウマチ性多発筋痛	1 (0.4)	0	0	0	0	0	0
横紋筋融解症	0	0	0	1 (1.1)	0	0	1 (0.2)
肩回旋筋腱板症候群	2 (0.8)	1 (1.9)	0	0	2 (0.8)	0	3 (0.5)
側弯症	0	0	0	0	1 (0.4)	0	1 (0.2)
脊柱変形	0	0	0	0	1 (0.4)	0	1 (0.2)
変形性脊椎症	1 (0.4)	0	0	0	2 (0.8)	2 (1.2)	4 (0.7)
脊椎炎	0	0	0	0	0	1 (0.6)	1 (0.2)
脊椎関節障害	1 (0.4)	0	0	0	0	0	0
脊椎すべり症	1 (0.4)	0	0	0	0	0	0
滑液嚢腫	2 (0.8)	0	0	0	0	1 (0.6)	1 (0.2)
滑膜炎	0	0	0	1 (1.1)	0	0	1 (0.2)
腱障害	0	0	0	0	1 (0.4)	0	1 (0.2)
腱炎	0	0	0	2 (2.2)	1 (0.4)	0	3 (0.5)

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201試験 Core

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腱鞘炎	1 (0.4)	0	0	0	0	0	0
狭窄性腱鞘炎	1 (0.4)	0	0	0	0	0	0
斜頚	0	0	0	0	1 (0.4)	0	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	21 (8.6)	10 (19.2)	3 (5.9)	11 (12.0)	25 (9.9)	8 (5.0)	57 (9.4)
アクロコルドン	1 (0.4)	0	0	0	0	0	0
結腸腺癌	0	0	0	0	1 (0.4)	0	1 (0.2)
副腎腺腫	0	0	0	0	1 (0.4)	0	1 (0.2)
基底細胞癌	7 (2.9)	4 (7.7)	2 (3.9)	6 (6.5)	4 (1.6)	3 (1.9)	19 (3.1)
膀胱癌	0	0	0	0	1 (0.4)	0	1 (0.2)
再発膀胱癌	0	0	0	0	1 (0.4)	0	1 (0.2)
ボーエン病	0	1 (1.9)	0	1 (1.1)	0	1 (0.6)	3 (0.5)
脳新生物	0	1 (1.9)	0	0	0	0	1 (0.2)
慢性リンパ性白血病第 0期	0	0	0	0	1 (0.4)	0	1 (0.2)
膵腺管癌	0	0	0	0	1 (0.4)	0	1 (0.2)

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SOC/PT別の有害事象発現率

201試験 Core

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異形成母斑	0	1 (1.9)	0	1 (1.1)	2 (0.8)	0	4 (0.7)
眼血管腫	0	0	0	0	1 (0.4)	0	1 (0.2)
血管腫	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
良性毛包腫瘍	0	1 (1.9)	0	0	0	0	1 (0.2)
肝細胞癌	1 (0.4)	0	0	0	0	0	0
良性単クローン性高γグロブリン血症	0	0	0	1 (1.1)	0	0	1 (0.2)
乳管内増殖性病変	1 (0.4)	0	0	0	0	0	0
浸潤性乳管癌	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
ケラトアカントーマ	1 (0.4)	0	0	2 (2.2)	0	0	2 (0.3)
口唇扁平上皮癌	0	0	0	0	1 (0.4)	0	1 (0.2)
脂肪腫	1 (0.4)	0	0	0	0	0	0
リンパ腫	0	0	0	1 (1.1)	0	0	1 (0.2)
悪性黒色腫	4 (1.6)	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
骨髄異形成症候群	0	0	1 (2.0)	0	0	0	1 (0.2)
皮膚の新生物	0	0	0	0	0	1 (0.6)	1 (0.2)

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201試験 Core

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骨腫	0	0	0	0	1 (0.4)	0	1 (0.2)
咽頭新生物	0	0	0	0	1 (0.4)	0	1 (0.2)
前立腺癌	0	0	0	1 (1.1)	3 (1.2)	0	4 (0.7)
肉腫	1 (0.4)	0	0	0	0	0	0
脂漏性角化症	3 (1.2)	1 (1.9)	1 (2.0)	1 (1.1)	1 (0.4)	0	4 (0.7)
皮膚癌	0	0	0	0	1 (0.4)	0	1 (0.2)
皮膚乳頭腫	0	0	0	0	0	1 (0.6)	1 (0.2)
扁平上皮癌	0	0	0	0	2 (0.8)	0	2 (0.3)
皮膚有棘細胞癌	4 (1.6)	3 (5.8)	1 (2.0)	2 (2.2)	3 (1.2)	1 (0.6)	10 (1.6)
移行上皮癌	0	0	0	0	0	1 (0.6)	1 (0.2)
神経系障害	92 (37.6)	23 (44.2)	16 (31.4)	46 (50.0)	110 (43.5)	70 (43.5)	265 (43.5)
動作時振戦	1 (0.4)	0	0	0	0	0	0
味覚消失	0	0	0	0	1 (0.4)	0	1 (0.2)
意識変容状態	0	0	0	1 (1.1)	0	0	1 (0.2)
アミロイド関連画像異常	2 (0.8)	1 (1.9)	1 (2.0)	3 (3.3)	25 (9.9)	16 (9.9)	46 (7.6)

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SOC/PT別の有害事象発現率

201試験 Core

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失語症	0	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)
運動失調	0	0	0	0	0	1 (0.6)	1 (0.2)
自律神経失調	0	0	0	0	1 (0.4)	0	1 (0.2)
平衡障害	0	0	0	1 (1.1)	2 (0.8)	1 (0.6)	4 (0.7)
大脳基底核梗塞	2 (0.8)	0	0	0	0	0	0
脳幹微小出血	1 (0.4)	0	0	0	0	0	0
頚動脈狭窄	0	0	1 (2.0)	0	0	0	1 (0.2)
手根管症候群	0	0	0	0	1 (0.4)	0	1 (0.2)
中枢神経系病変	0	0	0	0	0	1 (0.6)	1 (0.2)
小脳梗塞	0	2 (3.8)	0	0	0	0	2 (0.3)
小脳虚血	1 (0.4)	0	0	0	0	0	0
小脳微小出血	0	1 (1.9)	0	1 (1.1)	0	0	2 (0.3)
大脳動脈血栓症	1 (0.4)	0	0	0	0	0	0
脳出血	0	0	0	0	0	1 (0.6)	1 (0.2)
脳梗塞	3 (1.2)	1 (1.9)	2 (3.9)	0	1 (0.4)	3 (1.9)	7 (1.1)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Total (N = 609) n (%)
脳微小出血	12 (4.9)	2 (3.8)	7 (13.7)	12 (13.0)	22 (8.7)	10 (6.2)	53 (8.7)
脳血管発作	1 (0.4)	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
頚髄神経根障害	0	0	0	0	2 (0.8)	0	2 (0.3)
認知障害	0	0	0	0	3 (1.2)	1 (0.6)	4 (0.7)
協調運動異常	0	0	0	0	0	1 (0.6)	1 (0.2)
振動覚低下	0	0	0	0	0	1 (0.6)	1 (0.2)
レヴィ小体型認知症	0	0	0	0	1 (0.4)	0	1 (0.2)
浮動性めまい	19 (7.8)	4 (7.7)	0	10 (10.9)	9 (3.6)	14 (8.7)	37 (6.1)
体位性めまい	0	2 (3.8)	0	1 (1.1)	3 (1.2)	1 (0.6)	7 (1.1)
異常感覚	0	0	0	0	1 (0.4)	0	1 (0.2)
味覚異常	0	0	0	0	2 (0.8)	2 (1.2)	4 (0.7)
書字障害	0	0	0	0	0	1 (0.6)	1 (0.2)
塞栓性脳卒中	1 (0.4)	0	0	0	0	0	0
脳症	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
過剰驚愕反応	1 (0.4)	0	0	0	0	0	0

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SOC/PT別の有害事象発現率

201試験 Core

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認知障害発作	0	0	0	1 (1.1)	0	0	1 (0.2)
卒中の出血性変化	0	1 (1.9)	1 (2.0)	0	0	0	2 (0.3)
頭部不快感	2 (0.8)	0	0	1 (1.1)	1 (0.4)	1 (0.6)	3 (0.5)
頭痛	25 (10.2)	9 (17.3)	4 (7.8)	17 (18.5)	43 (17.0)	23 (14.3)	96 (15.8)
不全片麻痺	1 (0.4)	0	0	0	0	0	0
知覚過敏	1 (0.4)	0	0	1 (1.1)	0	0	1 (0.2)
味覚過敏	0	0	0	0	0	1 (0.6)	1 (0.2)
反射亢進	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
過眠症	0	0	0	0	1 (0.4)	0	1 (0.2)
感覚鈍麻	0	0	0	0	3 (1.2)	1 (0.6)	4 (0.7)
低血糖性痙攣	0	0	0	0	0	1 (0.6)	1 (0.2)
運動低下	0	0	0	1 (1.1)	0	0	1 (0.2)
反射減弱	0	0	0	0	0	1 (0.6)	1 (0.2)
頭蓋内動脈瘤	0	0	0	0	0	1 (0.6)	1 (0.2)
虚血性脳梗塞	1 (0.4)	0	0	0	0	0	0

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

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虚血性脳卒中	0	0	0	1 (1.1)	0	0	1 (0.2)
ラクナ梗塞	1 (0.4)	1 (1.9)	0	0	2 (0.8)	1 (0.6)	4 (0.7)
嗜眠	0	0	0	1 (1.1)	3 (1.2)	1 (0.6)	5 (0.8)
意識消失	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
腰髄神経根障害	2 (0.8)	0	0	0	0	1 (0.6)	1 (0.2)
記憶障害	1 (0.4)	2 (3.8)	0	0	2 (0.8)	0	4 (0.7)
代謝性脳症	0	0	0	1 (1.1)	0	0	1 (0.2)
片頭痛	1 (0.4)	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
運動障害	0	0	0	0	0	1 (0.6)	1 (0.2)
ミオクローヌス	0	0	0	0	0	1 (0.6)	1 (0.2)
神経圧迫	1 (0.4)	0	0	0	0	0	0
末梢性ニューロパチー	0	0	0	1 (1.1)	2 (0.8)	0	3 (0.5)
正常圧水頭症	0	0	0	0	1 (0.4)	0	1 (0.2)
眼振	1 (0.4)	0	0	0	0	0	0
後頭神経痛	3 (1.2)	0	0	0	0	0	0

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

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錯感覚	1 (0.4)	0	1 (2.0)	0	2 (0.8)	5 (3.1)	8 (1.3)
不全対麻痺	1 (0.4)	0	0	0	0	0	0
パーキンソン病	0	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
パーキンソニズム	0	0	0	0	2 (0.8)	0	2 (0.3)
嗅覚錯誤	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
睡眠の質低下	0	0	0	0	1 (0.4)	0	1 (0.2)
失神寸前の状態	1 (0.4)	0	0	0	3 (1.2)	1 (0.6)	4 (0.7)
精神運動亢進	1 (0.4)	1 (1.9)	0	0	0	0	1 (0.2)
神経根痛	1 (0.4)	0	0	0	0	0	0
坐骨神経痛	2 (0.8)	0	1 (2.0)	1 (1.1)	4 (1.6)	5 (3.1)	11 (1.8)
鎮静	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
痙攣発作	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
副鼻腔炎に伴う頭痛	0	0	0	1 (1.1)	0	0	1 (0.2)
傾眠	2 (0.8)	0	0	0	2 (0.8)	2 (1.2)	4 (0.7)
脊髄圧迫	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

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硬膜下ヒグローマ	1 (0.4)	0	0	0	0	0	0
脳表ヘモジデリン沈着症	1 (0.4)	0	1 (2.0)	5 (5.4)	7 (2.8)	1 (0.6)	14 (2.3)
失神	9 (3.7)	1 (1.9)	1 (2.0)	1 (1.1)	5 (2.0)	4 (2.5)	12 (2.0)
緊張性頭痛	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
一過性全健忘	1 (0.4)	0	0	0	0	0	0
一過性脳虚血発作	3 (1.2)	1 (1.9)	2 (3.9)	0	1 (0.4)	1 (0.6)	5 (0.8)
振戦	3 (1.2)	1 (1.9)	0	2 (2.2)	4 (1.6)	1 (0.6)	8 (1.3)
三叉神経痛	0	0	0	0	0	1 (0.6)	1 (0.2)
尺骨神経炎	1 (0.4)	0	0	0	0	0	0
視野欠損	1 (0.4)	0	1 (2.0)	0	0	0	1 (0.2)
製品の問題	1 (0.4)	0	0	2 (2.2)	1 (0.4)	2 (1.2)	5 (0.8)
医療機器破損	0	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
医療機器損傷	0	0	0	0	1 (0.4)	0	1 (0.2)
医療機器位置異常	0	0	0	1 (1.1)	0	0	1 (0.2)
医療機器不具合	1 (0.4)	0	0	0	0	0	0

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SOC/PT別の有害事象発現率

201試験 Core

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医療機器リーク	0	0	0	0	0	1 (0.6)	1 (0.2)
医療機器のゆるみ	0	0	0	1 (1.1)	0	0	1 (0.2)
精神障害	55 (22.4)	13 (25.0)	14 (27.5)	24 (26.1)	49 (19.4)	28 (17.4)	128 (21.0)
異常行動	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
異常な夢	3 (1.2)	1 (1.9)	0	1 (1.1)	2 (0.8)	1 (0.6)	5 (0.8)
適応障害	0	0	0	1 (1.1)	0	0	1 (0.2)
抑うつ気分を伴う適応障害	0	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
混合性不安抑うつを伴う適応障害	0	0	0	0	1 (0.4)	0	1 (0.2)
感情不安定	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
攻撃性	2 (0.8)	1 (1.9)	0	2 (2.2)	2 (0.8)	0	5 (0.8)
激越	4 (1.6)	2 (3.8)	2 (3.9)	5 (5.4)	7 (2.8)	5 (3.1)	21 (3.4)
不安	15 (6.1)	1 (1.9)	3 (5.9)	4 (4.3)	10 (4.0)	6 (3.7)	24 (3.9)
身体疾患による不安障害	0	0	0	0	0	1 (0.6)	1 (0.2)
錯乱状態	8 (3.3)	2 (3.8)	0	1 (1.1)	4 (1.6)	5 (3.1)	12 (2.0)
譫妄	3 (1.2)	0	0	0	2 (0.8)	0	2 (0.3)

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SOC/PT別の有害事象発現率

201試験 Core

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妄想	2 (0.8)	1 (1.9)	1 (2.0)	0	0	2 (1.2)	4 (0.7)
妄想性障害、詳細不明	0	0	0	1 (1.1)	0	0	1 (0.2)
抑うつ気分	0	0	0	0	1 (0.4)	0	1 (0.2)
うつ病	13 (5.3)	1 (1.9)	3 (5.9)	6 (6.5)	13 (5.1)	5 (3.1)	28 (4.6)
抑うつ症状	0	0	1 (2.0)	0	2 (0.8)	0	3 (0.5)
失見当識	1 (0.4)	0	0	0	2 (0.8)	0	2 (0.3)
フラッシュバック	0	0	1 (2.0)	0	0	0	1 (0.2)
幻覚	2 (0.8)	0	1 (2.0)	1 (1.1)	4 (1.6)	0	6 (1.0)
幻聴	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
幻視	2 (0.8)	1 (1.9)	0	0	1 (0.4)	1 (0.6)	3 (0.5)
初期不眠症	0	0	0	1 (1.1)	0	0	1 (0.2)
不眠症	7 (2.9)	3 (5.8)	3 (5.9)	3 (3.3)	7 (2.8)	2 (1.2)	18 (3.0)
易刺激性	2 (0.8)	1 (1.9)	0	2 (2.2)	3 (1.2)	3 (1.9)	9 (1.5)
精神疲労	1 (0.4)	0	0	0	0	0	0
精神状態変化	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)

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201試験 Core

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中期不眠症	1 (0.4)	0	0	0	0	0	0
身体疾患による気分障害	0	0	1 (2.0)	0	0	0	1 (0.2)
気分動揺	0	0	0	1 (1.1)	0	0	1 (0.2)
病的思考	0	0	0	1 (1.1)	0	0	1 (0.2)
悪夢	3 (1.2)	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
パニック発作	4 (1.6)	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
精神病性障害	1 (0.4)	0	0	0	2 (0.8)	0	2 (0.3)
レム睡眠行動障害	2 (0.8)	0	0	0	0	0	0
不適切な性的行動	0	1 (1.9)	0	0	0	0	1 (0.2)
睡眠障害	0	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
夢遊症	1 (0.4)	1 (1.9)	0	0	0	0	1 (0.2)
自殺念慮	0	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
早朝覚醒型不眠症	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
腎および尿路障害	16 (6.5)	4 (7.7)	4 (7.8)	8 (8.7)	19 (7.5)	16 (9.9)	51 (8.4)
急性腎障害	1 (0.4)	0	1 (2.0)	1 (1.1)	0	2 (1.2)	4 (0.7)

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201試験 Core

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膀胱充血	0	0	0	0	0	1 (0.6)	1 (0.2)
膀胱結石	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
慢性腎臓病	0	1 (1.9)	1 (2.0)	0	0	0	2 (0.3)
出血性膀胱炎	0	0	0	0	1 (0.4)	0	1 (0.2)
排尿困難	0	0	1 (2.0)	1 (1.1)	0	3 (1.9)	5 (0.8)
糸球体腎炎	1 (0.4)	0	0	0	0	0	0
糖尿	1 (0.4)	0	1 (2.0)	0	1 (0.4)	3 (1.9)	5 (0.8)
血尿	5 (2.0)	1 (1.9)	1 (2.0)	1 (1.1)	6 (2.4)	6 (3.7)	15 (2.5)
尿路出血	1 (0.4)	0	0	0	0	0	0
緊張性膀胱	0	0	0	0	1 (0.4)	2 (1.2)	3 (0.5)
白血球尿	0	0	0	1 (1.1)	0	0	1 (0.2)
腎結石症	4 (1.6)	0	0	1 (1.1)	3 (1.2)	1 (0.6)	5 (0.8)
神経因性膀胱	1 (0.4)	0	0	0	0	0	0
夜間頻尿	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
頻尿	1 (0.4)	1 (1.9)	0	4 (4.3)	2 (0.8)	0	7 (1.1)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

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蛋白尿	0	0	0	0	1 (0.4)	0	1 (0.2)
腎嚢胞	1 (0.4)	0	1 (2.0)	0	2 (0.8)	0	3 (0.5)
腎障害	1 (0.4)	0	0	0	0	0	0
腎不全	1 (0.4)	0	0	0	0	0	0
腎機能障害	0	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
尿道出血	0	0	0	0	0	1 (0.6)	1 (0.2)
膀胱ポリープ	0	0	0	0	0	1 (0.6)	1 (0.2)
排尿躊躇	1 (0.4)	0	0	0	0	0	0
尿失禁	2 (0.8)	1 (1.9)	0	1 (1.1)	1 (0.4)	1 (0.6)	4 (0.7)
尿閉	0	0	1 (2.0)	1 (1.1)	0	0	2 (0.3)
生殖系および乳房障害	4 (1.6)	0	2 (3.9)	2 (2.2)	2 (0.8)	3 (1.9)	9 (1.5)
良性前立腺肥大症	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
乳房石灰化	0	0	0	0	0	1 (0.6)	1 (0.2)
乳房腫瘤	0	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
乳房痛	1 (0.4)	0	0	0	0	0	0

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勃起不全	0	0	0	1 (1.1)	0	0	1 (0.2)
性器発疹	1 (0.4)	0	0	0	0	0	0
前立腺炎	1 (0.4)	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
膣脱	1 (0.4)	0	0	0	0	0	0
外陰膣不快感	0	0	0	0	1 (0.4)	0	1 (0.2)
外陰膣そう痒症	0	0	1 (2.0)	0	0	0	1 (0.2)
呼吸器、胸郭および縦隔障害	38 (15.5)	9 (17.3)	5 (9.8)	14 (15.2)	37 (14.6)	29 (18.0)	94 (15.4)
急性呼吸不全	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
アレルギー性副鼻腔炎	0	0	0	0	0	1 (0.6)	1 (0.2)
喘息	1 (0.4)	2 (3.8)	0	0	2 (0.8)	3 (1.9)	7 (1.1)
無気肺	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
気管支分泌物貯留	1 (0.4)	0	0	0	0	0	0
カタル	0	0	0	0	1 (0.4)	0	1 (0.2)
息詰まり	0	0	0	0	1 (0.4)	0	1 (0.2)
慢性閉塞性肺疾患	0	0	0	0	1 (0.4)	2 (1.2)	3 (0.5)

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201試験 Core

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咳嗽	12 (4.9)	1 (1.9)	2 (3.9)	4 (4.3)	11 (4.3)	14 (8.7)	32 (5.3)
咽喉乾燥	0	0	0	0	1 (0.4)	0	1 (0.2)
発声障害	0	0	1 (2.0)	0	0	0	1 (0.2)
呼吸困難	0	1 (1.9)	1 (2.0)	4 (4.3)	2 (0.8)	2 (1.2)	10 (1.6)
労作性呼吸困難	1 (0.4)	0	0	0	0	0	0
鼻出血	2 (0.8)	1 (1.9)	1 (2.0)	0	2 (0.8)	1 (0.6)	5 (0.8)
喀血	1 (0.4)	0	0	0	0	0	0
下気道うっ血	0	0	0	0	0	1 (0.6)	1 (0.2)
鼻閉	8 (3.3)	1 (1.9)	0	1 (1.1)	3 (1.2)	3 (1.9)	8 (1.3)
口腔咽頭痛	4 (1.6)	0	1 (2.0)	1 (1.1)	4 (1.6)	2 (1.2)	8 (1.3)
副鼻腔不快感	0	0	0	0	1 (0.4)	0	1 (0.2)
副鼻腔分泌過多	2 (0.8)	0	0	0	0	0	0
咽頭紅斑	2 (0.8)	0	0	0	0	0	0
肺臓炎	0	0	0	0	1 (0.4)	0	1 (0.2)
気胸	0	0	0	0	0	1 (0.6)	1 (0.2)

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付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

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湿性咳嗽	0	0	0	0	0	1 (0.6)	1 (0.2)
肺アミロイドーシス	0	0	0	0	0	1 (0.6)	1 (0.2)
肺塞栓症	0	0	0	0	1 (0.4)	2 (1.2)	3 (0.5)
肺腫瘤	0	2 (3.8)	0	0	0	1 (0.6)	3 (0.5)
ラ音	0	0	0	0	1 (0.4)	0	1 (0.2)
呼吸不全	0	0	0	0	1 (0.4)	0	1 (0.2)
呼吸器症状	0	0	0	0	0	1 (0.6)	1 (0.2)
アレルギー性鼻炎	2 (0.8)	0	0	1 (1.1)	3 (1.2)	0	4 (0.7)
鼻漏	0	1 (1.9)	0	3 (3.3)	0	0	4 (0.7)
副鼻腔うっ血	4 (1.6)	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
睡眠時無呼吸症候群	1 (0.4)	1 (1.9)	0	2 (2.2)	2 (0.8)	0	5 (0.8)
喀痰増加	0	0	0	0	1 (0.4)	0	1 (0.2)
頻呼吸	0	0	0	0	1 (0.4)	0	1 (0.2)
上気道うっ血	1 (0.4)	0	0	0	0	0	0
上気道咳症候群	0	0	0	0	3 (1.2)	1 (0.6)	4 (0.7)

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血管運動性鼻炎	0	0	0	1 (1.1)	0	0	1 (0.2)
声帯萎縮	0	0	1 (2.0)	0	0	0	1 (0.2)
喘鳴	1 (0.4)	0	0	0	0	0	0
皮膚および皮下組織障害	35 (14.3)	14 (26.9)	15 (29.4)	18 (19.6)	33 (13.0)	19 (11.8)	99 (16.3)
ざ瘡	0	0	0	0	2 (0.8)	0	2 (0.3)
光線角化症	8 (3.3)	2 (3.8)	2 (3.9)	1 (1.1)	5 (2.0)	0	10 (1.6)
脱毛症	0	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
水疱	0	0	1 (2.0)	1 (1.1)	0	0	2 (0.3)
冷汗	0	0	0	0	1 (0.4)	0	1 (0.2)
頭部粃糠疹	0	0	0	1 (1.1)	0	0	1 (0.2)
皮膚嚢腫	1 (0.4)	0	0	1 (1.1)	3 (1.2)	1 (0.6)	5 (0.8)
皮膚炎	1 (0.4)	0	1 (2.0)	0	3 (1.2)	0	4 (0.7)
アレルギー性皮膚炎	0	0	1 (2.0)	0	0	0	1 (0.2)
アトピー性皮膚炎	1 (0.4)	0	0	0	0	0	0
接触皮膚炎	6 (2.4)	0	2 (3.9)	4 (4.3)	8 (3.2)	4 (2.5)	18 (3.0)

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SOC/PT別の有害事象発現率

201試験 Core

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糖尿病性足病変	0	0	0	1 (1.1)	0	0	1 (0.2)
薬疹	1 (0.4)	3 (5.8)	0	2 (2.2)	4 (1.6)	1 (0.6)	10 (1.6)
皮膚乾燥	0	0	0	1 (1.1)	0	1 (0.6)	2 (0.3)
斑状出血	1 (0.4)	1 (1.9)	1 (2.0)	1 (1.1)	2 (0.8)	2 (1.2)	7 (1.1)
湿疹	1 (0.4)	1 (1.9)	0	2 (2.2)	1 (0.4)	1 (0.6)	5 (0.8)
紅斑	2 (0.8)	0	3 (5.9)	1 (1.1)	1 (0.4)	1 (0.6)	6 (1.0)
毛質異常	0	0	0	1 (1.1)	0	0	1 (0.2)
手皮膚炎	1 (0.4)	0	0	0	0	0	0
多汗症	0	1 (1.9)	1 (2.0)	1 (1.1)	1 (0.4)	2 (1.2)	6 (1.0)
過角化	1 (0.4)	0	0	1 (1.1)	0	0	1 (0.2)
多毛症	1 (0.4)	0	0	0	0	0	0
嵌入爪	0	1 (1.9)	0	0	0	0	1 (0.2)
間擦疹	0	1 (1.9)	0	0	0	0	1 (0.2)
ケロイド瘢痕	0	0	0	1 (1.1)	0	0	1 (0.2)
汗疹	0	0	0	0	0	1 (0.6)	1 (0.2)

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201試験 Core

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神経皮膚炎	2 (0.8)	0	0	0	0	0	0
寝汗	0	0	0	0	0	1 (0.6)	1 (0.2)
爪破損	0	0	0	0	1 (0.4)	0	1 (0.2)
丘疹	0	0	0	0	1 (0.4)	0	1 (0.2)
天疱瘡	0	0	0	1 (1.1)	0	0	1 (0.2)
点状出血	0	0	0	0	0	1 (0.6)	1 (0.2)
光線過敏性反応	0	0	0	0	1 (0.4)	0	1 (0.2)
前癌性皮膚病変	1 (0.4)	0	0	0	0	0	0
そう痒症	3 (1.2)	0	2 (3.9)	1 (1.1)	4 (1.6)	1 (0.6)	8 (1.3)
須毛偽毛包炎	0	1 (1.9)	0	0	0	0	1 (0.2)
乾癬	0	0	0	1 (1.1)	0	0	1 (0.2)
紫斑	1 (0.4)	1 (1.9)	0	0	0	0	1 (0.2)
発疹	2 (0.8)	0	1 (2.0)	1 (1.1)	1 (0.4)	1 (0.6)	4 (0.7)
紅斑性皮疹	0	0	1 (2.0)	0	0	0	1 (0.2)
全身性皮疹	1 (0.4)	0	0	0	0	0	0

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斑状皮疹	1 (0.4)	0	0	1 (1.1)	1 (0.4)	1 (0.6)	3 (0.5)
斑状丘疹状皮疹	0	0	1 (2.0)	0	0	0	1 (0.2)
酒さ	1 (0.4)	1 (1.9)	0	0	0	0	1 (0.2)
脂漏性皮膚炎	0	0	0	0	0	2 (1.2)	2 (0.3)
皮膚障害	2 (0.8)	0	0	0	0	0	0
皮膚剥脱	0	0	0	0	0	1 (0.6)	1 (0.2)
皮膚刺激	0	0	0	0	2 (0.8)	0	2 (0.3)
皮膚病変	3 (1.2)	1 (1.9)	0	0	0	4 (2.5)	5 (0.8)
皮膚潰瘍	0	0	1 (2.0)	1 (1.1)	0	0	2 (0.3)
臍出血	0	0	0	0	1 (0.4)	0	1 (0.2)
蕁麻疹	0	0	0	0	1 (0.4)	0	1 (0.2)
コリン性蕁麻疹	1 (0.4)	0	0	0	0	0	0
社会環境	0	0	0	1 (1.1)	0	0	1 (0.2)
アルコール摂取	0	0	0	1 (1.1)	0	0	1 (0.2)
外科および内科処置	1 (0.4)	0	0	0	0	0	0

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歯科インプラント埋込み	1 (0.4)	0	0	0	0	0	0
抜歯	1 (0.4)	0	0	0	0	0	0
血管障害	31 (12.7)	6 (11.5)	5 (9.8)	10 (10.9)	23 (9.1)	15 (9.3)	59 (9.7)
大動脈瘤	0	0	0	1 (1.1)	0	0	1 (0.2)
大動脈硬化症	1 (0.4)	0	0	0	0	0	0
大動脈狭窄	0	1 (1.9)	0	0	0	0	1 (0.2)
腋窩静脈血栓症	0	0	0	0	0	1 (0.6)	1 (0.2)
深部静脈血栓症	1 (0.4)	0	0	1 (1.1)	1 (0.4)	0	2 (0.3)
潮紅	1 (0.4)	0	2 (3.9)	0	0	1 (0.6)	3 (0.5)
血腫	1 (0.4)	1 (1.9)	0	1 (1.1)	2 (0.8)	1 (0.6)	5 (0.8)
ほてり	2 (0.8)	0	0	1 (1.1)	6 (2.4)	0	7 (1.1)
高血圧	13 (5.3)	1 (1.9)	1 (2.0)	3 (3.3)	10 (4.0)	7 (4.3)	22 (3.6)
高血圧クリーゼ	1 (0.4)	0	0	0	0	0	0
低血圧	5 (2.0)	2 (3.8)	3 (5.9)	2 (2.2)	5 (2.0)	2 (1.2)	14 (2.3)
内出血	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)

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MedDRA Version 20.1.
MedDRA = Medical Dictionary for Regulatory Activities, TEAE = treatment-emergent adverse event.

付録 2.7.6-3

SOC/PT別の有害事象発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
不安定血圧	1 (0.4)	0	0	0	0	0	0
起立性高血圧	1 (0.4)	0	0	0	0	0	0
起立性低血圧	1 (0.4)	0	0	2 (2.2)	2 (0.8)	4 (2.5)	8 (1.3)
末梢冷感	0	0	0	1 (1.1)	0	0	1 (0.2)
末梢静脈疾患	2 (0.8)	0	0	0	0	0	0
表在性血栓性静脈炎	0	1 (1.9)	0	0	0	0	1 (0.2)
静脈瘤	1 (0.4)	0	0	0	0	0	0

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MedDRA Version 20.1.
MedDRA = Medical Dictionary for Regulatory Activities, TEAE = treatment-emergent adverse event.

付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
Subjects with Any Treatment-related TEAEs	65 (26.5)	23 (44.2)	25 (49.0)	31 (33.7)	135 (53.4)	76 (47.2)	290 (47.6)
血液およびリンパ系障害	2 (0.8)	1 (1.9)	1 (2.0)	0	7 (2.8)	5 (3.1)	14 (2.3)
貧血	1 (0.4)	1 (1.9)	0	0	3 (1.2)	2 (1.2)	6 (1.0)
白血球増加症	1 (0.4)	0	0	0	0	0	0
リンパ節症	0	0	1 (2.0)	0	0	0	1 (0.2)
リンパ球減少症	0	0	0	0	4 (1.6)	4 (2.5)	8 (1.3)
心臓障害	4 (1.6)	1 (1.9)	0	0	2 (0.8)	2 (1.2)	5 (0.8)
狭心症	1 (0.4)	0	0	0	0	0	0
不整脈	0	0	0	0	1 (0.4)	0	1 (0.2)
心房細動	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
心房粗動	1 (0.4)	0	0	0	0	0	0
洞性徐脈	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
ストレス心筋症	0	1 (1.9)	0	0	0	0	1 (0.2)
心室性期外収縮	1 (0.4)	0	0	0	0	0	0

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MedDRA Version 20.1.

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
耳および迷路障害	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
耳痛	0	0	0	0	1 (0.4)	0	1 (0.2)
回転性めまい	2 (0.8)	0	0	0	0	0	0
眼障害	0	0	0	0	2 (0.8)	2 (1.2)	4 (0.7)
眼刺激	0	0	0	0	0	1 (0.6)	1 (0.2)
羞明	0	0	0	0	1 (0.4)	0	1 (0.2)
視力障害	0	0	0	0	0	1 (0.6)	1 (0.2)
硝子体剥離	0	0	0	0	1 (0.4)	0	1 (0.2)
胃腸障害	10 (4.1)	4 (7.7)	4 (7.8)	2 (2.2)	12 (4.7)	3 (1.9)	25 (4.1)
腹部不快感	1 (0.4)	0	0	0	0	0	0
腹痛	1 (0.4)	0	0	0	0	0	0
上腹部痛	0	1 (1.9)	0	0	0	0	1 (0.2)
バレット食道	1 (0.4)	0	0	0	0	0	0
便習慣変化	1 (0.4)	0	0	0	0	0	0
便秘	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

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下痢	2 (0.8)	2 (3.8)	3 (5.9)	1 (1.1)	2 (0.8)	1 (0.6)	9 (1.5)
十二指腸炎	1 (0.4)	0	0	0	0	0	0
消化不良	0	1 (1.9)	0	0	0	0	1 (0.2)
鼓腸	1 (0.4)	0	0	0	0	0	0
排便回数増加	0	0	0	0	1 (0.4)	0	1 (0.2)
胃炎	1 (0.4)	0	0	0	1 (0.4)	0	1 (0.2)
歯肉痛	0	0	0	0	1 (0.4)	0	1 (0.2)
悪心	2 (0.8)	0	2 (3.9)	1 (1.1)	6 (2.4)	1 (0.6)	10 (1.6)
口蓋腫脹	1 (0.4)	0	0	0	0	0	0
嘔吐	1 (0.4)	0	0	0	2 (0.8)	0	2 (0.3)
一般・全身障害および投与部位の状態	11 (4.5)	5 (9.6)	2 (3.9)	6 (6.5)	23 (9.1)	9 (5.6)	45 (7.4)
無力症	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
胸部不快感	1 (0.4)	0	0	0	0	0	0
胸痛	1 (0.4)	0	0	0	0	0	0
悪寒	1 (0.4)	0	0	0	2 (0.8)	2 (1.2)	4 (0.7)

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

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疲労	6 (2.4)	4 (7.7)	0	1 (1.1)	15 (5.9)	5 (3.1)	25 (4.1)
冷感	0	0	0	0	2 (0.8)	0	2 (0.3)
インフルエンザ様疾患	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
注入部位内出血	0	0	0	0	1 (0.4)	0	1 (0.2)
注入部位血管外漏出	0	1 (1.9)	1 (2.0)	1 (1.1)	0	0	3 (0.5)
注入部位疼痛	0	0	0	1 (1.1)	0	0	1 (0.2)
注入部位反応	0	0	0	1 (1.1)	0	0	1 (0.2)
倦怠感	0	0	0	0	1 (0.4)	0	1 (0.2)
末梢性浮腫	0	0	0	1 (1.1)	0	0	1 (0.2)
疼痛	0	0	1 (2.0)	0	2 (0.8)	0	3 (0.5)
発熱	0	0	0	2 (2.2)	4 (1.6)	0	6 (1.0)
口渇	1 (0.4)	0	0	0	0	0	0
血管穿刺部位内出血	0	0	0	0	0	1 (0.6)	1 (0.2)
肝胆道系障害	2 (0.8)	1 (1.9)	0	1 (1.1)	0	0	2 (0.3)
胆管嚢胞	0	1 (1.9)	0	0	0	0	1 (0.2)

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

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胆管炎	1 (0.4)	0	0	0	0	0	0
胆石症	0	0	0	1 (1.1)	0	0	1 (0.2)
高ビリルビン血症	1 (0.4)	0	0	0	0	0	0
免疫系障害	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
過敏症	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
感染症および寄生虫症	3 (1.2)	1 (1.9)	2 (3.9)	2 (2.2)	4 (1.6)	3 (1.9)	12 (2.0)
耳感染	0	0	0	0	1 (0.4)	0	1 (0.2)
真菌尿	1 (0.4)	0	0	1 (1.1)	1 (0.4)	1 (0.6)	3 (0.5)
胃腸炎	1 (0.4)	0	0	0	0	0	0
ウイルス性胃腸炎	0	0	1 (2.0)	0	0	0	1 (0.2)
帯状疱疹	0	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
インフルエンザ	0	0	0	0	1 (0.4)	0	1 (0.2)
上咽頭炎	0	1 (1.9)	0	0	0	0	1 (0.2)
口腔ヘルペス	0	0	0	0	0	1 (0.6)	1 (0.2)
上気道感染	1 (0.4)	0	0	0	0	0	0

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

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水痘帯状疱疹ウイルス感染	0	0	0	1 (1.1)	0	0	1 (0.2)
ウイルス感染	0	0	0	0	1 (0.4)	0	1 (0.2)
傷害、中毒および処置合併症	11 (4.5)	3 (5.8)	4 (7.8)	11 (12.0)	58 (22.9)	33 (20.5)	109 (17.9)
挫傷	0	0	0	0	1 (0.4)	0	1 (0.2)
転倒	3 (1.2)	0	0	0	0	0	0
手骨折	1 (0.4)	0	0	0	0	0	0
注入に伴う反応	8 (3.3)	3 (5.8)	4 (7.8)	11 (12.0)	58 (22.9)	32 (19.9)	108 (17.7)
硬膜下出血	1 (0.4)	0	0	0	0	1 (0.6)	1 (0.2)
臨床検査	5 (2.0)	1 (1.9)	2 (3.9)	3 (3.3)	6 (2.4)	4 (2.5)	16 (2.6)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	1 (1.1)	0	0	1 (0.2)
血中ビリルビン増加	1 (0.4)	0	0	0	0	0	0
血中クレアチニン増加	0	0	0	0	1 (0.4)	0	1 (0.2)
血圧上昇	0	0	0	0	1 (0.4)	0	1 (0.2)
血中ナトリウム減少	0	0	0	0	0	1 (0.6)	1 (0.2)

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

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血中トリグリセリド増加	0	0	0	1 (1.1)	0	0	1 (0.2)
血中尿素増加	2 (0.8)	0	0	0	1 (0.4)	0	1 (0.2)
血中尿酸増加	1 (0.4)	0	0	0	0	0	0
心電図異常	0	0	0	0	1 (0.4)	0	1 (0.2)
糸球体濾過率減少	0	0	0	0	1 (0.4)	0	1 (0.2)
心拍数不整	0	0	0	1 (1.1)	0	0	1 (0.2)
肝機能検査値上昇	0	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
リンパ球数減少	0	0	1 (2.0)	0	0	2 (1.2)	3 (0.5)
好中球数増加	0	0	0	0	0	1 (0.6)	1 (0.2)
トランスアミナーゼ上昇	1 (0.4)	0	0	0	0	0	0
体重減少	1 (0.4)	1 (1.9)	0	1 (1.1)	2 (0.8)	0	4 (0.7)
代謝および栄養障害	3 (1.2)	1 (1.9)	1 (2.0)	1 (1.1)	8 (3.2)	1 (0.6)	12 (2.0)
アシドーシス	0	0	1 (2.0)	0	0	0	1 (0.2)
食欲減退	0	0	0	0	4 (1.6)	0	4 (0.7)
糖尿病	0	1 (1.9)	0	0	0	0	1 (0.2)

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

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コントロール不良の糖尿病	1 (0.4)	0	0	0	0	0	0
高血糖	0	0	0	0	0	1 (0.6)	1 (0.2)
高カリウム血症	2 (0.8)	0	0	0	2 (0.8)	0	2 (0.3)
高ナトリウム血症	0	0	0	0	2 (0.8)	0	2 (0.3)
高尿酸血症	0	0	0	1 (1.1)	0	0	1 (0.2)
低カリウム血症	0	0	0	0	1 (0.4)	0	1 (0.2)
低ナトリウム血症	0	0	0	0	1 (0.4)	0	1 (0.2)
筋骨格系および結合組織障害	3 (1.2)	2 (3.8)	3 (5.9)	0	3 (1.2)	1 (0.6)	9 (1.5)
背部痛	1 (0.4)	1 (1.9)	1 (2.0)	0	1 (0.4)	0	3 (0.5)
線維筋痛	0	0	0	0	1 (0.4)	0	1 (0.2)
側腹部痛	1 (0.4)	0	0	0	0	0	0
筋痙縮	1 (0.4)	0	1 (2.0)	0	0	0	1 (0.2)
筋攣縮	0	1 (1.9)	0	0	0	0	1 (0.2)
筋力低下	1 (0.4)	0	0	0	0	0	0
筋肉痛	0	0	0	0	0	1 (0.6)	1 (0.2)

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 possibly or probably related to study drug.

MedDRA Version 20.1.

MedDRA = Medical Dictionary for Regulatory Activities, TEAE = treatment-emergent adverse event.

付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
頚部痛	0	0	0	0	1 (0.4)	0	1 (0.2)
四肢痛	0	0	1 (2.0)	0	0	0	1 (0.2)
顎痛	0	0	0	0	1 (0.4)	0	1 (0.2)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	1 (1.9)	0	0	0	0	1 (0.2)
脳新生物	0	1 (1.9)	0	0	0	0	1 (0.2)
神経系障害	30 (12.2)	10 (19.2)	7 (13.7)	17 (18.5)	69 (27.3)	35 (21.7)	138 (22.7)
アミロイド関連画像異常	2 (0.8)	1 (1.9)	1 (2.0)	3 (3.3)	25 (9.9)	16 (9.9)	46 (7.6)
失語症	0	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)
脳幹微小出血	1 (0.4)	0	0	0	0	0	0
中枢神経系病変	0	0	0	0	0	1 (0.6)	1 (0.2)
小脳梗塞	0	1 (1.9)	0	0	0	0	1 (0.2)
脳出血	0	0	0	0	0	1 (0.6)	1 (0.2)
脳梗塞	1 (0.4)	0	0	0	0	0	0
脳微小出血	9 (3.7)	2 (3.8)	6 (11.8)	7 (7.6)	21 (8.3)	10 (6.2)	46 (7.6)

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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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
脳血管発作	0	0	0	1 (1.1)	0	0	1 (0.2)
浮動性めまい	3 (1.2)	1 (1.9)	0	1 (1.1)	5 (2.0)	5 (3.1)	12 (2.0)
異常感覚	0	0	0	0	1 (0.4)	0	1 (0.2)
味覚異常	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
塞栓性脳卒中	1 (0.4)	0	0	0	0	0	0
脳症	0	0	0	0	0	1 (0.6)	1 (0.2)
過剰驚愕反応	1 (0.4)	0	0	0	0	0	0
認知障害発作	0	0	0	1 (1.1)	0	0	1 (0.2)
卒中の出血性変化	0	1 (1.9)	0	0	0	0	1 (0.2)
頭部不快感	2 (0.8)	0	0	0	0	0	0
頭痛	10 (4.1)	3 (5.8)	1 (2.0)	1 (1.1)	25 (9.9)	8 (5.0)	38 (6.2)
反射亢進	1 (0.4)	0	0	0	0	0	0
感覚鈍麻	0	0	0	0	0	1 (0.6)	1 (0.2)
運動低下	0	0	0	1 (1.1)	0	0	1 (0.2)
虚血性脳梗塞	1 (0.4)	0	0	0	0	0	0

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Total (N = 609) n (%)
ラクナ梗塞	0	1 (1.9)	0	0	0	0	1 (0.2)
嗜眠	0	0	0	0	2 (0.8)	0	2 (0.3)
記憶障害	0	2 (3.8)	0	0	0	0	2 (0.3)
ミオクローヌス	0	0	0	0	0	1 (0.6)	1 (0.2)
末梢性ニューロパチー	0	0	0	0	1 (0.4)	0	1 (0.2)
錯感覚	0	0	0	0	0	1 (0.6)	1 (0.2)
嗅覚錯誤	1 (0.4)	0	0	0	0	0	0
傾眠	0	0	0	0	1 (0.4)	0	1 (0.2)
脳表ヘモジデリン沈着症	1 (0.4)	0	1 (2.0)	5 (5.4)	7 (2.8)	1 (0.6)	14 (2.3)
失神	2 (0.8)	0	0	0	0	0	0
緊張性頭痛	0	0	0	0	1 (0.4)	0	1 (0.2)
一過性脳虚血発作	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
精神障害	9 (3.7)	5 (9.6)	2 (3.9)	5 (5.4)	11 (4.3)	5 (3.1)	28 (4.6)
異常行動	1 (0.4)	0	0	0	0	0	0
異常な夢	2 (0.8)	1 (1.9)	0	0	0	0	1 (0.2)

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Lecanemab Total (N = 609) n (%)
感情不安定	0	0	0	0	1 (0.4)	0	1 (0.2)
攻撃性	0	1 (1.9)	0	0	0	0	1 (0.2)
激越	0	0	0	0	0	2 (1.2)	2 (0.3)
不安	2 (0.8)	0	0	0	0	2 (1.2)	2 (0.3)
錯乱状態	1 (0.4)	1 (1.9)	0	1 (1.1)	3 (1.2)	1 (0.6)	6 (1.0)
うつ病	2 (0.8)	1 (1.9)	0	2 (2.2)	2 (0.8)	1 (0.6)	6 (1.0)
失見当識	0	0	0	0	1 (0.4)	0	1 (0.2)
フラッシュバック	0	0	1 (2.0)	0	0	0	1 (0.2)
幻覚	0	0	0	0	2 (0.8)	0	2 (0.3)
幻聴	0	0	0	0	1 (0.4)	0	1 (0.2)
幻視	0	0	0	0	1 (0.4)	0	1 (0.2)
不眠症	0	0	1 (2.0)	2 (2.2)	2 (0.8)	0	5 (0.8)
易刺激性	0	1 (1.9)	0	0	1 (0.4)	0	2 (0.3)
精神状態変化	0	0	0	1 (1.1)	0	0	1 (0.2)
悪夢	1 (0.4)	0	0	0	0	0	0

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付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Total (N = 609) n (%)
精神病性障害	1 (0.4)	0	0	0	0	0	0
レム睡眠行動障害	1 (0.4)	0	0	0	0	0	0
睡眠障害	0	0	0	0	1 (0.4)	0	1 (0.2)
夢遊症	0	1 (1.9)	0	0	0	0	1 (0.2)
腎および尿路障害	2 (0.8)	0	2 (3.9)	0	0	0	2 (0.3)
急性腎障害	0	0	1 (2.0)	0	0	0	1 (0.2)
慢性腎臓病	0	0	1 (2.0)	0	0	0	1 (0.2)
糖尿	1 (0.4)	0	1 (2.0)	0	0	0	1 (0.2)
腎不全	1 (0.4)	0	0	0	0	0	0
呼吸器、胸郭および縦隔障害	0	1 (1.9)	0	0	1 (0.4)	1 (0.6)	3 (0.5)
喘息	0	1 (1.9)	0	0	0	1 (0.6)	2 (0.3)
副鼻腔不快感	0	0	0	0	1 (0.4)	0	1 (0.2)
皮膚および皮下組織障害	4 (1.6)	2 (3.8)	4 (7.8)	1 (1.1)	9 (3.6)	2 (1.2)	18 (3.0)
冷汗	0	0	0	0	1 (0.4)	0	1 (0.2)
皮膚嚢腫	0	0	0	0	1 (0.4)	0	1 (0.2)

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MedDRA = Medical Dictionary for Regulatory Activities, TEAE = treatment-emergent adverse event.

付録 2.7.6-4

SOC/PT別の副作用発現率

201試験 Core

Safety Analysis Set

MedDRA System Organ Class J Preferred Term_J	Placebo (N = 245) n (%)	Lecanemab 2.5 mg/kg Biweekly (N = 52) n (%)	Lecanemab 5 mg/kg Monthly (N = 51) n (%)	Lecanemab 5 mg/kg Biweekly (N = 92) n (%)	Lecanemab 10 mg/kg Monthly (N = 253) n (%)	Lecanemab 10 mg/kg Biweekly (N = 161) n (%)	Total (N = 609) n (%)
皮膚炎	0	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
薬疹	0	1 (1.9)	0	1 (1.1)	4 (1.6)	1 (0.6)	7 (1.1)
多汗症	0	0	1 (2.0)	0	0	1 (0.6)	2 (0.3)
多毛症	1 (0.4)	0	0	0	0	0	0
そう痒症	2 (0.8)	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
紫斑	1 (0.4)	0	0	0	0	0	0
発疹	0	0	1 (2.0)	0	1 (0.4)	0	2 (0.3)
酒さ	0	1 (1.9)	0	0	0	0	1 (0.2)
血管障害	6 (2.4)	1 (1.9)	0	0	9 (3.6)	2 (1.2)	12 (2.0)
深部静脈血栓症	0	0	0	0	1 (0.4)	0	1 (0.2)
ほてり	2 (0.8)	0	0	0	4 (1.6)	0	4 (0.7)
高血圧	2 (0.8)	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
低血圧	2 (0.8)	0	0	0	2 (0.8)	0	2 (0.3)
起立性低血圧	0	0	0	0	1 (0.4)	1 (0.6)	2 (0.3)
表在性血栓性静脈炎	0	1 (1.9)	0	0	0	0	1 (0.2)

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Treatment-related TEAEs include TEAEs that were considered by the investigator to be possibly or probably related to study drug.

MedDRA Version 20.1.

MedDRA = Medical Dictionary for Regulatory Activities, 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 (%)
Subjects with Any TEAEs	171 (95.0)
血液およびリンパ系障害	17 (9.4)
貧血	8 (4.4)
ビタミンＢ１２欠乏性貧血	1 (0.6)
失血性貧血	1 (0.6)
鉄欠乏性貧血	2 (1.1)
白血球増加症	4 (2.2)
リンパ節症	1 (0.6)
リンパ球減少症	2 (1.1)
単球増加症	1 (0.6)
汎血球減少症	1 (0.6)
血小板減少症	2 (1.1)
血小板増加症	1 (0.6)
心臓障害	21 (11.7)
急性心筋梗塞	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 (%)
狭心症	3 (1.7)
大動脈弁閉鎖不全症	1 (0.6)
大動脈弁狭窄	1 (0.6)
不整脈	1 (0.6)
冠動脈硬化症	2 (1.1)
心房細動	3 (1.7)
心房頻脈	1 (0.6)
徐脈	1 (0.6)
冠動脈疾患	1 (0.6)
冠動脈狭窄	1 (0.6)
左室機能不全	1 (0.6)
僧帽弁閉鎖不全症	2 (1.1)
心筋梗塞	2 (1.1)
洞性頻脈	1 (0.6)
上室性頻脈	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 (%)
頻脈	3 (1.7)
三尖弁閉鎖不全症	2 (1.1)
心室性期外収縮	1 (0.6)
耳および迷路障害	8 (4.4)
耳不快感	2 (1.1)
耳鳴	3 (1.7)
回転性めまい	3 (1.7)
内分泌障害	2 (1.1)
副腎嚢胞	1 (0.6)
甲状腺嚢腫	1 (0.6)
甲状腺腫瘤	2 (1.1)
眼障害	18 (10.0)
アレルギー性眼瞼炎	1 (0.6)
白内障	2 (1.1)
結膜充血	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 (%)
複視	2 (1.1)
ドライアイ	3 (1.7)
網膜上膜	1 (0.6)
眼痛	1 (0.6)
眼球斜位	1 (0.6)
眼充血	1 (0.6)
高眼圧症	1 (0.6)
霧視	1 (0.6)
視野欠損	3 (1.7)
胃腸障害	50 (27.8)
腹部不快感	3 (1.7)
腹痛	6 (3.3)
上腹部痛	6 (3.3)
肛門失禁	2 (1.1)
腹水	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 (%)
顕微鏡的大腸炎	1 (0.6)
便秘	5 (2.8)
齲歯	1 (0.6)
下痢	7 (3.9)
憩室	1 (0.6)
腸憩室	3 (1.7)
消化不良	2 (1.1)
糞塊	1 (0.6)
胃潰瘍	1 (0.6)
胃炎	2 (1.1)
胃食道逆流性疾患	3 (1.7)
痔核	1 (0.6)
裂孔ヘルニア	2 (1.1)
鼠径ヘルニア	1 (0.6)
腹腔内石灰化	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 (%)
大腸ポリープ	6 (3.3)
口腔内潰瘍形成	1 (0.6)
悪心	10 (5.6)
食道障害	1 (0.6)
口腔障害	1 (0.6)
膵臓障害	1 (0.6)
直腸裂	1 (0.6)
小腸閉塞	1 (0.6)
歯痛	7 (3.9)
嘔吐	9 (5.0)
一般・全身障害および投与部位の状態	40 (22.2)
医薬品副作用	1 (0.6)
無力症	2 (1.1)
カテーテル留置部位皮膚炎	1 (0.6)
カテーテル留置部位紅斑	1 (0.6)

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胸部不快感	3 (1.7)
胸痛	3 (1.7)
悪寒	1 (0.6)
泣き	1 (0.6)
疲労	8 (4.4)
歩行障害	3 (1.7)
インフルエンザ様疾患	1 (0.6)
注入部位血管外漏出	3 (1.7)
注入部位血腫	2 (1.1)
倦怠感	3 (1.7)
非心臓性胸痛	1 (0.6)
末梢性浮腫	4 (2.2)
疼痛	3 (1.7)
発熱	9 (5.0)
恥骨上痛	1 (0.6)

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ワクチン接種部位疼痛	1 (0.6)
血管穿刺部位疼痛	1 (0.6)
肝胆道系障害	3 (1.7)
胆嚢炎	1 (0.6)
胆石症	2 (1.1)
脂肪肝	1 (0.6)
免疫系障害	1 (0.6)
薬物過敏症	1 (0.6)
感染症および寄生虫症	94 (52.2)
無症候性ＣＯＶＩＤ－１９	1 (0.6)
無症候性細菌尿	3 (1.7)
細菌感染	1 (0.6)
細菌尿	1 (0.6)
気管支炎	2 (1.1)
ＣＯＶＩＤ－１９	12 (6.7)

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蜂巣炎	2 (1.1)
眼窩蜂巣炎	1 (0.6)
慢性副鼻腔炎	1 (0.6)
コロナウイルス感染	1 (0.6)
膀胱炎	6 (3.3)
耳感染	2 (1.1)
精巣上体炎	1 (0.6)
大腸菌性菌血症	1 (0.6)
大腸菌性尿路感染	1 (0.6)
眼感染	1 (0.6)
胃腸炎	2 (1.1)
ウイルス性胃腸炎	2 (1.1)
帯状疱疹	5 (2.8)
麦粒腫	2 (1.1)
咬傷感染	1 (0.6)

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感染性皮膚嚢腫	1 (0.6)
インフルエンザ	3 (1.7)
限局性感染	2 (1.1)
上咽頭炎	18 (10.0)
爪真菌症	2 (1.1)
口腔ヘルペス	1 (0.6)
歯周炎	2 (1.1)
咽頭炎	1 (0.6)
肺炎	6 (3.3)
誤嚥性肺炎	2 (1.1)
処置後感染	1 (0.6)
ウイルス性気道感染	1 (0.6)
鼻炎	1 (0.6)
敗血症	2 (1.1)
副鼻腔炎	2 (1.1)

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皮膚感染	3 (1.7)
ＣＯＶＩＤ－１９の疑い	2 (1.1)
足部白癬	1 (0.6)
歯膿瘍	4 (2.2)
歯感染	2 (1.1)
上気道感染	15 (8.3)
尿路感染	27 (15.0)
尿路性敗血症	1 (0.6)
ウイルス感染	1 (0.6)
皮膚ウイルス感染	1 (0.6)
外陰部腟カンジダ症	1 (0.6)
傷害、中毒および処置合併症	93 (51.7)
偶発的過量投与	1 (0.6)
動物咬傷	3 (1.7)
節足動物咬傷	4 (2.2)

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MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
節足動物刺傷	3 (1.7)
骨挫傷	1 (0.6)
頚椎骨折	4 (2.2)
凍瘡	2 (1.1)
脳振盪	1 (0.6)
挫傷	11 (6.1)
頭蓋顔面骨折	1 (0.6)
眼擦過傷	1 (0.6)
眼挫傷	2 (1.1)
眼外傷	1 (0.6)
顔面骨骨折	1 (0.6)
転倒	40 (22.2)
足骨折	3 (1.7)
仙骨骨折	1 (0.6)
手骨折	2 (1.1)

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股関節部骨折	2 (1.1)
上腕骨骨折	2 (1.1)
注入に伴う反応	37 (20.6)
関節損傷	1 (0.6)
靱帯捻挫	2 (1.1)
四肢損傷	2 (1.1)
下肢骨折	1 (0.6)
半月板損傷	2 (1.1)
筋挫傷	1 (0.6)
肉離れ	4 (2.2)
眼窩周囲血腫	1 (0.6)
眼窩周囲出血	1 (0.6)
処置後低血圧	1 (0.6)
術後譫妄	1 (0.6)
処置による疼痛	2 (1.1)

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MedDRA System Organ Class J Preferred Term J	Lecanemab 10 mg/kg Biweekly (N = 180) n (%)
製品適用過誤	1 (0.6)
肋骨骨折	4 (2.2)
交通事故	3 (1.7)
皮膚擦過傷	8 (4.4)
皮膚裂傷	12 (6.7)
脊髄損傷	1 (0.6)
皮下血腫	2 (1.1)
硬膜下血腫	1 (0.6)
硬膜下出血	1 (0.6)
腱断裂	1 (0.6)
熱傷	1 (0.6)
胸椎骨折	1 (0.6)
歯牙破折	5 (2.8)
外傷性血腫	1 (0.6)
外傷性腎損傷	1 (0.6)

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